Imagio® Breast Imaging System

Model 9100

Operator/User Manual

for use with probe models 8100 and 8500

I About Seno Medical Instruments®

Seno Medical Instruments® is a medical device company focused on the detection of cancer using its patented Opto-acoustic (OA) technology. Opto-acoustic (OA) imaging combines light and sound to produce functional images.

Legal Manufacturer

Seno Medical Instruments, Inc.
8023 Vantage Dr. Ste 1000
San Antonio, TX 78230-4726
Tel: 210-615-6501

Seno Medical Service

Tel: 888-978-8835
Email: service@senomedical.com

Caution: Rx Only in the United States (Federal law restricts this device to sale by or on the order of a physician).

https://senomedical.com

https://senomedical.com/patents/

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Service Statement

Service and/or troubleshooting to be performed only by Seno Medical personnel and/or their designated third-party service companies and referred to as the local service provider throughout the manual.

Seno Medical Service

Tel: 888-978-8835

Email: service@senomedical.com

Training Statement

Seno Medical provides training for medical personnel on the OA/US modality. Prior to installation, medical personnel can arrange to participate by notifying Seno Medical. In addition, Seno Medical provides user on-site Imagio® Breast Imaging System training by a Clinical Applications Specialist.

Warranty Statement

Subject to the terms below, Seno Medical Instruments, Inc. (“Seno”) provides the following limited warranty for its products. The Imagio® Breast Imaging System is a medical diagnostic device that should only be operated by trained operators.

The warranty period commences on the date of shipment. Seno’s sole obligation for this limited warranty is to repair or replace a defective product at no charge to Customer, or to credit Customer’s account for the purchase price paid for the defective product, at Seno’s discretion.

Under no circumstances should anyone other than authorized Seno Service personnel make any modifications to the Imagio® Breast Imaging System. Each of the system’s safety circuits has been designed to minimize potential adverse situations. These safety circuits must never be bypassed, altered, or disabled. The manufacturer and distributor assume no responsibility or liability for personal injury or property damage resulting from misuse of the systems.

Seno warrants the equipment to be free from defects in workmanship and materials for the contracted warranty period. Seno has robustly tested and can reliably promote a functional life of at least 1 year for the system. Seno recommends a six (6) month preventive maintenance schedule to maintain optimal performance of the Imagio® Breast Imaging System.

This limited warranty does not apply if the defective product (i) has been damaged due to abuse, misuse, neglect, accident, unusual physical or electrical stress, or tampering, (ii) has not been used in accordance with Seno’s written instructions for use (IFU), (iii) was not purchased from Seno or an authorized dealer of Seno, or (iv) was modified from its original configuration or repaired or altered by anyone other than Seno or a person authorized by Seno.

To make a warranty claim, Seno’s Customer Care Department must be contacted within five days of discovery of the defect to obtain a return authorization number. Seno will be responsible for shipping costs on defective products that are under warranty which are returned by customer to Seno with a return authorization number. Replaced or repaired product will be shipped to customer’s site and installed by Seno or an authorized representative of Seno at Seno’s expense.

Seno aims for the use of the Imagio® Breast Imaging System to be fully operational and trouble-free throughout the useful life of the system. However, periodic repairs may be needed to be performed by an authorized Seno Service provider. All parts that are replaced become the property of Seno. The operator is responsible for backing up and maintaining any data stored on the Imagio® system.

Due to the complex nature of the system and the importance of safety to patients and operators, all service work must be performed by an authorized Seno Service representative. Call Seno Service for assistance at (888) 978-8835.

Safety Descriptors

This manual uses the following safety descriptors:

Warning statements inform the operator of safety alerts that must be followed carefully to avoid bodily injury.

Caution: Caution statements inform the operator of safety alerts that must be observed to avoid damage to the equipment.

Chapter 1 System Overview

1.1 Documentation Access

To access the latest version of the Imagio® Breast Imaging System Operator Manual, please go to:

https://senomedical.com/manuals/current

1.2 Overview

The purpose of this manual is to describe the Ultrasound and Opto-acoustic (OA) functionality of the Imagio® Breast Imaging System and to provide usage instructions.

This manual contains:

- Intended Use
- Online Access to Imagio® Breast Imaging System Operator Manual.
- Device description
- Important safety information
- An introduction to the Imagio® Breast Imaging System
- Detailed instructions for operating the Imagio® Breast Imaging System
- How to save scanned images and upload them to a facility's Picture Archiving and Communication System (PACS)
- How to perform laser energy calibration, maintenance, and cleaning

1.3 Who Should Use This Manual?

This operator manual is a reference for operators of the Imagio® Breast Imaging System. It is designed for a reader familiar with ultrasound imaging techniques; it does not provide training in sonography or clinical procedure or practices. This manual is written for the individual who has attended and received Imagio® Breast Imaging System training from Seno personnel or their agents. This manual is intended to assist with the safe and effective operation of the Imagio® Breast Imaging System.

Formal System training from Seno personnel or their agents combined with the information in this manual contain necessary and enough information to operate the Imagio® Breast Imaging System safely. Read and understand all instructions in this manual before attempting to use the Imagio® Breast Imaging System and strictly observe all warnings and cautions.

1.3.1 Permissible/Impermissible Impairments for operators of the system

Permissible impairments include:

- Latex allergy

Impermissible impairments include:

- Vision impaired persons without corrections.
- Persons unable or unwilling to wear Laser Protective Eyewear.

1.4 Risk Management To Medical Devices

Seno follows the requirements for risk management described in ISO 14971:2019 Medical devices – Application of risk management to medical devices.

1.5 Safety, EMC, and Regulatory Compliance

1.5.1 Laser Safety

For the Imagio® Breast Imaging System, Seno Medical recommends the facility should check and abide by any country/state regulations as pertaining to our laser classifications noted below.

1.5.2 Laser Classification

The Class 3B laser beams emitted by the Imagio® Breast Imaging System can cause loss of sight. Any energy transmitted by the Imagio® Breast Imaging System that enters the eye may be focused directly on the retina. Direct absorption of laser energy by the retina may result in temporary clouded vision, retina lesion, long term scotoma and long term photophobia.

The potential for loss of sight exists in any case of:

- Direct laser radiation
- Reflected laser radiation
- Diffused laser radiation

Reference “Laser Classification” on page 158 and “Specifications” on page 165 for additional information on Laser classification and specifications.

1.5.3 Least Favorable Working Conditions

The “least favorable working condition” (i.e. the most hazardous scenario) has been determined to be when the Imagio® Breast Imaging System laser is emitting.

1.5.4 Laser Cooling System

The laser cooling system is filled with distilled water. The laser cooling system must contain a sufficient amount of distilled water at all times to ensure proper operation.

The Add Coolant message will appear on the lower right of the Display Monitor if the amount of distilled water in the laser coolant reservoir is insufficient.

1.5.5 Device Information Standards

The Imagio® Breast Imaging System is designed to meet the following standards:

IEC/EN/ANSI AAMI ES 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC/EN 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/EN 60601-1-6	Medical electrical equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
IEC/EN 60601-2-22	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, therapeutic and diagnostic laser equipment
IEC/EN 60601-2-37	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC/EN 60825-1	Safety of laser products - Part 1: Equipment classification and requirements
EN ISO 10993-1	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

1.5.6 Device Information Classifications:

The Imagio® Breast Imaging System is designed to the following classifications:

IEC/EN 60601-1-2, Medical Equipment, Electromagnetic Compatibility Classification:

- Group 1 Class A equipment (CISPR11)
- Suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes

IEC/EN 60601-1, Medical Electrical Equipment: General Requirements for Basic Safety and Essential Performance Classification:

- Class I Equipment
- Type BF Applied Part: OA/US L18-1 Probe IPX1
- Type BF Applied Part: US L18-5 Linear Probe IPX1
- Electrical Ratings: 208-240V, 50/60Hz, 10A
- OA duty cycle: 5 minutes ON / 10 minutes OFF
- Laser Output energy accuracy: +/- 20%
- Ingress Protection: The Imagio® Breast Imaging System IPX20
- Ingress Protection: Foot Switch IPX8

Isolation of the Imagio® Breast Imaging System from supply mains is accomplished internally by means of isolation transformers.

Note: The Imagio® Breast Imaging System is a medical device used for diagnostic purposes only and is not intended for life critical applications. Therefore; the Imagio® Breast Imaging System was not designed to respond to interruptions to the main supply voltage of greater than 500 milliseconds in duration.

1.5.7 Electrical Safety

All patient-contact devices, such as probes, and ECG leads not specifically indicated as defibrillation-proof must be removed from patient contact before application of a high-voltage defibrillation pulse.

Warning: Do not remove Imagio® Breast Imaging System covers. Hazardous voltages are present inside the Imagio® Breast Imaging System.

Warning: To avoid the risk of electrical shock, this equipment must only be connected to a supply mains with protective earth.

• To avoid electrical shock, use only the supplied power cords and connect to properly grounded wall receptacles.

1.5.8 Thermal Safety

Our device has been designed to have a surface temperature not exceeding 50°C in air and 43°C when in contact with the patient or user when measured under the requirements of the IEC 60601-2-37 standard. Some heat is generated by the Imagio® Breast Imaging System, and by the probe. Heat generated by the electrical components of the Imagio® Breast Imaging System is dissipated through specific outlets. Heat may also be generated at the surface of the ultrasound probe. In some cases the heat of the probe may be detected at the surface of the skin. This would occur if the probe remains in contact with a part of the body for a prolonged period of time.

The Imagio® Breast Imaging System has been equipped with internal sensors which monitor the temperature rise within the chassis. Alerts messages may be displayed on the Imagio® Breast Imaging System in the event of an overheating condition. In the case of extreme or prolonged heat build-up, the Imagio® Breast Imaging System may automatically power off.
If heating of either the probe or Imagio® Breast Imaging System is determined to be a problem, please call your Seno service representative immediately.

Warning: Imagio® Breast Imaging System overheating may occur if the environment exceeds the recommended ambient operating conditions. To avoid overheating, be sure the Imagio® Breast Imaging System is operated under normal "room temperature" conditions, and adequate ventilation is provided.

- Ultrasound can produce harmful effects in tissue and potentially result in patient injury. Always minimize exposure time and keep ultrasound levels low when there is no medical benefit (ALARA principle).
- The Imagio® Breast Imaging System which is overheating due to external conditions or an internal fault may issue a warning followed by a spontaneous power off to prevent heat damage or fire. If this occurs, discontinue use of the Imagio® Breast Imaging System and call your Seno service representative.
- Probe surfaces may experience heat-build up. This is especially true if the probe is in prolonged use and/or the point of contact with the body is stationary. Please use ALARA principles to prevent unnecessary heating of the patient or the probe.
- Using the "Freeze" control is recommended to suspend acoustic energy to the probe when not in use.
- Do not maintain the probe in one position on the body for prolonged periods of time. Prolonged exposure can produce minor burns.

1.5.9 Mechanical Safety

The Imagio® Breast Imaging System has been ergonomically and mechanically optimized to be pleasant, efficient and safe, provided that it is used as intended and all instructions, warnings and cautions specified in this Guide are followed. If the Imagio® Breast Imaging System suffers mechanical damage, discontinue use and call an authorized Seno representative for assistance.

Warning: Never use the Imagio® Breast Imaging System if any of the exterior covers are cracked, damaged, missing or improperly installed.

- Touching internal electrical or mechanical parts may cause injury or death
- If a foreign object should fall into an opening in the Imagio® Breast Imaging System and discontinue use until the Imagio® Breast Imaging System can be inspected by an authorized service representative.
- Do not push or pull the Imagio® Breast Imaging System from the side or from the monitor, or against an excessive resistance. The Imagio® Breast Imaging System could tip over.

Warning: To avoid potential injury, do not position or store the system on slopes or uneven surfaces.

Warning: Use caution when moving the system. It could cause injury to you or others if it rolls over feet or into shins.

1.5.10 Alert System

The usage of the Imagio® Breast Imaging System requires the physical presence of the operator. The operator and patient are co-located to the Imagio® Breast Imaging System. Thus the Imagio® Breast Imaging System alert system is composed of visual alerts only. The Imagio® Breast Imaging System alert system utilizes either a pop-up window with suggested actions or a message in the information area of the main monitor. The Imagio® Breast Imaging System alert conditions are not configurable by an operator.

The Imagio® Breast Imaging System logs the occurrences of alerts for later review by a Seno representative. Refer to “Status, Alerts, Notifications, and Messages” on page 110.

1.5.11 Remote Interlock

Your facility or regulatory body may require the Imagio® Breast Imaging System be configured with a remote room door interlock and laser emitting light as an added precaution to help prevent accidental Laser emission. Check with your facility manager, laser safety officer or local regulatory body to identify if a remote interlock is needed and call Seno Service for assistance at (888) 978-8835.

Remote Interlock Input - Laser emission will cease or be prevented if the interlock is tripped (i.e. door open)

Remote Interlock Output - Can be used to control a light. Light will be on if the laser is in emission or is capable of emission (i.e. Ready or Emission State), otherwise it will be off.

1.5.12 Environmental Temperature for safe operation and storage of the Imagio® Breast Imaging System

Operating Temperature Range	10° C to 30° C (50° F to 86° F)
Storage/Transport Temperature Range	4° C to 50° C (39° F to 122° F)
Operating Humidity Range	30% to 70%, non-condensing
Storage/Transport Humidity Range	30% to 80%, non-condensing

1.5.13 Receiving and Storing the Imagio® Breast Imaging System

The Imagio® Breast Imaging System must be installed only by Seno authorized personnel.

Upon delivery and initial installation, please allow Seno authorized personnel to open the system packaging. If the Imagio® Breast Imaging System needs to be returned back to Seno for service, please do not pack it. Call Seno Service for assistance at (888) 978-8835.

1.5.14 Storage of the Device

The Imagio® Breast Imaging System may be stored indefinitely if it is done so under ambient conditions which do not exceed the storage environmental limits.

It is also prudent to have an authorized Seno Service representative re-start the system for the first time after prolonged storage.

1.5.15 Regulatory Requirements

Regulatory requirements for imaging facilities vary by country/province/state.

If your region has laser safety requirements, the facility’s Laser Safety Officer is responsible for verifying and complying with such regulatory requirements concerning the use of lasers in the facility.

1.5.16 Emissions and Immunity Information

Please refer to “Declaration of Electromagnetic Emission” on page 161 for the Imagio® Breast Imaging System emissions and immunity tables.

1.5.17 Cybersecurity

Caution: When connected to a network, the Imagio® Breast Imaging System is potentially able to be compromised by unauthorized access to data, extraction of data, loss of data and corruption of data.

- Application parameters can only be configured by a trained and authorized operator.
- Do not operate the Imagio® Breast Imaging System without appropriate network security measures. Organizations that elect to configure/use the networking functionality provided by Seno are assuming all liabilities and risks associated with that decision.
- We recommend operating the Imagio® Breast Imaging System with a firewall. Seno designed the Imagio® Breast Imaging System to be compatible with PACS systems.
- Do not install software or hardware on the Imagio® Breast Imaging System.
- Always call Seno Service for assistance at (888) 978-8835 for a suspected cybersecurity compromise on the Imagio® Breast Imaging System.
- Always maintain configuration and data backups for the Imagio® Breast Imaging System.

1.5.18 Security Management

All unnecessary communication ports and all remote logging services are disabled.

Only the DICOM port remains opened (TCP/IP Network Port 11112 by default).

The Imagio® Breast Imaging System is designed according to the principle of least functionality: only DICOM services are available. Only configured AEs can push objects to the Imagio® Breast Imaging System.

1. All operating Imagio® Breast Imaging System services that are not used by the Imagio® Breast Imaging System application software are disabled to minimize the sources of security vulnerabilities. The Imagio® Breast Imaging System provides only essential capabilities: The use of non-essential functions, ports, protocols and services is prohibited or restricted to prevent unauthorized connection of devices, unauthorized transfer of information, or unauthorized tunneling.
2. Healthcare delivery organizations can utilize network scanning tools, intrusion detection and prevention systems to identify and prevent the use of prohibited functions, ports, protocols, and services.

The operator interface does not allow operators to interact with the operating system. There is no access for a operator to the underlying operating system. The operator has only access to the ultrasound interface controls. The operator cannot load software, open email, or browse Internet.

The “auto run” feature is disabled on the Imagio® Breast Imaging System. The Imagio® Breast Imaging System will not open or run a program available on USB memory stick inserted into the Imagio® Breast Imaging System.

Seno Medical is performing monitoring of potential cybersecurity vulnerabilities. Should a security problem be discovered; the customer will be notified, and a cybersecurity patch will be provided. For security problems discovered by the facility, please contact cybersecurity@senomedical.com.

In order to minimize the consequences of any security event, Seno Medical strongly recommends to send images to a secured PACS.

To ensure patient and operator data protection, it is necessary to use secured tools for any data sharing containing Protected Health Information (PHI).

Recommendations regarding use of USB devices

To mitigate the threat of a potentially infected thumb drive plugged the Imagio® Breast Imaging System, the following measures should be taken at a minimum:

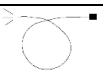
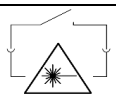
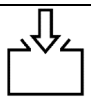
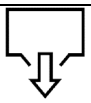
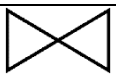
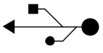
- Ensure the use of approved, trusted vendors for hardware purchases.
- Scan all hardware, especially removable storage media, on an external computer prior to its insertion into Imagio® Breast Imaging System.
- Operators should protect themselves and organizations by practicing good browsing habits, ensuring they do not respond to or select unsolicited email, and to not plug unknown USB devices into their workstations.
- If operators don't have the expertise to properly handle or identify potential cyber threats please seek out an expert who can provide the expertise needed to secure your organization.

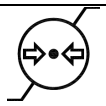
1.5.19 Anonymization

It is possible to anonymize images before export, however anonymization of image pixel data is ultimately the responsibility of the site even if applications are used to anonymize the data. Anonymization of data burned into the image itself (i.e., image pixel data) is notoriously difficult. Review of all such images for accurate anonymization is strongly recommended when such images are batch anonymized by computer application.

1.5.20 Symbols and Markings Glossary

Symbol / Marking	Definition
	Manufacturer
	Date of Manufacture
	Authorized Representative in the European Community
	Catalogue number
	Serial number
	General warning sign
	General caution sign
	Warning; Laser beam
	Refer to instruction manual/booklet

Symbol / Marking	Definition
	Wear eye protection
	Type BF applied part
	Optical applicator
	Foot switch
	Remote interlock connector
	Filling
	Draining; emptying
	Valve; shut-off element
	Mass; weight
IPn1n2	Ingress Protection Mark
	WEEE Mark (EU only). This symbol indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of the equipment.
Rx Only	Rx Only Mark
	CE Conformity Mark
	ETL Mark
	On the power switch, represents Imagio® Breast Imaging System power ON and OFF
	On the console represents Imagio® Breast Imaging System ON/Standby
	USB input/output port

Symbol / Marking	Definition
	Ethernet connection
	Equipotentiality ground
	DisplayPort out
	Humidity limitation Indicates the range of humidity to which the medical device can be safely exposed.
	Atmospheric pressure limitation. Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	Temperature limitation. Indicates the range of temperature to which the medical device can be safely exposed.
	Probe connector. Indicates the state of the probe connector lock.
	FCC identification number unique to Seno Imagio Breast Imaging System, Model 9100 is 2A7QE-9100[a]. RF frequency band: 13.56MHz Maximum RF output power: -16.1dBuA/m at 10m This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

a. *NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.*

1.5.21 As Low As Reasonably Achievable (ALARA) Principle and Output Displays

The Acoustic Power Output Display for the Imagio® Breast Imaging System acoustics meets FDA requirements and the guidance standards set out by AIUM and NEMA: Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment.

The Imagio® Breast Imaging System provides real-time Mechanical Index (MI) and Thermal Index (TI) acoustic power output display values. Display of the acoustic power output value enables the User to better implement the ALARA principle.

- MI: Mechanical Index
- TI: Thermal Index

The ALARA principle, provided by AIUM in Medical Ultrasound Safety, guides the User on Bioeffects and Biophysics, Prudent Use, and Implementing ALARA. It is highly recommended the Imagio® Breast Imaging System users read the AIUM documents to become more familiar with Ultrasound safety. The User can determine the right balance of acoustic exposure benefits to risks by using acoustic power output levels that are As Low As Reasonably Achievable (ALARA). Without compromising imaging quality, patient acoustic exposure should be kept to a minimum while using the lowest output power possible.

As Low As Reasonably Achievable (ALARA) Principle:

The potential benefits and risks of each examination should be considered. The ALARA (As Low As Reasonably Achievable) Principle should be observed when adjusting controls that affect the acoustical output and by considering transducer dwell times. Further details on ALARA may be found in the AIUM publication.

https://www.aium.org/resources/official-statements

Recommended Maximum Scanning Times for Displayed Thermal Index (TI) Values

https://www.aium.org/resources/official-statements

The AIUM document "Medical Ultrasound Safety" may be obtained by contacting the AIUM:

American Institute of Ultrasound in Medicine
14750 Sweitzer Lane, Suite 100
Laurel, Maryland 20707-5906
USA telephone: 1-800-638-5352 or 301-498-4100

Chapter 2 Imagio® Breast Imaging System

2.1 Device Description

The Imagio® Breast Imaging System is a diagnostic functional and morphologic imaging system that combines Opto-acoustic (OA) imaging with conventional diagnostic ultrasound (US) imaging to aid in diagnostic evaluation of breast lesions. The Imagio® Breast Imaging System acquires, processes, and displays co-registered OA and US images to provide structural and functional information about breast abnormalities in real-time. OA/US imaging technology combines the high contrast resolution of optical imaging with the high spatial resolution and deep penetration of ultrasound imaging.

In OA imaging (also known as Photo-acoustic (PA) imaging in the literature), short nanosecond pulses of laser light are delivered into tissue. When that light is absorbed, for instance by hemoglobin molecules found in blood, those molecules undergo thermoelastic expansion and generate acoustic pressure signals that can be detected at the tissue surface using a hand-held probe. The probe has optical windows that deliver light to tissue and an array of piezoelectric transducers that detect acoustic signals. The received OA signal increases with both the absorption strength and concentration of light-absorbing molecules. Two strong absorbers in tissue are oxygenated and de-oxygenated hemoglobin found in blood vessels. By performing OA imaging using two near-infrared optical wavelengths (757 nm and 1064 nm) for which oxygenated and de-oxygenated hemoglobin absorb light differently, the Imagio® Breast Imaging System can estimate the relative oxygen saturation of hemoglobin in tissue.

2.2 Indications for Use

The Imagio® Breast Imaging System is indicated for use by a trained and qualified healthcare provider for evaluation of palpable and non-palpable breast abnormalities in adult patients who are referred for a diagnostic imaging breast work-up, following clinical presentation or either screening or diagnostic mammography or other imaging examinations. The ultrasound mode should be initially used in a targeted fashion, to assess any focal area(s) of clinical or imaging concerns. In ultrasound mode, the device can be used to assign a BI-RADS category to either breast tissue or a mass that is causing clinical or imaging concerns. Masses that are classified as BI-RADS categories 3 through 5 can then be assessed using the Opto-acoustic (OA) mode. In the OA Mode, the Imagio® Breast Imaging System provides information about the central nidus, boundary, and peripheral zones, based on vascularity and blood oxygen saturation of the imaged tissues, to assist in the diagnosis of the benign or malignant mass(es) of interest. For ultrasound BI-RADS 3-5 masses, using the OA features of the mass allows for improved classification of the mass of interest as compared to ultrasound alone. The OA Mode is not indicated for ultrasound BI-RADS 1 and 2 findings. The Imagio® Breast Imaging System includes an artificial intelligence (AI) based software function to assist the operators in assessing BI-RADS classifications.

This device is not intended to be used as a replacement for mammographic screening or for definitive pathologic diagnosis.

2.3 Intended Use

The Imagio® Breast Imaging System is intended to be used in the evaluation of breast abnormalities, regardless of the method or mechanism of initial detection.

The Imagio® Breast Imaging System is a diagnostic functional and morphologic imaging system intended for the opto-acoustic (OA) evaluation of breasts in adult patients who have findings of suspicious masses (including both palpable and non-palpable masses) or imaging findings (such as architectural distortion, asymmetry, or suspicious calcifications).

The Imagio® Breast Imaging System utilizes real-time opto-acoustic and ultrasound technologies to acquire, process, display, and log co-registered structural and functional information about breast abnormalities. This information is presented to the operator as fused and temporally interleaved opto-acoustic and ultrasonic images.

The Imagio® Breast Imaging System also includes real-time diagnostic ultrasound with color and pulsed Doppler. The grayscale ultrasound includes image enhancing features, and the ability to measure and annotate images. The system is DICOM compliant and has PACS connectivity.

The Imagio® Breast Imaging System is intended to support qualified healthcare professionals in the differentiation of benign from malignant breast lesions and to support them in their decisions.

The Imagio® Breast Imaging System is not intended to be used as a screening device or for definitive pathologic diagnosis.

2.4 Probe Intended Use and Indications

System	**Imagio® Breast Imaging System**						
Probe	**OA/US L18-1 Probe (Model 8100)**						
Intended Use	Real-time conventional diagnostic ultrasound with color and pulsed wave Doppler for fluid flow analysis						
Indications as follows:							
Clinical Application	Modes of Operation						
Specific (Track 3)	B	SWE™	PWD	CWD	Color/Power Doppler (CD/PD)	Combined	OA
Small Organ: Breast	Yes	Yes	Yes	No	Yes	Yes	Yes
Probe	**US L18-5 Linear Probe (Model 8500)**						
Intended Use	Real-time conventional diagnostic ultrasound with color and pulsed wave Doppler for fluid flow analysis						
Indications as follows:							
Clinical Application	Modes of Operation						
Specific (Track 3)	B	SWE™	PWD	CWD	Color/Power Doppler (CD/PD)	Combined	OA
Small Organ: Breast	Yes	Yes	Yes	No	Yes	Yes	No

This device has not been evaluated for use on an individual who:

- Has a condition or impediment which could interfere with the intended field of view.
- Has or has had cancer in the ipsilateral breast within the same quadrant(s) as the mass(es) to be biopsied.
- Has had prior benign excisional breast biopsy within the immediate vicinity of the currently evaluated mass within the past 18 months.
- Has greater than three lesions.
- Has lesion(s) of interest greater than 4 cm.
- Currently has mastitis, is known to be pregnant or lactating.
- Has focal pain without thickening or mass.

- Has open sores including insect bites, rash, poison ivy, and/or chafing on the skin of the ipsilateral breast.
- Has an acute or a chronic hematoma and/or acute ecchymosis of the ipsilateral breast.
- Is experiencing photo-toxicity or photo-sensitivity or is undergoing treatment or taking medication for a photosensitive condition such as porphyria or lupus erythematosus.
- Has concurrent neoadjuvant therapy at the time of the Imagio® Breast Imaging System evaluation or the biopsy.
- Has previously had image guided core biopsy, image guided DVAB, or surgical biopsy of the mass of interest.
- Has a nipple ring and is unwilling to remove for the exam when the mass is <4cm from the nipple.
- Has applied fragrance or lotion on the skin where the probe will be applied.

The benefits and risks of use of the system are always to be weighed by the treating physician.

2.4.1 Contraindications

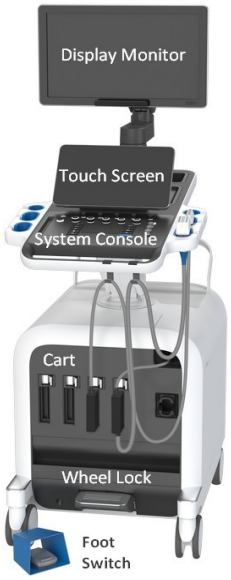
Absolute contraindications are as follows:

- Is pregnant.
- Has open sores including insect bites, rash, poison ivy, and/or chafing on the skin of the ipsilateral breast.
- Is experiencing photo-toxicity associated with currently taking, or having taken, photosensitizing agents within the previous 72 hours such as sulfonamides, ampicillin, tetracycline.
- Is currently undergoing phototherapy.
- Has a history of any photosensitive disease (e.g., porphyria, lupus erythematosus) or is undergoing treatment for a photosensitive disease and is experiencing photosensitivity.

2.5 Components

The Imagio® Breast Imaging System uses specialty components designed to perform Opto-acoustic (OA) imaging exams.

The Imagio® Breast Imaging System



2.5.1 Cabinet

The Imagio® Breast Imaging System cabinet contains computers, the laser, an Ultrasound module, and power supplies.

There are indentations on top of the cabinet that may be used to store basic items such as notebooks, charts, and towels.

Caution: Liquids stored or placed on the Imagio® Breast Imaging System, outside of the recommended ultrasound gel, may spill and damage the Imagio® Breast Imaging System components rendering the device unusable.

- Do not place cups, drinks, or other fluid containers on the Imagio® Breast Imaging System.

2.5.2 System Console

The System Console is the Operator interface for entering patient data, exam settings, and for performing the exam. The Console, mounted on an adjustable arm, includes physical buttons and dials, a Touch Screen, TouchPad, probe holders, gel holder/warmer, and a cleaning wipes holder.

2.5.3 Display Monitor

The Display Monitor displays the Opto-acoustic images detected by the Imagio® Breast Imaging System probes during the exam. The Display Monitor is mounted on an adjustable arm.

2.5.4 Front Probe Cable Storage Tray

A front storage tray is available to hold excess probe cable length off the floor when, for example, when not using a probe. This reduces excess probe cable length of a probe which is in use or keeping stored probe cables off the floor when moving the Imagio® Breast Imaging System.

2.5.5 Flat Breast Phantom

The Phantom Box contains an Opto-acoustic Flat Breast Phantom during, for example, assessment of image quality or when performing the Machine Check optional procedure.

2.5.6 Foot Switch

The laser foot switch controls the emission of the Imagio® Breast Imaging System laser.

2.5.7 Power Cord

A power cord is supplied with the Imagio® Breast Imaging System.

2.5.8 Ethernet Cable

A 3 meter (10 foot) Ethernet cable is provided for connection to a site-provided RJ45 network connection jack to enable the Imagio® Breast Imaging System images to the site's Picture Archiving and Communication System (PACS) and support remote service.

2.5.9 Laser Protective Eyewear

Warning: Invisible laser light is emitted from the OA/US L18-1 Probe. Reflected and/or misdirected laser light may damage eyes.

- Do not use any controls or adjustments or performance settings other than those specified herein.
- The Patient, the Imagio® Breast Imaging System Operator, and everyone else in the scan room must always wear Seno approved Laser Protective Eyewear when the Imagio® Breast Imaging System is powered on and the laser is enabled.
- Wearing Seno approved Laser Protective Eyewear is a laser safety requirement. It is necessary to wear Laser Protective Eyewear when, for example; scanning, inspecting and cleaning the OA/US L18-1 Probe, and calibrating laser energies or any other time the Ima-

gio® Breast Imaging System is powered on and the laser is enabled.

- Do not look directly at the laser beam even when Laser Protective Eyewear is being worn.
- Do not look at a laser beam emitted from the Imagio® Breast Imaging System that is visible. The Imagio® Breast Imaging System uses lasers that are classified as invisible; however, some individuals can see light beyond the visible spectrum.
- Always point the OA/US L18-1 Probe away from everyone's eyes.
- Only use your foot to press the foot switch.
- Always release the foot switch before removing the OA/US L18-1 Probe from the skin or calibration port.
- Always follow the laser safety precautions prior to laser emitting to protect the Patient, Operator, and Observers.
- Always place the OA/US L18-1 Probe in the Probe holder when not in use.

The Seno Laser Protective Eyewear has been specifically selected for two main reasons:

- The Laser Protective Eyewear is designed to protect the Operator, Patient, and Observers from the specific wavelengths of the Imagio® Breast Imaging System laser
- The Laser Protective Eyewear is designed to prevent interference with reading images

There are specific styles of eyewear only for the operator and observer. There is a specific style of eyewear only for the patient. Optical density, or OD, is a logarithmic function that corresponds to the amount of light that a lens transmits at a specific wavelength. OD is specified for specific wavelengths or ranges of wavelengths. Laser Protective Eyewear of OD4 or greater provides protection for the 1064 nm wavelength and OD5 or greater for the 757 nm wavelength.

For best comfort when wearing goggle style frames, adjust the strap so there is just enough tension to create a seal that prevents observation of visible light around the entire goggle seal.

After the laser has been authorized, a message appears on the display to remind the operators and everyone in the scan room wear Laser Protective Eyewear.

- Seno has designated the Laser Protective Eyewear required and this eyewear is the only Seno approved Laser Protective Eyewear to be used with the Imagio® Breast Imaging System. They must be available for installation, service, training, and patient scans.

2.5.9.1 Laser Protective Eyewear for the Operator and Observer

The three styles of Laser Protective Eyewear are only for the Operator and Observers. There are three different frame styles to accommodate different facial dimensions.

Inspect the eyewear prior to use or if they are dropped. Do not use the eyewear if damage to the eyewear is observed. If damage is discovered during a visual inspection, discontinue use and call Seno Service for assistance at (888) 978-8835. It is recommended operators always wear eyewear with clean lenses.

2.5.9.1.1 Modern Frame

For Operator and Observer only.

2.5.9.2 Laser Protective Eyewear for the Patient, Operator, or Observer

Laser Protective Eyewear for the patient provides protection against stray laser light during an Imagio® Breast Imaging System scan and must be worn by each patient. The direct wear goggle style Laser Protective Eyewear is the only style permitted to be worn by the Patient. Prescription inserts are available for this style of eyewear if the operator finds that the over the glasses eyewear uncomfortable.

2.5.9.2.1 Goggle-Style Frame

Important: Patient Laser Protective Eyewear can also be worn by the Operator or Observer.

2.6 Compatible Accessories and Kits

Under some use conditions, additional materials provided by third-party vendors may be used by clinicians performing exams with the system. The decision to use the system and probes with third-party products is completely at the discretion of the clinician. Use of third party product outside of that specified by Seno Medical Instruments, Inc is considered off-label and is done at risk to the Imagio® Breast Imaging System, and potentially, the patient.

Chapter 3 Scan Room and the Imagio® Breast Imaging System Preparation

3.1 The Imagio® Breast Imaging System Heating

It is recommended the operator prepare the scan room and Imagio® Breast Imaging System before the first scan of the day because once powered on, the Imagio® Breast Imaging System lasers may take up to 15 minutes to reach operating temperature.

3.2 Positioning the Imagio® Breast Imaging System

A wheel locking mechanism is incorporated into the front of the Imagio® Breast Imaging System frame to secure the Imagio® Breast Imaging System once positioned in the scan room. The foot activated wheel lock locks/unlocks the front wheels (swivel casters) allowing the Imagio® Breast Imaging System to be swiveled but not moved.

Warning: To avoid potential injury, do not position or store the system on slopes or uneven surfaces.

- Brakes and wheel locks are not intended to stabilize the system on ramps or inclines.
- If you encounter any failure of the wheels, handles or braking mechanisms, position the system on a level surface in a safe area, lock the wheels and discontinue use until the mechanical parts can be inspected by an authorized Seno Service representative.

Warning: Use caution when moving the system. It could cause injury to you or others if it rolls over feet or into shins.

Caution: The Imagio® Breast Imaging System requires uninterrupted airflow through the rear cooling intake. Any obstruction to airflow may cause overheating and Imagio® Breast Imaging System power off.

- Always position the Imagio® Breast Imaging System with a minimal distance of 31 cm (12") between the Imagio® Breast Imaging System and the wall.

3.2.1 Rear Cabinet Handle

A large rear cabinet handle allows firm and safe grasp of the Imagio® Breast Imaging System cabinet when steering/moving in the scan room. The front wheels swivel. The rear wheels are fixed and do not swivel to steer.

To steer the cabinet right or left, push the rear handle forward on the opposite side (e.g. push the rear handle forward on the right move cabinet to the left).

Important: Pushing the system is much easier and safer than pulling it. Grasp the handles firmly and maintain an upright posture when pushing. When moving the system over long distances, make sure to use the rear handle to push the system to avoid damaging it.

3.2.2 Brake and Wheel Locks

Wheel locks are provided to stabilize the system when stationary, such as when scanning or storing.

A wheel lock foot pedal is located at the front bottom middle and controls the wheel lock on or off.

3.3 Probe Storage/Transportation

A box is always provided for the probes as part of the entire Imagio® Breast Imaging System. Retain this box for storage, carrying, and transport/shipping. Failure to properly secure the probe during storage, transport and shipping may result in damage.

3.4 Moving the Imagio® Breast Imaging System

3.4.1 Preparing to Move the Imagio® Breast Imaging System

Step 1: Put the console back in the centered and lowered position

Step 2: Turn the system power off.

Step 3: Unplug the main power cord, and disconnect any accessory cords (network, etc.).

Step 4: Use the probe cable management system to raise probe cables up from wheel level. Do not allow the wheels to roll over accessory cables.

Step 5: Remove or ensure that all peripherals and items in the storage area are secure.

Step 6: Lock the articulating monitor arm in its lowest position.

Step 7: Unlock the wheel locks.

3.4.2 Moving the System

Step 1: Grasp the handle at the rear of the cabinet firmly.

Step 2: Keeping an upright posture, push the system forward. Do not push the system from either side with excessive force.

Step 3: Use ramps or elevators where possible and do not attempt to lift the system manually. Move system to the intended location.

Note: If moving this system between facilities by truck or other vehicle, please call Seno Service for assistance at (888) 978-8835.

3.5 Positions of Operator, Patient, and Individuals in the Scan Room

Clinical operators of the Imagio® Breast Imaging System should be in the standing position and have clear view of the Touchscreen and Display Monitor and unobstructed movement to the controls, probe, and foot switch.

Patients are in the supine semi right or left lateral decubitis position with their contra-lateral arm raised above and their head so their breast lies uniformly flat.

3.6 Confirm Laser Safety Items

3.6.1 Signs, Safety Labeling, Notices, and Laser Protective Eyewear Requirement and Warning

- The facility/hospital Laser Safety Officer (LSO) needs to reference state and or local requirements for laser safety signage. The LSO is responsible for understanding and implementing the state and or local and hospital regulations for laser safety for the Imagio® Breast Imaging System.
- Everyone in the scan room must wear the Seno provided Laser Protective Eyewear when the Imagio® Breast Imaging System is powered on and the laser is enabled.
- Verify that the Laser Warning Sign, provided by your LSO is affixed to the outside of each door leading into the scan room. This is to warn people not to enter the room without wearing Laser

Protective Eyewear. Scattered laser radiation may be emitted from the OA/US L18-1 Probe during an exam and cause potential harm to anyone not wearing designated Laser Protective Eyewear.

- Example of a Laser Warning Sign below:

- Verify that a Laser Warning Sign is also displayed near the Imagio® Breast Imaging System and is visible to the System Operator and the Patient. This is to remind the Patient, Operator, and Observers of the hazards of lasers.
- Verify safety labeling and notices are in place on the Imagio® Breast Imaging System.

3.7 Ensure Proper Environmental Operating Conditions

Warning: The system and its accessories are not intended to be used outdoors.

Caution: The Imagio® Breast Imaging System is sensitive to temperature and may be damaged if used after exposure to low temperatures.

- Do not expose the Imagio® Breast Imaging System to freezing temperatures (at or below 4° C or 39° F).
- In case of exposure, do not use the Imagio® Breast Imaging System. Call Seno Service for assistance at (888) 978-8835.

Important: The following environmental requirements are recommended to ensure optimal performance of the Imagio® Breast Imaging System. Please notify your Facility Engineer if there are environmental concerns.

Operating Temperature Range 15 °C to 30 °C (59 °F to 86 °F)
Operating Humidity Range 30% to 70%, non-condensing.
Dust/Dirt Contamination Minimized, not in construction area.
Chemical Contamination Minimized; not subjected to chemical fumes.
Operating Magnetic Flux Density must be less than 5 gauss.

Caution: The OA/US L18-1 Probe may be damaged if exposed to temperatures outside of the stated range.

- Do not store the OA/US L18-1 Probe in environments beyond -20° C to 50° C or 30% to 85% relative humidity, as this was the range tested and verified by Seno Medical.
- Do not operate the OA/US L18-1 Probe in environments beyond 15° C to 30° C, or 30% to 70% relative humidity, as this was the range tested and verified by Seno Medical.
- In case of exposure to excessive humidity or temperature, do not use the Imagio® Breast Imaging System. Call the Seno Service for assistance at (888) 978-8835.

Refer to “Environmental Temperature for safe operation and storage of the Imagio® Breast Imaging System” on page 13 for additional information.

3.7.1 Potential Equalization Conductor Terminal

( )To use another medical device in combination with this system, an equipotential wire for connecting to an equipotential bus must be supplied. For more information, call the Seno Service for assistance at (888) 978-8835.

Caution: The Imagio® Breast Imaging System is sensitive and may be damaged if adjacent equipment is placed in close proximity to the Imagio® Breast Imaging System.

- The Imagio® Breast Imaging System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Imagio® Breast Imaging System should be observed to verify normal operation in the configuration in which it will be used.

3.7.2 Login and Lock/Logout

3.7.2.1 Logging In A Session

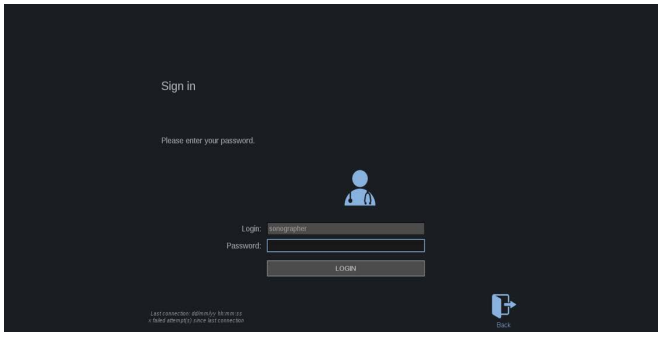
This feature aims at reinforcing the Imagio® Breast Imaging System's security by means of operator profiles and logins.
Below is a table which gives an overview of each access given to each operator profile:

Operator Profiles	**Access To**		
	Exam (measurement, save image...)	**System Configuration**	
		Operator Settings	**Administration**
Emergency Access	YES	NO	NO
Sonographer	YES	YES	MINIMUM(1)
Admin	YES	YES	YES

(1) A minimum set of administrative settings is accessible to the operator.

At Imagio® Breast Imaging System startup, the main login screen will be displayed.

Select the desired profile.



Enter your password and select Login.

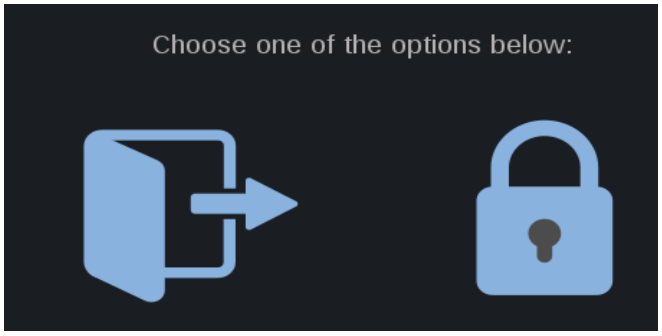
Note: Enable the auto-login feature to skip the login screen displayed at the Imagio® Breast Imaging System startup. For more information about the auto-login feature, please refer to "Operator Management" on page 141.

Note: When logged in, the Touchscreen top right most icon indicates which profile is in use.

3.7.2.2 Locking Your Session And Logging Out

Select the icon located in the top right-hand corner of the Touchscreen.

Either Lock your session or Log out.



To log out, select the dedicated icon, the main login screen is displayed.

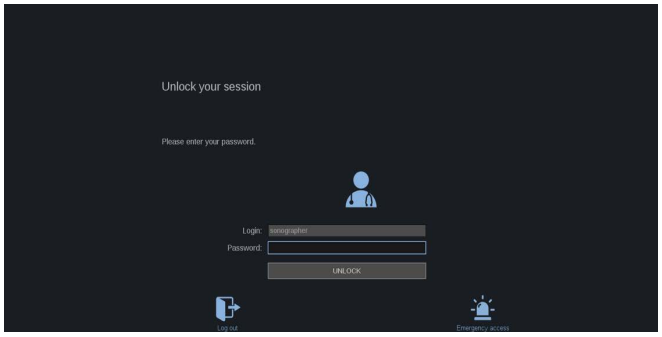
Note: Logging out is equivalent to an End Exam.

To lock your session, select the dedicated icon. The previously displayed information is now hidden until the operator unlocks their session.

Step 1: To unlock your session, first Select any system console key

Step 2: The unlock screen is now displayed

Step 3: Enter your password and Select Unlock to go back to the current exam.



Note: Log out and/or Start an Emergency exam through the unlock screen by selecting the dedicated icon, which will automatically end the current exam.

3.7.3 Setting the Time and Date

The Imagio® Breast Imaging System includes a clock/calendar function, which maintains accurate time and date even when the Imagio® Breast Imaging System is turned off and disconnected from power.

Refer to “Regional parameters” on page 125 for instructions on setting up time and date.

3.7.4 Setting the Language

Your authorized Seno Service provider will configure the operator interface language and regional parameters in the System Configuration during installation.

Refer to “Regional parameters” on page 125 for instructions on setting up the language.

3.7.5 Getting Connected to a Network

The Imagio® Breast Imaging System supports standard network functions, which include sending exam data to a DICOM storage server.

Refer to “Ethernet Configuration” on page 137 for instructions on network configuration.

3.7.6 Selecting a Probe

The Imagio® Breast Imaging System uses four ports for connecting probes that can be occupied at the same time, but only one probe can be active at a time.

Always use the cable management system to prevent cables from being stepped on or run over by the cabinet wheels.

3.7.6.1 Connecting a Probe

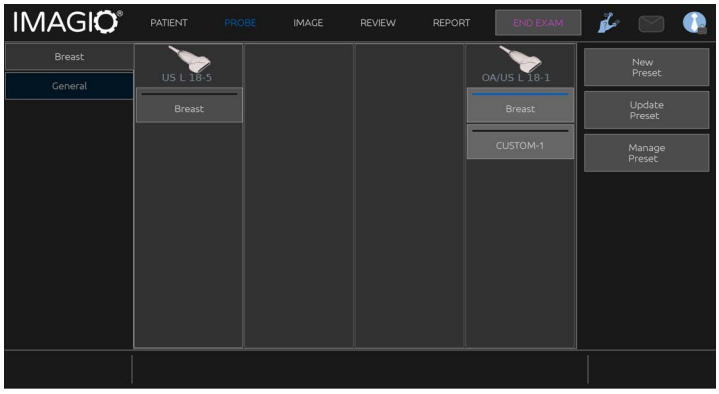
Refer to “Connecting and Disconnecting Probes and Accessories” on page 118.

3.7.6.2 Selecting a Probe and Preset for an Exam

When the Imagio® Breast Imaging System is turned on, the Imagio® Breast Imaging System defaults to the last used probe, application, and preset.

It is possible to select among the probes during Imagio® Breast Imaging System operation.

Step 1: Select Probe on the Touchscreen.



The Touchscreen will display the applications that are compatible with the probes that are connected to the Imagio® Breast Imaging System

Step 2: Touch the tab corresponding to the desired clinical application. Ex: Breast. The Touchscreen will display the probes Use for the selected application, and the associated Presets.

Step 3: Select the desired Preset. For example, Breast. The Probe Touchscreen closes and the Imagio® Breast Imaging System is in live B Mode. The factory presets appear in darker gray and the operator-created presets appear in lighter gray.

Note: It is possible to customize the displayed list of presets in the System Configuration. Refer to "System Configuration" on page 121.

The selected probe, application and preset appear on the header of the imaging main display.

3.7.7 Beginning an Exam

3.7.7.1 Getting Ready

Before acquiring images, optionally create a patient exam or retrieve a patient already created in the Imagio® Breast Imaging System.

Before scanning a new patient, make sure the previous exam has been ended, by doing one of the following:

- Select End Exam on the Touchscreen.

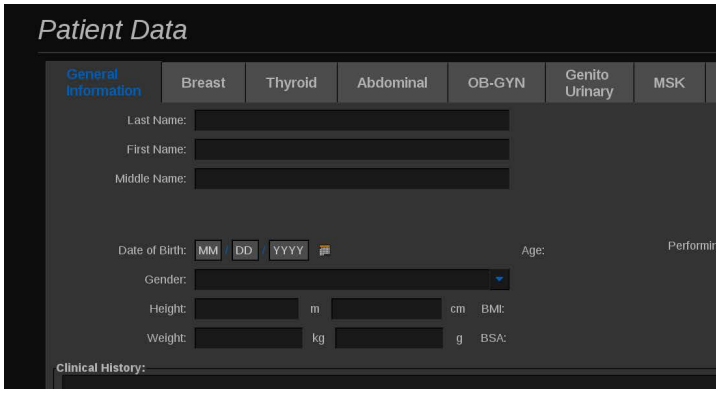
Note: Pressing End Exam automatically disables the laser.

- Select New Patient on the Touchscreen.

3.7.7.2 Creating a New Patient

3.7.7.2.1 Patient Data Entry

Step 1: Select Patient on the Touchscreen. The Patient Data Entry is displayed on the main screen.



The General Information tab of the Patient Data Entry gathers the fields related to the patient identity.

The Worklist Information tab of the Patient Data Entry displays information coming from the Modality Worklist (if associated and configured).

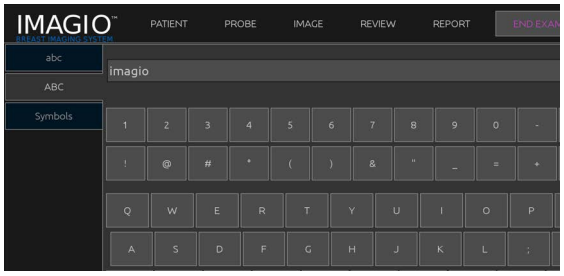
Eight other tabs are available, each of them displaying specific clinical information:

- Breast, Thyroid, Abdominal, OB-GYN, Genitourinary, MSK, Vascular, Cardiac

To navigate through the tabs, move the cursor to the desired tab to open and press the Touchpad.

To enter new data, place the cursor in the desired field. The active field is automatically highlighted.

Type the desired text with the keyboard. Text appears when typing directly on the Touchscreen, in the preview area.



Note: Patient ID: The Imagio® Breast Imaging System uses a unique ID to identify each patient. You may enter your own ID, or the Imagio® Breast Imaging System will create one automatically.

Images and reports are stored based on the patient ID.

The name and ID appear at the top of all image displays.

3.7.7.2.1.1 To choose a Value in a List

- Move the cursor to the arrow on the right of the drop-down list.
- Press the Touchpad to display the list.
- Move the cursor down to the selected value and press the Touchpad again to validate your choice.

Save the Patient Data Entry as an image of the exam.

Select Save Image while in the Patient Data Entry.

This will save the active tab as a screen-shot. Patient data screen-shots may be exported from the Review screen but are not displayed in the Image thumbnail strip.

3.7.7.3 Loading a Patient from the Modality Worklist

3.7.7.3.1 Finding Exams in the Worklist

This feature is available if the Imagio® Breast Imaging System is connected to the network and the DICOM feature is enabled.

Step 1: Select Patient on the Touchscreen.

- The Patient Data Entry is displayed on the main screen.
- The Patient Touchscreen is now displayed.

Note: If a Modality Worklist is configured and associated, pressing End Exam will automatically display the Modality Worklist (if configured).

Step 2: Touch Modality Worklist on the Touchscreen.

- The modality worklist is displayed on the main screen.

There are three ways to locate a patient:

1. Check the boxes above the list to filter it.
2. Place the cursor over a column header and then press the Touchpad to sort the list by the selected column.
3. Use the search box to find a given patient.

Step 1: Move the cursor over the desired patient file to open.

Step 2: Press the Touchpad.

The Patient Data Entry is displayed on the main screen and pre-populated. Edit some of the information for this patient. Refer to “System Configuration” on page 121 for more information on how to configure the Modality Worklist.

3.7.7.3.2 Broad Query, Patient Query

Imagio® Breast Imaging System offers the two types of queries defined by the IHE (Integrating the Healthcare Enterprise): broad queries and patient queries.

By default, the Worklist performs broad queries.

Patient Query limits the number of answers that are returned, and therefore increases the confidentiality, limits the risk to select by mistake the wrong patient in the worklist, and limits the quantity of data to be transferred to the Imagio® Breast Imaging System.

To use Patient Query:

Step 1: Select Patient Query on the Touchscreen to perform a query on a specific patient only. Use this mode especially if the network is slow. A window pops up.

Step 2: Enter data for the specific patient to retrieve on the worklist. At least one mandatory field must be filled in to perform the query.

Step 3: Select Query to perform the query on the specific patient.

Select Broad Query on the Touchscreen to switch to the Broad Worklist query mode. The Modality Worklist can be used when the Imagio® Breast Imaging System is disconnected from the network. Refer to “System Configuration” on page 121 for more details.

3.7.7.4 Editing Patient Data

3.7.7.4.1 Editable Data

Data may be edited for the current patient. Some information can be edited at any time during an exam, if not imported from the Modality Worklist.

3.7.7.4.1.1 To Edit Patient Data

Step 1: Place the text cursor in the desired field. The active field is highlighted.

Step 2: Type the new text with the keyboard.

If editing one of the identifier fields, a pop-up message is displayed. Select Yes to confirm or No to cancel.

The identifier fields are the following:

- Patient Last Name
- Patient First Name
- Patient Middle Name
- Patient ID
- Accession Number
- All the fields in the DICOM tab of the Patient Data Entry

If editing one of the fields listed above AFTER the exam was sent to a server, the DICOM store may start a new exam with the new patient information.

Entering the patient's height and weight automatically calculates the Body Mass Index (BMI).

3.7.8 Ending an Exam

Make sure all the images required are saved. After the exam is complete, end the exam as follows: Press End Exam on the touchscreen.

Note: Pressing End Exam automatically disables the laser.

Chapter 4 Probes

4.1 Probe/Clinical Applications Compatibility

The following table lists all clinical applications and probe compatibility available with Imagio® Breast Imaging System.

Clinical Application	**Probes**	
	US L18-5 Linear Probe	**OA/US L18-1 Probe**
Breast	x	x

4.1.1 OA/US L18-1 Probe (Model 8100)

The hand-held OA/US L18-1 Probe is used to obtain images of tissue. The OA/US L18-1 Probe consists of two internally sheathed cables: one cable (Optic Bundle) plugs into the Imagio® Breast Imaging System Laser Output Aperture and the second cable plugs into the Ultrasound Probe Port.

The OA/US L18-1 Probe is the only part that contacts the patient.

Refer to “Product Specifications” on page 165.

4.1.2 US L18-5 Linear Probe (Model 8500)

A US L18-5 Linear Probe (US Probe) is available should your clinical needs call for a high resolution, small footprint ultrasound probe. The US Probe is a high resolution broad bandwidth linear probe for use with the Imagio® Breast Imaging System. Refer to “Product Specifications” on page 165.

4.1.3 Probe Indicator and Orientation

All probes have a raised marker on their housing indicating channel 1 or element one. It is recommended the operator align this cephalic and/or to the patients’ right when they are in the supine position. For example: when scanning a patient in anatomic position, this indicator is oriented cephalic (longitudinal scan plane) or towards the patients’ right (transverse scan plane).

4.2 Probe Handling

Caution: The OA/US L18-1 Probe cable contains delicate optic cables that can be easily damaged if not handled carefully. If the optic cables are damaged, the OA/US L18-1 Probe may not emit the proper amount of laser light and the exam results may be degraded.

- Always store the OA/US L18-1 Probe in the Probe holder when not in use.
- Do not allow the OA/US L18-1 Probe cable to be crushed (for example: between equipment or stepped on.)
- Do not allow the cable to become crimped.
- The minimum bend radius for the optic cable is 5 cm (2”); therefore, the cable should not be wrapped tighter than an 11 cm (4”) diameter.

Probe damage may be mitigated or eliminated by closely following recommendations provided below. Adhering to these “Do’s and Do Not’s” will help prolong the life of the Seno Medical probes. Caution: Failure to follow these recommendations can result in damage to the equipment.

DO:

- Use care when handling the probes.
- Only connect or disconnect the probes by holding onto the connectors.
- Routinely inspect the entire probe assembly: optic ferrule, ultrasound connector, cabling, and the probe for any damage prior to connecting it to the Imagio® Breast Imaging System. If damage is discovered during a visual inspection, discontinue use and call Seno Service for assistance at (888) 978-8835.
  - Possible damage may include, but is not limited to:
    - Probe pins that are bent or broken within the ITT Cannon ZIF Connector
    - Split or cut cabling or shielding
    - Surface cracks, gouges or rough spots on the housing
    - Surface cracks on the face of the probe
    - Damage/separation of the acoustic lens
    - Damage/cracked/chipped on OA/US L18-1 Probe Optic Ferrule
    - Debris on the light sensor pads that are adjacent to the Optic Ferrule
    - Chips or cracks on glass windows
- Ensure that the OA/US L18-1 Probe glass windows and calibration port shield are clean and dry prior to performing laser energy calibration.
- Follow procedures contained in this manual regarding probe inspecting, cleaning, and disinfection.

DO NOT:

- Drop or hit the probe or probe face. Even moderate blunt force to the probe may damage the crystal elements and lead to product failure.
- Allow probe cabling to hang where it could be run over, caught, or pulled by the Imagio® Breast Imaging System cabinet wheels/casters while stationary or during movement.
- Apply excess force when removing or inserting the OA Probe Optic ferrule from or into the Laser Output Aperture or the removing or inserting the ITT Cannon ZIF connector.

4.3 Probe Sheaths for Use with US L18-5 Linear Probe Only

Under certain conditions where the probe may encounter mucous membranes, blood or other bodily fluids, the use of a probe sheath is recommended.

- After use, the single-use sheath should be removed and discarded.

The following tables list basic information regarding sterile probe sheaths which will physically fit our ultrasound probes. Please check whether the recommended products in the tables below are approved for use. Call the Seno Service for assistance at (888) 978-8835 for an equivalent.

4.3.1 US L18-5 Linear Probe Dimensions and Compatible Sheaths (for reference only)

Probe width 6.58 cm (2.6 in.), cable length 2.1 m (82.7 in.)

For reference only. Always refer to each CIVCO sheaths current instruction for use.

Manufacturer	Sterility	Latex/Latex Free	Description	Product Number	Dimensions
CIVCO	Sterile	Latex Free	CIV-Flex/ Telescopically Folded	610-637	8.9 x 91.5cm
CIVCO	Sterile	Latex Free	CIV-Flex/ Telescopically Folded	610-1000	10.2 x 147cm
CIVCO	Sterile	Latex Free	CIV-Flex/Flat Folded	610-001	8.9 x 61cm

Warning: When using a sheath with a probe, only non-latex sheaths should be used due to the prevalence of latex allergies.

4.4 Ultrasound Transmission Gel

Only use Seno approved gel.

Aquasonic Clear® Ultrasound Gel is required because of its optical compatibility with our probes.

4.5 Gel Holder/Warmer

An on-cabinet gel holder has been provided as a convenience.

The gel holder is located on the right side of the Console.

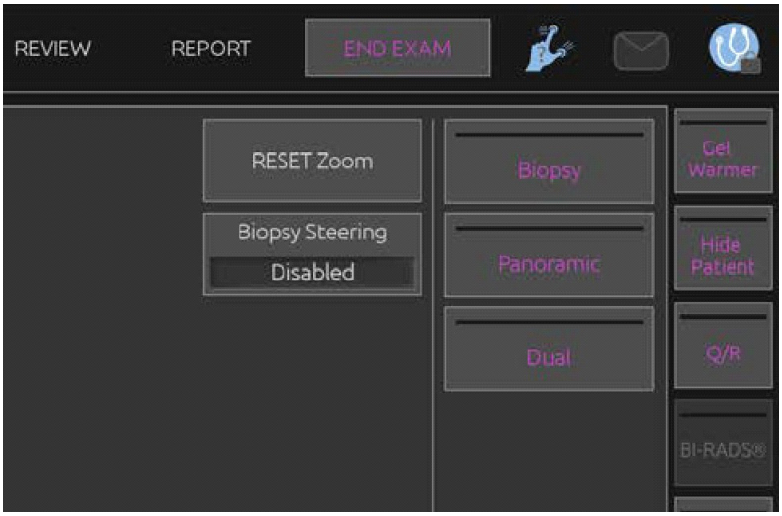
Warning: Only use the gel warmer with Seno approved gels for Imagio Breast Imaging System. Respect the expiry date of the gel.

Important: Place gel bottles in the holder with the nozzle down so that the gel is always ready to flow.

A gel warmer is built into the System Console for your convenience. It is directly integrated onto the gel holder. It heats gel to 86°F (30°C) in an hour and up to 98.6°F (37°) in 4 hours.

Note: If it is activated, please note that the gel warmer will alternatively and automatically activate and deactivate in order to regulate the gel temperature.

To activate or deactivate the gel warmer, press the gel warmer icon located on the top right of the Touch Screen.



Chapter 5 Cleaning System Components

5.1 Cleaning and Disinfecting Agents

The following cleaning and disinfectant agents have been tested by Seno. They are the only cleaner/disinfectants approved by Seno for cleaning the probe holder, calibration port, OA/US calibration probe adapter, and to clean and disinfect the Ultrasound only probe as well as the OA/US probe. Always reference the manufacturer's directions for use labeling affixed to each cleaner/disinfectant agent. Please reference the websites immediately below for availability to specific regions/countries for cleaning and disinfection purposes.

- Sani-Cloth® AF3 is approved for use on both L18-5 US Probe and L18-1 OA/US Probe. http://pdihc.com
- CaviWipes™ US is approved for use only on L18-1 OA/US Probe. http://www.metrex.com
- CaviWipes™ EU is approved for use only on L18-1 OA/US Probe. http://www.metrex.com/EU/
- Sani-Cloth® Bleach is approved for use (globally) with the L18-5 US probe. http://pdihc.com
- Sani-Cloth® Super is approved for use (globally) with the L18-5 US probe. http://pdihc.com

5.1.1 Cleaning the Laser Protective Eyewear

Caution: The Imagio® Breast Imaging System Laser Protective Eyewear has delicate lenses which may be easily damaged by misuse of cleaning agents and solvents.

- Do not use cleaning solvents on the Laser Protective Eyewear.
- Only use water and a soft cloth or approved lens cleaning towelettes.

5.1.2 Cleaning the Cabinet, System Console, Handles, Power Cord, Monitor Housing, and Gel Warmer

Be sure to clean any unused gel from the surface of the system console after Imagio® Breast Imaging System use.

Power off the Imagio® Breast Imaging System and Unplug the power cord from mains power outlet and the Imagio® Breast Imaging System before cleaning the power cord.

Apply a small amount of one of the following recommended cleaning solutions to a soft, non-abrasive cloth and wipe down the bezel:

- Water
- Mild detergent (PH level at or near 7) and water solution.
- Use warm water and a soft bristle brush to remove stubborn dried gel.

5.1.3 Cleaning the Monitor Display Screen and Touchscreen Display

A clean, soft cotton cloth dampened with an ammonia-based window cleaner should be used to clean the monitor display. Do not use paper towels, as these may scratch the monitor display. The cleaning agent should be sprayed onto the cloth, not directly onto the display surface. Take care not to get any cleaning agent into the housing of the Imagio® Breast Imaging System. This may lead to Imagio® Breast Imaging System damage.

5.1.4 Cleaning the Probe Holder, OA/US L18-1 Probe Calibration Adapter, Calibration Port - Energy Sensor Shield, and Flat Breast Phantom

Daily or as needed. Clean or disinfect with Seno approved cleaner disinfectants. For Energy Sensor Shield cleaning refer to “Performing Laser Energy Calibration” on page 87.

5.1.5 Cleaning the Foot Switch

Apply a small amount of one of the following recommended cleaning solutions to a soft, non-abrasive cloth:

- Water or 70% isopropyl alcohol

5.1.6 Cleaning the Air Filter

The Imagio® Breast Imaging System is equipped with an air filter. The Imagio® Breast Imaging System displays an icon on the display left bottom as a reminder to check the air filter. The air filter is located at the back of the Imagio® Breast Imaging System.

It is recommended that the air filter be cleaned monthly or more frequently if a significant accumulation of dust or debris is noted.

The air filter should be checked at least monthly and cleaned as needed to keep the system functioning properly and avoid overheating. The air filter is located on rear of the cabinet. To check the filter, perform the following steps.

Step 1: Power off the Imagio® Breast Imaging System.

Step 2: Remove the air filter using the built-in hand hold on the air filter cover.

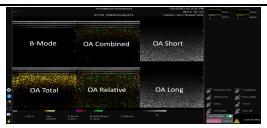
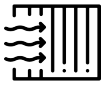
Step 3: Inspect the filter and clean as needed using one of the following methods. Replace the air filter if it is damaged. Additional air filters can be ordered. Call Seno Service for assistance at (888) 978-8835

- **Method 1 Vacuum Clean:** A few passes of a vacuum cleaner will remove accumulated dust and dirt quickly.
- **Method 2 Blow with Compressed Air:** Point compressed air nozzle in opposite direction of operating air flow (blow from exhaust side toward intake side).
- **Method 3 Water:** Under normal conditions, collected dirt is washed away quickly and easily using just a standard hose nozzle with plain water. If stubborn air-borne dirt is present, the filter may be dipped in a solution of warm water and mild detergent. Then simply rinse in clear water, let stand until completely dry and free of moisture, and return to service.

Important: Ensure that filter is completely dry before returning to service.

5.1.7 Cleaning Frequency

Perform the maintenance operations as described in this chapter. Cleaning of the Imagio® Breast Imaging System should occur at regular intervals, or more frequently as needed. Seno provides the following recommended cleaning intervals as guidelines:

Part		Recommended Cleaning Frequency
	Probes	Inspect, clean, and disinfect between patients.
	Laser Protective Eyewear	Inspect the eyewear prior to use. Clean if visibly dirty. It is recommended operators always wear eyewear with clean lenses.
	Display Monitor	Clean weekly, or as needed.
	System Console	Clean daily, or between patients.
	Touchscreen Display	Clean daily, or between patients.
	Exterior: chassis and Handles	Clean weekly, or as needed.
	Air Filter	Clean monthly.

It is prudent to continually survey the Imagio® Breast Imaging System for maintenance needs. Call Seno Service for assistance at (888) 978-8835.

5.2 Probe Inspecting Cleaning and Disinfecting

5.2.1 Probe Inspecting Cleaning and Disinfection Guidance

Use Seno approved cleaning and disinfecting agents only. Probes are sensitive and may easily be damaged by harsh cleaning agents, corrosive chemicals, or mishandling. Always use care when handling the probes.

The following generalized instructions for inspecting, cleaning, and disinfection are indicated for use with the probes.

The probe must be cleaned after each use for further disinfection.

The functional life of the probe(s) which are accessories to the Imagio® Breast Imaging System have been robustly tested and their functionality will be verified by the service technician as part of the recommended Seno 6-month Service and Maintenance program. However, repeated misuse, improper cleaning and disinfection, or careless handling may cause damage to the probe.

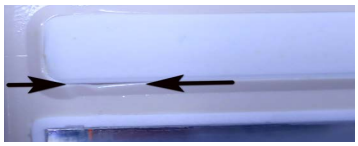
5.2.1.1 Inspecting the Probes

Step 1: **<u>Disable the laser</u> when inspecting the probe, cleaning the probe or when the Imagio® Breast Imaging System will be unattended.** ***It is not necessary to disconnect the probe from the cabinet.***

Step 2: As a precaution, visually inspect the probe face from an acute angle. Look for damage, especially cracks, or breaks, in the glass windows. For all probes; look for damage, especially separation of the lens, gouges or breaks in the housing or gasket material that could scratch the patient or that could be a void for contaminants to accumulate. Inspect the probe cable for damage, especially tears and signs of it being crushed. Call Seno Service for assistance at (888) 978-8835 if damage is observed.

Cracked Glass

Lens Separation



Step 3: After the probe and probe cable passes visual inspection, place into the Imagio® Breast Imaging System probe holder and proceed to the instructions for cleaning the probe.

5.2.1.2 Cleaning and Disinfecting the Probes with Germicidal Disposable Wipe

To prepare to clean and disinfect the probe(s) it is important to check the directions provided with the cleaner/disinfectant as well as to follow those steps that have been verified effective. With all cleaning and disinfecting products called out below, it is important to:

- wear gloves,
- it is recommended user wear chemically protective eyewear,
- prepare the cannister or packet holding the cleaning/disinfecting agent per the directions for use on the packaging,
- check the cleaner/disinfecting agent directions for use, and
- visually inspect the probe in a well-lit area prior to cleaning, following cleaning pre-disinfection, and post disinfection.

A) ***Using Sani-Cloth® Super Cleaner/Disinfectant on L18-5 US Probe***

Step 1: Following the generic preparations cited above, wipe the internal surface of the probe holder, and continue until all visible soil is removed using the Sani-Cloth® Super Disposable Wipe.

Step 2: Use Sani-Cloth® Super Disposable Wipes to thoroughly clean all surfaces of the L18-5 US probe, paying special attention to crevices and hard-to-clean-areas. Include the cable but avoid applying liquid to the electrical connection end. Replace soiled wipe as needed and use additional wipes to ensure that all surfaces are uniformly cleaned and that no visible soil remains.

A1) Disinfect with Sani-Cloth® Super Cleaner/Disinfectant on L18-5 US Probe www.metrex.com.

Step 1: As long as there is no visible soil remaining on the L18-5 US Probe, disinfection can begin by wetting the surface of the probe face for two (2) minutes.

Step 2: Allow the surface to air dry.

B) *Using Cavi-Wipe® Cleaner/Disinfectant on L18-1 OA/US Probe*

Step 1: Following the generic preparations cited above, Wipe the internal surface of the probe holder, and continue until all visible soil is removed using the using the Cavi-Wipe® Cleaner/Disinfectant.

Step 2: Use Cavi-Wipe® Disposable Wipe to thoroughly clean all surfaces of the L18-1 OA/US probe, paying special attention to crevices and hard-to-clean-areas. Include the cable but avoid applying liquid to the electrical connection end. Replace soiled wipe as needed and use additional wipes to ensure that all surfaces are uniformly cleaned and that no visible soil remains.

B1) Disinfecting using the Cavi-Wipe® Disposable Wipe on L18-1 OA/US Probe

Step 1: As long as there is no visible soil remaining on the L18-1 OA/US Probe, disinfection can begin by wetting the surface of the probe face for two (2) minutes.

Step 2: Allow the surface to air dry.

C) *Using Sani-Cloth® Bleach Cleaner/Disinfectant on the L18-5 US Probe*

Step 1: Following the generic preparations cited above, wipe the internal surface of the probe holder, and continue until all visible soil is removed using the Sani-Cloth® Bleach Disposable Wipe.

Step 2: Use Sani-Cloth® Bleach Disposable Wipes to thoroughly clean all surfaces of the L18-5 US probe, paying special attention to crevices and hard-to-clean-areas. Include the cable but avoid applying liquid to the electrical connection end. Replace soiled wipe as needed and use additional wipes to ensure that all surfaces are uniformly cleaned.

C1) Disinfect with Sani-Cloth® Bleach Cleaner/Disinfectant

Step 1: Using a second Sani-Cloth® Bleach Wipe, wet the external surface of the probe face for a minimum of four (4) minutes. Use additional wipes as needed to keep the surface of the probe face wet for the full four (4) minutes. At the end of the four (4) minutes, wipe until all visible soil is removed.

Step 2: Visually inspect the probe in a well-lit area. If any soil remains, clean and disinfect until all visible soil is removed.

D) *Using Sani-Cloth® AF3 Cleaner/Disinfectant on the L18-5 US and L18-1 OA/US Probes*

Step 1: Following the generic preparations cited above, wipe the internal surface of the probe holder, and continue until all visible soil is removed using the Sani-Cloth® AF3 Disposable Wipe.

Step 2: Use Sani-Cloth® AF3 Disposable Wipes to thoroughly clean all surfaces of the probe, paying special attention to crevices and hard-to-clean-areas. Include the cable but avoid applying liquid to the electrical connection end. Replace soiled wipe as needed

and use additional wipes to ensure that all surfaces are uniformly cleaned.

D1) Disinfect with Sani-Cloth® AF3 Cleaner/Disinfectant

Step 1: Using another Sani-Cloth® AF3 Wipe, wet the external surface of the probe face for a minimum of three (3) minutes. Use additional wipes as needed to keep the surface of the probe face wet for the full three (3) minutes. At the end of the three (3) minutes, allow to air dry.

Step 2: Visually inspect the probe in a well-lit area. If any soil remains, clean and disinfect until all visible soil is removed.

Chapter 6 System Power

6.1 Circuit Breaker

The Imagio® Breast Imaging System Circuit Breaker is located on the lower, back of the cabinet. Always leave the circuit breaker in the ON position for standard, daily operation.

6.2 Power On Procedures

Step 1: Ensure the power cord is plugged in to the Imagio® Breast Imaging System.

Step 2: Momentarily press the Power button located on the Console to begin the power on sequence.

Important: If the Imagio® Breast Imaging System is started without a probe attached, the message, "Please connect a transducer" is displayed. Connect and select the transducer on the Probe tab.

Important: If the Imagio® Breast Imaging System was just turned on, it may take up to 15 minutes for the lasers to reach operating temperature and before an OA Scan can be performed. The following Laser Icon will be displayed on the bottom right of the display monitor.

6.3 To Power Off the Imagio® Breast Imaging System

Step 1: Press and release the Power button located on the Console. The power off sequence can take up to 5 minutes and will be complete when the cooling fans stop.

Caution: The Imagio® Breast Imaging System is a sensitive electronic instrument and may be damaged or data may be lost by improper or misuse.

- Do not disconnect the active probe during live imaging.
- Do not use the Circuit breaker or main power for regular power off.
- Always perform an orderly power off of the Imagio® Breast Imaging System.

Chapter 7 System Console

7.1 Controls

7.1.1 General Information

The system console includes the Touchpad and controls such as buttons, dials, and dial-buttons.

Press a button to activate or deactivate its function.

Turn a dial to change the selected setting.

Press a dial-button to activate its function. When a dial-button is associated to a value, turn it clockwise to increase the value of the settings or turn it counterclockwise to decrease the value of the settings (unless configured differently in System Configuration).

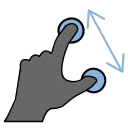
Note: Pressing on buttons related to options that are not available will have no effect.

7.1.2 Touchpad

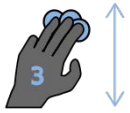
The Touchpad allows movement and navigation of the cursor in the operator interface of Imagio® Breast Imaging System. It also enables the operator to perform basic actions and measurements during exams by means of gestures.

Note: The Touchpad is designed to be used while wearing barrier protective gloves and while being covered during an interventional procedure.

The following table indicates how to perform the different gestures mentioned in this Operator Manual (unless configured differently in the System Configuration):

Gesture name	**How to perform the gesture**
Press	Press on the Touchpad 
Swipe	Move your finger(s) vertically or horizontally 
Pinch/Spread	Do a pinch or spread gesture using 2 fingers 

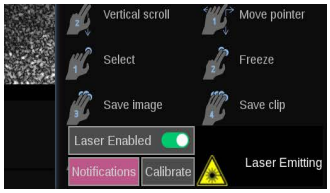
The following table lists the main gestures available by default (unless configured differently in System Configuration):

Controls	Associated gesture
Select/Press	Press with 1 finger 
Freeze	Press with 2 fingers 
Clip navigation	When in frozen mode: Swipe right with 2 fingers to navigate the clip forward Swipe left with 2 fingers to navigate the clip backward 
Save image	Press with 3 fingers 
Save clip	Press with 4 fingers 
Depth	Swipe up with 3 fingers to decrease the depth Swipe down with 3 fingers to increase the gain 
Gain	Swipe right with 3 fingers to increase the gain Swipe left with 3 fingers to decrease the gain 
Zoom	Pinch with 2 fingers to decrease the zoom Spread 2 fingers to increase the zoom 
Move a box	Swipe 1 finger in the desired direction 
Arbitration (Update)	Press the Touchpad with 4 fingers to change between Box Move (position of the box) and Box size (resize the box). Swipe in the direction needed to reposition or resize the box.  Press the Touchpad with 4 fingers to switch between Img1 and Img2 in dual displays.

Note: Make sure your fingers are placed on the Touchpad before pressing.

A gesture reminder area is available by pressing the gesture icon on the top right of the Touchscreen.

The gesture reminder area is now displayed on the display monitor bottom right.

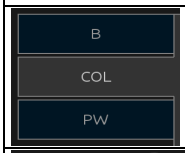
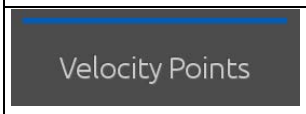
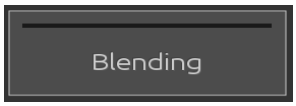
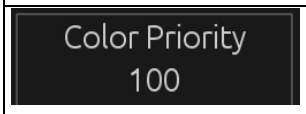
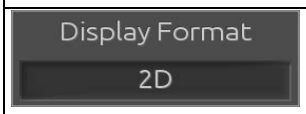


These gestures are entirely customizable in System Configuration.

Please refer to "Common Imaging Controls" on page 62 for more information about each control/ gesture combination.

7.1.3 Touchscreen

The Touchscreen contains several types of controls, depending on the function to perform.

Touching this type of control...	**... triggers this event**
	Touch a tab to display a different imaging menu.
	Touch to open a page or function. Touching the Keyboard control in this example displays the keyboard.
 	Touch to turn a function On or Off. The LED button is blue when the function is on, and black when it is Off.
	Touch to change the value displayed on the button. Repeatedly pressing this type of button cycles through all the values. The value displayed is indicated by the position of the mark.
	Rotate the dial located below the Touchscreen label to change the value.
	Touch to change the value displayed on the button. The value displayed is indicated in the box.

Note: Adjust the Touchscreen brightness in System Configuration, System sub-tab.

7.2 Monitor and Articulated Arm

The monitor is mounted on an articulated arm that permits it to be positioned vertically and horizontally.

Adjust the position of the monitor to suit different operating positions and operator heights.

When it is released from its locked transport position, the monitor can be tilted up and down, swiveled left and right, and moved from side to side.

To release the monitor from its locked transportation position, rotate the knob on the arm counterclockwise (blue arrow).

For transportation, put the monitor in its lower position and rotate the knob clockwise (red arrow) in order to lock the monitor in this position. It the system needs to be packed for transportation the monitor can be put in flat position.

To adjust the monitor, grasp it by its handle and tilt, swivel, or move it.

Configure the brightness of the screen using the -/+ buttons located at the bottom right hand corner of the monitor.

7.3 How to Move the Console

The Imagio® Breast Imaging System must be powered on to move the console.

Press and hold the console release button located on the handle and move the console to the desired left-right, up-down position and release the button to lock the console's position.

7.3.1 Speakers and Audio Adjustment

The Audio Volume may be adjusted in System Configuration.

Note: Either mute system sounds such as Save Image and Save Clip (in System Configuration, System/ Display tab, System sub-tab) or mute spectral audio volume when in PW by pressing on the Audio volume button.

Chapter 8 OA Mode

8.1 OA Mode Selection

Press the OA button on the System Console to enter OA Mode. All OA parameters are automatically optimized.

Only trained and authorized operators are permitted to perform OA scans with the Imagio® Breast Imaging System. Safeguards have been designed into the Imagio® Breast Imaging System to protect the Operator and the Patient from laser energy; however, it is the responsibility of the Operator to follow all Warnings and Cautions outlined in this manual. Refer to “Safety Descriptors” on page 8.

Once the Imagio® Breast Imaging System completes a power on it defaults to OA Mode and the laser is in standby mode. To enter OA Mode at any time, press the Console OA button.

Important: Laser Icons and Status Codes appear on the bottom right of the display monitor to communicate the laser state to the Operator and can be found by referring to “Status Codes” on page 111.

Warning: Invisible laser light is emitted from the OA/US L18-1 Probe. Reflected and/or misdirected laser light may damage eyes.

- **Do not use any controls or adjustments or performance settings other than those specified herein.**
- **The Patient, the Imagio® Breast Imaging System Operator, and everyone else in the scan room must always wear Seno approved Laser Protective Eyewear when the Imagio® Breast Imaging System is powered on and the laser is enabled.**
- Wearing Seno approved Laser Protective Eyewear is a laser safety requirement. It is necessary to wear Laser Protective Eyewear when, for example; scanning, inspecting and cleaning the OA/US L18-1 Probe, and calibrating laser energies or any other time the Imagio® Breast Imaging System is powered on and the laser is enabled.
- Do not look directly at the laser beam even when Laser Protective Eyewear is being worn.
- Do not look at the probe face while the laser is in emission from the Imagio® Breast Imaging System. The Imagio® Breast Imaging System uses lasers that are classified as invisible; however, some individuals can see the light emitted from the Imagio® Breast Imaging System. Additionally the skin detection sensors in the OA/US L18-1 Probe emit red visible light when the laser is in the ready state (not lasing).
- Always point the OA/US L18-1 Probe away from everyone’s eyes.
- Only use your foot to press the foot switch.
- Always release the foot switch before removing the OA/US L18-1 Probe from the skin or calibration port.
- Always follow the laser safety precautions prior to laser emitting to protect the Patient, Operator, and Observers.
- Always place the OA/US L18-1 Probe in the Probe holder when not in use.

Warning: Operation of the Imagio® Breast Imaging System by untrained, unauthorized individuals may result in harm to patient and/or operator.

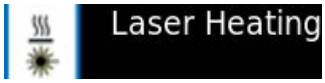
- Do not allow the Patient to touch the Console.
- Do not share your password or Laser Authorization Card with anyone. Only trained operators can use the Imagio® Breast Imaging System.
- Always disable the laser by selecting the Display Laser Control button when the Imagio® Breast Imaging System will be left unattended.

Warning: Laser emission in the presence of flammable materials may cause fire or explosion.

- Do not emit laser in the presence of flammable materials, solutions, or gases; or in an oxygen enriched environment to include:
  - Gases containing more than 21% oxygen
  - A breathing atmosphere containing more than 21% oxygen
  - A liquid with greater than 21% oxygen (for example, RL (rich liquid) is usually 35-40% oxygen)
  - The use of nasal prongs is not considered an oxygen rich environment.

8.2 Laser Heating

Laser is warming up and has not reached operating temperature. Warmup.. % complete status code will also be displayed. This laser status icon will change, and the status code will disappear when the laser reaches operating temperature.



The Laser Icon will be displayed on the bottom right of the display monitor.

Laser Heating will take up to 15 minutes from initial power on or laser sleep.

Laser Heating will occur upon power on or after the laser is enabled and the freeze button is pressed twice freeze then unfreeze.

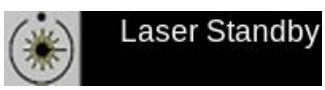
8.3 Laser Sleep

Laser will discontinue heating and enter laser sleep if no operator input is detected within 60 minutes by default. The time may be adjusted in the System Configuration.

To exit sleep, Laser Authorization must be performed to enter Laser Status Enabled.

8.4 Laser Standby

The Imagio® Breast Imaging System defaults to Laser Standby. However, if the Laser is Enabled and in Laser Ready, pressing the Console Freeze button in OA Mode commands the Imagio® Breast Imaging System Laser to stop all laser energy generation. The Laser Status icon displays Laser standby.



8.4.1 To Place the Imagio® Breast Imaging System in Laser Standby

Step 1: Press the Console Freeze button in OA Mode.

The following occurs:

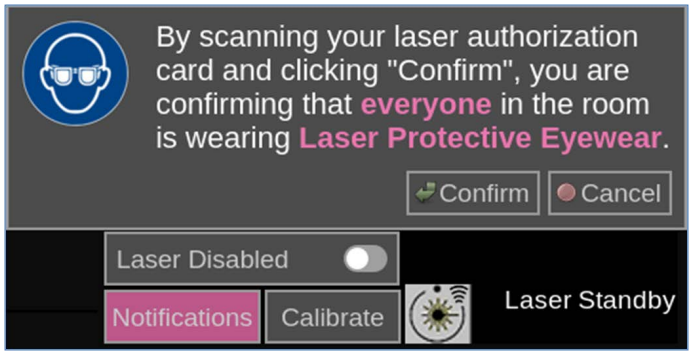
The laser state message icon changes to Laser Standby.

8.5 To Enable the Laser - Authorizing the Laser

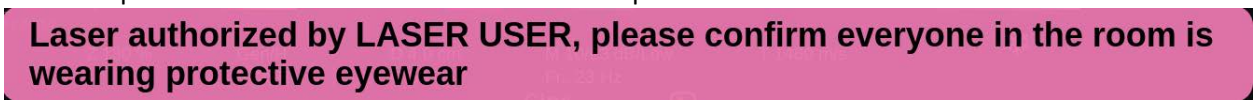
Step 1: Confirm that the Display Monitor is displaying the message Laser Disabled on the imaging screen.

Step 2: Place a registered Laser Authorization Card over the NFC Reader located on left of TouchPad of the Imagio® Breast Imaging System Console.

- A dialog box appears above the laser status requesting that the user confirm protective eyewear.



- After the user presses Confirm on the dialog box, a message appears on the monitor bottom left to indicate who authorized the laser and the authorization is logged to the Notifications list. Operator name is “LASER USER” in this example.



- The laser status will change to Laser Enabled and the switch will slide to the right and the background color will be green.

- If the imaging is not frozen and laser is heated the Laser Ready Icon is displayed, 

.
- If the laser is not heated the icon will indicate Laser Heating, 

.

A message appears on the monitor bottom left reminding the operators to check that everyone in the scan room is wearing Laser Protective Eyewear.

The Imagio® Breast Imaging System will remain in the Laser Enabled State if the operator selects B Mode and the operator keeps the Imagio® Breast Imaging System active. This allows the operator to toggle back and forth into other imaging modes, the laser will not emit until OA Mode is selected and foot switch is pressed.

Important: Laser will be disabled after 15 minutes of inactivity, even if Laser Authorization Card is left on console.

8.6 Laser Adjustment Period

The Laser Adjustment Period is designed to ensure that the laser has time to compensate for variations prior to OA/US L18-1 Probe laser emission. The Laser Adjustment Period occurs when the thermal state of the Imagio® Breast Imaging System laser has changed, for example, after being powered off or allowed to sleep.

The Imagio® Breast Imaging System will begin a Laser Adjustment Period after the laser is first powered on, laser energy calibration, or laser sleep. During the adjustment period the Imagio® Breast Imaging System will emit laser with the Imagio® Breast Imaging System internal laser shutter closed so there is no laser emission from the OA/US L18-1 Probe. The adjustment period generally requires 3-10 seconds and a maximum of 60 seconds.

- No laser energy will emit from the OA/US L18-1 Probe during the Laser Adjustment Period; however, it is required the everyone in the Imagio® Breast Imaging System suite wear Laser Protective Eyewear and still take all necessary laser safety precautions
- The Laser Adjustment Period is started when a operator unfreezes the Imagio® Breast Imaging System (with or without the foot switch pressed)
- The laser status icon Preparing is shown on the bottom right of the display
- No OA images will be displayed on the monitor until adjustment is complete

8.7 To Enter Laser Ready

Step 1: From the Freeze state press the Freeze button on the Console.

The following occurs:

- The laser state message icon changes to Laser Ready if the laser is enabled and up to operating temperature. The laser needs to be up to operating temperature for this to occur.

A message appears on the display monitor bottom to remind the operator to check that everyone in the scan room is wearing Laser Protective Eyewear.

Step 2:

8.8 Probe Contact Sensor

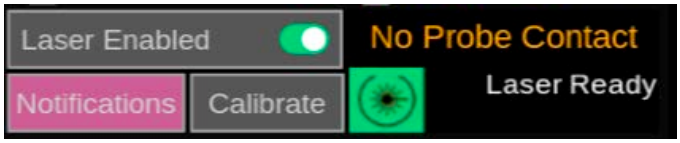
The OA/US L18-1 Probe is equipped with surface detection sensors which disable laser emission when the probe face is not in direct contact with a reflecting surface in order to help prevent accidental laser emission.

- Laser emission will occur when the operator completes the following steps:

1. The Imagio® Breast Imaging System is in OA Mode. Press the OA button on the System Console.
2. The Laser has been authorized as indicated by the message “Laser Enabled” and the slide switch positioned right and displaying green. A message appears on the display to remind the operators and everyone in the scan room wear Laser Protective Eyewear.

3. The laser is available (in live imaging), the laser status icon indicates “Laser Ready”. Press Freeze/ Unfreeze icon (snowflake) if the image is frozen and the laser status icon is indicating “Laser Standby”.
4. The probe face is in contact with the patient skin.
5. The foot switch is pressed.

If probe contact is not detected, a message will also flash on the bottom right of the display stating “No Probe Contact.”



8.8.1 Foot Switch Operation

The foot switch controls laser light emission from the OA/US L18-1 Probe.

Important: If OA Mode has been exited, the foot switch must be released before unfreezing in OA Mode.

Step 1: Enter OA Mode.

Step 2: Authorize the Laser. Ensure Laser Ready.

Step 3: Place the OA/US L18-1 Probe in contact with the surface. Be sure Laser Ready is indicated. If laser standby is indicated, press the system freeze button.

Step 4: Press the foot switch down and hold it to emit laser. The laser state icon indicates laser emitting.

Release the foot switch (or press the freeze button on the system console), to stop laser emission. The laser status icon indicates laser ready. Pressing freeze will stop laser emission and the laser status icon will indicate laser standby.

8.9 To Disable the Laser

Step 1: Confirm that the Display Monitor is displaying the message Laser Enabled on the imaging screen.

Step 2: Press the cursor button to activate the cursor and click the Laser Enabled switch on the display to the left.

- The message Laser Disabled appears and the switch moves to the left revealing a gray background.

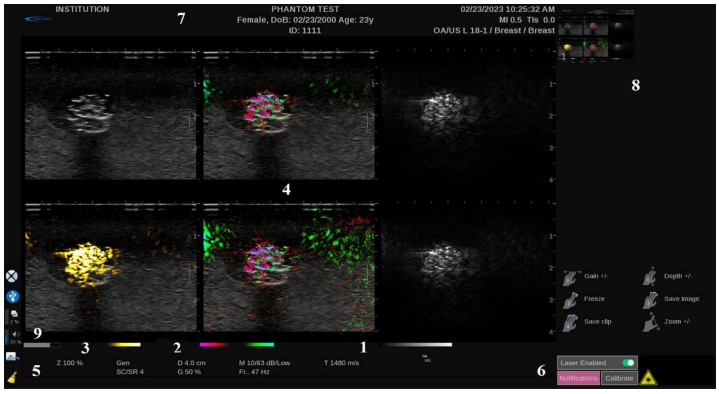
Note: Pressing End Exam automatically disables the laser.

8.10 OA Display

When the Imagio® Breast Imaging System power on initialization is complete, the Imagio® Breast Imaging System automatically enters OA Mode as the default mode.

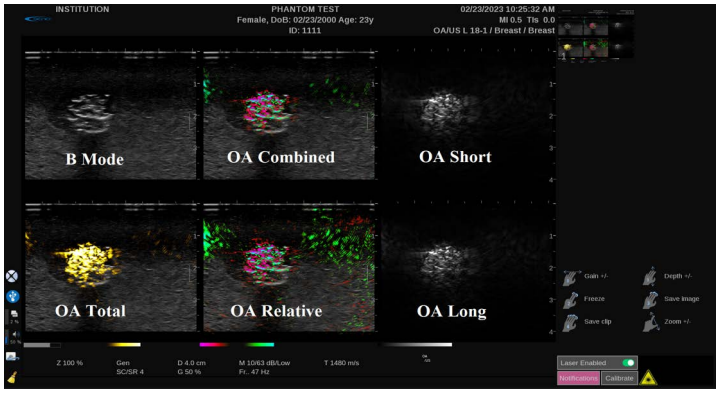
If the Patient tab is active, press the Image tab to enter the live imaging.

8.10.1 Display Description



Areas of the Display		
1	Gray Scale	The gray scale applies to the B Mode image and to the grayscale overlay in the OA Combined, OA Total, and OA Relative regions.
2	Total Absorption Color Scale	Displays the order in which colors are used to depict total levels of laser light absorption.
3	Relative Absorption Color Scale	Displays the order in which colors are used to depict relative levels of laser light absorption.
4	Image area	Displays gray-scale and co-registered and temporally interleaved OA images.
5	B Mode Ultrasound Parameters	Current B Mode Ultrasound parameters.
6	Laser Status Bar	Displays status such as: Laser state (e.g. Standby, Ready, Emitting) Provides laser enable control, calibration control, a history of laser notifications. Software patents and version information are located in the “About” section of the Notifications control window.
7	Exam Information	Facility ID + Patient ID, Patient Initials, Probe Name-Imaging Mode, Operator ID, Date of Exam, Time of Exam
8	Data Store	Still Images and Clips
9	Clip Buffer	Retrospective recording memory

8.10.2 Display Monitor Screen (During Live OA Scan)



Description of the OA Display	
B Mode	Displays grayscale ultrasound to identify the morphology of the imaging area.
OA Total	The OA Total image represents the features that appear prominently in both the OA Short and OA Long image.
OA Relative	The OA Relative image presents features that appear in the OA Short but not the OA Long image as a Red indication and features that appear in the OA Long but not the Short as a Green indication.
OA Combined	The combined image represents features in the OA Relative image that appear prominently in the OA Total image.
OA Short	Represents the Opto-acoustic (OA) images for the short laser wavelength, before the colorization process.
OA Long	Represents the Opto-acoustic (OA) images for the long laser wavelength, before the colorization process.

8.11 Description of OA Mode Imaging Parameters

B Mode imaging parameters are available in OA Mode. Refer to “Description of B Mode Imaging Parameters” on page 68.

8.12 SenoGram®

The SenoGram® is clinical decision support software with artificial intelligence (AI) designed to provide a frame of reference for a radiologist’s reading of OA/US images. The SenoGram® helps translate the Imagio® Breast Imaging System OA/US feature score input by the Radiologist into a continuous POM and subsequently the probability of cancer. Feature scores and various patient data are entered into the SenoGram® in order to aid the physician in determining the final POM, subsequent BI-RADS category, and ultimately the decision to biopsy or not.

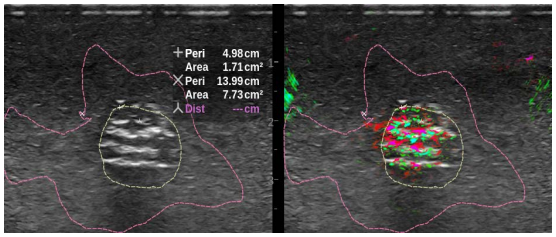
Note: Refer to the didactic SenoGram® training module.

8.13 Region of Interest (ROI)

The Operator can “trace” multiple regions of interest (ROI) on the OA mode while the image is frozen then save the image with the drawn ROI. Alternatively, the ROIs may be drawn on an already saved image and re-saved with the ROI. The ROIs propagate to all 6 fields of view (OA Combined, OA Short, OA Total, OA Relative, and OA Long) of the OA mode 6 on 1 display. Drawn ROIs assist the user with localizing the OA colorized and OA short and long wavelength in the three feature scoring zones; peripheral zone, boundary zone, and internal zone.

Free-form ROIs can be traced around an object of interest and graphics arrows and/or text can be applied. The ROI is pink when being drawn or modified and white when the ROI is closed. If two ROIs are drawn in OA Mode, the outer ROI is pink and the inner ROI is yellow. Refer to “Trace Region of Interest (ROI)” on page 95.

8.13.1 To Draw a Region of Interest (ROI)



There are two ways to draw an ROI:

8.13.1.1 Touchpad ROI

Step 1: Select the Measure button.

Step 2: Select the Trace button.

a) A pink cross appears or an alternate icon indicator if there is more than one ROI.

Step 3: Drag your finger to position the start location and press Touchpad to set start location.

Step 4: Drag the cursor to outline the shape with your finger on the Touchpad.

Step 5: End the ROI at the start location by lifting your finger off the Touchpad or end by lifting your finger off the Touchpad in close proximity to the start location and press the End button to close the ROI.

a) The perimeter and distance is indicated on the display.

8.13.1.2 Touchscreen ROI

Step 1: Select the Measure button

Step 2: Select the Trace button

a) A pink cross appears or an alternate icon indicator if there is more than one ROI

Step 3: On the Touchscreen grayscale display, press and hold anywhere on the Touchscreen then drag your finger to the shape of the ROI

Step 4: End the ROI at the start location by lifting your finger or end by lifting your finger off the touch-screen in close proximity to the start location and press the End button to close the ROI.

a) The perimeter and distance is indicated on the display.

Note: Press Touchscreen Clear Last ROI or Clear All ROI button to remove ROIs from the image on the display.

Chapter 9 Imaging Artifacts

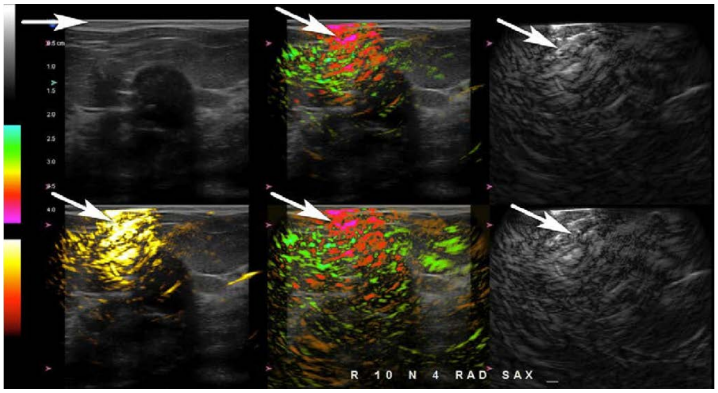
9.1 OA Artifacts

The Imagio® Breast Imaging System displays co-registered Opto-acoustic and Ultrasound (US) images in real-time. As with any imaging modality, consideration must be given to the physical principles by which it works and how these principles affect the output image.

Only trained and authorized operators may interpret OA images and video for medical diagnosis. The following potential combination Opto-acoustic and US only image artifacts are noted:

9.1.1 Gel Standoff, Air Trapping, and Air Gap

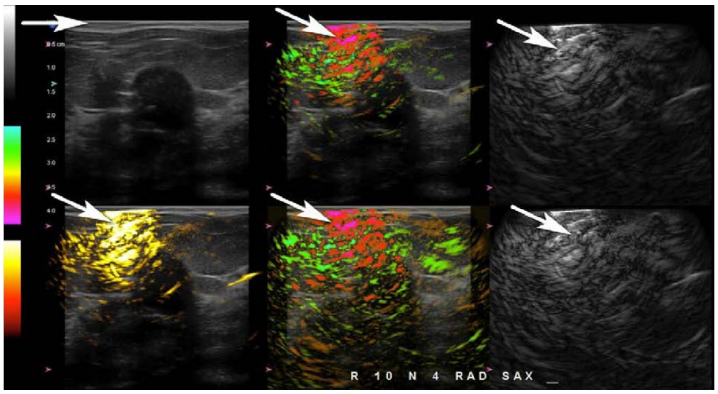
Gel standoff occurs when there is too much gel applied to the skin causing the probe face to not be in close contact with the skin. On grayscale it appears as a anechoic line between the probe face and skin surface. On OA it prevents light from penetrating tissue. It is resolved by spreading out the gel so that only a wet surface exists.



Air trapping occurs when the gel contains trapped air bubbles. On grayscale it may appear as a ring-down artifact. On OA it may appear as a drop out or cause interference lines. It is resolved by spreading out the gel so that only a wet surface exists.

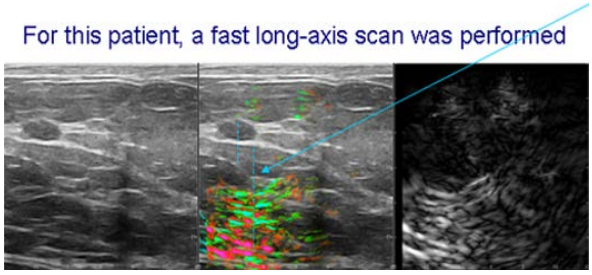
Air gap occurs when the probe face is lifted off the surface. On both grayscale and OA there is a drop out of signal. It is resolved by placing the entire probe face in contact with the surface.

Air Trapping and Air Gap have a similar appearance:



9.1.2 Temporal Mis-registration

Because the OA and US images are temporally interleaved, there can be a slight difference in the location of the probe during the time between OA image acquisition and the US image acquisition. This will manifest itself in the OA Combined, OA Relative and OA Total regions of the display showing colorization on areas of the B Mode image that are displaced by the amount of probe movement. To minimize, operators are trained to use a slow scanning technique of no more than 5 mm/sec. Moving the probe faster, could result in potential mis-registration of the OA colorization and gray-scale images and can affect the diagnostic quality of the image.



Opto-acoustic reflection artifact should be directly under the tumor, but there is a 3mm offset.

Since the probe was in motion along the long axis, the delay between the ultrasound frame capture and the opto-acoustic frame capture resulted in a 3mm horizontal misalignment between the OA/US and Ultrasound.

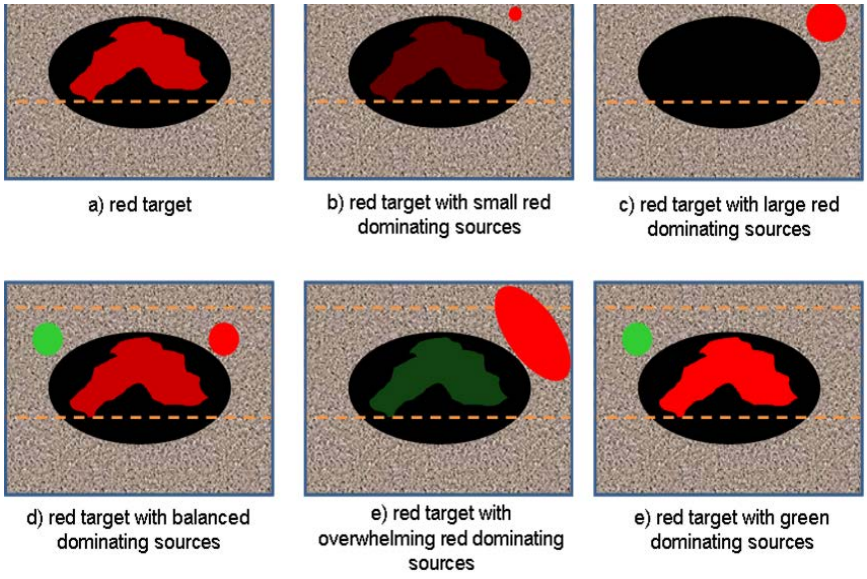
9.1.3 Sound Velocity Errors

Both the OA and US reconstruction algorithms use a speed of sound parameter to account for the propagation of acoustic signal through the tissue. This can cause mis-registration between the US and OA due to the bi-directional nature of the US acoustic signal compared to the uni-directional nature of the OA acoustic signal. The operator is advised to adjust the speed of sound parameter on the console to obtain the best co-registration and the best (most focused) appearance of targets in the OA short and long wavelength images.

Additionally, speed of sound variations within the imaging plane can cause mis-registration that must be accounted for. In US, this can cause a speed displacement artifact. In OA, this can cause both a speed displacement artifact and a co-registration displacement. To correct for this, ensure the speed of sound for breast imaging is set to the average speed of sound through breast tissue.

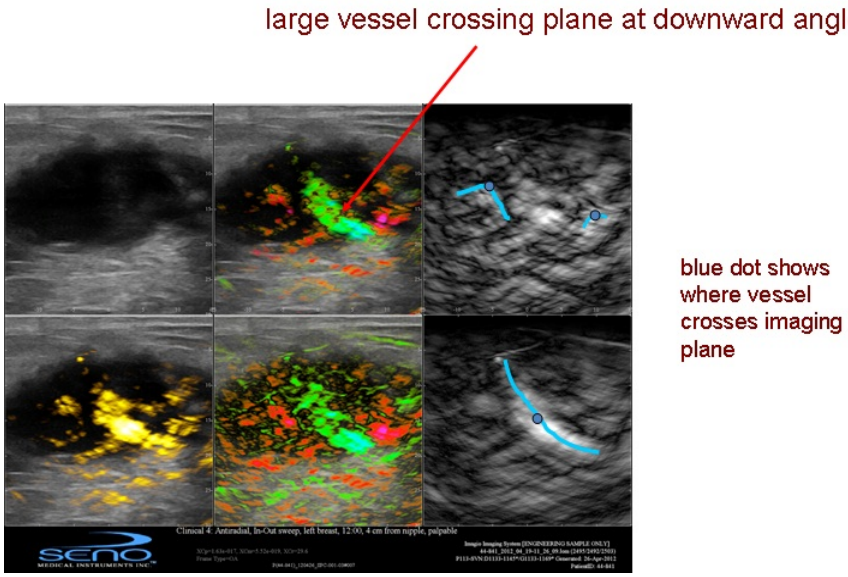
9.1.4 Non-Uniformity

In the OA images (OA Short and Long, Total, Relative, and Combined), it is important to consider that the two wavelengths of light can penetrate the tissue in different ways and can be absorbed in different amounts. A key component of the operation of the device is the preferential absorption of the 757 nm wavelength by de-oxygenated blood. This absorption means that there is less light that penetrates beyond the area of high absorption. In the alternate wavelength (1064 nm), the absorption in the same area of the image may not be affected in the same degree and hence colorization accuracy may be affected beyond the strong absorbing area, e.g. it may be colored with more green than it would normally be. Conversely, high absorption in the 1064 nm wavelength can yield the opposite effect and cause redder colorization beyond a strong absorbing target. To compensate for this effect, operators are advised to scan around dominant absorbers whenever possible by taking multiple video sweeps in multiple different scan planes to avoid and minimize the non-uniformity artifact.



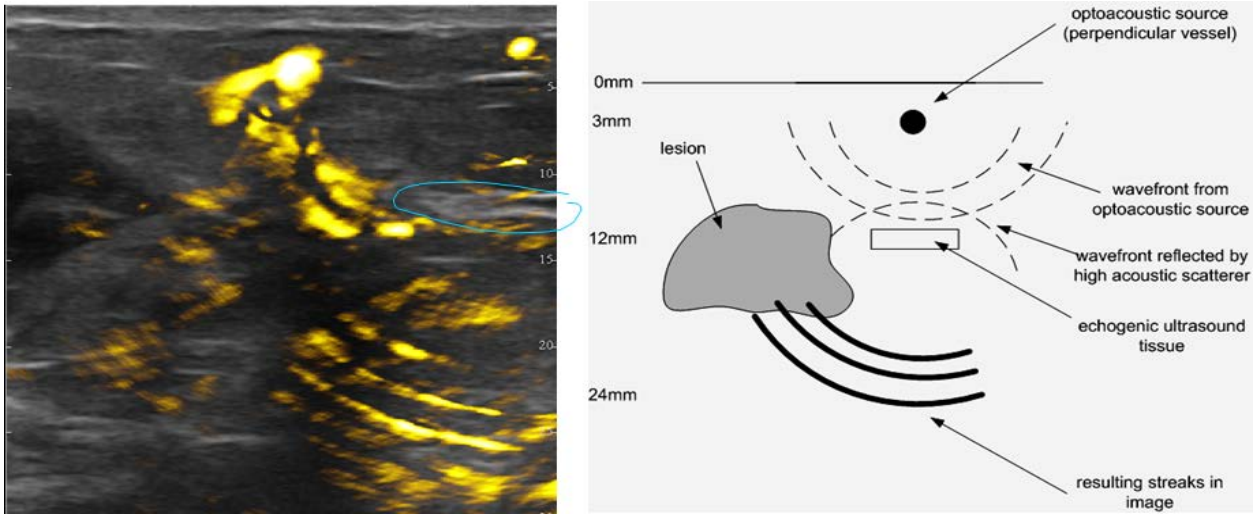
9.1.4.1 Out-Of-Plane Artifacts

OA imaging is not focused in the same way that Ultrasound imaging is. As such, signals may appear in images that are outside of the imaging plane. This is referred to as 'out of plane artifact'. Out of plane artifacts often appear in the image below a target lesion or vessel in the OA short and long wavelength images and result in colorization in the colorized images that does not represent the tissue immediately under the probe. This is real signal and can cause the colorization of items in plane to be affected. To correct for this, scan the target lesion from multiple directions and scanning planes to create a good understanding of the morphology of the lesion.



9.1.5 Reflections

The OA return signal may reflect off tissue boundaries and cause the appearance of phantom targets typically in the lower part of the image. Operators are advised to scan the target lesion from multiple directions and scanning planes to create a good understanding of the morphology of the lesion.



Ultrasound Artifacts

Because the OA return signal is an ultrasound response, the same issues that affect B Mode ultrasound can affect the OA image. These issues include but are not limited to propagation and attenuation artifacts.

Propagation Artifacts:	**Attenuation Artifacts:**
Reverberation	Enhancement
Comet Tail	Edge shadow
Ring-down	Shadowing
Refraction	
Slice thickness	
Range ambiguity	
Grating lobe	
Mirror Image	
Speed error	
Speckle	

For future reference, the Radiological Society of North America (RSNA) supplies training on US artifacts at https://education.rsna.org/diweb/catalog/item/eid/33845735

Additional resources may be found through the European Society of Radiology (ESR) at

https://www.myesr.org/education/

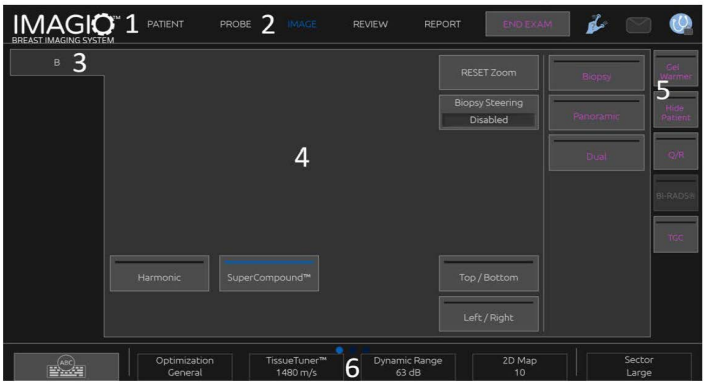
Chapter 10 System Controls

10.1 About the Imaging Touchscreen

The Imaging Touchscreen varies according to the scanning Mode.

It contains:

- permanent controls available in all imaging Modes
- imaging parameters that are related to the current active Mode(s)
- controls that can be used with their corresponding dials, located under the Touchscreen
- Additional controls may be available at the bottom of the Touchscreen by swiping with one finger.



1. System Configuration (Select Gear)
2. Workflow Menus
3. Imaging Mode tabs
4. Imaging Parameters
5. Permanent Controls
6. Control Bar (swiping)

10.2 Common Imaging Controls

Some controls are common to all imaging modes. These controls are detailed below.

For a description of controls specific to each imaging mode, refer to the detailed section on each imaging mode.

10.2.1 Freeze

When in Live imaging, press Freeze on the system console to freeze the image. A snowflake appears on the image to indicate the image is frozen. When the image is frozen, press Freeze to unfreeze the image and return to live imaging.

Note: Freeze and unfreeze the image by using the Touchpad. Press with two fingers on the Touchpad (unless configured differently in System Configuration) to freeze the image.

10.2.2 Depth

Depth controls the distance over which the B Mode displays anatomy.

When the depth is increased, echoes are captured from deeper in the body. Therefore, it takes longer for the probe to receive all the signal. The receive time is increased and there is more information to process. The time between two ultrasound beams is increased.

As a result, the frame rate is decreased.

Depth is located on the system console and adjustable only in live imaging.

Rotate Depth:

- clockwise to increase the depth and visualize deeper structures
- counterclockwise to reduce the depth and focus on shallower structures.

Note: Increase or decrease the depth by using the Touchpad. Swipe up with three fingers to decrease the depth or swipe down to increase the depth (unless configured differently in System Configuration).

10.2.3 Gain

Overall gain increases or decreases the amount of echo information displayed in an image.

It may have the effect of brightening or darkening the image if sufficient echo information is generated.

Gain is adjustable in live imaging and on a frozen image.

Gain is adjustable in all modes with each Mode dial.

Rotate B, CM, SWE™, COL or PW according to the active Mode:

- clockwise to increase the overall gain in order to obtain a brighter image
- counterclockwise to decrease the overall gain in order to obtain a darker image.

Note: Increase or decrease the gain by using the Touchpad. Swipe right with three fingers to increase the gain, or swipe left to decrease the gain (unless configured differently in System Configuration).

10.2.4 Time Gain Compensation (TGC)

10.2.4.1 Auto

Auto automatically adjusts the B Mode gain at different depths and for different tissue attenuations.

Overall brightness is automatically adjusted depending on setting of Auto Offset,

refer to “Description of B Mode Imaging Parameters” on page 68. Auto is located on the system console.

Press Auto. If needed, make independent gain adjustments, refer to Gain above.

Note: While in PW, press Auto to automatically adjust the Scale and Baseline. Refer to “Setting Up PW” on page 81.

Turning this Mode on enables the automatic TGC adjustments when changing the imaging controls. To activate or deactivate it, refer to “Exam” on page 127.

10.2.4.2 ManualTouchTGC™

Selectively adjust the uniformity of brightness throughout the image.

Press TGC on the Touchscreen.

The B Mode image is simultaneously displayed behind the sliders.

Draw the TGC curve as needed with a finger.

Change the position of each virtual control on its line by touching another place on the same line.

10.2.5 Focal Zone Management

The focal zone is the depth at which the lateral resolution is the best on the image.

The focal position is the depth at which the transmitted ultrasound energy is focused.

Choose the Focal Zone Management to be Manual or Automatic.

Control this setting in the Imagio® Breast Imaging System/Display sub-tab Imagio® Breast Imaging System.

10.2.5.1 Manual Focal Zone Management

By selecting manual, the focal zone and position are adjustable.

Focus is adjustable only on live imaging.

Focus is located on the system console.

Rotate Focus:

- clockwise to place the focal zone deeper
- counterclockwise to place the focal zone at a shallower depth

Press Focus and then rotate it:

- clockwise to increase the size of the focal zone
- counterclockwise to decrease the size of the focal zone

Press Focus again to move the focal zone.

- Changing the size of the focal zone affects the frame rate.
- The larger the focal zone, the slower the frame rate.

10.2.5.2 Automatic Focal Zone Management

By using the automatic option, the focal zone will be automatically managed to provide the most appropriate focal zone size and position. The ratio between the Focal Zone size and depth will be maintained and the focal zone position will be adjusted within any depth change.

10.2.6 Zoom

A region of interest in imaging Modes can be magnified for closer examination. Two types of zoom are available on Imagio® Breast Imaging System: HD Zoom and Digital Zoom.

10.2.6.1 HD Zoom

HD Zoom concentrates the Imagio® Breast Imaging System acquisition and processing ability on a specific region of interest in the real-time image display.

The result is a reduced field of view overall, but greater detail and higher frame rate, which contribute to better image quality over the region of interest.

HD Zoom is adjustable only in live imaging.

Step 1: Press Zoom on the system console. A box appears on the image.

Step 2: Use the Touchpad to move the zoom box location.

Step 3: Press on the Touchpad to alternate box location to size.

Step 4: Use the Touchpad to resize the zoom box width and height.

Step 5: Press Zoom again to have an enlarged image

Step 6: Press Zoom again to exit zoom

10.2.6.2 Digital Zoom

Digital Zoom is a magnifying post-processing function. As such, it has no effect on the frame rate.

Digital Zoom is adjustable in live imaging and on a frozen image. Rotate Zoom to change its value.

Note: In live imaging, both HD Zoom and Digital zoom may be used at the same time.

Press Reset Zoom on the Touchscreen to set the zoom back to the preset default value.

Note: Increase or decrease the zoom by using the Touchpad. Do a spread gesture with two fingers to increase the zoom, or pinch to decrease the zoom (unless configured differently in System Configuration).

10.2.7 Left/Right

If applicable, Left/Right flips the image along the left-right axis.

Touch Left/Right to flip the image.

10.2.8 Top/Bottom

If applicable, Top/Bottom flips the image along the up-down axis.

Touch Top/Bottom to flip the image.

10.2.9 Dual

Touch Dual to activate or deactivate dual imaging. The left image will be active.

Press the Touchpad to freeze the left side and make the right side active.

Press Freeze to have both sides frozen.

- the active image has an pink S as the orientation marker
- the inactive image has a white S as the orientation marker

Switch which of the dual images is active by pressing the Touchpad. Imaging settings will always be applied to the active image in dual. Imaging settings will be maintained independently for the dual images.

Pressing freeze before pressing the Touchpad, changes image settings and parameters on the active side.

10.2.10 Dual Top/Bottom

Dual Top/Bottom is the same feature as Dual, but split the screen into a top image and a bottom image.

- Press Dual to enable Dual Top/Bottom.
- Press Dual Top/Bottom to activate or deactivate the Dual Top/Bottom display format.

10.2.11 Hide Patient Name

Hide Patient Name temporarily hides the patient information from the imaging screen (screen displays the star character, “*” in place of patient information). However, the hidden information remains in the database.

10.2.12 Arbitration (Update)

If several functions are available, they are displayed at the bottom of the image. The active function is displayed in pink. Swipe right or left with 4 fingers on the active Touchpad function.

The following are examples of arbitration:

- Press the Touchpad to change between Box Move (position of the box) and Box size (resize the box).
- Press the Touchpad to switch between Img1 and Img2 in dual displays.

10.2.13 Play Clip

When the image is frozen, in all modes, a Play Clip button appears on the Touchscreen.

Play Clip enables viewing clips.

Chapter 11 Ultrasound Imaging Modes

11.1 Entering/Exiting Modes

The Imagio® Breast Imaging System offers a set of imaging modes via the mode selection buttons. On the system console, the mode buttons are located above the Touchpad.

- Press PW to scan Pulsed Wave Doppler
- Press SWE™ to scan in grayscale B Mode with a ShearWave™ color elasticity map superimposed.
- Press COL to scan Color Flow Imaging (CFI), Color Power Imaging (CPI), or Directional Color Power imaging (dCPI)
- Press B to scan in grayscale B Mode.
- Press OA to scan in OA Mode.

Note: In any mode other than B Mode, whenever the B key is pressed, the current mode is exited, and B Mode is displayed. The previous settings are restored.

11.2 Common Imaging Parameters

The following imaging parameters are available in all modes unless otherwise specified.

Parameter	Description	Usage
Acoustic Power	Acoustic Power regulates the output power of the Imagio® Breast Imaging System. Refer to "Acoustic Output Tables" on page 172 for acoustic power guidance.	Acoustic Power is available only in live imaging. Rotate the dial located under Acoustic Power: • clockwise to increase acoustic power output • counterclockwise to decrease acoustic power output
Dynamic Range	Dynamic Range enables changing the range over which the amplitudes of returning ultrasound signals are displayed. Dynamic Range is available in live imaging and on a frozen image.	Rotate the dial located under Dynamic Range: • clockwise to increase the dynamic range • counterclockwise to decrease the dynamic range

Parameter	Description	Usage
Optimization	Optimization enables changing of the center frequency to obtain increased resolution or increased penetration. Optimization is available in live imaging in all modes except PW.	Rotate the dial located under Optimization to change value: • Resolution • General • Penetration In SWE™, both B and SWE™ optimization settings are available. The SWE™ Optimization setting has the following values (see "SWE™ Scanning TIPS" on page 75 for more information): • Res • Std • Pen
Persistence	Persistence is a frame averaging technique that reduces noise on the image. Persistence is available in live imaging for all modes except PW.	Rotate the dial located under Persistence: • clockwise to increase persistence • counterclockwise to decrease persistence
Sector Size	Sector Size widens or narrows the size of the sector angle to maximize the image's region of interest. Sector size is available in B and SWE™ modes.	Changing the sector size affects the frame rate. The narrower the sector size, the faster the frame rate.
Smoothing	Smoothing is a spatial filter used to smooth the image in order to provide a more homogeneous appearance. Smoothing is available only in live imaging. Available in SWE™, COL, and Panoramic modes.	Rotate the dial located under Smoothing: • clockwise to increase smoothing • counterclockwise to decrease smoothing

11.3 B Mode Imaging

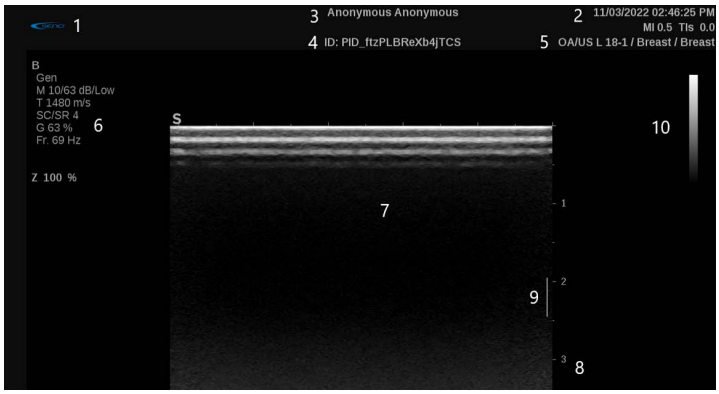
B Mode is an Ultrasound Imaging Mode which enables assessment of two-dimensional anatomy by displaying the echoes returning from tissues of different density in various shades of gray.

11.3.1 Accessing B Mode

B Mode is available on the OA/US L18-1 (Model 8100) and the US L18-5 (Model 8500) linear probes.

Press B on the system console from any other Modes.

11.3.2 About B Mode Main Display



11.3.3 About B Mode Touchscreen

1. Institution Name
2. Date and Time
3. Patient Name
4. Patient ID
5. Probe/Preset
6. Imaging Parameters
7. Ultrasound Image
8. Depth Scale
9. Focal Zone
10. Gray Scale

When in B Mode, the Touchscreen displays various image controls which optimizes the B Mode image.

These settings are controlled by touching the control on the Touchscreen, or by turning the dial directly below the Touchscreen. Additional controls are available at the bottom of the Touchscreen by swiping left or right with one finger.

11.3.4 Description of B Mode Imaging Parameters

B Mode imaging parameters not already described in the Common Imaging Parameters section are listed below.

Parameter	Description	Usage
Harmonic Imaging	Harmonic Imaging available on the OA/US L18-1 and the US L18-5 linear probes. Harmonic imaging mode is used to reduce image clutter and reverberation and enhance borders. Harmonic imaging is available only in live imaging.	Press Harmonic to activate/deactivate harmonic imaging.

Parameter	Description	Usage
TissueTuner™	TissueTuner™ is available on the OA/US L18-1 and the US L18-5 linear probes. TissueTuner™ enables adjustment of the receive parameters associated with the assumed speed of sound of ultrasound in the body. Adjusting the speed of sound parameter to match the type of tissue being interrogated results in increased spatial and lateral resolution. TissueTuner™ is available only in live imaging. TissueTuner™ range is set by the selected application.	Rotate the dial located under TissueTuner™: • clockwise for a denser tissue (higher speed of sound values) • counterclockwise for a less dense tissue (lower speed of sound values)
2D Map	2D Map is available on the OA/US L18-1 and the US L18-5 linear probes. 2D Map assigns the display of echo amplitudes to a range of gray-scale or chromatic colors. 2D Map is available in live imaging and on a frozen image.	Rotate the dial located under 2D Map: • clockwise to view next map • counterclockwise to view previous map
SuperCompound™	SuperCompound™ is available on the OA/ US L18-1 and the US L18-5 linear probes. SuperCompound™ combines the returning ultrasound from a large number of steered echo lines to create an image which provides superior texture, enhanced edge delineation and reduces shadowing. SuperCompound™ is available in live imaging only.	Press SuperCompound™ to activate or deactivate the SuperCompound™ mode.
Pulse Repetition Frequency (PRF)	PRF is available on the OA/US L18-1 and the US L18-5 linear probes. PRF enables changing the pulse repetition frequency for the B Mode image. Decreasing the PRF may correct the reverberation artifacts.	Rotate the dial located under PRF to change its value.
Auto Offset	Auto offset enables programming automatic overall gain when using the Auto. Auto Offset is located on the second page of parameters.	Rotate the dial located under Auto offset: • clockwise for a brighter image • counterclockwise for a darker image
SuperRes™	SuperRes™ is an image processing feature which reduces speckle, improves image texture, and enhances borders without an impact on frame rate. SuperRes™ is available in live imaging and on a frozen image. SuperRes™ values depend on whether SuperCompound™ is On or Off.	Rotate the dial located under SuperRes™: • clockwise to increase SuperRes™ • counterclockwise to decrease SuperRes™

11.3.5 B Mode Scanning

Use appropriate Preset for each organ being scanned by the OA/US L18-1 and the US L18-5 linear probes. The OA/US L18-1 probe is only indicated for breast imaging.

- Set depth to achieve desired field of view.
- Place focal zone at the depth of the area of interest or slightly below.
- Press Auto TGC as the tissue profile changes to optimize spatial brightness uniformity of OA/US image. Press the Touchscreen TGC button then press or slide your finger on the touchscreen TGC curve to increase or decrease brightness at specific depths.
- Adjust overall gain to obtain the appropriate brightness.
- Adjust TissueTuner™ to achieve the best resolution. 1480 m/s for breast imaging decrease to 1420 m/s for fatty tissue.
- Increase focal zone region for a larger focal area and increased resolution.
- Use Harmonic Imaging to clear fluid-filled structures.
- Use Resolution setting of Optimization control for increased image resolution.

11.3.6 Panoramic Imaging

Panoramic imaging registers individual frames as the probe is moved along a structure of interest and superimposes the registered frames to generate a composite image, allowing the visualization and measurement of large structures of interest that would not fit within the probe's field of view.

Important: Use adequate quantities of gel along the entire segment to be scanned to ensure smooth motion during the panoramic acquisition.

Panoramic imaging is available for the US L18-5 Linear Probe.

11.3.6.1 Acquiring panoramic images

Step 1: Adjust the available imaging parameters to optimize image quality and frame rate.

Step 2: Press Panoramic on the Touchscreen.

- The Imagio® Breast Imaging System enters the Panoramic Stand-by stage.

Step 3: Press on the Touchpad to start the acquisition.

Step 4: Move the probe in a smooth and continuous manner along the structure of interest, making sure that the scanning motion is as much as possible parallel to the scan plane.

- The Imagio® Breast Imaging System automatically detects the probe’s motion direction and the composite image is created accordingly. If needed, scan backwards to erase unwanted parts of the panoramic composite image, then resume scanning along the original motion direction.

Step 5: Press Freeze.

- The Imagio® Breast Imaging System displays the whole composite image.

11.3.6.2 Scanning Recommendations

- Ensure that the scanned surface is flat or gently curved and avoid tissue areas dominated by noise or lacking structural details.
- Use a slow and steady scanning motion without wobbling, twisting or abrupt changes in the scanning direction, staying within the same scan plane as much as possible.

Important: Panoramic registration errors are manifested by the presence of artifacts such as image gaps, irregular skin line contours and jagged edges, clearly visible “seams” between successive input image frames and blurred or poorly defined areas.

Note: All measurements derived from a Panoramic composite image are marked by an asterisk, to indicate that they represent estimated measurement results and may have been affected by Panoramic registration errors.

Note: When the structure to be measured can fit within the probe's field of view, it is strongly recommended to use a standard B Mode image frame and not the Panoramic composite image.

11.3.6.3 Manipulating panoramic images

Use the Zoom functionality as for regular B Mode.

Use the Pan functionality as for regular B Mode.

Use the Rotate button or the Touchpad to rotate the panoramic composite image.

Use the Smoothing dial to soften abrupt transitions between input frames in the Panoramic composite image.

11.3.6.3.1 Trim

Trim enables discarding of frames from the start or end of the panoramic acquisition, so that they don't contribute to the panoramic composite image.

Step 1: Press Trim on the Touchscreen to start trimming.

Step 2: The Touchpad is changed to Trim Start.

Step 3: Move the Touchpad towards the end of the panoramic acquisition to discard the required frames from the start of the acquisition.

Step 4: Press the Touchpad to switch to Trim End.

Step 5: Move the Touchpad towards the start of the panoramic acquisition to discard the required frames from the end of the acquisition.

Step 6: Turn Trim off to cut the trimmed frames out.

The remaining panoramic composite image will be automatically zoomed to fit on the screen.

Press Trim Reset to return the Trim Start and Trim End frames to the start and end of the panoramic acquisition, respectively.

11.3.6.3.2 Skinline Tick-Marks

Skinline Tick-Marks enables displaying or hiding of the tick marks along the skinline.

Press Skinline Tick-Marks to activate/deactivate the skinline tick marks.

11.3.6.3.3 Smoothing

Smoothing is a spatial filter used to smooth the panoramic image in order to provide a more homogeneous appearance.

Rotate the dial located under Smoothing:

- clockwise to increase smoothing.
- counterclockwise to decrease smoothing.

11.3.6.4 Performing measurements on panoramic images

Press Meas. on the system console to access measurements available in panoramic imaging.

Important: Do not perform measurements on Panoramic composite images acquired with substantial out-of-plane motion components (such as when following a tortuous structure).

Important: Do not perform measurements across structures which appear as strongly hypoechoic or very noisy in the Panoramic composite image.

Important: Do not perform measurements on Panoramic composite images of highly curved objects such as transverse sections through the arm or leg.

Basic measurements (distance, ellipse, trace, etc.) on a Panoramic composite image are performed as in standard B Mode.

11.3.6.4.1 Curved Distance Measurements

The Curved Distance measurement tool is similar to the Trace measurement tool, but the curved distance trace is not closed. The Curved Distance measurement tool provides a distance measurement result.

To perform a Curved distance measurement:

Step 1: Acquire the panoramic image.

Step 2: Press Meas. on the system console.

Step 3: Press Curved Distance on the Touchscreen.

- A first caliper is displayed.

Step 4: Move the first caliper at the desired location.

Step 5: Press the Touchpad to anchor the first caliper.

Step 6: Move the Touchpad to start tracing the curve.

Step 7: Use the Trace dial to erase the trace if needed.

Step 8: Press the Touchpad to complete the measurement.

- The Imagio® Breast Imaging System displays the curved distance measurement result in the measurement result area.

11.3.6.5 Saving panoramic images

Press Save Image to store the current Panoramic composite image so that it can be reviewed, manipulated, trimmed and measured at a later time.

11.3.6.6 Exiting panoramic imaging

Press the Panoramic button on the Touchscreen to turn it off and exit panoramic imaging.

11.4 ShearWave™ Elastography

The ShearWave™ Elastography (SWE™) Mode displays information about tissue elasticity in the form of an easy to interpret color-coded image. ShearWave™ Elastography (SWE™) is available on both the OA/US L18-1 and US L18-5 linear probes.

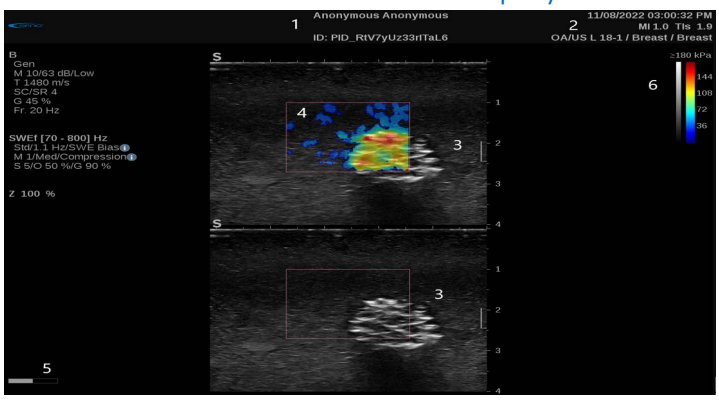
The elasticity information is also quantitative. Local estimation of the tissue stiffness is displayed per pixel and can be expressed in kPa or in m/s over a wide range of values.

Note: Please note that the SWE™ algorithms and sequences are optimized accordingly for each clinical application needs.

11.4.1 Accessing ShearWave™ Elastography

Press SWE™ on the system console from any other Mode.

11.4.2 About the SWE™ Main Display



1. Exam and Patient Information
2. Probe/Preset/MI/TI
3. Ultrasound Image
4. Elasticity Map
5. Clip Buffer
6. Gray Scale and Elasticity Bars

11.4.3 About SWE™ Touchscreen

When in SWE™, the Touchscreen displays various image settings which help optimize the elasticity image.

These settings are controlled by touching the control on the Touchscreen or turning the dial directly below it.

Additional controls are available at the bottom of the Touchscreen by swiping with one finger.

11.4.4 Description of SWE™ Parameters

SWE™ imaging parameters not already described in the Common Imaging Parameters section are listed below.

Parameter	Description	Usage
SWE™ Unit	This control enables changing of the color bar scale for SWE™ from kPa to m/s. SWE™ Unit is available in live mode and on a frozen image.	Touch SWE™ Unit to change value.
Elasticity Range	The Elasticity Range in SWE™ mode is similar to the dynamic range in B Mode. It changes the maximum elastic value displayed. It is used to compress the colored image for better visualization of tissues which have a variety of stiffnesses. Changing the Elasticity Range does not affect the actual values of elasticity, as long as they are within the elasticity range. Elasticity Range is displayed in kPa; the values depend on the selected application. Stiff tissue should appear yellow, orange or red. Increase the Elasticity Range if there is predominantly dark red in the color box. Elasticity Range is available in live imaging or on a frozen image.	Rotate the dial located under Elasticity Range: • clockwise to increase the elasticity range • counterclockwise to decrease the elasticity range
Velocity Range	The Velocity Range works in the same manner as the Elasticity Range. Velocity Range appears and replaces Elasticity Range when the Display Unit is set to m/s. It changes the maximum velocity value displayed. It is used to compress the colored image for better visualization of tissues which have a variety of stiffnesses. Changing the Velocity Range does not affect the actual values of velocity, as long as they are within the velocity range.	Rotate the dial located under Velocity Range: • clockwise to increase the velocity range • counterclockwise to decrease the velocity range
Display Format	This control changes the format in which B Mode and SWE™ images are presented on the main SWE™ display. Display Format is available in live imaging and on a frozen image.	Press Display Format repeatedly until the desired format is shown. The top/bottom format is the default setting. Three formats are available: • top/bottom • side by side • single

Parameter	Description	Usage
Opacity	Opacity enables changing of the transparency of the elasticity/viscosity map over the B Mode image. Opacity is available in live imaging and on a frozen image.	Rotate the dial located under Opacity: • clockwise to increase the prominence of the color image over the B Mode image • counterclockwise to decrease the prominence of the color image over the B Mode image
Elasticity Map	Elasticity Map determines how elasticity values are displayed in terms of color graduations. Elasticity Map is available in live imaging and on a frozen image.	Rotate the dial located under Elasticity Map: • clockwise to go to the next map • counterclockwise to go to the previous map

11.4.5 SWE™ Scanning TIPS

11.4.5.1 Notes and Recommendations

As is the case with all other ultrasound imaging Modes - the SWE™ Mode is associated with a significant learning curve and may exhibit operator dependence if suboptimal scanning techniques are employed.

It is recommended to carefully review “Elastography Measurements” on page 170 in order to become aware of the SWE™ capabilities and limitations with regards to penetration depth, spatial resolution, estimation bias and estimation precision.

When SWE™ is used to document the stiffness of a lesion, be aware that the bias and precision of shear wave velocity estimates vary as a function of lesion size and probe resolution.

The manual pressure used while scanning in SWE™ should be minimal. Please keep in mind that compression with the probe may change the velocity of shear waves in the tissue being imaged.

Recommended Optimization Settings:

Optimization	Dial Setting	Use Case
Resolution	Res	Use this setting when imaging small shallow areas of interest. This setting will also help to clear any erroneous visco-elastography signal out of areas which are suspected to be comprised of fluid.
Standard	Std	This setting is balanced between resolution and penetration. Use this setting as the default starting point for the stiffness and viscosity evaluation of an object of interest.
Penetration	Pen	Use this setting when imaging deeper or larger areas (anechoic or hypoechoic) which may show posteriordropout in the echo image. These areas are suspected to be stiff and viscous and require a penetration mode optimized for high velocity shear waves.

11.4.5.2 SWE™ Scanning

Remember the 3 S's:

Scan Softly, Smoothly and Slowly

Scan Softly: no manual compression is needed (with the exception of intercostal liver scanning), just a light touch and plenty of gel between skin and probe

Scan Smoothly: probe automatically induces vibrations in tissues so no need to shake or push on the probe

Scan Slowly: Adapt your speed of scanning to the frame rate. Once imaging the area of interest, avoid any movements and wait for image stabilization.

Always start with the default setting of Standard for Optimization, and then go to Resolution or Penetration to fine tune the image.

Controls that can be used in live or frozen imaging such as Elasticity Range, display format, etc. should be done after freezing to make it easier for the operator since it is imperative to hold a steady hand during elastography.

11.5 Color Mode Imaging

Color Mode Imaging uses Doppler principles to generate a color image of the mean flow velocity or flow power.

On the Imagio® Breast Imaging System, three color options are available: Color Flow Imaging (CFI), Color Power Imaging (CPI), and Directional Color Power Imaging (dCPI).

11.5.1 Color Flow imaging (CFI)

Color Flow Imaging is Doppler intended to add color-coded quantitative information concerning the relative velocity and direction of fluid motion within the B Mode image.

11.5.2 Color Power Imaging (CPI)

Color Power Imaging is a color flow mapping technique used to map the strength of the Doppler signal coming from the flow rather than the frequency shift of the signal. Using this technique, the ultrasound Imagio® Breast Imaging System displays the magnitude of the flow based on the number of reflectors that are moving, regardless of their velocity. CPI does not map flow velocity.

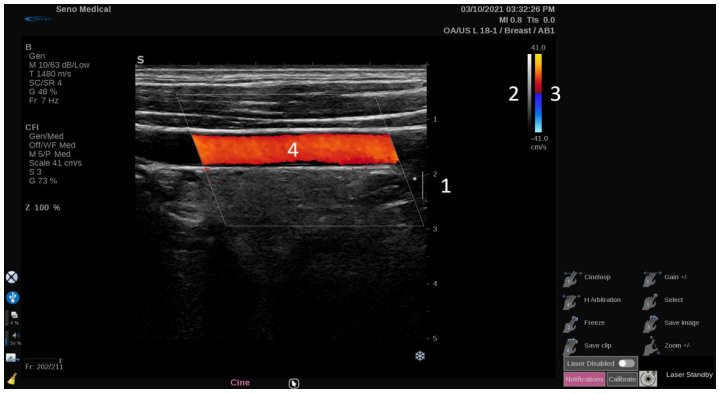
11.5.3 Directional Color Power Imaging (dCPI)

Directional Color Power Imaging (dCPI) displays the mean Doppler frequency of each pixel inside the Color box, including the direction of flow relative to the probe. The color maps used in dCPI are separated into parts which typically contain red and blue hues, respectively, with positive Doppler frequencies (flow towards the probe) displayed using the top part of the dCPI color map, and negative Doppler frequencies (flow away from the probe) displayed using the bottom part of the dCPI color map. dCPI is useful in indicating the flow direction within the vessels of interest, as well as identifying areas of high flow velocities (aliasing), flow reversals, etc.

11.5.4 Accessing Color Options

Press COL on the system console from any other Modes.

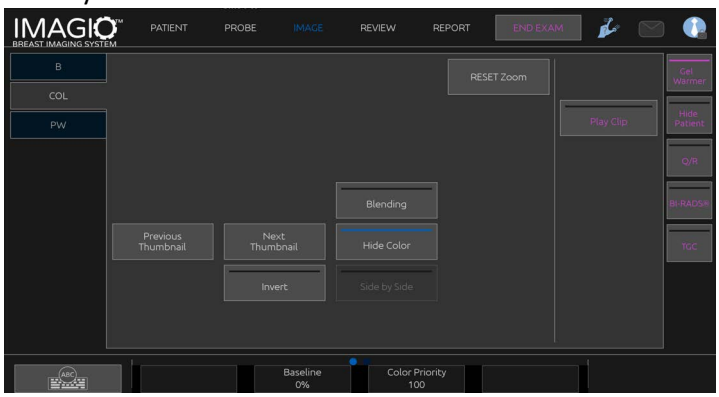
11.5.5 About Color Mode Main Display



11.5.6 About Color Mode Touchscreen

1. Focal Zone
2. Gray Scale
3. Color Bar
4. Color Box

When in Color Modes, the Touchscreen displays various image settings which helps optimize the color image. These settings are controlled by touching the control on the Touchscreen or turning the dial directly below it.



Additional controls are available at the bottom of the Touchscreen by swiping with one finger.

11.5.7 Description of Color Imaging Parameters

11.5.7.1 Dual

Refer to “Dual” on page 65.

Parameter	Description	Usage
Color Gain	Changes the gain of the Color Mode Imaging overlay.	Rotate the COL button in order to change the gain both in live imaging and frozen mode: clockwise to increase the gain counterclockwise to decrease the gain
Modes	The Modes control enables switching between CFI, dCPI and CPI. Available only in live imaging.	Rotate the dial located under Mode to select the desired Color Imaging mode.
Dual	Enables swapping between frozen and live images on the same display.	Touch Dual to activate or deactivate dual imaging. The left image will be active. Press the Touchpad to freeze the left side and make the right side active. Press Freeze to have both sides frozen. • the active image has an pink S as the orientation marker • the inactive image has a white S as the orientation marker
Optimization	Optimization enables changing of the center frequency to obtain increased resolution or increased penetration. Optimization is available only in live imaging.	Rotate the dial located under Optimization to change value: • Resolution • General • Penetration
Boost	Boost enables adjustment of the frame rate and line density to achieve increased spatial or temporal resolution.	Rotate the dial located under Boost to change its value. • High Definition • Medium • High Frame Rate
Invert	Invert enables viewing of blood flow from an inverse perspective, e.g. red away (negative velocities) and blue toward (positive velocities) the probe. Invert is available in live imaging and on a frozen image. Invert is available only in CFI Mode.	Touch Invert to activate and deactivate it.
Scale	Scale enables adjustment of the maximum displayed velocity. Scale is available only in live imaging.	Rotate the dial located under Scale: • clockwise to increase the scale • counterclockwise to decrease the scale
Hide Color	Hide Color hides the color information over the B Mode image. Hide Color is available in live imaging and on a frozen image.	Touch Hide Color to activate and deactivate it.

Parameter	Description	Usage
Wall Filter	This parameter filters out low velocity signals. It helps to decrease motion artifacts caused by patient or probe motion. Wall Filter is available only in live imaging.	Touch Wall Filter repeatedly to select the desired value.
Velocity Flow Optimization (Velocity Flow Opt.)	Velocity Flow Opt. enables quick optimization of multiple parameters with one control to achieve a desired flow optimization. Velocity Flow Opt. is available only in live imaging. Velocity Flow Opt. changes the following parameters: • Scale • Wall filter • Resolution/frame rate • Persistence	Touch Velocity Flow Opt. repeatedly to select the desired value: • Off • Low Flow • Med Flow • High Flow
Side by Side	Side by Side enables splitting of the screen in two live parts: • the left side displays the B Mode only, for reference • the right side displays the B Mode and the color image	Touch Side by Side to change the screen display.
Color Priority	Color Priority enables selecting a level beyond which color data are not displayed over the gray map. Color Priority is available in live imaging and on a frozen image. The range and default value depend on the Color Imaging mode.	Rotate the dial located under Color Priority: • clockwise to increase the color priority • counterclockwise to decrease color priority
Color Map	Color Map determines how flow values are displayed in terms of color graduations. Color Map is available in live imaging and on a frozen image.	Rotate the dial located under Color Map: • clockwise to go to next map • counterclockwise to go to previous map
Blending	This button controls the level of transparency of the color image that is superimposed on the B Mode image. When Blending is on, the color image is smoothly overlaid on the gray-scale image. When Blending is Off, the transition between B Mode and color is sharper. Blending is available in live imaging and on a frozen image.	Press Blending to turn it On or Off.
Flash Suppression	Flash Suppression utilizes an adaptive wall filtering scheme to suppress the flash artifacts due to tissue motion. When Flash Suppression in On, the frame rate is reduced. Flash Suppression is available only in live imaging.	Press Flash Suppression to turn it On or Off.

11.5.8 Color Scanning

Scan to obtain best angle to maximize flow sensitivity.

Use the Touchpad to change size of color box if needed. A larger box will cause a decrease in temporal resolution (frame rate).

Increase Color Gain until noise is visible and then reduce the gain just to eliminate noise. This will ensure the best color flow sensitivity possible.

If scanning smaller vessels (i.e. breast, thyroid), center steer is typically the best choice. In larger vessels (i.e. carotid artery, axillary artery) steer color box to obtain the best (least) angle to flow. A change in sensitivity will be observed when the appropriate steering angle is chosen.

Select the appropriate Velocity Optimization level according to the type of vessel being interrogated.

Low is typically used for smaller vessels with lower velocities and venous flows.

High is used for larger vessels with higher velocities and for arteries.

To increase flow sensitivity, lower the Scale or lower the Wall Filter. To eliminate aliasing (CFI only), increase the Scale.

11.6 Pulsed Wave Doppler Mode

Pulsed Wave Doppler (PW) is a Doppler that measures velocity of blood flow within a small region called the Doppler sample volume.

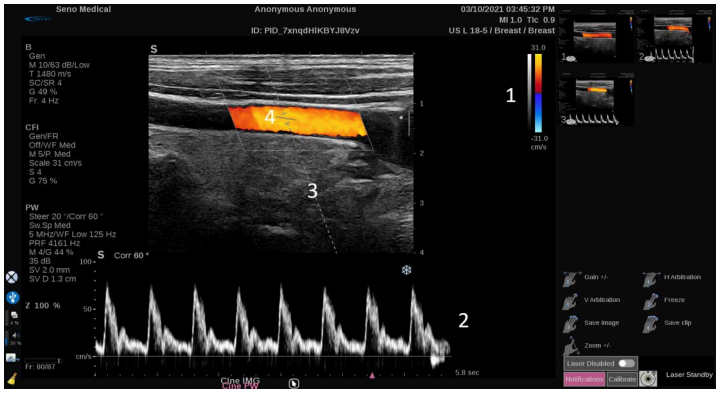
This information is presented as a sweeping display of velocity (or Doppler frequency) over time. This display is often called a spectral Doppler trace, or Doppler trace. The information may also be heard as a stereo audio output.

In addition to the Doppler velocity display, an image (grayscale only or grayscale and color) is also presented for proper positioning of the Doppler sample volume.

11.6.1 Accessing PW

Press PW on the system console from any other Modes.

11.6.2 About PW Main Display



1. Gray Scale Image
2. Spectral Display
3. Doppler Line
4. Sample Volume

11.6.3 About PW Touchscreen

When in PW, the Touchscreen displays various image settings which help optimize the PW image and trace. These settings are controlled by touching the control on the Touchscreen or turning the dial directly below it.

Additional controls are available at the bottom of the Touchscreen by swiping with one finger.

11.6.4 Setting Up PW

11.6.4.1 Doppler Line

Swipe left and right on the Touchpad to move the Doppler line in the 2D image.

11.6.4.2 Sample Volume Position

Swipe up and down on the Touchpad to move the sample volume on the Doppler line.

11.6.4.3 Sample Volume Size

Slide your finger on the Touchpad to change the size of the sample volume.

11.6.5 Description of PW Imaging Parameters

PW imaging parameters are listed below.

Parameter	Description	Usage
Doppler Coarse Angle	Provides a coarse angle control for rapid PW angle adjustment. Doppler Coarse Angle is available in live imaging and on a frozen image.	Touch Doppler Coarse Angle repeatedly to select the desired value.
Fine Angle Correct	Provides a fine angle control for fine PW angle adjustment. Fine Angle Correct is available in live imaging and on a frozen image.	Rotate the dial located under Fine Angle Correct.

Parameter	Description	Usage
Display Format	Changes the layout of the PW display. Display Format is available in live imaging and on a frozen image.	Press Display Format to change its value. • 2D: 2D only • Side by side: B Mode and spectral side by side display • ½-1/2: ½ B Mode and ½ spectral display • 2/3-1/3: 2/3 B Mode and 1/3 spectral display • 1/3-2/3: 1/3 B Mode and 2/3 spectral display
PW Map	Changes the PW Map applied to the trace. PW Map is available in live imaging and on a frozen image.	Rotate the dial located under PW Map: • clockwise to go to previous map • counterclockwise to go to next map
Scale	Scale enables adjustment of the maximum velocities displayed on the Doppler spectrum. Scale is available only in live imaging.	Rotate the dial located under Scale: • clockwise to increase the scale • counterclockwise to decrease the scale
Sweep Speed	Sweep Speed enables changing the speed that the spectral columns are updated on the display. Sweep Speed is available in live imaging and on a frozen image.	Touch Sweep Speed repeatedly to reach the desired value.
Simultaneous (Duplex and Triplex)	Simultaneous allows live display of combinations of PW Doppler trace, Color Doppler, and B Mode imaging. Duplex imaging is active if Simultaneous is enabled during PW scanning (B Mode and PW trace are live). Triplex imaging is active if Simultaneous is enabled during PW scanning with Color Imaging (B Mode, Color Imaging, and PW trace are live). Simultaneous is available only in live imaging.	Touch Simultaneous to turn it On or Off.
High PRF	High PRF enables measuring flows of higher velocities than those that can be measured with the maximum conventional available PRF, by increasing the PRF above the Nyquist limit and avoiding aliasing. The maximum scale available is increased as a function of depth. Available in live imaging.	Touch High PRF to turn it on. See High PRF Scanning Tips for more information.

11.6.5.1 High PRF Scanning Tips

High PRF enables measuring flows of higher velocities than those that can be measured with the maximum conventional available PRF, by increasing the PRF above the Nyquist limit and avoiding aliasing.

11.6.5.1.1 How it works:

High PRF extends the PW Doppler velocity scale beyond the maximum velocity limit that can be measured for a given sample volume (SV) in a non-ambiguous manner. Beyond this limit, the Pulse Repetition Frequency (PRF) of the transmitted PW Doppler pulses corresponds to a Pulse Repetition Interval (PRI) which is shorter than the round-trip propagation time from the probe to the current sample volume depth, resulting in range ambiguity (the analyzed Doppler signals emanate not only from the primary sample volume of interest but also from one or two secondary sample volumes along the Doppler beam.

11.6.5.1.2 How to use it:

Touch High PRF to turn it on.

The maximum scale available is increased as a function of depth.

High PRF is available for all presets on all probes in live PW.

Scanning Recommendations:

- Position the primary SV in the area of interest, in a manner similar to conventional PW Doppler.
- Avoid, as much as possible, placing secondary SV's in areas dominated by noise artifacts, shadowing, or areas of flow.
- Tips to assist in positioning secondary High PRF SV's to optimize the signal and avoid interference with the primary SV:
  - Vary the velocity range to change the secondary sample volume position.
  - Vary the depth of the image to change the secondary sample volume position.
  - Reduce the velocity range to remove the secondary sample volume.
  - Reduce gain.
  - Vary 2D image orientation.
  - Change the acoustic window.

11.6.5.2 PW Auto Trace Parameters

The parameters for PW Auto Trace are listed below.

Parameter	Description	Usage
Doppler Auto Trace	This control enables automatic PW trace measurements. Doppler Auto Trace is available in live imaging and on a frozen image. Doppler Auto Trace enables access to the additional settings in this table.	Press Doppler Auto Trace to display the envelope of the peak velocity of the flow as a function of time.
Mean Trace	Displays the mean flow velocity as a function of time.	Press Mean Trace to toggle on or off.
Velocity Points	Displays the PSV and EDV on the spectrum.	Press Velocity Points to toggle on or off.
Trace Detection	Enables detection of the various velocity traces.	Press Trace Detection to change its value. • Above: the velocities above the baseline • Below: the velocities below the baseline • Full: the velocities both above and below the baseline

Parameter	Description	Usage
Sensitivity	Defines the detection threshold for the Doppler Auto Trace.	Press Sensitivity to change its value. • Low • Medium • High • Maximum

11.6.6 PW Scanning Tips

As in color Doppler, optimize the scan plane for the best angle to flow.

Activate the PW cursor by pressing PW. Optimize the steering angle and sample volume size before initiating the PW spectral trace. If Color is activated before pressing PW, then the cursor will be at the same steer angle as the color box. Optimize Doppler gain. Decrease gain to eliminate background noise.

Increase scale or shift baseline to eliminate aliasing. Shift baseline, change display format, PW map and sweep speed are available after freezing.

Use Simultaneous imaging when vessels are difficult to follow due to respiration, motion or small vessel size.

Chapter 12 Operator Activities

12.1 Adding Distilled Water to the Laser Coolant Reservoir

The Imagio® Breast Imaging System has a laser coolant reservoir that contains distilled water used to cool the lasers. The rate of distilled water consumption is dependent on Imagio® Breast Imaging System usage. Operators add distilled water to the laser coolant reservoir as needed. Additionally, the "Add Coolant" message appears on the bottom right of the display to alert the Operator of the need to add distilled water to the laser coolant reservoir.

12.1.1 Distilled Water

Distilled Water Specifications

Purified Water – Distilled

Conductivity <= 5 µs/cm (less than or equal to 2 micro Siemens per centimeter)

Caution: The Imagio® Breast Imaging System is a sensitive electronic instrument and may be damaged by using the incorrect fluid and the incorrect or improper laser coolant reservoir filling technique.

- Do not place the refill bottle or overflow bottle on any surface of the Imagio® Breast Imaging System.
- Using anything other than distilled water may result in microbial contamination of the cooling system. Use only distilled water when filling the laser coolant reservoir.

12.1.2 To Add Distilled Water to the Laser Coolant Reservoir

Step 1: On the rear of the Imagio® Breast Imaging System cabinet, connect the overflow bottle spout to the distilled water outlet. Push the connector onto the outlet until an audible click is heard which indicates the connector is locked to the outlet.

Step 2: On the rear of the Imagio® Breast Imaging System cabinet, connect the refill bottle spout to the distilled water inlet. Push the connector onto the inlet until an audible click is heard which indicates the connector is locked to the inlet.

Add water, replace cap, and ensure securely tightened.

Step 3: Squeeze the bottle to feed distilled water into the reservoir until distilled water is visually seen flowing into the overflow bottle.

Step 4: Remove the refill bottle by pressing the silver buttons on the Imagio® Breast Imaging System connector and place it away from the Imagio® Breast Imaging System.

Step 5: Remove the overflow bottle by pressing the silver buttons on the overflow connector hose and gently pulling the hose away from the outlet.

Important: If required to record the Imagio® Breast Imaging System usage by your local laser authority, record "Distilled Water Added" and the date in the Imagio® Breast Imaging System Log with details (e.g. regular maintenance.)

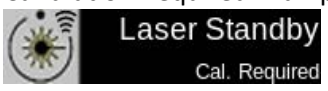
Important: Avoid contaminating the distilled water.

12.2 Laser Energy Calibration

Calibrating the Imagio® Breast Imaging System lasers maximizes image quality. Laser Energy Calibration is to be performed whenever the Imagio® Breast Imaging System displays a message to the Operator that a laser energy calibration is due. (The Imagio® Breast Imaging System may require additional calibration checks based on the Imagio® Breast Imaging System usage.) After 25 calendar days, the Imagio® Breast Imaging System will recommend that calibration be performed by displaying messages in the bottom left of screen. After 28 calendar days, the Imagio® Breast Imaging System will require calibration. The laser status code Cal. Required will appear on the bottom right.

The Imagio® Breast Imaging System Calibration routine is a software application that steps the Operator through the laser energy calibration procedure used to check the OA/US L18-1 Probe energy output. Upon completion of the Imagio® Breast Imaging System Calibration, the Imagio® Breast Imaging System software uses the data collected during the procedure to calibrate the laser output energy for optimum image quality and performance.

Calibration Required Example



Important: If calibration is determined to be required, the Operator is allowed 60 minutes of use to finish the current scan.

Please allow 5 minutes to complete the calibration procedure.

The laser must be authorized to perform the calibration.

Important: Perform Imagio® Breast Imaging System Calibration and the Machine Check if an OA/US L18-1 Probe is replaced with a new OA/US L18-1 Probe. The system will inform operator if calibration is required. Refer to "Machine Check" on page 90.

Important: If a calibration error is detected at any time during the procedure that requires the Imagio® Breast Imaging System Calibration routine to be terminated, a termination message will appear on the Display. Call Seno Service for assistance at (888) 978-8835. Minor error messages may appear on the Display Monitor that will not terminate the Calibration routine. If these messages appear, continue the Calibration through to completion. The error messages are transient and will automatically dismiss.

12.2.1 Performing Laser Energy Calibration

It is necessary to reach the end of the Imagio® Breast Imaging System Calibration routine (Exit screen) to enable the software to analyze the data and determine the success of the calibration. If the calibration is canceled before the Exit screen is reached, or an error occurs that causes the Imagio® Breast Imaging System Calibration routine to exit early, the OA/US L18-1 Probe calibration has failed. Call Seno Service for assistance at (888) 978-8835.

Important: The Imagio® Breast Imaging System will inhibit calibration if the laser is not at operating temperature as indicated by the Laser Ready icon.

Important: A dirty OA/US L18-1 Probe face or Calibration Port Shield during calibration may cause calibration errors.

Step 1: Inspect and clean the face of the OA/US L18-1 Probe with the Seno approved wipes ensuring all gel (wet and dry) and other debris are completely removed. Refer to "Cleaning System Components" on page 39.

Step 2: The OA/US L18-1 Probe Calibration Adapter is a device used to guide and properly seat the OA/US L18-1 Probe in the Calibration Port. The OA/US L18-1 Probe Calibration Adapter is stored in the Calibration port. The Energy Sensor Shield is a clear window barrier that protects the light sensor.

a) Remove the OA/US L18-1 Probe Calibration Adapter.

b) Look into the Calibration OA/US L18-1 Probe Port and perform a visual check of the Energy Sensor Shield to ensure the Energy Sensor Shield is free of gel and visible contamination.

Step 3: If the Energy Sensor Shield appears dirty: Thoroughly clean the Energy Sensor Shield with Seno approved wipes ensuring all gel (wet and dry) and other debris are completely removed.

Step 4: Place the OA/US L18-1 Probe Calibration Adapter over the OA/US L18-1 Probe.

Step 5: Verify the Calibration Port is dry before inserting the OA/US L18-1 Probe and equipped Calibration Adapter.

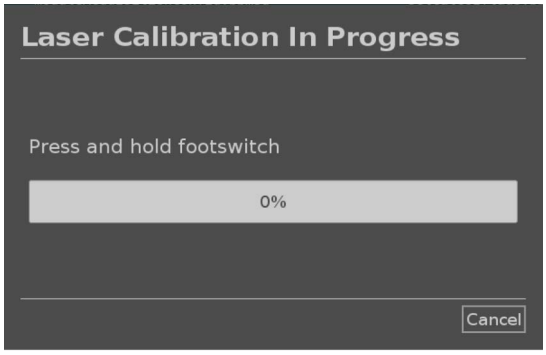
Step 6: Insert the OA/US L18-1 Probe with the equipped Calibration Adapter into the Calibration Port until it is seated firmly against the Energy Sensor Shield.

Step 7: Select the Probe option on the touchscreen.

Step 8: If the laser is not authorized, authorize it by using a Laser Authorization card.

Step 9: Select the next button.

Note: The "Next" button is not enabled until all pre-conditions are met.

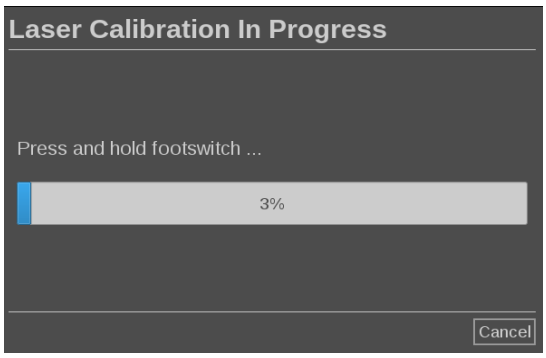


Important: The foot switch may be released and pressed during calibration, but approximately 2.5 minutes of continuous pressing is required to complete the process.

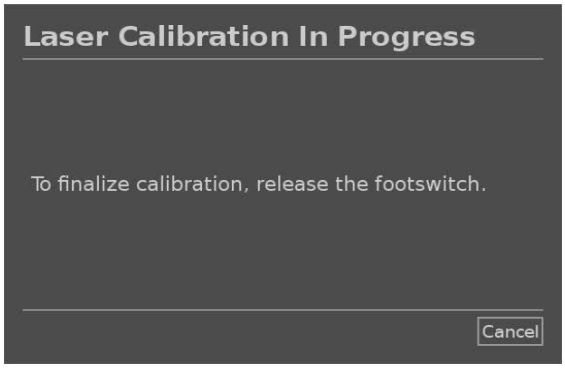
Note: Any of the below conditions will halt calibration and show an error message:

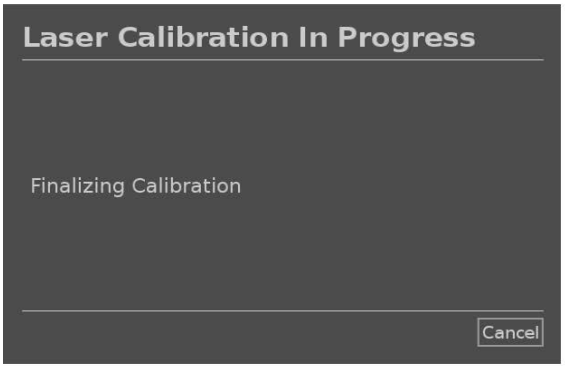
- Probe removed from Calibration Tool
- Laser Disabled
- Foot switch released for 5 minutes
- Interlock Broken (Optic, Lid, Cover, Remote)

Step 10: Press the foot switch down completely to begin. The calibration screens will update as the calibration proceeds to 100%.



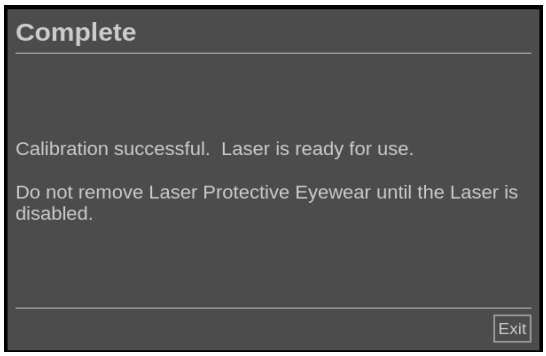
Step 11: Release the foot switch when the following message appears. The finalization message appears.





Note: The following message appears after successful calibration.

Note: Do not remove Laser Protective Eyewear until the Laser is Disabled.



Step 12: On the Calibration Completed dialog select the Exit button when prompted.

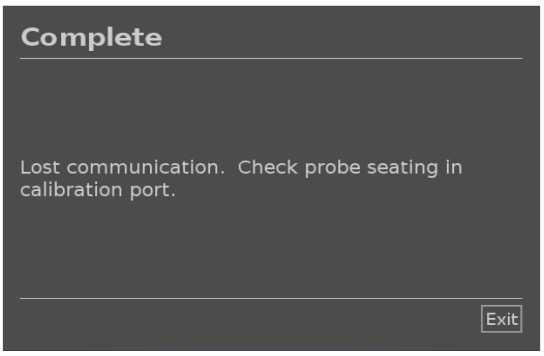
Step 13: Remove the OA/US L18-1 Probe from the Calibration Port.

Step 14: Remove the Calibration adapter from the probe and place the Calibration adapter in the Calibration port. Place the OA/US L18-1 Probe in the Probe Holder.

12.2.1.1 Unsuccessful Calibration

Important: The following is an example of a message that appears after unsuccessful calibration. Any calibration where the Complete screen does not show the message, "Calibration successful. Laser is ready for use" is an unsuccessful calibration.

Important: The following message appears after unsuccessful calibration.



Follow any Calibration screen instructions provided to correct error conditions (e.g. "Check probe seating") and then repeat calibration. If Calibration is still unsuccessful, power off the Imagio® Breast Imaging System, then power on Imagio® Breast Imaging System, and attempt to run the Imagio® Breast Imaging System Calibration. If the calibration fails again, please call Seno Service for assistance at (888) 978-8835.

12.3 Machine Check

An operator may be asked to perform the machine check procedure by Seno Service if there are any changes in image quality between service intervals. Optionally, an operator may also perform the machine check to practice their OA imaging training.

12.3.1 To Initiate the Machine Check Procedure

Ensure everyone in the scan room is wearing Laser Protective Eyewear. This is a laser safety requirement.

Warning: Invisible laser light is emitted from the OA/US L18-1 Probe. Reflected and/or misdirected laser light may damage eyes.

- Do not use any controls or adjustments or performance settings other than those specified herein.
- The Patient, the Imagio® Breast Imaging System Operator, and everyone else in the scan room must always wear Seno approved Laser Protective Eyewear when the Imagio® Breast Imaging System is powered on and the laser is enabled.
- Wearing Seno approved Laser Protective Eyewear is a laser safety requirement. It is necessary to wear Laser Protective Eyewear when, for example; scanning, inspecting and cleaning the OA/US L18-1 Probe, and calibrating laser energies or any other time the Imagio® Breast Imaging System is powered on and the laser is enabled.
- Do not look directly at the laser beam even when Laser Protective Eyewear is being worn.
- Do not look at a laser beam emitted from the Imagio® Breast Imaging System that is visible. The Imagio® Breast Imaging System uses lasers that are classified as invisible; however, some individuals can see light beyond the visible spectrum.
- Always point the OA/US L18-1 Probe away from everyone’s eyes.
- Only use your foot to press the foot switch.
- Always release the foot switch before removing the OA/US L18-1 Probe from the skin or calibration port.
- Always follow the laser safety precautions prior to laser emitting to protect the Patient, Operator, and Observers.

- Always place the OA/US L18-1 Probe in the Probe holder when not in use.

Important: A dirty OA/US L18-1 Probe face during the Machine Check may cause imaging artifacts.

Step 1: Ensure the face of the OA/US L18-1 Probe is completely free of dried gel and other debris.

Step 2: Place the OA Flat Breast Phantom within reach of the OA/US L18-1 probe.

Step 3: Apply the Seno approved gel to the Flat Breast Phantom.

Step 4: Press the Patient button on the Touchscreen.

Step 5: It is suggested to enter "Machine Check 000" in the Patient ID field, where 000 represents the sequential numbering of machine checks.

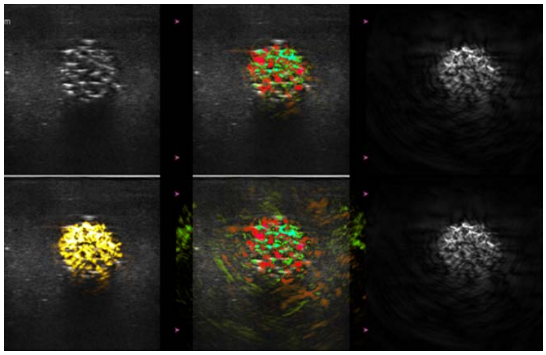
Step 6: Enter your name in the Performing physician/sonographer field.

Step 7: Press the Image button to enter live imaging and if needed, press the System Console OA button to enter OA Mode. Press freeze, if the image is frozen.

Step 8: Wear Laser Protective Eyewear then enable the laser.

Step 9: Observing the Display Monitor, press the foot switch completely and fully to the floor, and ensure that a clear, complete image is displayed.

Step 10: Move/rotate the OA/US L18-1 Probe on the Breast Flat Phantom and attempt to duplicate the image below. Call Seno Service for assistance at (888) 978-8835 if this image cannot be duplicated or artifacts appear that prohibit a diagnostic quality image. These images should be saved for troubleshooting.



Step 11: Press the Freeze button.

Step 12: Press the Save Image button.

Step 13: Release the foot switch.

Step 14: Press End Exam button to save and close out the Machine Check exam.

Note: Pressing End Exam automatically disables the laser.

Step 15: Remove Laser Protective Eyewear.

Step 16: Clean the OA/US L18-1 Probe with the Seno approved wipes, and then securely store the OA/US L18-1 Probe in the probe holder.

Step 17: Clean the gel from the Flat Breast Phantom using the Seno approved wipes.

Step 18: Cover the OA Flat Breast Phantom and return it to the designated storage location.

Chapter 13 Managing Patient Data

13.1 Saving Data

13.1.1 Capturing Images and Clips

Capture and save a single image, or clip(s). Clips can be captured retrospectively or prospectively. The captured frame or clip(s) is saved in the patient exam, and a thumbnail is available in the live imaging display and the Review display. When the capture is complete, a thumbnail of the image is displayed.

13.1.1.1 Capturing a single Image

Step 1: Press the Freeze button.

Step 2: Press the Save Image button.

- The image appears in the thumbnail strip on the right side of the screen.

13.1.1.2 Capturing a Retrospective Clip

Step 1: Press Freeze.

Step 2: Press Save Clip when frozen to save the images in the clip just acquired.

- The clip appears in the thumbnail strip on the right side of the screen.

13.1.1.3 Play Clip

When the image is frozen, in all modes, a Play Clip button appears on the Touchscreen. Play Clip enables viewing of retrospective clips.

13.1.1.4 Capturing a Prospective Clip

The Imagio® Breast Imaging System enables capturing of prospective clips in live imaging. Operators can set the duration of the prospective clip from 3-15 seconds, refer to “OA Clip Settings Configuration” on page 136 for OA or Clip preferences in “Exam” on page 127 for all other modes.

Step 1: Press Save Clip during live imaging to initiate a prospective clip capture.

- Prospective clip capture will automatically complete after the duration specified in the System Configuration.

Step 2: Press Save Clip again or Freeze to stop the capture. The clip appears in the thumbnail strip on the right side of the screen.

Note: Prospective OA clips cannot be reviewed on the Imagio® Breast Imaging System.

Note: Do not change the scaling of the image during the prospective clip capture, especially the following settings:

- Digital Zoom
- Display Format
- Dual Top/Bottom
- Sector

Note: Pressing Save Image while acquiring a clip does not stop the clip acquisition.

13.1.1.5 Trimming Clips

Trim enables discarding of frames from the start or end of a retrospective clip.

Step 1: Touch Trim on the Touchscreen.

- The Touchpad is changed to the pink active Trim End.

Step 2: Slide your finger on the Touchpad towards the beginning of the clip to discard the required frames from the end of the clip.

Step 3: Press the Touchpad to set the end and activate the pink Trim Start.

- The Touchpad is changed to Trim Start

Step 4: Move the Touchpad towards the end of the clip to discard the non-desired frames from the start of the clip. Press the Touchpad to set the beginning position.

Step 5: Touch Trim off to cut the trimmed frames out.

Step 6: Press Save Clip to save a new clip without the non-desired frames.

- If needed, press Trim Reset to return the original clip Start and End frames.
- Press Trim Clip, Image or the Mode button to return to live imaging.

Note: Prospective Clips collected in OA Mode (movie camera icon on thumbnail) will not play back in review as clips on the Imagio system but will play back as clips when exported. Prospective OA clips cannot be trimmed on the Imagio.

13.2 Performing measurements

13.2.1 Accessing measurements

Perform measurements to assess the dimension, area, perimeter, or volume of anatomical features.

Two types of measurements are available on Imagio® Breast Imaging System:

- Basic measurements, which can be done with a set of measurement tools.
- Labeled measurements, which correspond to the actual anatomy of the body. Labeled measurements are not linked to an image. They appear in the report even if the image on which they were performed is deleted.

Important: Measurements are replicated across the 6 on 1 display on OA Mode.

Important: Make sure the image is correctly optimized before performing any measurements.

Important: Press the "Back to Image parameters" button to permit scrolling back in the timeline.

Press Measures on the system console to enter the measurements. A default caliper appears on the main display.

The image area is duplicated on the Touchscreen to facilitate stylus measurements.

Measurements that appear with a star (*), ellipse for example, are estimated measurement results.

13.2.2 Basic measurements

Step: 1 Press the Measurements button on the system console.

Step 2: Touch Measures on the Touchscreen.

- The Imagio® Breast Imaging System displays the measurement tools that are available for the active Mode.
- Measurement results are displayed in the Measurement ResultBox which is located to the lower right of the image, below the gray-scale bar, on the main display. This ResultBox can be moved and placed all over the image.

Step 3: In More Meas. Tools, press the Reset ResultBox position button to automatically replace the ResultBox to its initial place.

Step 4: Touch the desired measurement tool:

13.2.2.1 Distance

Distance is available in all operational modes.

Method 1 (with the Touchpad):

Step 1: Press Measure.

Step 2: Use the Touchpad to move the active cursor to the first measurement point.

Step 3: Press the Touchpad to anchor the first point. The Imagio® Breast Imaging System anchors the first cursor and displays a second active cursor. The Imagio® Breast Imaging System displays the value of distance in the measurement result area to the right of the image on the main display.

Step 4: Touching End will end the measurement.

Method 2 (with the Touchscreen):

Step 1: Press Measure.

- The active cursor appears.

Step 2: Touch the image on the Touchscreen to anchor the first cursor location. The Imagio® Breast Imaging System moves the cursor to the position indicated, anchors the first cursor, and displays a second active cursor.

Step 3: Touch the image on the Touchscreen to position the second cursor location.

Step 4: Touch End to anchor the second cursor.

It is possible to combine the approaches of Method 1 and Method 2 to optimize the measurement work flow.

13.2.2.2 Ellipse

Ellipse is available in all modes.

Method 1 (with the Touchpad):

Step 1: Press Measure.

Step 2: Touch Ellipse.

Step 3: Press the Touchpad to anchor the first point. The Imagio® Breast Imaging System anchors the first cursor and displays a second active cursor.

Step 4: Use the Touchpad to move the active cursor to the second point of measurement.

Step 5: Press the Touchpad to anchor the second cursor. The Imagio® Breast Imaging System displays an ellipsoid trace between the two points.

Step 6: Use the Touchpad to adjust the shape of the ellipse.

Step 7: Pressing the Touchpad will sequentially switch control to the first cursor, second cursor and ellipse trace.

Step 8: Press End to complete the measurement.

Method 2 (with the Touchscreen):

Step 1: Press Measure.

Step 2: Touch Ellipse. The active cursor appears.

Step 3: Touch the image on the Touchscreen to anchor the first cursor location. A second cursor will automatically appear.

Step 4: Without lifting the finger or stylus, drag the second active cursor along the axis of the ellipse. The Imagio® Breast Imaging System displays an ellipsoid trace between the two points. Lifting the stylus or finger will anchor the second cursor.

Step 5: Touch the image near the opposite axis of the ellipse.

Step 6: Without lifting the finger or stylus, drag the ellipse trace to the desired position.

Step 7: Touch End to complete the measurement.

It is possible to combine the approaches of Method 1 and Method 2 to optimize the measurement work flow.

13.2.2.3 Trace Region of Interest (ROI)

Trace is available in all modes.

Method 1 (with the Touchpad):

Step 1: Press Measure.

Step 2: Touch Trace button.

Step 3: Use the Touchpad to move the active cursor to the first measurement point.

Step 4: Press the Touchpad to anchor the first point. The Imagio® Breast Imaging System anchors the first cursor and displays a second active cursor directly on top of the first.

Step 5: Use the Touchpad to move the active cursor to the second measurement point. The path will be displayed.

Step 6: Press on the Touchpad to anchor the second cursor. The Imagio® Breast Imaging System will automatically connect the end points of the trace.

Step 7: Alternately, touch End to complete the measurement.

If the start and end points of the trace become very near to each other, the Imagio® Breast Imaging System will automatically close the trace.

The dial under Trace can be used on an active trace to incrementally erase the trace in reverse and redo the trace.

Method 2 (with the Touchscreen):

Step 1: Press Measure.

Step 2: Touch Trace.

- The active cursor appears.

Step 3: Touch the image on the Touchscreen to anchor the first cursor location.

- A second cursor will automatically appear directly on top of the first.

Step 4: Without lifting the finger or stylus, drag the second active cursor along the path of the desired trace.

- The path will be displayed.
- Lifting the finger will pause the trace.
- Touching the cursor will reactivate the trace.

Step 5: Touch End to complete the measurement. If the start and end points of the trace become very near to each other, the Imagio® Breast Imaging System will automatically close the trace.

13.2.2.4 Depth

This tool enables defining of the depth on the image at a particular point of interest.

Step 1: Press Measure.

Step 2: Touch More Meas. Tools.

Step 3: Touch Depth.

Step 4: Press the Touchpad to anchor it at the desired depth.

Step 5: The depth value will be displayed.

13.2.2.5 Volume

A three-distance volume enables using three independent distances in the same or in orthogonal images to create a volume calculation.

Step 1: Press Measure.

Step 2: Press More Meas. Tools.

Step 3: Touch Volume.

Step 4: Use your preferred method (refer to above, Distance measurements) to draw three distances.

Step 5: The Imagio® Breast Imaging System calculates a volume from the three distances.

Calculate a volume with labeled measurements is available. Refer to “Labeled Measurements” on page 98.

13.2.2.6 Ellipse distance volume

Step 1: Press Measure.

Step 2: Touch More Meas. Tools.

Step 3: Touch Volume (Ellipse + Distance).

Step 4: Use your preferred method to draw an ellipse on the plane of interest Once the ellipse is drawn, the Imagio® Breast Imaging System displays the first caliper of a distance measurement.

Step 5: Choose an orthogonal plane to draw the distance Once the distance is drawn, the Imagio® Breast Imaging System displays the values of the volume in the measurement result area.

13.2.2.7 Q-Box™

The Quantification Box (Q-Box™) enables accurate quantification of the stiffness of an area. Q-Box™ is available only in SWE™ mode on a frozen image.

Step 1: Press Measure.

Step 2: Touch Q-Box™.

- Q-Box™ displays a circle that can be resized or moved, and that is duplicated on the B Mode image (in side by side and top bottom formats), for reference purposes.

Step 3: Select to anchor it.

13.2.2.8 Q-Box™ Ratio

Q-Box™ Ratio enables comparison of the stiffness of two areas on the same image. Q-Box™ Ratio is available only in SWE™ mode on a frozen image.

Step 1: Press Measure.

Step 2: Touch Q-Box™ Ratio.

- Q-Box™ Ratio displays a circle that can be resized or moved, and that is duplicated on the B Mode image (in side by side and top bottom formats), for reference purposes.

Step 3: Place the Q-Box™ within the stiffest visualized area.

Step 4: Press the Touchpad to anchor it.

Step 5: Another Q-Box™ is displayed.

Step 6: Place it on soft tissue.

Step 7: Press the Touchpad to anchor it.

Note: The values for ShearWave™ speed and tissue modulus are relative indices intended only for the purpose of comparison with other measurements performed using the Imagio® Breast Imaging System, and absolute values for these measurements should not be compared to shear wave elastography measurements from other manufacturers' ultrasound imaging systems.

Note: Breast lesions on mammography and sonography may contain blue coded areas. This may be due to soft focal areas in the tumor or noisy data that triggers errors in ShearWave™ speed estimation. Place the ROI in the stiffest part of either the lesion or tissue immediately adjacent to the lesion to gain the most relevant diagnostic information.

13.2.2.9 Q-Box™ Trace

Q-Box™ Trace enables manually tracing a Q-Box in SWE™ imaging mode in order to obtain some elasticity values within the traced area. Q-Box™ Trace is available only in SWE™ mode, on a frozen image.

Step 1: Press measure.

Step 2: Touch Q-Box™ Trace.

Step 3: Use your preferred method (with the Touchpad or Touchscreen).

Step 4: Press the Touchpad to end the measurement.

13.2.2.10 Multi Q-Box™

Multi Q-Box™ enables automatic calculation of the average of several Q-Box measurements.

Multi Q-Box™ is available only in SWE™ mode on a frozen image

Step 1: Press measure.

Step 2: Touch Multi Q-Box™

Step 3: Resize and move the Q-Box™ as needed.

Step 4: Press the Touchpad to validate.

Step 5: To add another Q-Box™, repeat the operation the Imagio® Breast Imaging System calculates the average of each Q-Box™ result. Optionally, continue the Multi Q-Box™ measurement cycle on several images.

Step 6: Press End to end the Multi Q-Box™ measurement cycle.

13.2.3 Other Touchscreen measurement functionalities

The measurements Touchscreen has some specialty controls to facilitate measurement work flow.

13.2.3.1 Erase All

Erase All enables erasing all of the measurements displayed on the frozen image.

13.2.3.2 Erase Last

Erase Last enables erasing only the last caliper anchored.

13.2.3.3 End

End will end the active measurement.

13.2.3.4 Undo/Redo

The dial under Undo/Redo can be used on an active trace to incrementally erase the trace in reverse and redo the trace.

13.2.3.5 Zoom

Zoom enables enlarging of the size of the image on the Touchscreen.

Rotate the dial located under Zoom:

- clockwise to increase the zoom factor
- counterclockwise to decrease the zoom factor

13.2.4 Labeled Measurements

Step 1: Press Meas. on the system console.

- A list of labeled measurements is displayed on the right side of the image
- The available labels depend on the selected application and on the current active Mode
- The label packages can be configured in the System Configuration. Refer to “Packages” on page 151.

Step 2: Press Cursor.

Step 3: To scroll the list, place the cursor over it, and scroll on the Touchpad.

Step 4: Pick the appropriate label from the list by using the Touchpad.

- The appropriate measurement tool is launched (distance...)

Step 5: Perform the measurement as for a basic measurement.

- Make up to 5 measurements for the same label. They appear with their corresponding caliper in the list.

Note: Labeled measurements may be hidden, depending on the selected option from the System Configuration.

13.2.4.1 Assign last

Assign Last enables assignment of the last measurement performed to a label.

Step 1: Perform a measurement.

Step 2: Touch Assign Last on the Touchscreen.

- The Imagio® Breast Imaging System displays the list of available labels for your measurement

Step 3: Select the desired label.

For more information on labeled measurements, refer to “Labeled Measurements” on page 98.

13.3 Using annotations

13.3.1 How to use annotations

Add text annotations and arrows on an image to denote anatomical structures and locations. Annotate is located on the system console.

The annotation feature is available in live imaging and on frozen image.

To annotate an image, press the Annotate button on the system console.

A list of annotations appears on the Touchscreen and an annotation cursor appears on the main monitor display.

Rotate the Page dial to access various pages of annotations.

To add an annotation, choose from the following actions:

- Choose one of the pre-programmed annotations in the library of annotations. Touch the desired annotation to add it to the main display.
- Touch Keyboard to display a keyboard and manually enter an annotation.
- Touch Arrow on the Touchscreen to add an arrow graphic to the main display. Use the Touchpad to position the arrow.

To remove annotations from the main display, use the following functions:

- Clear All removes all the annotations and arrows from the main display.
- Delete Last Annot. removes the annotation last text annotation entry.
- Del. Last Arrow removes the last arrow marker applied to the image.

The annotations feature has some specialty controls to facilitate annotation work flow.

13.3.2 Annotation Mode

When adding an annotation as a title, it will remain when the image is unfrozen.

When adding an annotation as a free annotation, it will be removed when the image is unfrozen.

Press Mode to change the annotation mode.

13.3.3 Group of annotations

Annotations can be grouped by color. If they have a specific color, they belong to the same group. When selecting the first annotation from a group, it will be added to the screen. When selecting an annotation from the same group, it will replace the one that is already on the screen. Annotations all appear in white when the image is saved or printed.

13.3.4 Moving annotations

Step 1: Select an annotation from the Touchscreen to add it.

Step 2: Move the cursor over the newly added annotation.

Step 3: Press the Touchpad.

- The annotation is selected

Step 4: Move the cursor to move the new annotation location.

Step 5: Press the Touchpad to release the annotation.

Note: If moving an annotation over an existing annotation, the existing annotation will be replaced.

13.3.5 Annotation Library

To edit the library of pre-set annotations manually. Touch EDIT LIB. (edit library) to edit the library of annotations.

This opens the System Configuration page, the System/Display tab, and Annotation sub-tab.

To manage the annotations for the desired clinical application.

Refer to “System Configuration” on page 121 for more details.

13.3.6 Home

Touch Home to move the annotations cursor to the home position.

Touch Set Home to define the current position of the cursor as the Home position for the current display format.

13.3.7 Exit

Touch Back To Image Parameters or press the Freeze button twice to exit annotations.

13.4 Using body markers

13.4.1 How to use body markers

Body markers is available in live imaging and on frozen images.

Step 1: Press Annotate on the system console then Body markers on the Touchscreen to add a body marker to an image.

Note: To customize the access to Body markers. Please refer to "Bodymarker" on page 145

- The default body marker will appear on the on the Touchscreen and on the main monitor display to the lower right of the image.

Step 2: Touch PICTO to change the body marker pictogram.

A selection of body markers appears on the Touchscreen.

Step 3: Touch the desired body marker to select it.

- The probe orientation can be indicated directly on the pictogram.
- To add a probe orientation to the pictogram, simply touch the pictogram to indicate the edge of the probe that corresponds to the orientation marker on the probe.
- Then touch the pictogram again to indicate the edge of the probe opposite the orientation marker.
- The probe orientation appears. Use the Rotate dial to rotate the probe orientation on the body marker.

Step 4: Press Exit on the Touchscreen to close the Body Marker page.

- Touch HIDE to hide the PICTO on the image.
- To restore a body marker to the main display, touch SHOW.

13.5 Reviewing an Exam

During or after an exam, use Review to examine and compare images acquired in the exam. Multiple exams for one patient may be reviewed. In Review, operators look at the images or clips that have been stored. Stored images can be viewed, sent, printed, searched and backed up. Image analysis can also be performed in Review. Images that are stored on the ultrasound Imagio® Breast Imaging System hard-drive can be sent to a USB media, or to DICOM-compatible devices on a network.

In Review, a variety of tasks may be completed, including performing measurements and playing clips.

Prospective Clips collected in OA Mode (movie camera icon on thumbnail) will not play back in review as clips on the Imagio system but will play back as clips when exported.

13.5.1 Measurements in Review

In Review, measurements on images in the current exam can be performed. An image must first be displayed in full size. Measurements made in Review on the current exam can be saved in the report. Measurements made in Review on prior exams cannot be saved. To display the measurement controls on the Review Exam Touchscreen, press Meas. Clear all measurements from an image by touching Erase all on the Review Exam Touchscreen.

13.5.2 Starting Review

Step 1: Press Review to enter Review.

- The display that appears depends on whether an exam is active on the Imagio® Breast Imaging System.

- If an exam is in progress, pressing Review opens the Review Exam display and a reminder is displayed on each thumbnail indicating “Not from Current Exam”.
- If there is not an exam currently in progress when Review is selected, the Patient Directory will be displayed.
- If an automatic deletion is set up in the System Configuration, locking some exams to prevent them from being automatically deleted is available.

Step 2: To return to live imaging, press Review again.

13.5.2.1 Patient Directory

The Patient Directory is a list of exams that are stored on the selected disk drive. The Patient Directory includes options that allow the operator to sort, view, and transfer exams. If no current exam is in progress when Review is started, Patient Directory is displayed.

13.5.2.1.1 About patient directory headers

In the Patient Directory, exams are organized in a table containing several columns. Each column header describes the contents of that column using either text or an icon. Press a column header to sort the list by this column. The Exam Status column displays the number of times an exam has been continued (if any).

13.5.3 Selecting and Loading Exams

If an exam is currently in progress, pressing Review opens the Review Exam display with images loaded from the current exam.

If no exam is in progress, pressing Review opens the Patient Directory display, which lists previous exams.

To review previous exams, first select an exam in the Patient Directory.

Multiple exams of the same patient may be selected and loaded for review.

Select, Select All to include all exams.

Select Display Selected to load the selected exams for viewing

13.5.3.1 Viewing images

The Review Exam display is used for viewing and comparing exam images in the selected layout. Thumbnail images for the current or selected exam appear on the right side of the display. The Touchscreen display provides access to other review functions.

13.5.3.2 Navigating thumbnails of images

In Review small images, called thumbnails, can be viewed.

Thumbnails are located on the right side of the Review Exam display.

Touch Previous thumbnail and Next thumbnail on the Touchscreen to navigate through thumbnails of images. This will display the previous or the next image in full screen review.

Putting the cursor over a thumbnail makes it expand to a larger dimension.

Selecting the thumbnail image will bring the image up for review on the monitor.

Selecting the garbage icon over a thumbnail deletes that image.

13.5.3.3 Comparing images

In Review, two images from different exams of the same patient may be compared.

Step 1: Select the two exams in the Patient Directory.

Step 2: Select Display Selected.

Step 3: Select the patient name on the left side Thumbnails of the two exams will appear.

Step 4: Select the two images to be reviewed and touch Compare.

The two images appear side by side. They can be reviewed at the same time and measurements and annotations can be performed.

13.5.4 Sending an Exam

13.5.4.1 Export Formats

In Review, specific images can be pushed to DICOM printers (optional) and servers on a network or to a USB device. The format can be chosen before sending images or clips. To send an enlarged image to a printer or USB device, refer to “Enlarge Mode” in “System Configuration” on page 121.

13.5.4.2 Sending Images

In the Review Exam display, images can be pushed from the Imagio® Breast Imaging System to DICOM compatible printers and servers on a network.

Step 1: In the Review Exam display, select one or more images.

Step 2: Touch Export to DICOM or Export as JPEG/AVI (H264).

Step 3: In the Send To dialog box, select a destination.

In the Send To dialog box, the total space, as well as the free space available on the device are displayed for a USB device.

Note: In accordance with DICOM PS3.15 2019a, operators can check the Image de-identification check box in the Send To dialog box to send the image(s) with identification fields cleared from the database and the image.

Step 1: Select OK to send the selected images

- The exams will be exported into folders organized by patient name.

To eject a USB device:

Step 1: Wait until the  symbol (exporting data to USB) is replaced by  in the notification icons area

Step 2: Remove the USB device

At any time, operators check the export status, by selecting the appropriate notification icon on the left side of the screen. For information on icons, refer to “Main Display Notification Icons” on page 116.

13.6 Deleting exams and images

The Patient Directory enables deleting of exams from the Imagio® Breast Imaging System.

In the Review Exam display, stored images from an exam can be deleted.

This is only possible, however, when Send Images/Clips in Print/Network setups is set to At End of Exam.

When an image is deleted, it remains temporarily in the Review Exam display with an X marked through it.

Important: OA data is managed separately from the user-accessible thumbnails. The OA data is not deleted at the same time as thumbnails. OA data is managed under an automated storage maintenance process that will remove older data if the OA storage starts to fill up. The Imagio® should not be used as the primary source for long term storage. Exams should be backed up weekly or transferred to a PACS.

13.6.1 To delete one or more images

Step 1: Select the images to be deleted.

Step 2: Touch Delete Selected on the Touchscreen.

Step 3: Press Delete in the confirmation box.

13.6.2 To delete exams

Step 1: In the Patient Directory, select one or more exams. To select all exams, touch Select All.

Step 2: Press Delete Selected.

Step 3: Press Delete in the confirmation box.

13.7 Image Query and Retrieve

Prior to, or during an exam, a query may be performed to find patient exams located on a remote PACS or external USB media.

Qualified images can be extracted from these exams and retrieved by the Imagio® Breast Imaging System.

Once retrieved, the images can be browsed, and an appropriate image can be selected for Review.

A retrieved image may also be displayed in a side-by-side manner next to a live image in the current exam.

Important: The Query and Retrieve feature requires that the Imagio® Breast Imaging System is connected to a network hosting a DICOM compliant image archive.

13.7.1 General Information about Query-Retrieve

If there is no current exam, a query may be performed for any number of exams from the Q/R source.

These exams can be retrieved by the Imagio® Breast Imaging System in preparation for upcoming new exams.

If there is a current exam in progress, the query will attempt to find prior exams of the current patient (if the automatic Q/R was configured).

Valid types to be retrieved are as follows:

- DICOM Ultrasound images
- DICOM Ultrasound images extracted from ultrasound clips
- DICOM images from a variety of modalities: Computed Radiography (CR), Computed Tomography (CT), Magnetic Resonance (MR), Nuclear Medicine (NM), Secondary Capture (SC), X-Ray Angiographic (XA), Radio Fluoroscopy (RF), Mammography (MG)

Please consult the PACS operator's manual, DICOM conformance statement, or the PACS administrator for assistance with secondary captures.

Any retrieved exam can be displayed along with a live image in a current exam.

However, if there are mismatches in patient identification characteristics between the current exam and the retrieved exam, a warning will be displayed.

Refer to “Main Display Notification Icons” on page 116 for Query-Retrieve notification icon.

Important: Displaying a patient with a different patient identification to that in the current exam must be done with caution.

- This feature is provided in the event of a patient name change, or hospital ID change.
- The operator assumes all risk when performing query retrieve operations on Imagio® Breast Imaging System.

- Retrieved images can be very helpful when used for reference comparison to the same feature of interest in the live ultrasound image.
- Use caution when reviewing retrieved images on Imagio® Breast Imaging System, as they may be compressed or displayed at a lower level of image quality than observed on the PACS workstation.
- Images retrieved and displayed on the Imagio® Breast Imaging System are not intended to be used for sole diagnosis.

Note: As an optional feature, push exams from the PACS workstation to the Imagio® Breast Imaging System is an available option.

13.7.2 Performing a Query

13.7.2.1 Automatic Query

If configured, the Imagio® Breast Imaging System can perform an automatic query of various types of exams for a given patient.

When the exam is started for a given patient, press Save Image to save a first image for this patient.

The Imagio® Breast Imaging System automatically performs a query on the selected patient.

Press the Q/R button on the system console to view the queried exams.

Refer to “System Configuration” on page 121 for more details.

13.7.2.2 Manual Query

Press the Q/R button to initiate an exam query.

The query dialog box will appear.

Select the tab to query:

- Patient Name (Name)
- Patient ID (ID)
- Accession Number (Accession)

Use the appropriate filters to manage the query then press Query.

- A list of matching exams will be displayed.

13.7.2.3 Import from USB Media

Step 1: Press the Q/R button to initiate an exam query.

Step 2: Press the Import from Media button.

Step 3: A browser window appears.

Step 4: Select the location of data to be imported.

Note: You may select a folder containing DICOM data, a specific DICOM file or a DICOMDIR file to import.

Step 5: Press OK to confirm.

13.7.3 Performing a Retrieve

13.7.3.1 Automatic Retrieve

If configured, the Imagio® Breast Imaging System performs an automatic retrieve of the last acquired series for each of the selected modalities.

13.7.3.2 Manual Retrieve

After a query is performed, the Imagio® Breast Imaging System will return a list of matching exams.

Exams are displayed in a table with the following attributes:

- Patient Name
- Patient ID
- Date of Birth
- Modality
- Number of Images
- Date/Time

To see more information about a particular exam, place the cursor over an exam and a tool-tip box will appear with additional information.

Use the Touchpad to choose exams from the query list.

A checkmark will appear next to selected exams.

Choose the New Query button at the bottom of the menu, to query again.

Press the Retrieve button to retrieve the selected exams.

Note: These exams will be transferred to the Imagio® Breast Imaging System. Exams containing large numbers of images or long ultrasound loops may take a long time. It is best to perform a query and retrieve operation prior to the start of an exam.

When the selected exams have been retrieved, RETRIEVED appears next to each line.

13.7.4 Opening pushed DICOM data

You may send DICOM data from a PACS or a DICOM modality to the Imagio® Breast Imaging System.

The Q/R notification icon will be displayed to indicate data has been pushed on the Imagio® Breast Imaging System.

Press the notification icon or press the Q/R button on the system console to see the received exams.

13.7.5 Displaying and Navigating Retrieved Images

Double-Press the Touchpad on an image to display it in full screen.

The retrieve image will be displayed in the right pane.

Navigate through the retrieved images by using the buttons at the top of the pane:

- Previous will go to the previous image
- Next will advance to the next image.

Use the Touchpad to navigate through the retrieved images.

The full screen icon will enlarge the retrieved image to the side of the full screen, temporarily hiding the live or frozen image from the current exam.

All Imagio® Breast Imaging System controls will operate as usual on the current live or frozen image.

Imagio® Breast Imaging System controls will not affect the retrieved image.

13.7.6 Exiting Query and Retrieve

To quit viewing retrieved images, press the Q/R button on the system console.

13.8 Ending an Exam

Make sure all the images in the exam are saved.

After the exam is complete, end the exam as follows: Press End Exam on the Touchscreen.

Note: Pressing End Exam automatically disables the laser.

13.9 Continuing an Exam

You have the possibility to continue an exam that has ended.

Step 1: Touch End Exam to make sure there is no exam in progress.

Step 2: Touch Review.

Step 3: From the Patient Directory, select the exam to continue from.

Step 4: Touch Continue on the Touchscreen.

The Imagio® Breast Imaging System has re-opened the closed exam and is in B Mode. The thumbnails of the previous session(s) of the same exam are displayed on the right side.

The time limit to re-open an exam may be configured in the Imagio® Breast Imaging System/Display tab of the System Configuration.

Press End Exam to close the exam.

13.10 BI-RADS Analysis

The Breast Imaging Reporting and Data System (BI-RADS®), developed by the American College of Radiology, provides a standardized classification for ultrasound studies of the breast. It is composed of a series of descriptors, from which an assessment linked to a category can be made by the physician.

13.10.1 BI-RADS® assessment categories

BI-RADS® score	Assessment
0	Assessment incomplete: need additional imaging evaluation
1	Negative
2	Benign finding
3	Probably benign finding
4	Suspicious malignancy
4a	Low suspicion for malignancy
4b	Moderate suspicion for malignancy
4c	High suspicion for malignancy
5	Highly suggestive of malignancy
6	Known biopsy-proven malignancy

Note: All BI-RADS criteria are displayed in English on the Imagio® Breast Imaging System, regardless of the selected language.

Operators can easily perform BI-RADS® classification using the integrated BI-RADS® Lexicon Classification form. Up to twelve lesions may be classified in a single exam.

13.10.2 Performing BI-RADS® lexicon classification

Step 1: In any Mode, press freeze to freeze the image.

Step 2: Touch BI-RADS.

Step 3: Touch Add New Lesion. An arrow labeled “A” appears (first arrow, multiple sequential arrows B,C, D, with each press of Add New Lesion).

Step 4: Using the Touchpad, position the lesion arrow marker to indicate the lesion of interest on the main display.

Step 5: Press on the Touchpad to anchor the arrow marker.

- The BI-RADS® menu will appear to the left of the image on the main display.

Step 6: Select the lesion features in the BI-RADS® lexicon classification form using the Cursor and the Touchpad.

Step 7: Press the NEXT button in the menu or the Lesion Page control on the Touchscreen to move to the next page of the BI-RADS® menu.

Step 8: Press Save Image.

Step 9: Select the "X" to close the BI-RADS® menu.

Important: You must press Save Image after filling out the BI-RADS® classification form and exiting the menu or the data will not be saved.

The BI-RADS® menu can be accessed as many times as needed to complete the assessment for a particular lesion. Measurements performed while in the BI-RADS® menu will be directly associated with the Lesion selected (e.g. Lesion A) in the final report. Measurements performed in the BI-RADS® menu will appear on page 4 of the report.

13.10.3 Documenting BI-RADS® lexicon classification with images

A single image is not able to document all of the features contained in the BI-RADS® lexicon classification form.

To assist in documentation of lesion features, the integrated BI-RADS® menu offers the advantage of documenting one or more BI-RADS® features with an associated image.

Step 1: Define a new lesion and activate the BI-RADS® menu.

Step 2: Using the cursor and the Touchpad, results may be selected in the BI-RADS® lexicon classification form.

Step 3: Press Save Image.

Note: The image number appears to the right of the selected answer on the BI-RADS® lexicon classification form. You may exit BI-RADS® after each Save Image and return to the same lesion to enter additional data associated with new images. In the case that disparate results are entered for the same lesion, reconciliation of results can be done in the Report.

13.11 Description of the report feature

The Imagio® Breast Imaging System enables managing of all the information collected during the exam and generates a report.

Press Report to access the report feature.

The Report Builder is displayed.

13.11.1 Report builder

13.11.1.1 Description of the report builder

The Report Builder enables choosing of which elements of the examination are to be included in the final report.

The Report Builder is composed of the following tabs:

- Patient Info, for retrieval/editing of patient information
- Images, where the images acquired during the exam, associated measurements, BI-RADS® and comments are stored
- Measurements, where operators view all the labeled measurements and calculations of the exam
- Worksheet, where operators visualize the elements of the final report, modify patient information and patient data entry, use diagram or anatomical data to locate or
- view performed labeled measurements
- Conclusion, where operators add their conclusion of the exam

13.11.1.2 Patient information

The Patient Info tab displays the patient information, which is populated with the same information as the Patient Data screen.

As with the Patient Data screen, the Patient Information tab displays general information, as well as further information specific to each clinical application.

Operators can edit all the information from the Patient Information tab.

Operators can enter information in more than one tab if multiple applications have been used.

If Patient is pressed to return to Patient Data entry, all your edits from the Report Builder will be saved and updated.

Operators choose what information to show in the final report by using the Show/Hide Info icons:

- Selecting the Show Info icon will designate that information to appear in the final report
- Selecting the Hide Info icon will designate that information to not appear in the final report

Information which is hidden in the final report always remains part of the exam dataset as stored on the Imagio® Breast Imaging System.

13.11.1.3 Images

The Images tab in the Report Builder displays all of the images acquired in the exam.

The images are organized into clinical application tabs.

Vertical tabs are dedicated to images associated with BI-RADS® table.

Operators choose which images to show in the final report by selecting them.

Press the icon above the image to have it included in or excluded from the report.

Images which are not shown in the final report always remain part of the exam dataset as stored on the Imagio® Breast Imaging System.

Next to each image is a text box designated for comments.

Select the white text box next to the image for which comments need to be added.

Enter comments using the Keyboard.

Measurements associated with each image are shown in the area to the right.

Operators choose to show/hide the measurements in the final report by using the Show/Hide Info icons:

- Selecting the Show Info icon will designate the measurements to appear in the final report
- Selecting the Hide Info icon will designate the measurements to not appear in the final report

If no measurements were performed on the set of selected images, the region may appear empty.

13.11.1.4 Measurements

The Measurement tab enables viewing of the labeled measurement results and associated calculations performed during the exam.

In this tab, show or hide each label measurement result in the final report.

- Select the desired application sub-tab (available only for applications in which label measurements were performed during the exam).

Note: Even if the image on which the labeled measurements were taken was deleted, the corresponding labeled measurements are kept in the database.

Note: Show or hide each labeled measurement result individually with the check box next to each measurement.

Hidden labeled measurement results will not appear in the final report.

For multiple instances of the same measurement, select which instance will be displayed in the report. Press the + to display all the sub-results of the performed measurements.

13.11.1.5 Worksheet

The Worksheet tab is divided in sub-tabs corresponding to the applications and presets used to perform the exam. The Breast Worksheet displays the information contained in the Patient Data Entry and the Patient Information tab. It includes diagrams and clinical information for Breast. The measurements are also displayed and BI-RADS if they have been performed.

13.11.1.6 Generate Report

Press Generate Report to generate the desired report in .pdf. The Report Preview screen will be shown. Use the cursor and the Touchpad to navigate between pages.

13.11.2 Exporting reports

An option enables exporting of the report as DICOM images. This can be used in particular when your PACS does not support viewing of pdf.

Step 1: Touch Imagio® Breast Imaging System Config.

Step 2: Select the Administration tab.

Step 3: Select the Devices sub-tab.

Step 4: Add or edit an existing DICOM store.

Step 5: In the Advanced Options tab, enable the Report Export.

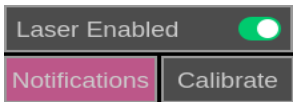
Step 6: In the drop-down list, select the Ultrasound image option.

Step 7: Select OK.

Chapter 14 Status, Alerts, Notifications, and Messages

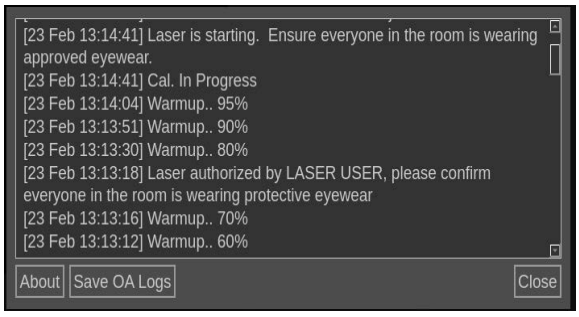
14.1 Notifications Window

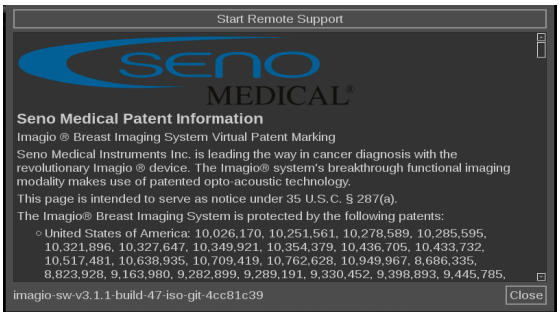
User information about the state of the laser is provided in the lower right corner of the Display and pink transient scrolling messages with laser status appear on the lower left/center area of the Display. Any pink messages that are scrolled on the Display may additionally be reviewed by selecting the Notifications button on the Laser Status Bar. The Notifications button turns pink when new notifications are available.



The Notifications Save Logs button allows the Operator to save logs encoded in a DICOM file which may be exported to a USB drive through the Review tab in the same manner as a normal patient image export.

Note: Two separate sets of system logs are generated. For instructions for the second log export refer to “System Diagnostics” on page 153.





The Notifications window About button displays Software patents, Software version, and Remote Support control. Refer to “Remote Support” on page 153.

14.2 No Probe Contact Message

A message will flash on the bottom right of the display stating “No Probe Contact” when the probe face is not in contact with the surface.

14.3 Laser Emitting Alerts

14.3.1 Laser Emitting Intermittent Tone

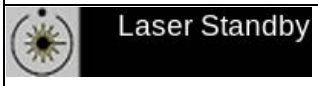
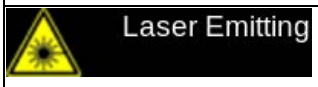
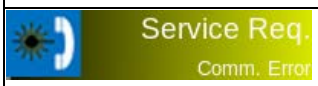
Laser emission intermittent tone sounds to alert everyone in the scan room that laser light energy is being emitted from the Imagio® Breast Imaging System. Foot switch is pressed, and the OA/US L18-1 Probe is emitting laser energy.

14.3.2 Laser Emitting Laser State Message

Laser state message “laser emitting” flashes to alert everyone in the scan room that laser light energy is being emitted from the Imagio® Breast Imaging System.

14.4 Laser State Messages

An icon and associated text that indicates the readiness and emission status of the laser is displayed in the bottom right corner of the Display Monitor.

Icon and text	Message Description	Flashing
	Laser is warming up and has not reached operating temperature. Warmup.. % complete status code will also be displayed. This laser status icon will change, and the status code will disappear when the laser reaches operating temperature.	No
	Laser Adjustment Period. Designed to ensure that the laser attenuator has time to change prior to OA/US L18-1 Probe laser emission. Typically, 3-10 seconds <60 seconds	No
	The laser enters standby and the Laser Standby icon is displayed when: Not in OA Mode, or the Console Freeze button is pressed when in OA Mode.	No
	During initial startup of the lasers, the Laser Starting icon(s) may be briefly displayed.	No
	Laser has been authorized and the system unfrozen to allow laser emission. At this point, pressing the footswitch will cause the system to go into Laser Emitting state.	No
	**Whenever the laser is authorized the user must wear protective eyewear.** Foot switch is pressed, and the OA/US L18-1 Probe is emitting laser energy.	Yes
	Laser communication errors are indicated when the laser state icon has a yellow background. Call Seno Service for assistance at (888) 978-8835.	No
	Laser communication errors are indicated when the laser state icon has a yellow background. Call Seno Service for assistance at (888) 978-8835.	No
	A condition has occurred that should be remedied as soon as possible. Call Seno Service for assistance at (888) 978-8835.	No
	This icon is briefly displayed at initial laser power on, and in the case of a laser malfunction. If the Laser Resetting icon is persistently displayed, call Seno Service for assistance at (888) 978-8835.	No

14.5 Status Codes

Status codes are additional messages that may appear with Laser State Messages that indicate other operational aspects of laser.

For example, when the laser is ready and distilled water (Add Coolant) is required to be added to the Imagio® Breast Imaging System, this message will appear:

Displayed Value	Description	Action
Cal. Required	Calibration required. (due to shot count, elapsed time, or change of firmware/ software).	Calibrate the laser energy.
Laser Starting	Software is in process of attempting communication with the Laser.	None.
Warmup.. % complete	The state of the laser temperature as the laser is heating to operating temperature expressed as a percentage.	This status code will disappear, and the Laser Status Icon will change to Laser Standby or Laser Ready when the laser has reached operating temperature.
Add Coolant	Coolant has dropped below low mark in reservoir.	Fill the reservoir with coolant.
PLC Disc.	The system does not detect the OA/US 18-1 Probe Optic Ferrule connection to the Laser Output Aperture.	Connect probe optic to laser head output port.
Probe Contact Sensor	Cannot communicate with probe energy sensor.	The probe energy sensor pads on probe may be dirty and the contacts should be cleaned.
Footswitch Disc.	Foot Switch Interlock signal is not present.	Connect foot switch.
FF	FF Codes are 4-character codes beginning with FF that Seno uses to identify issues.	Call Seno Service for assistance at (888) 978-8835 should an FF status code appear.
Comm. Error	Communication with laser lost. The laser state icon will display a yellow background.	Call Seno Service for assistance at (888) 978-8835.

14.5.1 FF Codes

- FF Codes are 4-character codes beginning with FF that Seno uses to identify issues.
- Notifications are text descriptions communicating Imagio® Breast Imaging System issues to the operator.
- FF Codes and Notifications appear on the display monitor bottom right.
- FF Codes and Notifications convey information about errors that prevent the Imagio® Breast Imaging Imagio® Breast Imaging System from acquiring data and do not pose a potential harm to the operator or patient.
- Record the code and call Seno Service for assistance at (888) 978-8835.

14.6 Information Message

- Convey information of interest to the operator.
- Appear on the display monitor bottom left.
- Example Laser Heating Percentage or Reminder Everyone Wear Laser Protective Eyewear

Message	Description	Actions to Take to Attempt to Resolve the Message
Prospective capture: [seconds] s	Time remaining during a prospective capture.	Press SAVE CLIP again to end the prospective clip or wait for the time displayed to elapse (automatically ending the clip).
Please wait during archiving...	Displayed during the final phase of saving a clip.	Wait for the message to be removed from the screen before saving another clip.
Please wait during archiving… [% complete]	Shows percent complete progress of a retrospective capture.	Wait for the message to be removed from the screen before saving another clip.
Unable to record clip while existing recording in progress	SAVE CLIP was attempted while another SAVE CLIP was still being processed.	Wait for the “Please wait during archiving” message to clear from the screen, then press SAVE CLIP to save the second clip.
Image orientation change not supported in OA Mode.	Top/Bottom or Left/Right was toggled during OA live imaging. This is not supported in OA Mode at this time. If Top/Bottom or Left/Right are toggled while frozen in OA, the button press will be ignored (no Image orientation message will be displayed).	None.
OA Data Unavailable for Review	Some frames of the OA data were not saved, for instance due to a B Mode parameter change during clip recording (e.g. changing the B Mode focus) The OA data was removed (for instance due to the periodic operation to prevent a full disk or due to re-imaging of the OA computer).	Export and check the images/clips. In some cases where only a limited number of frames have been dropped due to parameter change, the export may still be possible. Otherwise, a rescan is required to recapture the data. • Limit parameter changes during scanning. • OA data is managed separately from the user-accessible thumbnails. The OA data is not deleted at the same time as thumbnails. OA data is managed under an automated storage maintenance process that will remove older data if the OA storage starts to fill up. The Imagio® should not be used as the primary source for long term storage. Exams should be backed up weekly or transferred to a PACS.
Unable to save image. Contact the Local Service Provider.	An error occurred during DICOM processing of the image/clip.	Rescan to recapture data. Call Seno Service for assistance at (888) 978-8835.

Error saving clip. Please retry. OR Error saving clip!!	A software error occurred during the save clip process.	Rescan to recapture data. Call Seno Service for assistance at (888) 978-8835.

14.7 System Messages

- System Messages appear on the display monitor top center.
- System Messages indicate an automatic response to address a potential condition.
- Record the message and call Seno Service for assistance at (888) 978-8835 for all of these messages except normal, operator initiated, and Imagio® Breast Imaging System power off.

Message	**Type**	**Continued Correct Operation?**
HIGH laser energy – (x) WAVELENGTH	Alert	No
UNABLE TO COMMUNICATE WITH LASER	Alert	No
LASER SHUT DOWN DUE TO HIGH OUTPUT POWER	Alert	No
UNABLE TO START LASER DUE TO HIGH TEMPERATURE	Alert	No
LASER HIGH TEMPERATURE SHUTDOWN	Alert	No
LASER SHUT DOWN DUE TO LOW OUTPUT POWER	Alert	No

14.8 General System Messages

The Imagio® Breast Imaging System general system messages utilizes either a pop-up window with suggested actions or a message in the information area of the main display monitor.

The medium priority messages are used to intervene automatically by halting the Imagio® Breast Imaging System upon detection of an alert condition that may result in harm to the patient, operator, or the Imagio® Breast Imaging System. The operator is instructed via a visual message. The course of operator's actions is limited to contacting a Seno representative and acknowledgment of the restarting the Imagio® Breast Imaging System. The low priority messages are used as informational. The operator may be able to take action to resume Imagio® Breast Imaging System usage or the alert is strictly to inform the operator of a condition that may impact work flow.

The following alerts display pop-windows of a medium priority:

Alert	**Title/message**
HARDWARE ALERT	
HAL_ERROR_API	A problem in acoustic power intensity computation has occurred API error: please reboot and contact a Seno representative
Default case	Hardware control alert
	Hardware controller board alert
HAL_ERROR_LOADING SEQUENCE	A problem has occurred during sequence loading
SOFTWARE ALERT	
HWC_SP_MAY_HAVE_DIED	Hardware error: reboot is required Please contact a Seno representative

Alert	Title/message
MGR_PROCESS_DEAD	An error occurred, the Imagio® Breast Imaging System will restart
MGR_PROCESS_NO_RESPONSE	Process Name not responding, wait a few seconds or force restart
HWC_OSAWA_WATCHDOG_USB	OSAWA watchdog error
HWC_SHORT_CIRCUIT	Short circuit error
HWC_US_BOARD_OVERHEAT	US board overheat
HWC_VOLTAGE_ERROR	Voltage error
HSPM_SOFTWARE_ERROR_SEIJI_ACCESS	SEIJI communication error
HSPM_SOFTWARE_ERROR_LOG_PROM_WRITE	Log EEPROM write error
HSPM_SOFTWARE_ERROR_LOGGING_INFORMATION	Log EEPROM logging information error
HSPM_SOFTWARE_ERROR_OSAWA_ERROR	OSAWA access error
HSPM_SOFTWARE_ERROR_MGR_MSG_TIMEOUT	Manager keep alive timeout
HSPM_SOFTWARE_ERROR_MGR_MSG_SEND_ERROR	Manager message send error
HSPM_SOFTWARE_ERROR_HSPM_START_ERROR	HSPM start error
HSPM_SOFTWARE_ERROR_OSAWA_WATCHDOG_ENABLE	OSAWA watchdog enable error
HSPM_SOFTWARE_ERROR_OSAWA_WATCHDOG_DISABLE	OSAWA watchdog disable error
HSPM_SOFTWARE_ERROR_EVENT_SERVICE_NOT_OPEN	SSI event service not opened
HSPM_SOFTWARE_ERROR_TEMPERATURE_SENSOR	Temperature alert
MEAS_INVALID	ERROR

The following alerts display pop-windows of a low priority:

Alert	Title/message
HARDWARE ALERT	
HAL_ERROR_IRQ_TIMEOUT_DMA_EXPORT	You may unfreeze to continue. DMA Sequencing warning - 0x000001
HAL_ERROR_IRQ_TIMEOUT_DMA_IMPORT	You may unfreeze to continue. DMA Sequencing warning - 0x000003
HAL_ERROR_IRQ_TIMEOUT_OTHER	You may unfreeze to continue. DMA Sequencing warning - 0x000003
HAL_ERROR_IRQ_TIMEOUT_TRIGGER	Press a Mode button to continue. Trigger timeout - 0x000004
HAL_ERROR_INVALID_SQL	You may unfreeze to continue. DMA warning: invalid SGL Handle
HAL_ERROR_MAIN_LOOP_LOCK_TIMEOUT	You may unfreeze to continue. HWC main loop lock timeout
SOFTWARE ALERT	
COMPLUT_ALERT	Internal reconstruct LUT error
REVIEW_IMAGE_NOT_FOUND_ALERT	Review error: image cannot be loaded due to corrupted data
US_XML_VALIDATOR_ALERT	XML validator error: please contact an ultrasound engineer
MEAS_WARNING	ERROR
CONNECT_TOO_MANY_JOB	The job list contains more than 50 pending jobs. Please select and delete these jobs manually from the job list.

Alert	Title/message
CONNECT_TOO_OLD_JOB	The job list contains some pending jobs older than one week. Please select and delete these jobs manually from the job list.
ERROR_USB_TRANSFER	ERROR while transferring data to USB device
NOT_ENOUGH_SPACE	WARNING HARD DISK ALMOST FULL Please delete data on the Imagio® Breast Imaging System.
PARAMETER_BAD_USE	US parameter bad use

14.9 Main Display Notification Icons

Icons appear at the bottom left of the main display to indicate status or errors.

Icon	Meaning
	There is a USB device plugged in
	The Imagio® Breast Imaging System is exporting data to a USB device
	Error during USB export
	The Imagio® Breast Imaging System is connected to a network
	Network error
	The Imagio® Breast Imaging System is exporting data to a DICOM store SCP
	Error with the DICOM Modality Worklist SCP
	Error with the DICOM Store SCP
	The Imagio® Breast Imaging System is printing to a DICOM printer
	Error with a DICOM printer
	Error with a DICOM commit server
	The Imagio® Breast Imaging System is printing to a local printer
	Error with a local printer
	Modality Performed Procedure Step (MPPS) is busy
	Error with MPPS
	DICOM Modality Worklist is refreshing
	Error with DICOM Modality Worklist

Icon	Meaning
	DICOM Modality Worklist: Off line mode
	DICOM Modality Worklist filtered
	Check the air filters
	Available storage on the hard drive. Do not try to acquire more data if the hard drive is full.
	Query and Retrieve
	WIFI is deactivated

Chapter 15 Connecting and Disconnecting Probes and Accessories

Caution: The Imagio® Breast Imaging System is designed for use with the Imagio® Breast Imaging System OA/US L18-1 and US L18-5 Linear Probes only. Other Probes will not be recognized or usable and may damage the system.

- Do not attempt to attach any other probe to the Imagio® Breast Imaging System.

15.0.1 Connecting the OA/US 18-1 Probe

Step 1: Open the optic access panel located on the top right side of the cabinet.

Step 2: Feed the Probe Light Interface through the Optic Access opening on the front top right of the cabinet.

Step 3: Align the arrow on the Probe Light Interface to the top of the Laser Output Aperture.

Step 4: Gently push the Probe Light Interface into the Laser Output Aperture until it stops.

Step 5: Turn the Probe Light Interface in the direction of the arrow to lock it in place.

Step 6: Close the optic access panel.

Step 7: Push the ITT Cannon ZIF connector into the US connector port and lock handle left to secure.

15.0.1.1 Removing the OA/US L18-1 Probe

Step 1: Open the optic access panel.

Step 2: Turn the Probe Light Interface in the direction opposite of the arrow.

Step 3: Gently pull the Probe Light Interface out of the Laser Output Aperture.

Step 4: Feed the Probe Light Interface out of the Optic Access Opening located on the front top right of the cabinet.

Step 5: Unlock the lock handle to the right and gently pull the ITT Cannon ZIF connector from the port.

15.0.2 Connecting an Ultrasound Only Probe

Push the ZIF connector into the compartment and push the lock handle all the way to the left to lock the connector.

Important: When not in use, make sure the lock is in unlocked position (pushed to the right) and ensure the lock is in unlocked position (pushed to the right) before connecting a probe.

Unlocked

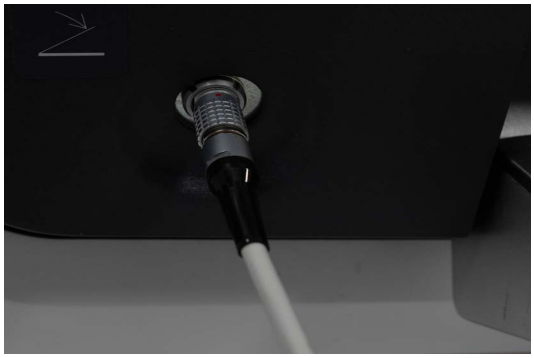
Locked

When disconnecting the probe, push the lock all the way to the right to unlock the connector and then hold the connector and pull it straight out.

15.1 Input/Output Connectors

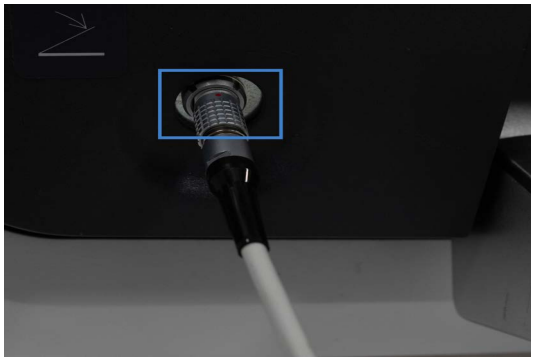
15.1.1 Removing/Connecting OA Foot Switch

15.1.1.1 To Remove the Foot Switch



Disconnect the Foot Switch connector by pulling the outer ring.

15.1.1.2 To Connect the Foot Switch



Line up the red orientation dot of the cable with the red notch on the connector port. Insert by pushing the connector in until the outer ring locks in place.

15.1.2 USB Ports

Caution: Externally powered USB devices are not permitted to be connected to the USB ports of the Imagio® Breast Imaging System. Any USB device may be connected to the system as long as it is SELF-powered through the USB port (two USB ports can be used) or powered from an external supply IEC60601 (1MOPP) compliant.

The following ports are available on the system:

- Two USB ports are located on the left side of the console

USB ports accept USB mass storage devices. The USB type B port at the rear of the cabinet is dedicated to Seno Service and is blocked from use by a service key. Do not connect any peripherals to this port.

15.2 Additional Video Devices

A DisplayPort connection is available on the system.

You may want to attach an additional video device such as an LCD monitor or video projector to the Imagio® Breast Imaging System.

The video output of the Imagio® Breast Imaging System is DisplayPort, with a native resolution of 1920x1080.

You may connect video devices to the Imagio® Breast Imaging System which are compatible with the port type and support this video resolution. The external video device must comply with the IEC 60601-1. To connect your video device with the Imagio® Breast Imaging System, perform the following steps:

- Power your external video device.
- Connect your external video device to the Imagio® Breast Imaging System by means of a Display-Port cable no longer than 5 m (15 ft) in length.
- Turn on the power of the Imagio® Breast Imaging System. The main display will be mirrored on the system display and on the external monitor.

Note: DisplayPort adapters (e.g. DisplayPort to HDMI) may not work as they rely on the 'DP_PWR' signal.

Note: External video devices which do not support the resolution of 1920x1080 may result in the following:

1. No signal displayed on the external video device
2. A "letterbox" effect where the video display is shown with a black border around the edges.
3. An aspect ratio adjusted signal is displayed. This may result in the image being stretched or compressed to fit the display.

If problems with the video quality or aspect ratio are observed, it is most likely caused by external video devices which do not support the native resolution of 1920x1080. This can be resolved by adding a "digital scaler" between the external monitor and the Imagio® Breast Imaging System. For more information, call the Seno Service for assistance at (888) 978-8835.

Chapter 16 System Configuration

The Imagio® Breast Imaging System can be customized in several ways to make it more useful for operators' needs.

Presets designed specifically for the exams performed can be created, and Imagio® Breast Imaging System settings can be changed to optimize work flow.

System Configuration enables configuring of the entire Imagio® Breast Imaging System, its applications, and additional options.

To access System Configuration, touch the top left Imagio® logo on the Touchscreen while in any active imaging Mode.

Any changes made to the System Configuration are automatically saved, unless otherwise specified.

Touch the top left Imagio® logo on the Touchscreen to exit System Configuration. A dialog may appear indicating the Imagio® Breast Imaging System is restarting due to configuration change. Accessible configuration features are dependent on log on credentials. Refer to "Login and Lock/Logout" on page 28.

The System Configuration displays:

- OA Settings configuration button
- System/Display tab
- Device Settings tab
- Administration tab
- Presets tab
- Measurements tab
- Online Services tab
- System Diagnostics tab

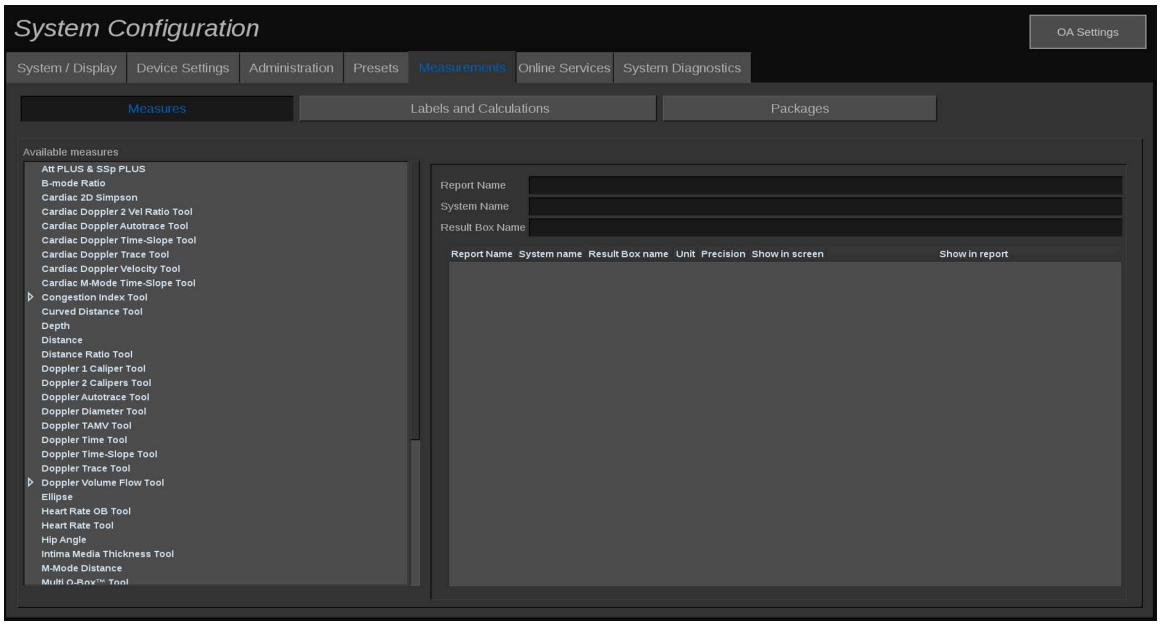
Refer to each section for detailed information.

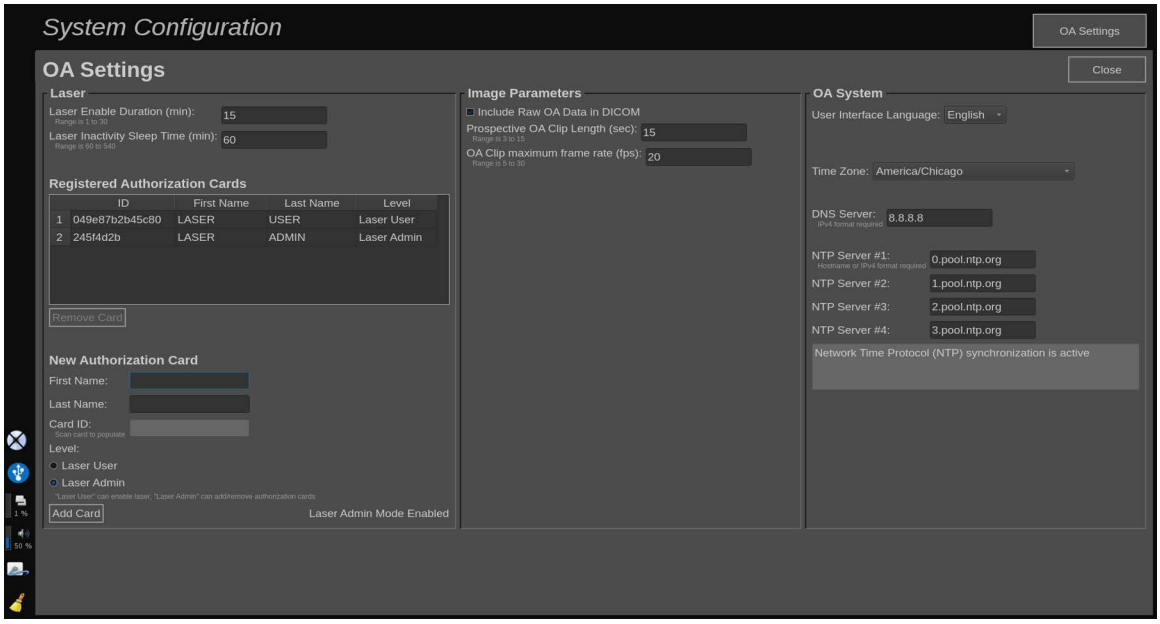
Warning: The Imagio® Breast Imaging System allows operators to configure Operator-defined Measurements, Calculations and Tables for diagnostic purposes, errors may lead to misdiagnosis or delay in treatment.

- Seno does not endorse operator-defined Measurements, Calculations, or Tables. These are utilized at the Operator's discretion and risk only.

16.1 OA Settings

OA Settings button is separate from the configuration tabs and located on the top right. Go to the Measurements tab and select the OA Settings button to enter the OA Settings configuration.





16.1.1 Laser Enable Duration

Laser Enable/Disable inactivity timeout occurs when there is no operator input detected. 15 minutes is the recommended duration and the default setting. Range is 1 to 30 minutes.

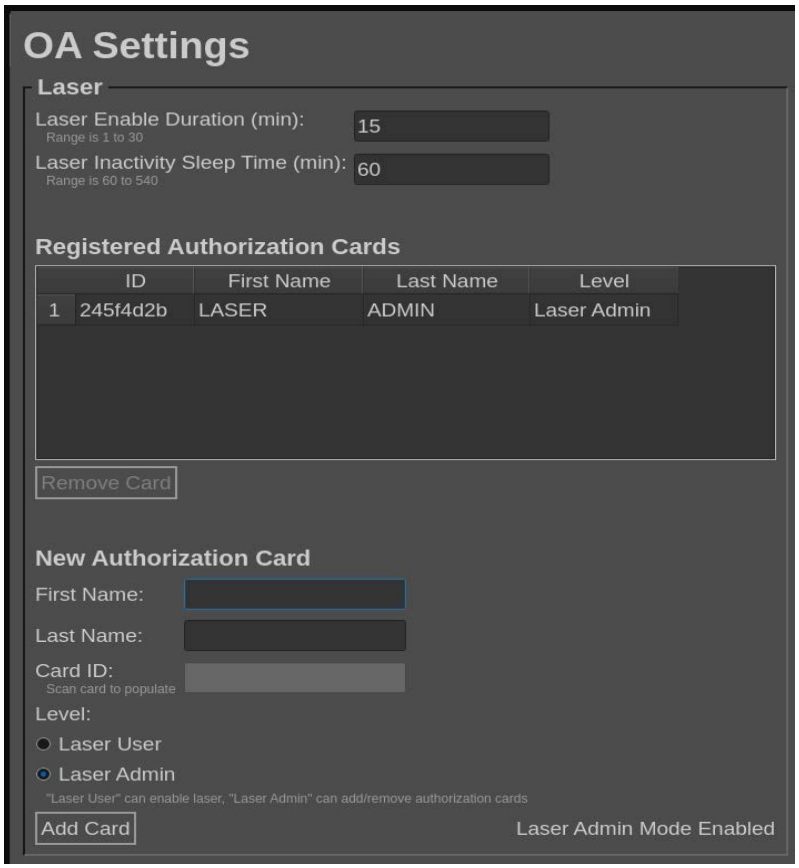
16.1.2 Laser Inactivity Sleep Time

Laser Heating inactivity timeout occurs when there is no operator input detected. The Laser will discontinue heating and enter laser sleep. 60 minutes is the recommended duration and default setting but can be adjusted to a longer duration to keep the Imagio® Breast Imaging System available for immediate use. Range is 60 to 540 minutes.

16.1.3 Registered and New Authorization Cards

The Imagio® Breast Imaging System authorization card database is initially empty when shipped. A Seno Representative will install the Admin authorization card.

Initially, the Imagio® Breast Imaging System will have no entries in the “Registered Authorization Cards” list. Select level Laser Admin and the message “Laser Admin Mode Enabled” is shown on bottom right. The first card added is Laser Admin.



“Laser Admin Mode Enabled” permits any number Laser Authorization Cards to then be added, either as a “Laser Admin” or “Laser User”.

Level:

Laser Admin - Permits modifying registered cards, (unable to authorize laser).

Laser Users - Permits authorizing laser.

Read a card to populate the “Card ID” field and enter the desired “First Name” and “Last Name” entries.

Once the required fields (First Name, Last Name, and Card ID) have been populated then the Add Card button will be active.

Note: Make sure to select “Laser Admin” or “Laser User” for the card level.

Click “Add Card” to add the new Laser Admin card to the Registered Authorization Cards list. Once a Laser Admin card has been enrolled then that card must be used in the future to enable Laser Admin Mode to remove and/or add new authorization cards to the Registered Authorization Cards list.

After a “Laser Admin” card is read and the “Laser Admin Mode Enabled” text appears, repeat the process of reading a new Card ID and entering the “First Name” and “Last Name” to add “Laser User” or “Laser Admin” cards.

16.1.4 Include Raw OA Data in DICOM

Allows inclusion/exclusion of OA raw data from the OA DICOM files (Seno Private DICOM Tag). Enabled by default.

16.1.5 Prospective OA Clip Length

Sets maximum length of OA prospective clips.

Prospective OA Clip Length may be adjusted from 3-15 seconds. Default is 15 seconds.

Retrospective recording time is fixed at 30 seconds.

16.1.6 OA Clip Maximum Frame Rate

Sets frame rate of OA clips (range 5-30 frames per second).

Default 20 fps.

Note that setting a frame rate higher than default may result in clips being split into multiple segments.

16.1.7 User Interface Language

Language for OA Mode and the laser controls.

To be set to the same language as specified in “Regional parameters” on page 125.

16.1.8 Time Zone

Time zone for the OA logs.

To be set to the same time zone as specified in “Regional parameters” on page 125

16.1.9 DNS Server

Domain Name Server (DNS) for the OA subsystem.

Note: OA DNS server is not updated in DHCP configurations.

16.1.10 NTP Server

To be set to the same time server as specified in “Regional parameters” on page 125.

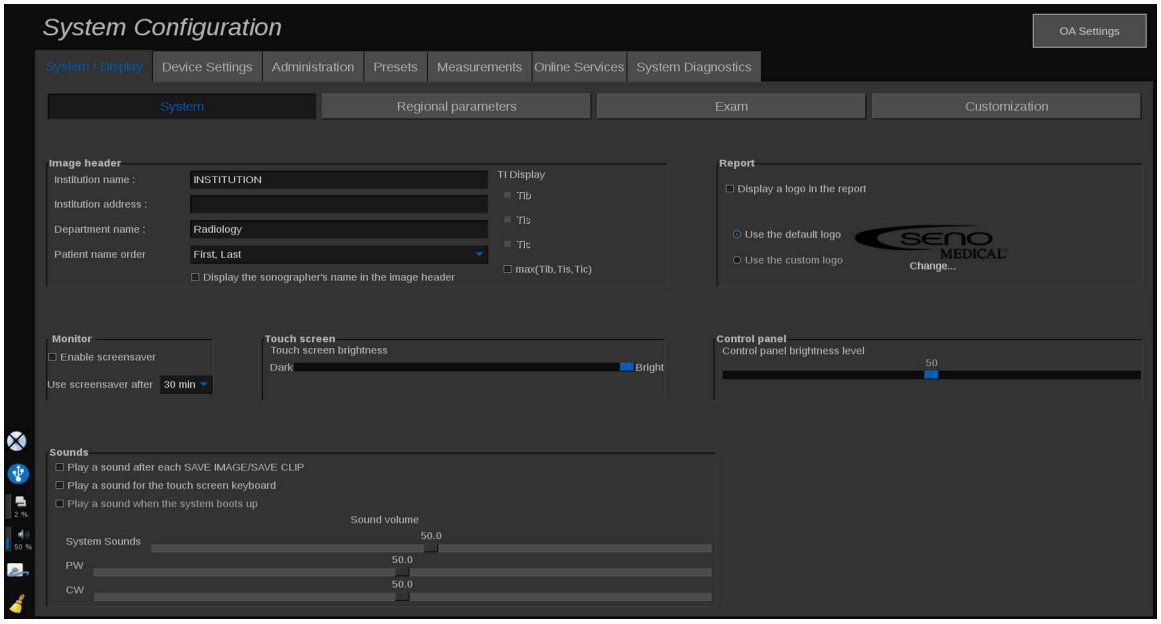
16.2 System Configuration

16.2.1 System/Display

System/Display is divided into tabs:

- System
- Regional parameters
- Exam
- Customization

16.2.2 System



Options:

- Enter the institution name and address
- Choose the patient name order
- Display/not display the sonographer's name in the image header
- Select the Thermal Index (TI) to display on the imaging screen
- Adjust the audio volume of the Imagio® Breast Imaging System
- Enable/disable the screen saver, and configure it (restart system to apply screen saver changes)
- Upload from a USB media and insert a logo which will be displayed on the report header or choose the default logo to be displayed on the report header

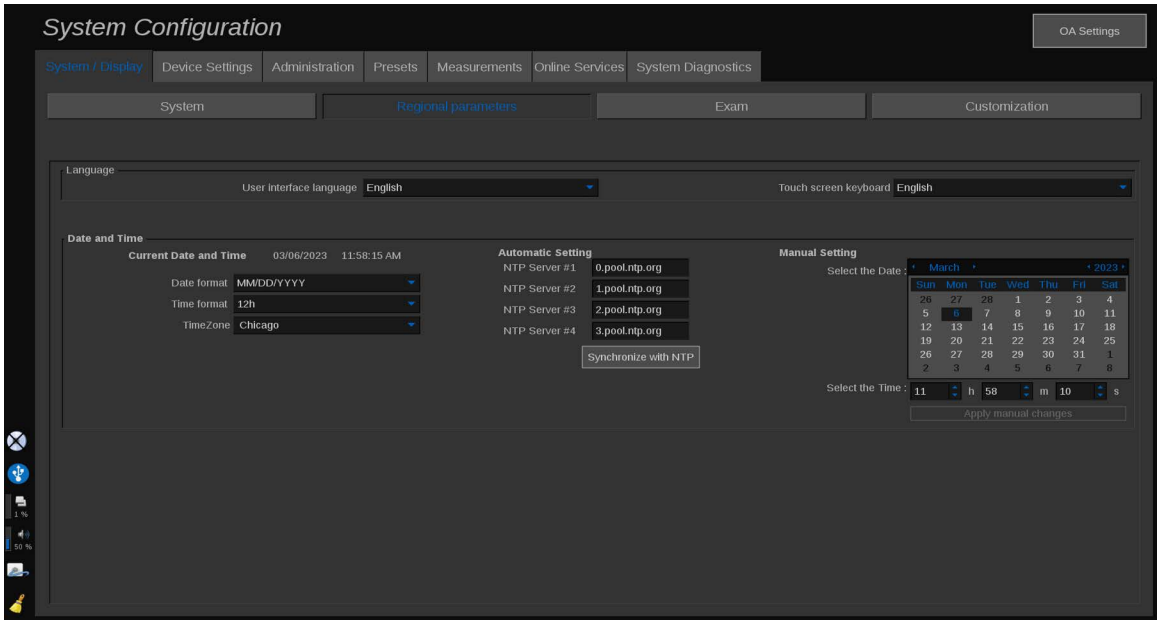
To change the logo to be displayed in the printed report:

Make sure the «Display a logo in report» check box is checked

Do one of the following:

- Select «Use the default logo» if using the Imagio® Breast Imaging System logo
- Select «Use the custom logo» if using your own logo
  - Then plug a USB device with the logo into the Imagio® Breast Imaging System
  - Then select the logo to browse for your own logo

16.2.3 Regional parameters



This section refers to the regional settings and language configuration of the Imagio® Breast Imaging System.

Options:

- change the Imagio® Breast Imaging System interface language
- set the keyboard language
- change the date and time format
- adjust the Imagio® Breast Imaging System's date and time.

Note: To set date and time:

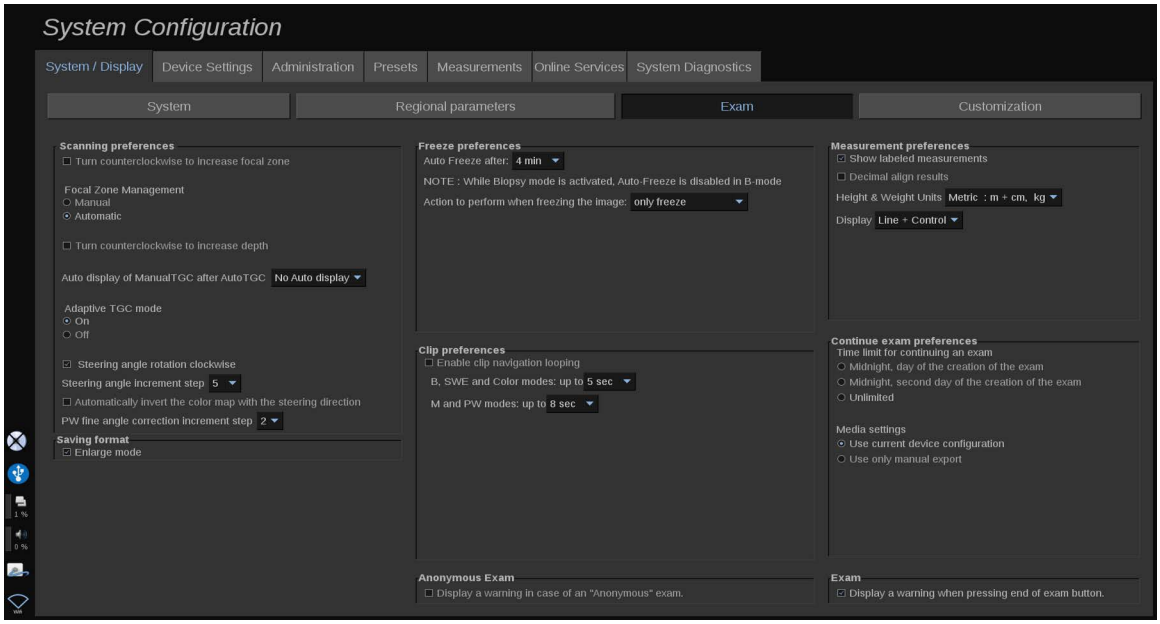
Step 1: Select a time zone from the drop-down list.

Step 2: Do one of the following:

- Enter a Network Time Protocol (NTP) server (by default, enter 1.pool.ntp.org), and Press "Synchronize with NTP" in the Automatic setting box
- Pick a date and set the time in the Manual setting box, then press "Apply manual changes"

Note: The date and time cannot be adjusted while an exam is in progress

Note: Ensure OA NTP server matches with this NTP

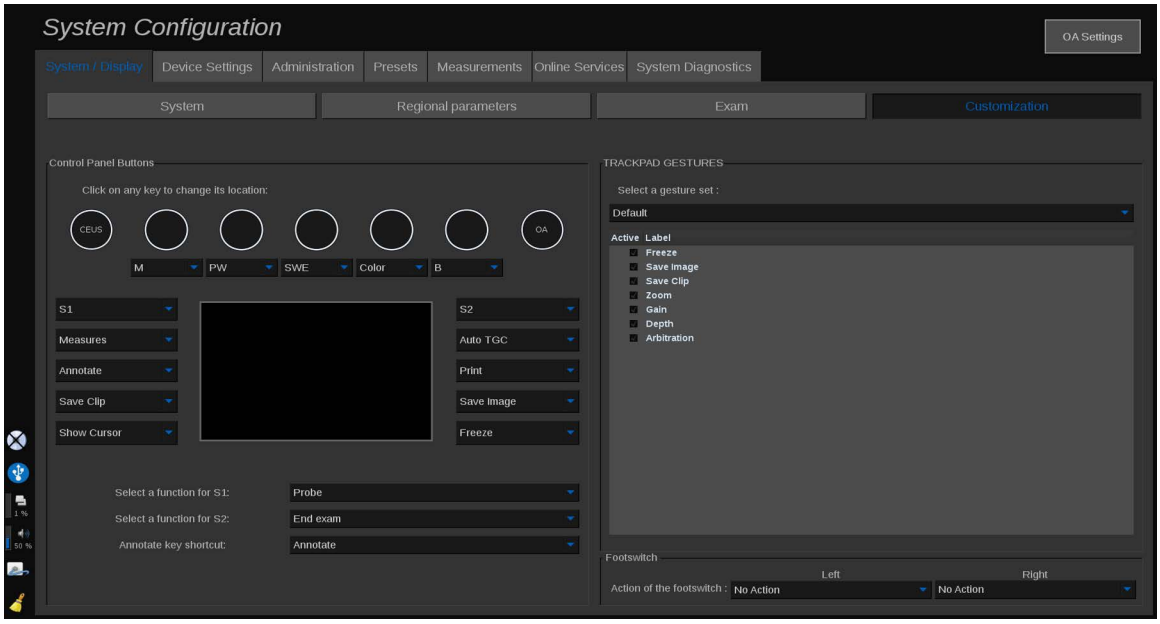


16.2.4 Exam

Options:

- Customizing scanning preferences:
  - Adjust some preferences for the Color and PW Modes
    - Steering Angle Step defines the incremental step for the steering of the color box
    - PW Fine Angle Step defines the incremental step for the Fine Angle Correction in PW
    - Choose to automatically invert the color flow map with the steering direction
    - Customize the dial rotation direction for the steering angle, focal zone and depth
  - Configure the duration of the Manual TGC auto display on the Touchscreen after activating the Auto TGC. By default, the auto display is off.
- Customize some Freeze options:
  - Set time for the live imaging auto freeze
  - Choose the action to perform after freezing the image:
    - only freeze
    - display body markers
    - display annotations
    - display measurements
  - Configure the limit duration of the prospective clip capture
- Customize the way the measurements are displayed
- Customize the Continue exam
- Choose to have a warning popup when saving an image for an anonymous patient
- Choose the Focal Zone Management to be manual or automatic
- Choose to activate or deactivate the Adaptive TGC
- Choose to enable looping in clips
- Customize the rotation direction for the Depth and Focus dials

- Choose to send enlarged images to a printer or USB device (Enlarge mode). Check to flag an image to be exported at 133% zoom. Only images in single layout (like standard B Mode or the SWE™ Mode with only SWE™ shown) support this feature. OA and SWE™/B Mode dual top/bottom are examples of layouts that do not export as “enlarged” even if this setting is selected.



16.2.5 Customization

Options:

- Assign the system console buttons to desired software functions
- Configure the Touchpad gestures

16.2.5.1 System Consoles Keys

Assign software function position as desired. Options:

Note: Please note that only the key position (located on both sides of the Touchpad) can be changed.

Select the labeled buttons (which are the currently assigned buttons) and change the associated software control as needed.

- Assign a function to the S1 and S2 keys.
- Select the buttons and choose the desired function.
- Customize the shortcut to access Body Markers or Annotation when pressing Annotate.
- Select the drop-down list and choose to access to Body Markers or Annotation first when pressing Annotate on the system console.

16.2.5.1.1 Customizable Buttons

Control panel buttons are customizable according to your needs. You can assign functions that are not available on the control panel to S1 and S2 buttons in the System configuration. You can also switch button location to your convenience by doing the following: Put a screwdriver in one of the small notches located on each side of the buttons to remove them, then put them at the desired location.

Important: To prevent cosmetic damage, use caution when removing buttons.

16.2.5.2 Touchpad Gestures

Activate or deactivate gesture control according to operators' needs. To do so, check or uncheck the check boxes.

16.2.5.3 Foot Switch

Additional foot switches are not supported on the Imagio® Breast Imaging System at this time.

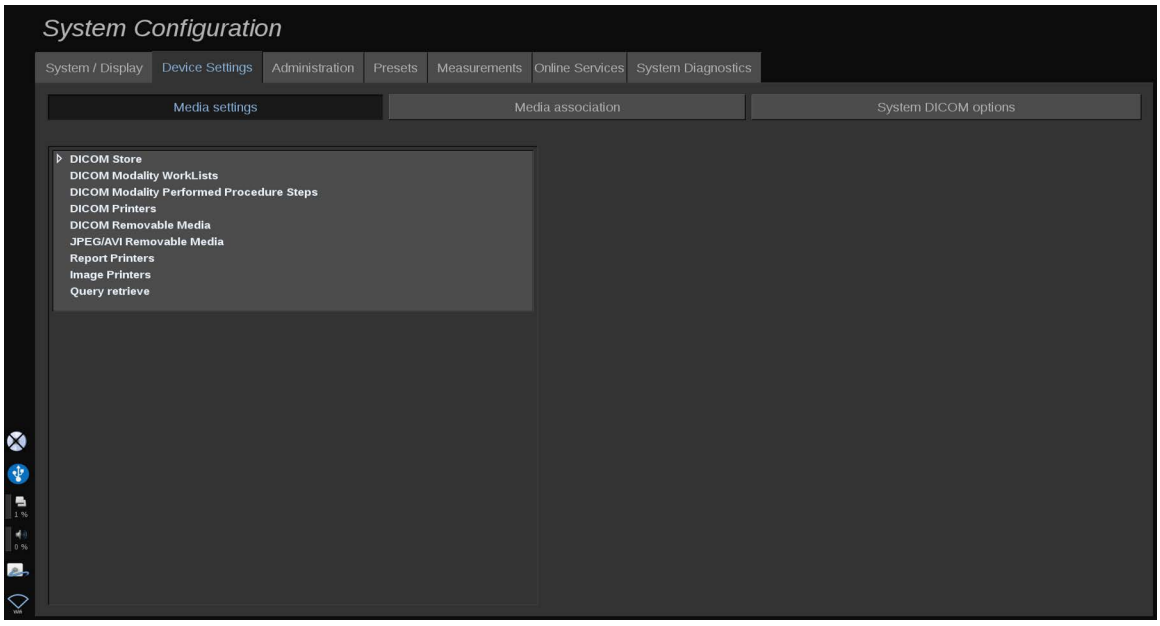
16.3 Device Settings

16.3.1 Description of the Device Settings

Device Settings is divided into tabs:

- Media settings
- Media association
- DICOM options

16.3.2 Media Settings



Configure all the media already added and associated. Options:

Select Media Settings to see the list of active devices.

For DICOM Stores devices, a menu enables defining of the method to send the data:

- Send after acquisition, Send on end exam, Send manually

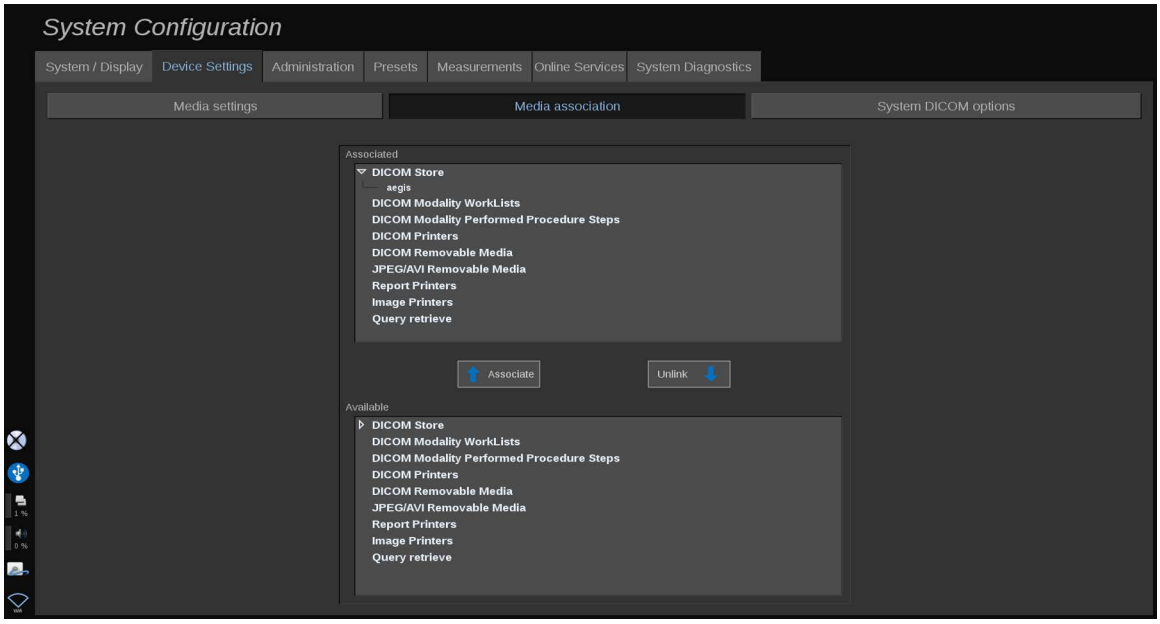
Defining printing parameters for DICOM printers, Reports Printers, and Image printers, as well as JPEG/ AVI Removable Media Export parameters (Compression level, export LUTs (Look Up Tables)) are options.

A dedicated “Worklist Settings” menu is available for the DICOM Modality Worklist servers. Set the way of querying the Modality Worklist SCP:

- By Modality, By AE Title, By Date

and set the maximum responses to receive from the Modality Worklist server(s) when this device is available and configured in the Administration part.

16.3.3 Media Association



Associate any media added in the tab Administration. Options:

This section enables adding of an active device to the working configuration. Choose from the device list which has been pre-configured in the Administration part of the System Configuration. To associate a device:

Step 1: Navigate to the bottom of the screen to the “available devices” list.

Step 2: Select the type of device, a list will be displayed.

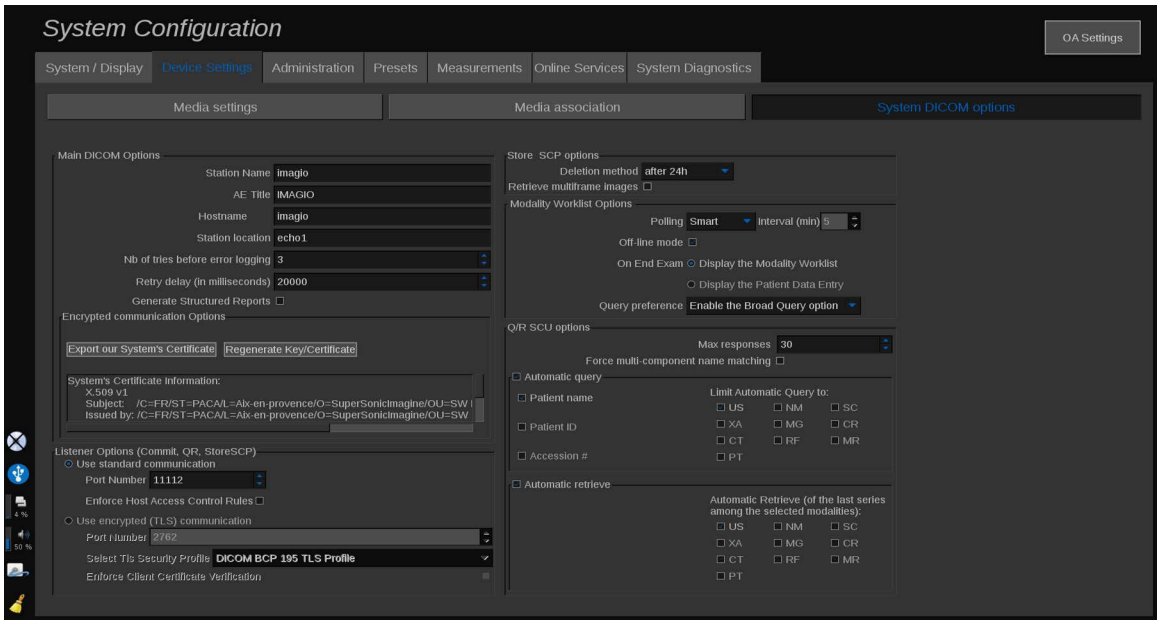
Step 3: Select the specific device to associate.

Step 4: Press “associate”. The device will appear at the top of the screen in the “associated devices” list.

Note: Associate one or several DICOM Worklist Servers, to be able to query several Worklist servers at the same time.

Note: Remove a device from the associate list by selecting it and pressing the ‘unlink’ button.

16.3.4 DICOM options



Adjust the DICOM parameters. Options:

In the Main DICOM Options part, enter all the DICOM parameters that identify the Imagio® Breast Imaging System on a DICOM network.

Configure the Imagio® Breast Imaging System to communicate with known hosts.

Set TLS configuration to be the same for all services (Store SCP, DICOM Store, DICOM Printers...) of the Imagio® Breast Imaging System, by checking the Use global TLS configuration check box. The following options are also available:

- Press “Export our Certificate” to export the public key on a USB device
- Choose to use an anonymous TLS connection by checking the dedicated box
- Require a Peer certificate by checking the dedicated check box
- Choose the TLS security profile, between DICOM AES or DICOM BCP 195
- Press “Regenerate Key/Certificate” to generate a new Key/Certificate pair

To configure the TLS connection differently for each service, go to the Administration tab, Devices sub-tab refer to Devices to configure the different services as needed.

Important: Please be aware that the confidentiality and integrity of the PII transmitted over non-DICOM TLS communication cannot be guaranteed.

In the Modality Worklist Options part, configure the way the Modality Worklist is refreshed with the “polling option”:

- Choose “Manual” to refresh the Worklist only manually
- Choose “Automatic” to set up a time to automatically refresh the Worklist
- Choose “Smart” to automatically refresh the Worklist each time End Exam is pressed on the system console.

Choose to use the Off-line, so that when the network is disconnected, the Worklist is still accessible, and by default this mode is on.

Set work flow preference for the end of the exam:

- Display the Modality Worklist
- Display the Patient Data Entry

Select the way of querying the Worklist when pressing End Exam in the “Query preference” drop-down list:

- Enable the Broad Query option
- Enable the Patient Query option
- Maintain the last selected option

In the Store SCP Options part, Choose the deletion method and whether or not to retrieve the multi-frame images.

- In the Q/R SCU options part, configure the Query/Retrieve parameters.
- Configure the automatic query and automatic retrieve by selecting the queried fields and modalities.

16.4 Administration

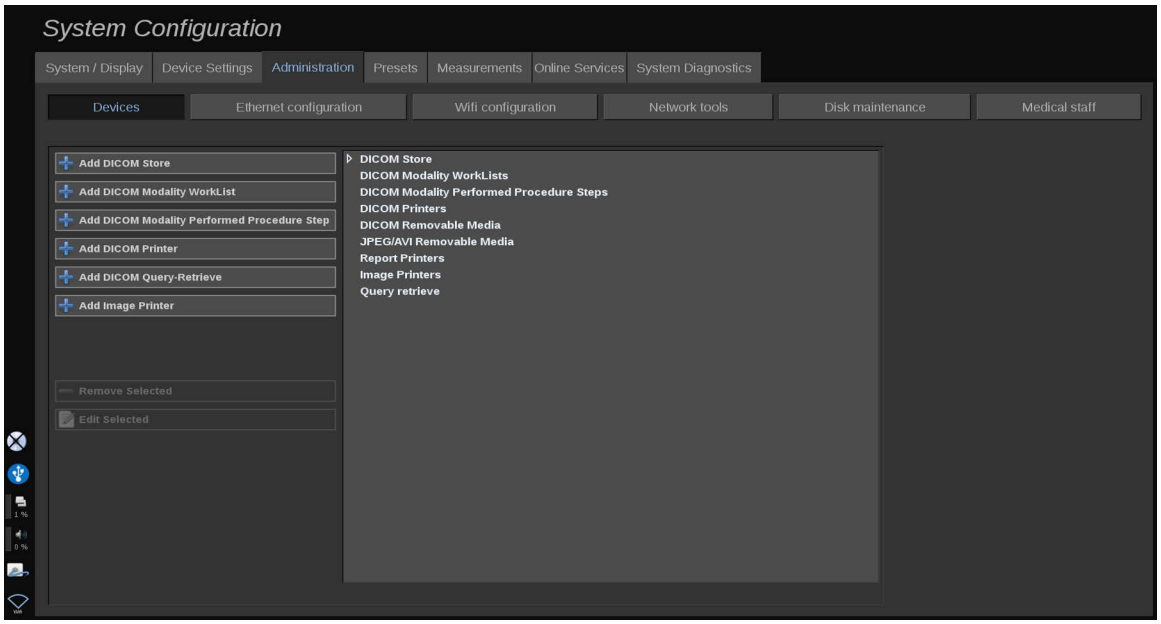
16.4.1 Description of the Administration

Administration is divided into tabs:

- Devices
- Ethernet configuration
- Wi-Fi Configuration
- Network tools
- Disk maintenance
- Medical Staff
- Operator Management

Important: Image compression may result in the loss of image information. While low levels of image compression are generally acceptable in medical imaging, using high levels of lossy compression may result in image degradation. It is the responsibility of the operator to set and maintain the degree of image compression which is diagnostically acceptable in exported images. If there is uncertainty as to what degree of compression is acceptable, consult the literature, or use the Imagio® Breast Imaging System default compression.

16.4.2 Devices



The Devices tab allows configuration of setting for communication between the Imagio® Breast Imaging System and other devices.

A list of device types that can be added is displayed on the left side of the screen:

- Add DICOM Store
- Add DICOM Modality Worklist
- Add DICOM Modality Performed Procedure Step (MPPS)
- Add DICOM Printer
- Add DICOM Query/Retrieve
- Add image Printer

After adding a Device, navigate to the Device Settings, Media Association tab to associate the device with its function. If only configuring DICOM Removable Media, no additional step is required. Refer to “Media Association” on page 130.

Press the appropriate button on the left to add a device and configure its parameters.

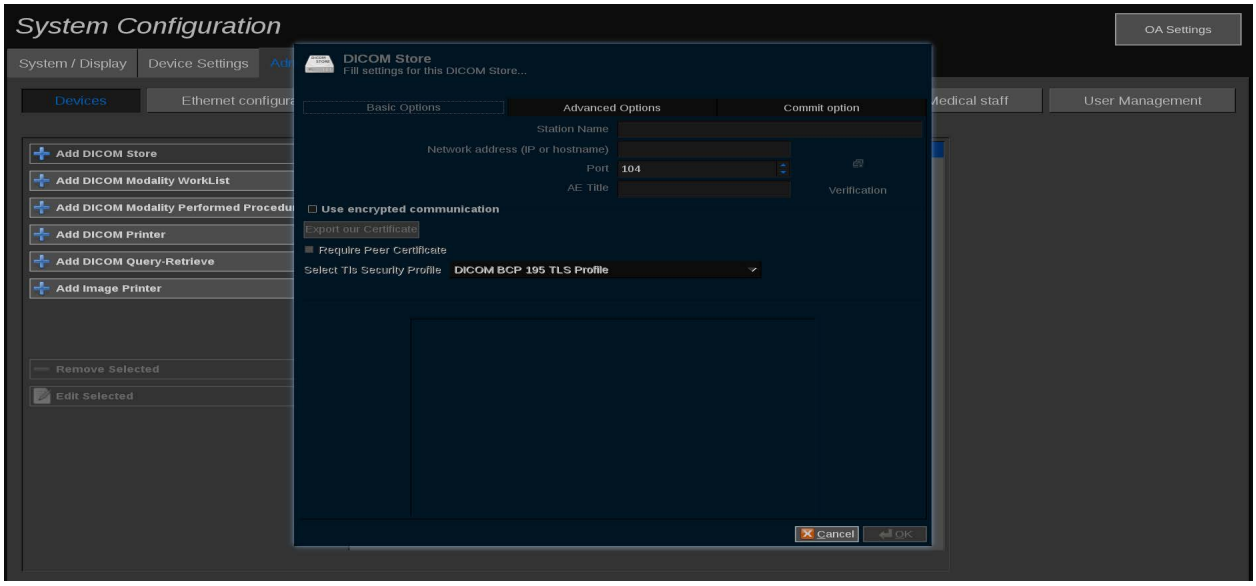
Select a device in the middle of the screen to view and configure its parameters.

Note: When adding any DICOM device using the DICOM network connection, the following Basic Options must be fulfilled:

- Station Name, IP Address, Port Number and Application Entity Title (AET)
- DICOM TLS configuration (if appropriate)

16.4.2.1 Configure a DICOM Store

To edit an existing DICOM Store device, select it on the devices list then press Edit Selected.



On the Basic Options tab, configure the DICOM device.

On the Advanced Options tab, manage the exportation settings.

1. In the General Export Settings choose:
   - to choose the patient's name to be shown or hidden on the exported files
   - the types of data to enable for exportation (single or multi frames, PDF reports)
   - the Look Up Table (LUT) to apply on the exported images/clips
   - the type of character encoding
2. In the Pictures and Clips Settings, define:
   - the transfer syntax with pre-set image compressions
   - the compression quality of the images
   - the support of Color or Monochrome modes at the exportation
   - the level of image size reduction
   - the duration of the retrospective clip

Note: For recommended DICOM Store Settings for OA refer to "OA DICOM Store Advanced Options Recommendations" on page 135.

In the Commit Option tab, choose to ask for a commitment from the storage service.

When all the desired options have been set, press OK to save the changes.

Note: The available LUTs are pre-set filters acting on specific Brightness and Contrast settings of the exported images and/or clips. They are used to make the images appear on a DICOM Review workstation Monitor as they appear on the Imagio® Breast Imaging System Monitor.

Important: Applying a too bright or too contrasted LUT can have outcomes on the quality of the image's information. It is the operator's responsibility to carefully adjust all imaging parameters to avoid image saturation and obtain optimal quantitative time-intensity data.

16.4.2.2 Configure a DICOM Printer

To edit an existing DICOM Printer, select it on the devices list then press Edit Selected.

On the Basic Options tab configure the DICOM Printer.

On the Advanced Options tab manage the printing settings:

- adjust the brightness and contrast
- choose the printing media type
- define the priority, the destination and the magnification type
- define the color and density of the borders and empty spaces of the document
- precise the session label, the configuration information and the smoothing type
- define the reduction percentage of document

When all the desired options have been set, press OK to save the changes.

16.4.2.3 OA Clip Configuration Recommendations

Due to the multi-view format of the six-up OA screen, it is recommended that the images and clips be exported at a high resolution since each section of the six-up image is a smaller screen area than a standard B Mode screen. As OA is a fusion modality that includes ultrasound data and OA data the clips and images are expected to be larger than those generated by standard ultrasound systems. The recommendations in this document are intended to produce the highest quality images and clips. Settings for reduced file sizes are also provided, but it is important to note that there will be a reduction in image quality with settings that produce smaller images and clips. The transfer syntax setting chosen should also be checked for compatibility with the site's PACS and DICOM viewers.

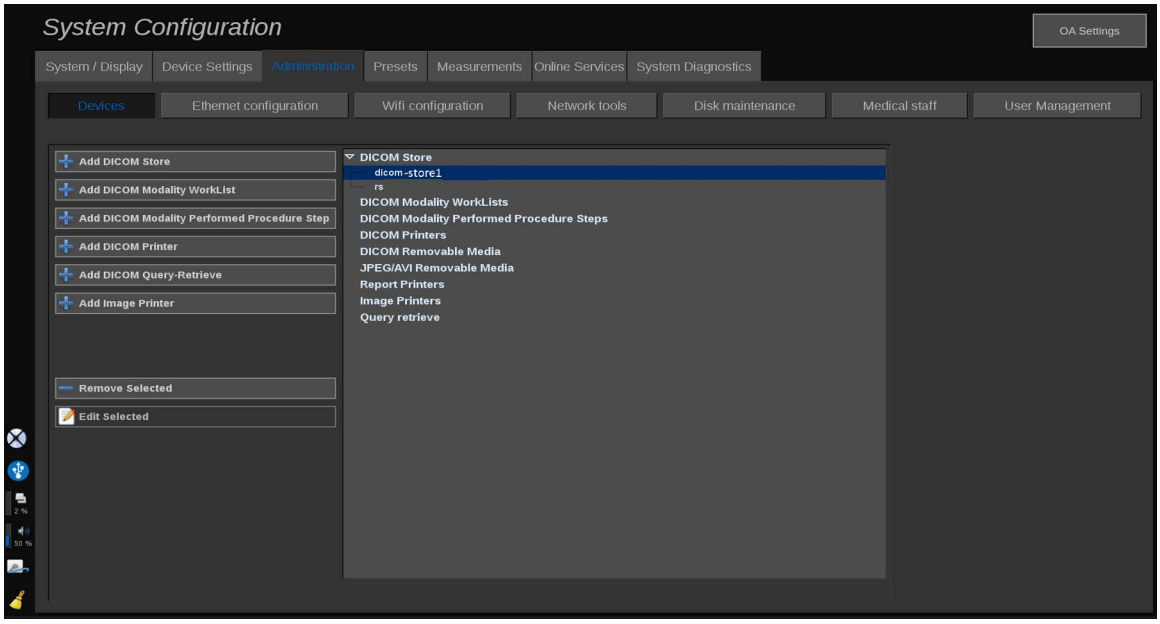
Settings	Transfer syntax - JPEG Lossless Quality - N/A (grayed out when using JPEG Lossless)	Transfer syntax - JPEG LS Lossless Quality - N/A (grayed out when using JPEG LS Lossless)	Transfer syntax - JPEG Lossy Quality - 100
Size*	~900MB for an OA 15s retrospective clip ~4MB for an OA still image	20% less than JPEG Lossless	40-50% less than JPEG Lossless
Image Quality	Highest	High	Slightly less contrast resolution with slightly less sharpness in the ultrasound and OA detail.
PACS/Viewer Compatibility	Compatible with most	Compatible with many	Compatible with most

**Clip and image sizes will vary depending on the variability of the target or background being imaged, especially during a clip.*

16.4.2.4 OA DICOM Store Advanced Options Recommendations

The OA Clip Configuration Recommendations may be set on DICOM Stores or DICOM Removable Media by going to the System Configuration Administration in the Devices Tab and selecting “Edit Selected”.

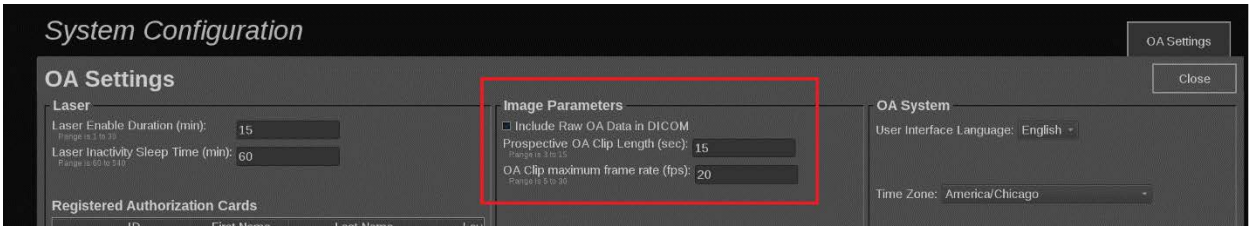
16.4.2.5 DICOM Export Configuration



In the “Advanced Options” DICOM Store dialog tab

- Set the “Enable Report export” to checked.
- Set the “Exportation LUT” to “LUT 5 (Id)”
- Set the “Enable single frame export” to checked (default).
- Set the “Enable multi frame export” to checked by default for USB, but NOT checked by default for PACS).
- “Pictures exportation settings” (left side) and “Clips exportation settings” (right side) should be set to:
  - Transfer syntax - JPEG Lossless
  - Quality - N/A - this value is grayed out because it is not used when using JPEG Lossless, so any value is acceptable
  - Color/Monochrome - All in Color
  - Reduction - Check box checked and a value of “100” (equivalent to no reduction)
  - Retrospective
  - clip duration - 30
  - Split clip after frames - 0

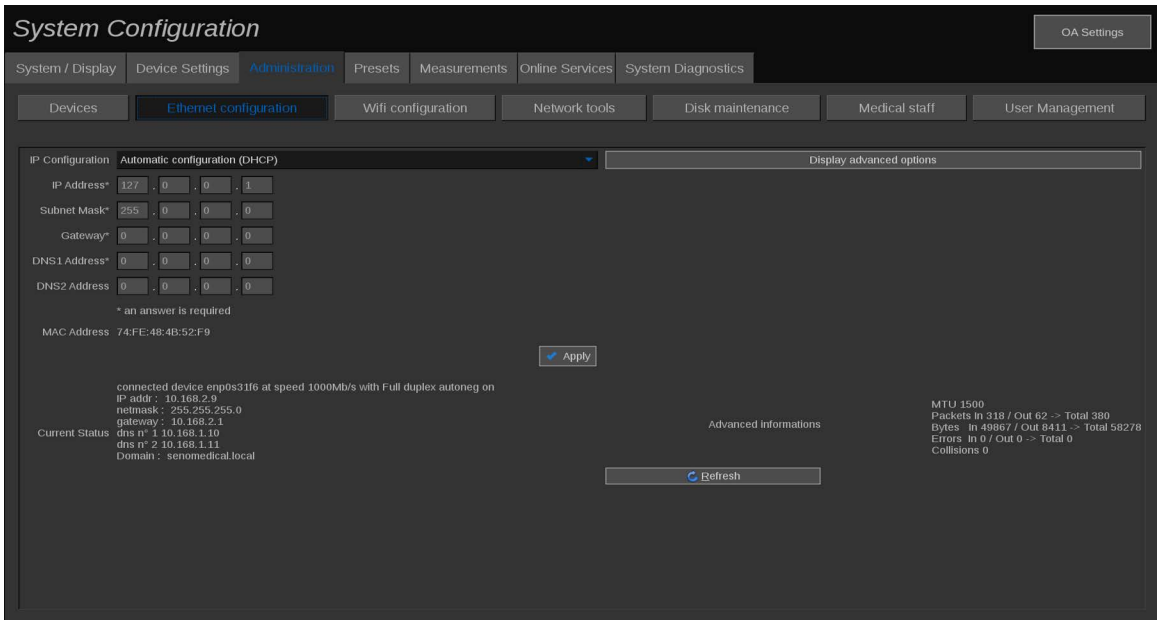
16.4.2.6 OA Clip Settings Configuration



The following settings are the default values for OA clip settings. It is recommended that these values not be changed without consulting with Seno.

- The “Include Raw OA Data in DICOM” check box is checked.
  - The OA raw data is saved in private tags in the DICOM file to allow for future reprocessing of the data. Removing the raw data may reduce the file size by approximately 10%.
- The “Prospective OA Clip Length” is set to 15
  - The user can also press “SAVE CLIP” a second time to create a shorter prospective clip while live imaging without modifying this setting.
- The “OA Clip maximum frame rate” is set to 20
  - A value of less than 20 will reduce clip size but may cause undesirable jumps in clip imaging frames during sweeps.
  - A value of greater than 20 may lead to automatic splitting of a clip into multiple “segments” as indicated by the appearance of multiple thumbnails for the same clip.

16.4.3 Ethernet Configuration



This section concerns the network configuration of Imagio® Breast Imaging System.

The Imagio® Breast Imaging System may be connected to the network through an ethernet cable. The Imagio® Breast Imaging System can be configured with a specific IP address and network setting, with a cable connected or can be automatically configured in DHCP mode.

For any network configuration, the MAC address is displayed and once connected, the network status is also displayed (especially important for the DHCP configuration).

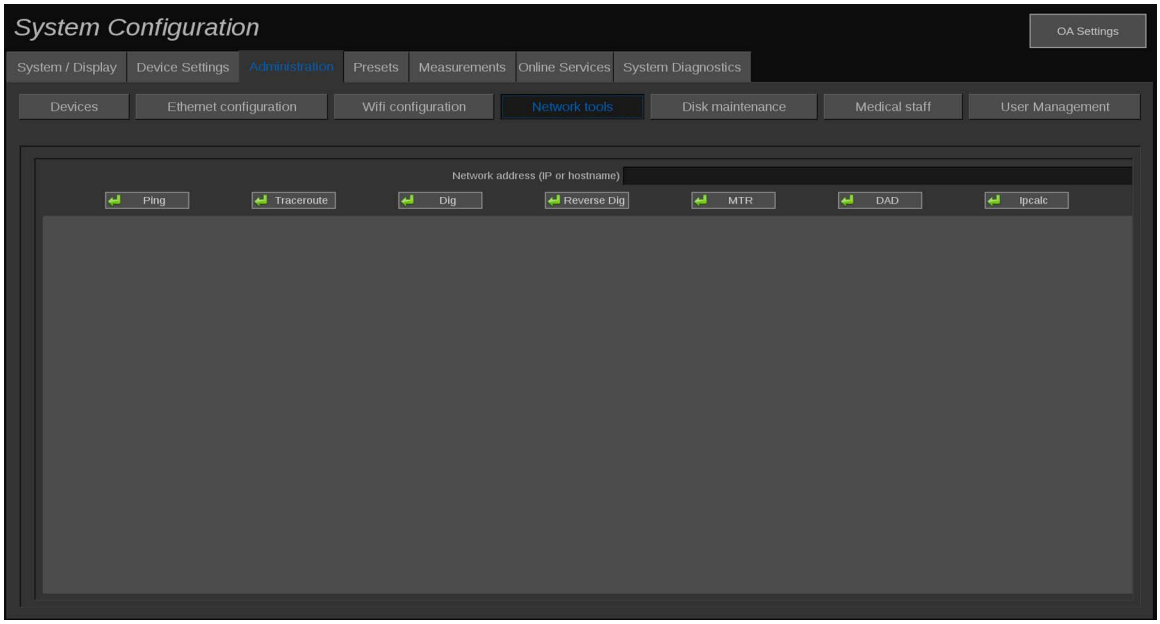
Note: When using DHCP ensure that NTP and DNS servers are manually configured in the OA Settings.

Caution: Integrating the Imagio® Breast Imaging System to a network with other connected devices may result in unpredictable risks. The operator is not permitted to install custom anti-virus software on the Imagio® Breast Imaging System.

16.4.4 Wi-Fi Configuration

Wi-Fi is not supported on the Imagio® Breast Imaging System at this time.

16.4.5 Network Tools

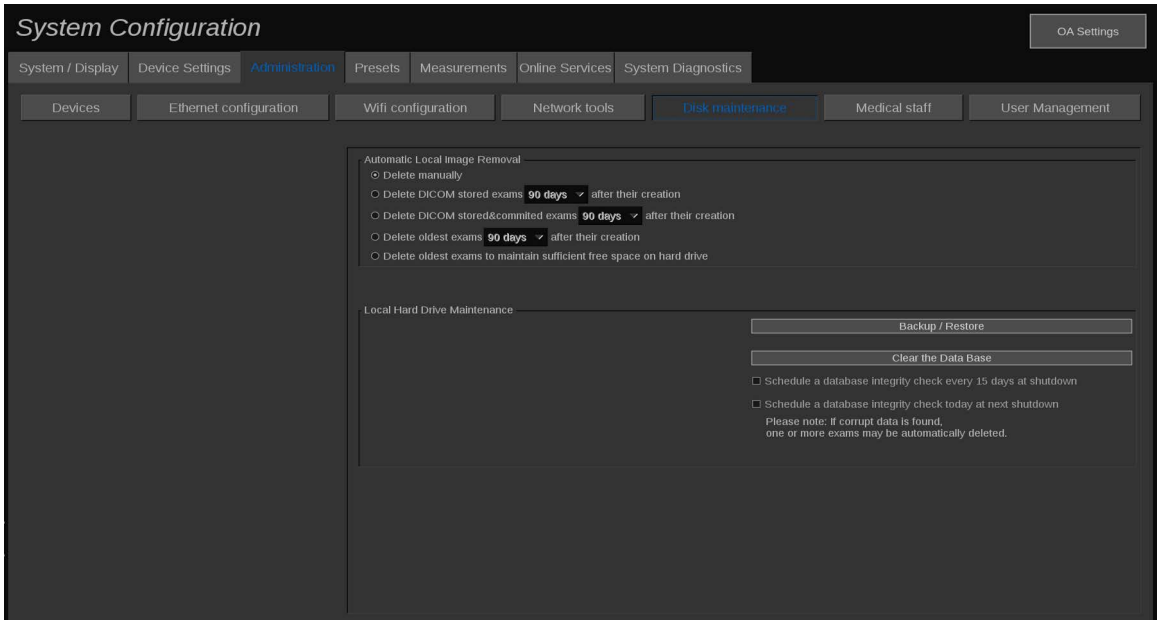


Once the network is configured, refer to “Ethernet Configuration” on page 137, these network tools are available:

- Ping
- Traceroute
- Dig and Reverse Dig
- MTR
- Duplicate address detection DAD
- IPcalc

Call Seno Service for assistance at (888) 978-8835 for further instructions on the use of these tools.

16.4.6 Disk Maintenance



This section concerns all of the options to manage the exams contained on the Imagio® Breast Imaging System hard drive.

Important: The HDD should not be used as the primary source for long term storage.

Exams should be backed up weekly or transferred to a PACS. If the Imagio® Breast Imaging System's storage needs to be replaced or the Imagio® Breast Imaging System is upgraded, the storage data will be erased and unrecoverable. The storage is not a user serviceable part. Call Seno Service at (888) 978-8835 for assistance.

16.4.6.1 Automatic Local Image Removal

This section enables managing of the way to purge the local exam database.

Delete manually is the default option, it enables manual deleting of any exam from the Patient Directory.

Important: Delete exams from time to time to prevent storage from being full.

- Delete DICOM stored exams requires the Imagio® Breast Imaging System to be connected to a PACS. Configure the Imagio® Breast Imaging System to automatically delete exams already stored on the PACS, 24h, 2 days, 3 days, 5 days, 10 days, 30 days, 60 days or 90 days after their creation.
- Delete DICOM stored & committed exams requires the Imagio® Breast Imaging System to be connected to a PACS. Configure the Imagio® Breast Imaging System to automatically delete exams already stored and committed on the PACS, 24h, 2 days, 3 days, 5 days, 10 days, 30 days, 60 days or 90 days after their creation.
- Delete oldest exams automatically deletes exams 24h, 2 days, 3 days, 5 days, 10 days, 30 days, 60 days or 90 days after their creation.
- Delete oldest exams to maintain sufficient free space on hard drive automatically deletes oldest exams after the data storage reaches less than 20Gb of free space. The Imagio® Breast Imaging System will delete exams until there is at least 50Gb of free space.

16.4.6.2 Backup/Restore

Backup and restore some elements from the Imagio® Breast Imaging System.

16.4.6.2.1 Back up

Step 1: Plug a USB device to back up some elements from the Imagio® Breast Imaging System.

Step 2: Press the Backup/Restore button.

Step 3: Enter the password.

Step 4: Press OK.

Step 5: Select the USB device.

Step 6: Select the elements to back up.

Step 7: Press Start.

Important: Make sure to offload data from time to time to prevent the storage from becoming full. Back up following the instructions above, or via DICOM.

- Imagio® Breast Imaging System is an imaging modality device and should not be used for archiving. In order to minimize the consequences of any security event, Seno strongly recommends archiving images to a PACS. In case of Imagio® Breast Imaging System failure, please note that the Imagio® Breast Imaging System disks are encrypted, which could make data recovery difficult.

16.4.6.2.2 Restore

Step 1: Plug the USB device which was backed up with some elements of the Imagio® Breast Imaging System.

Step 2: Press the Backup/Restore button.

Step 3: Enter the password.

Step 4: Press OK.

Step 5: Select the USB device which was backed up with some elements of the Imagio® Breast Imaging System.

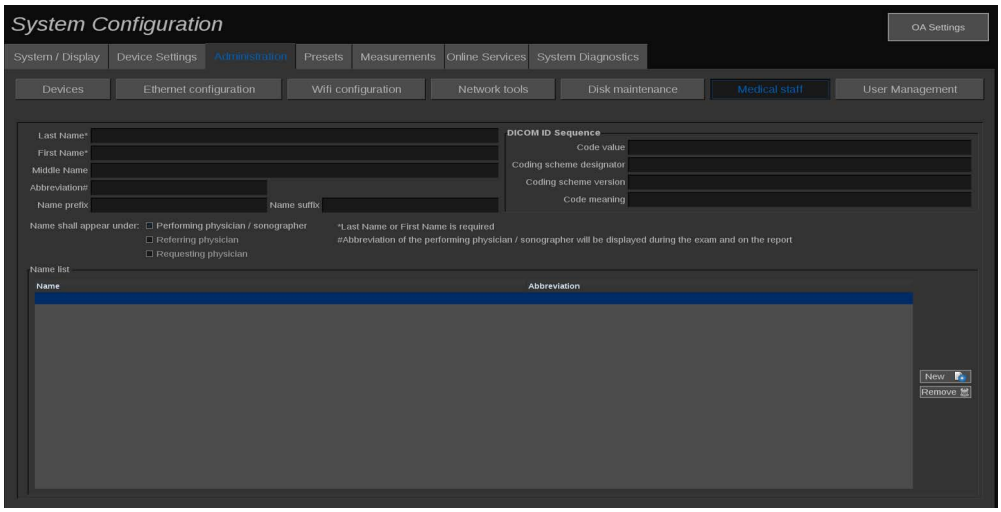
Step 6: Select the Restore tab.

Step 7: Select the backup file to restore on the left.

Step 8: Select the elements to restore on the right.

Step 9: Press Start.

16.4.7 Medical Staff



This section enables managing of the list of physicians and sonographers that are available to choose from in the Patient Data Entry.

In the list at the bottom of the screen, press a name to display the related information in the appropriate fields above the list.

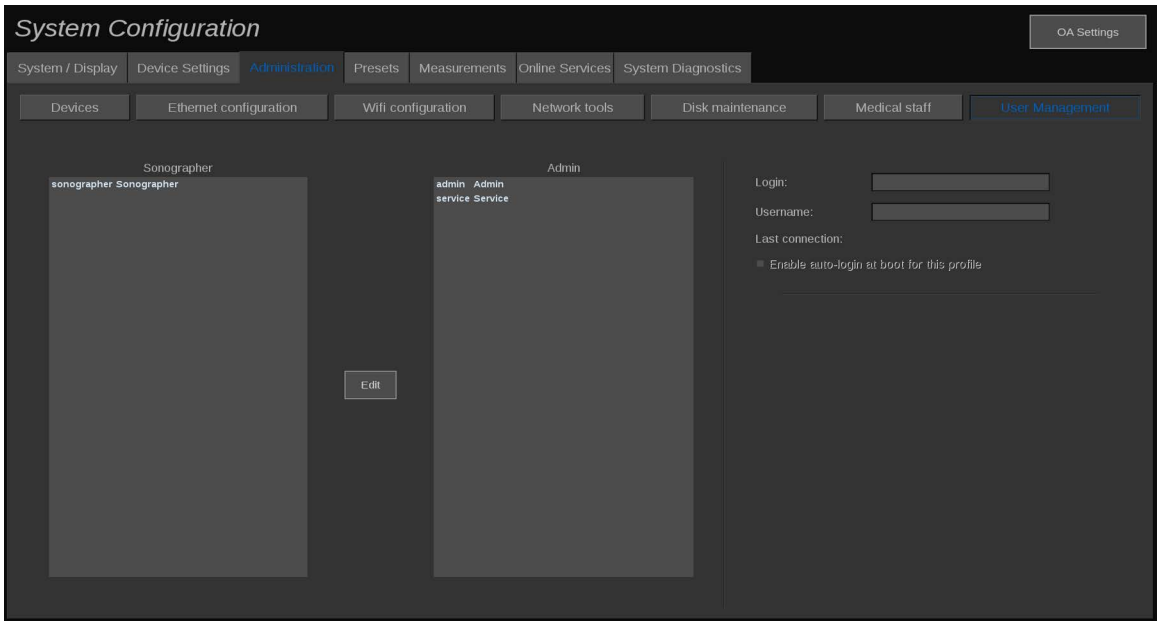
To add a name:

Step 1: Select New on the right side of the list.

Step 2: Enter the appropriate data.

The new name is automatically saved. They can be selected from the Patient Data form.

16.4.8 Operator Management

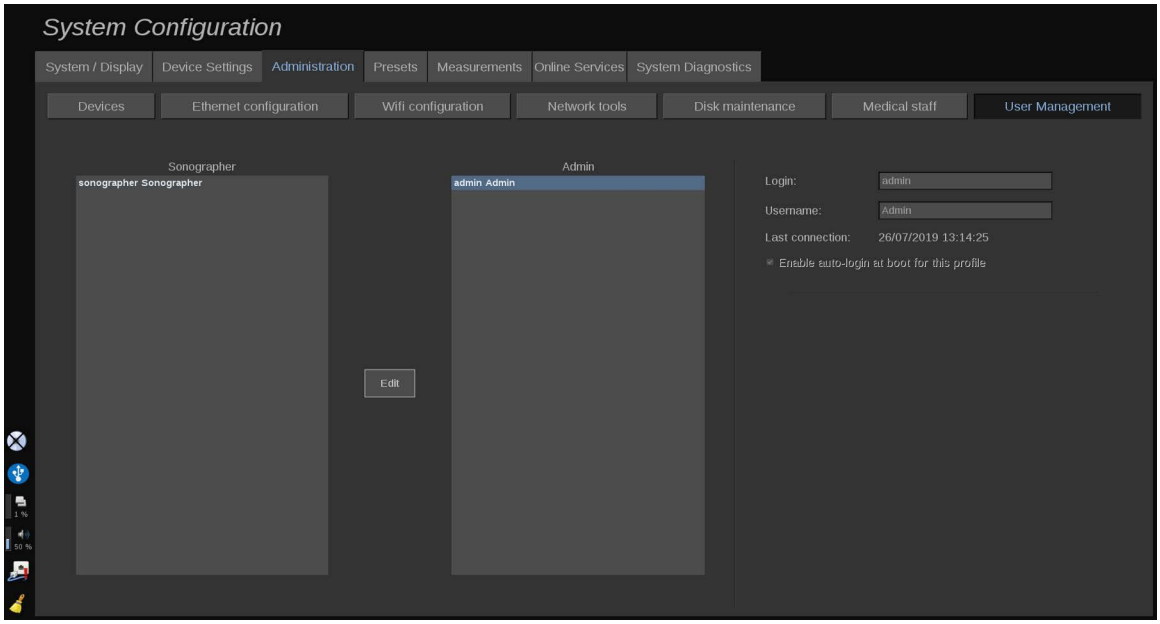


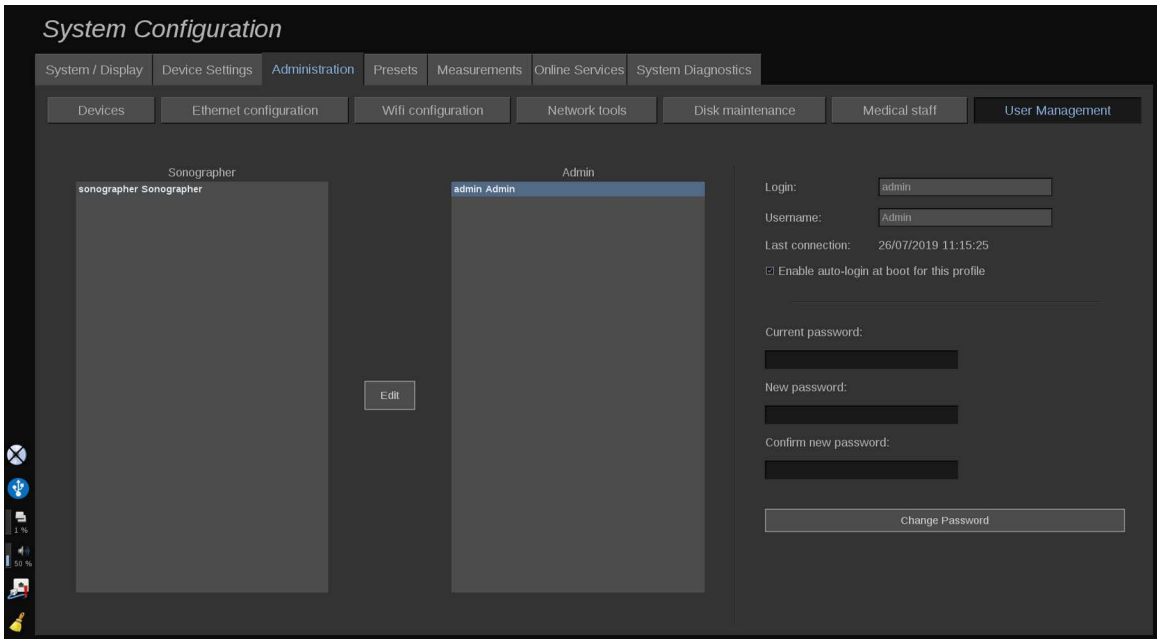
In this section, Admins can modify operator-related settings.

Step 1: Select a profile.

- Operator information is now displayed.

Step 2: Select Edit to modify or edit settings.





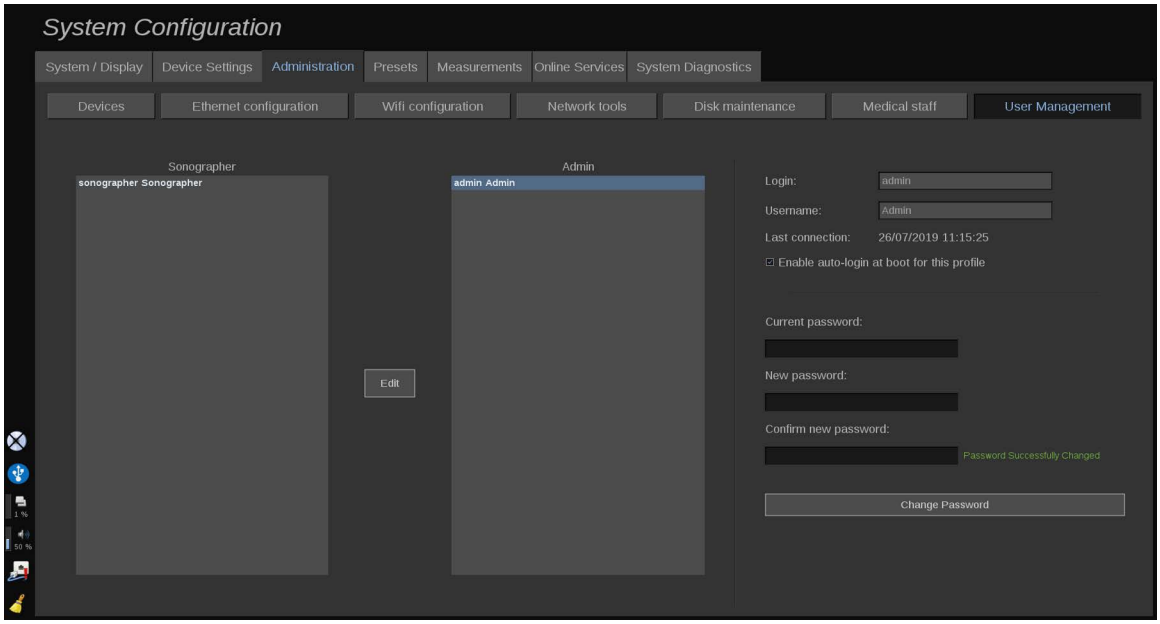
By doing so, the following settings can be changed:

- Auto-login: by enabling auto-login, operators won't have to enter their credentials at the Imagio® Breast Imaging System startup. Check or uncheck the dedicated check box to enable or disable auto-login.

Note: Please note that even if the auto-login is enabled, password entry is required when unlocking your session after a session lock. The auto-login can only enable one profile at a time.

Important: Enabling the auto-login feature will potentially expose PHI or configuration data to unauthorized users. Use with caution.

- To change the password of the selected profile, follow the steps.
- Press Change Password to save the new password.



16.5 Presets

A Preset is a group of settings that optimizes the Imagio® Breast Imaging System for a specific type of exam. Presets establish many initial settings, such as gain value, color map, filter, TissueTuner™, Flow Optimizations, etc.… When the Imagio® Breast Imaging System is turned on, the default Preset is active. Before beginning an exam, be sure that the appropriate Preset is active. Choose from several default Presets. These default Presets cannot be deleted. Several Presets per probe/application combination can be created and stored, depending on the number of buttons available on the individual probe Touchscreen.

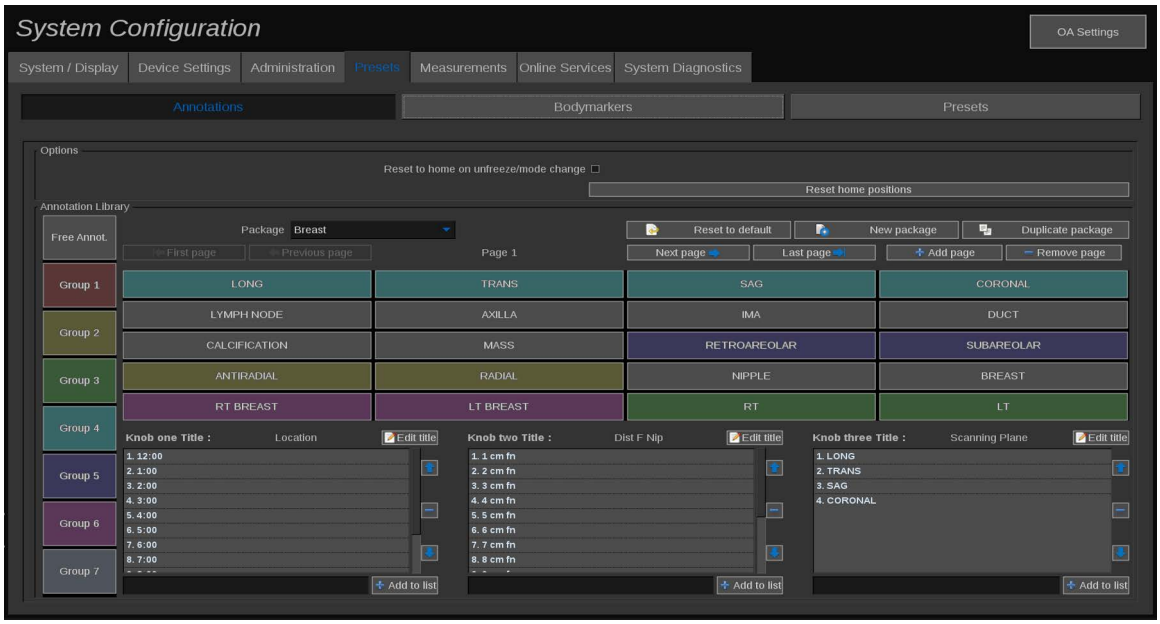
16.5.1 Description of the Presets

Presets is divided into tabs:

- Annotations
- Bodymarkers
- Presets

It enables customization of annotations and bodymarker packages, as well as imaging presets.

16.5.2 Annotation



This section enables editing of the annotation library for the current language. To edit the annotation library:

Step 1: Select a package.

Step 2: Select the page to edit by using the navigation controls, located above the annotation grid:

- First page/Last page
- Previous page/Next page
- Add page
- Remove page

Step 3: To create a new package, select New Package and enter a name in the pop-up window.

Step 4: To duplicate an existing package, select Duplicate Package and enter a new name in the pop-up window. A new package will be created with all the annotations from the initial package without modifying it.

Step 5: To change the name of an annotation, select it and change it in the pop-up window.

Step 6: To create a new annotation on an empty button, select the empty button and enter its name in the pop-up window.

Step 7: To remove an annotation from a group, select Free Annot (the first color box on the left side) and select the annotation to remove from its group. The annotation button becomes “transparent” (no color) and will not be replaced by another one.

Step 8: To move an annotation from one group to another, select the new group color to apply, and select the annotation. The annotation will change color.

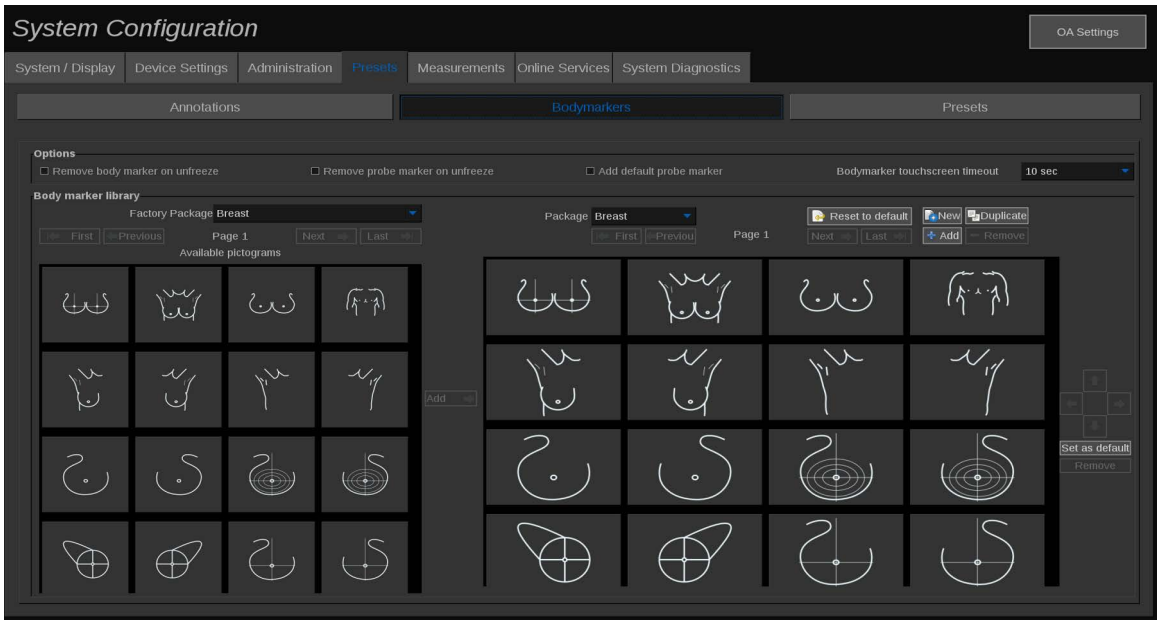
Step 9: To change a dial label or create a new one, select the Edit Title button located next to the dial to edit, and change it in the pop-up window.

Step 10: To delete a dial value, select the value and then select the- button next to it.

Step 11: To add a dial value, type the new value in the box and select the + Add to the list button next to it.

Step 12: To move a dial value within the list, select it and then select the arrows next to it.

16.5.3 Bodymarker



This section enables editing of the body marker libraries and to customize some options related to body markers.

16.5.3.1 Options

Choose to remove the body marker every time the image is unfrozen by checking the “Remove body marker on unfreeze” option. Choose to remove the probe marker from the body marker every time the image is unfrozen by checking the “Remove probe marker on unfreeze” option. Set up a time out for the body marker Touchscreen. At the end of this time out, the body marker Touchscreen will be automatically closed.

16.5.3.2 Body Marker Library Customization

16.5.3.2.1 To view the body marker library available for a given preset

Step 1: Select the package to modify on the right part.

- Navigate through the different pages of the library by using the following buttons:
  - First displays the first page of the library
  - Previous displays the previous page of the library
  - Next displays the next page of the library
  - Last displays the last page of the library

Add and remove pages for the selected library by using the Add and Remove buttons.

16.5.3.2.2 To remove a body marker from the package

Step 1: Select the body marker to remove.

Step 2: Select the Remove button below the arrow.

16.5.3.2.3 To move a body marker on the package page

Step 1: Select the body marker to move.

Step 2: Select the appropriate arrow.

16.5.3.2.4 To set a given body marker as default for the package

Step 1: Select the body marker to set as the default body marker for the library.

Step 2: Select Set as default below the arrows.

The selected body marker will be displayed by default every time Body Marker is pressed on the system console for the selected preset.

16.5.3.2.5 To add a body marker to a package

All the available libraries on the Imagio® Breast Imaging System are displayed on the left part.

Step 1: Select the appropriate package the available body markers are displayed below.

Step 2: Select the body marker to add to the library.

Step 3: Select the Add button.

The selected body marker will be added at the first available space in the library.

Note: All changes are automatically saved.

Reset a body marker library for a given preset as it was by default by selecting Reset to default.

16.5.3.2.6 To create a new body marker

Step 1: Select New and enter the name of the package in the pop-up window.

Step 2: Choose bodymarkers in the library and add them to the package. Refer to “To add a body marker to a package” on page 146.

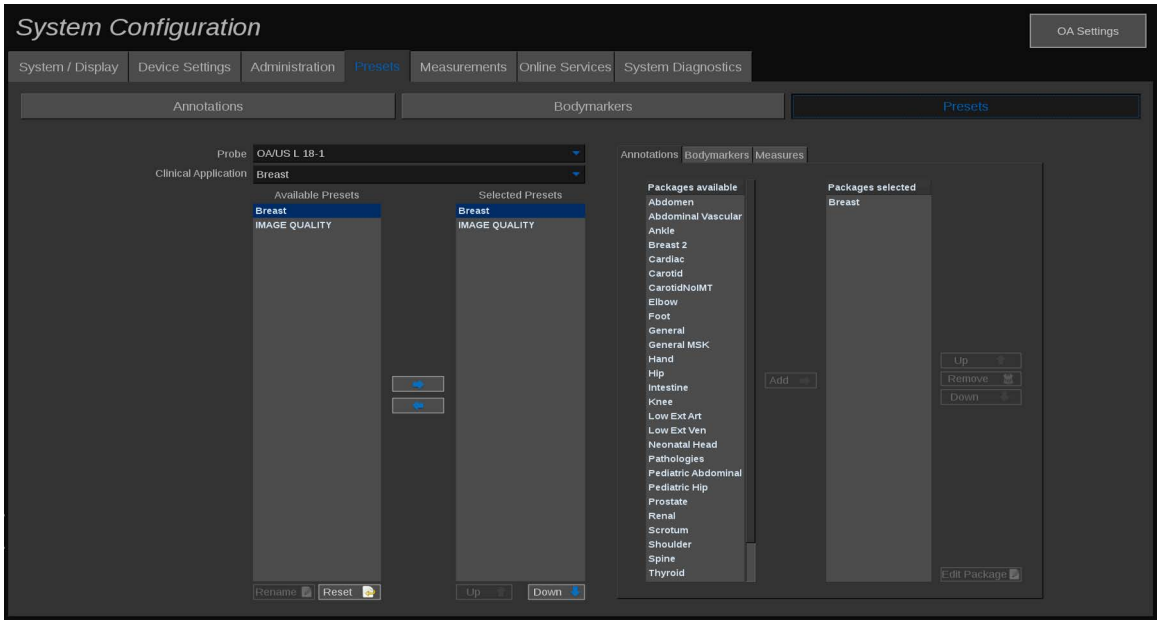
16.5.3.2.7 To duplicate a package

Select Duplicate and enter a new name in the pop-up window.

A new package will be created with all the bodymarkers from the initial package without modifying it.

To add a bodymarker from another package, select the appropriate package and proceed as for adding a bodymarker.

16.5.4 Imaging Presets



16.5.4.1 Creating a Preset

Step 1: Press Probe on the system console.

Step 2: Touch New Preset.

- A dialog box will appear on the main display.

Step 3: Select the application in which is needed to save the preset.

Step 4: Select an annotation library for the new preset.

Step 5: Select a body marker library for the new preset.

Step 6: Select a measurement library for the new preset.

Step 7: Using the keyboard, enter a name for the new Preset.

Step 8: Select OK.

Step 9: Select Probe on the system console to verify the Preset.

16.5.4.2 Managing Presets

Manage imaging presets in the Presets sub-tab.

Step 1: Select the appropriate probe and application on the left side of the screen.

The available resets for this probe and this application will appear.

16.5.4.2.1 Adding presets

Selected Presets lists the presets as they will appear on the Touchscreen.

Step 1: Select the preset needed to add from the Available Presets list on the left.

Step 2: Select the right arrow to add it to the Selected Presets list.

16.5.4.2.2 Removing presets

Selected Presets lists the presets as they will appear on the Touchscreen.

Step 1: Select the preset needed to remove from the Selected Presets list.

Step 2: Select the left arrow to add it to remove it.

16.5.4.2.3 Changing the display order of the presets on the Touchscreen

Step 1: Select the preset that needed to modify in the Selected Presets list.

Step 2: Move a preset within the list with the Up and Down buttons.

They will be displayed in the same order on the Touchscreen preset page.

Note: To reset a factory preset to the default configuration, select Reset.

16.5.4.2.4 Modifying the annotation package(s) of a preset

Step 1: Select the small annotation tab on the right side of the screen.

- You will see the available packages box on the left of the Add button and the selected packages box on the right.
- The selected packages are those already available in the preset.

Step 2: To add an annotation package, select the appropriate package in the available packages box and select Add.

- It will appear in the selected packages box.

Step 3: In the selected packages box, remove a package by selecting Remove.

Step 4: Move a package within the list using the Up and Down buttons.

Step 5: To edit the annotation package, select a package in the selected packages box and select Edit Package.

16.5.4.2.5 Modifying the body marker package(s) of a preset

Step 1: Select the small bodymarker tab on the right side of the screen.

- You will see the available packages box on the left of the Add button and the selected packages box on the right.
- The selected packages are those already available in the preset.

Step 2: To add a bodymarker package, select the appropriate package in the available packages box and select Add.

- It will appear in the selected packages box.

Step 3: Select Remove In the packages box to remove a package.

Step 4: Move a package within the list using the Up and Down buttons.

Step 5: To edit the bodymarker package, select a package in the selected packages box and select Edit Package.

16.5.4.2.5.1 Modifying the measurement package(s) of a preset

Step 1: Select the small measurement tab on the right side of the screen. You will see the available packages box on the left of the Add button and the selected packages box on the right.

- The selected packages are those already available in the preset.

Step 2: To add a measurement package, select the appropriate package in the available packages box and select Add. It will appear in the selected packages box.

Step 3: Select Remove in the selected packages box, to remove a package.

- Move a package within the list using the Up and Down buttons.

Step 4: Select a package in the selected packages box and select Edit Package to edit the measurement package.

16.5.4.3 Changing a Preset Name

Step 1: Do one of the following:

- Press Probe on the system console, then touch Manage Presets on the Touchscreen
- Touch Syst. Config. on the Touchscreen, then select Presets and Presets

Step: 2 Choose the probe and the application.

- The list of operator-defined Presets appears.

Step 3: Select the Preset needed to rename and select Rename.

- A popup menu appears

Step 4: Enter a new name.

Step 5: Select OK to validate.

16.5.4.4 Deleting a Preset

Delete the Presets created. The factory presets cannot be deleted.

Step 1: Do one of the following:

- Press Probe on the system console, then touch Manage Presets on the Touchscreen
- Touch Syst. Config. on the Touchscreen, then select Presets and Presets

Step 2: Choose the probe and the application.

- The list of operator-defined Presets appears.

Step 3: Select the Preset to delete and select Remove.

- A popup menu appears.

Step 4: Select OK to validate.

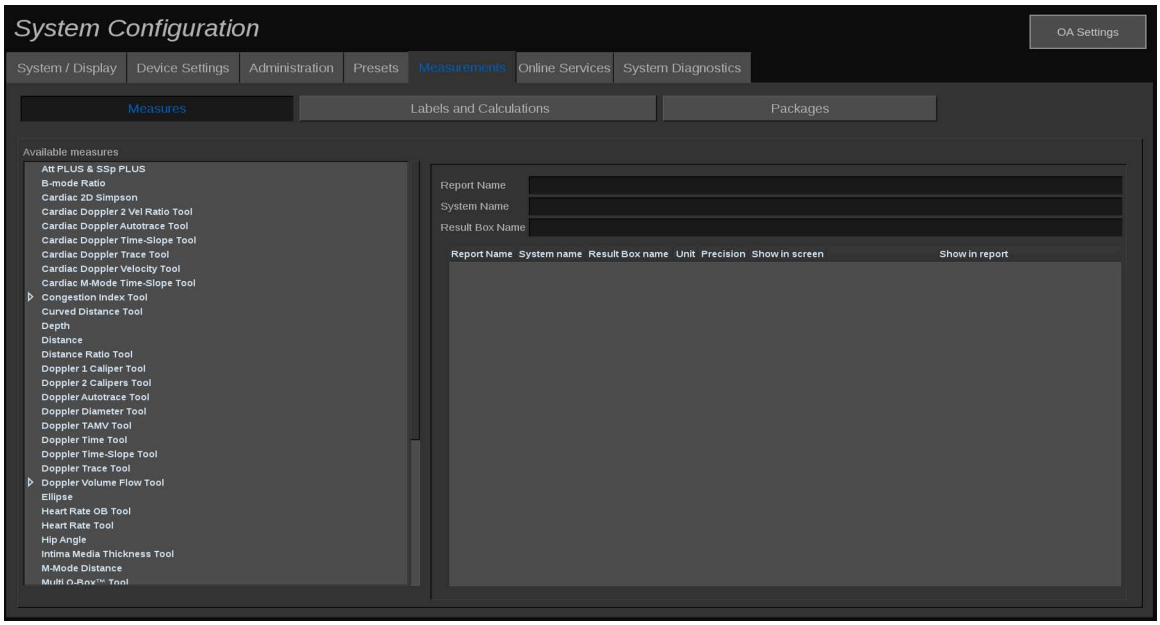
16.6 Measurements

16.6.1 Description of the Measurements

Measures is divided into tabs:

- Measures, Labels and Calculations, Packages

16.6.2 Measures



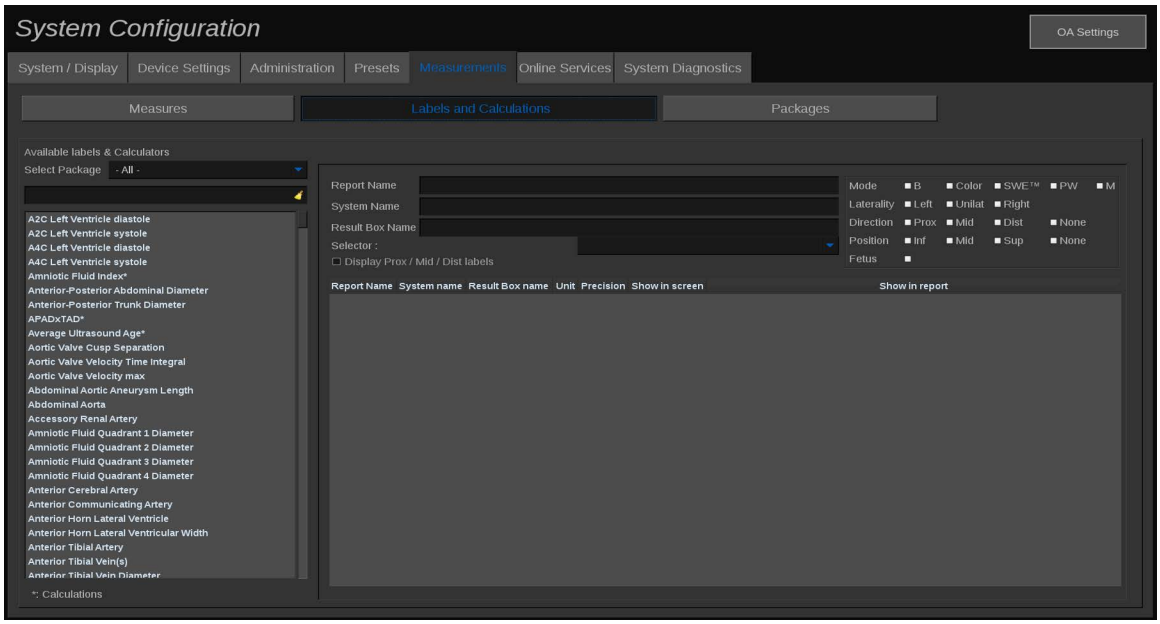
This section enables customization of the measurement tools.

Step 1: Select a measurement in the left list.

Step 2: Modify the unit and the precision. Select the unit or the precision needed to modify and select the appropriate unit in the drop-down list.

Step 3: Check the measurements that are needed to be displayed on screen and/or included in the report.

16.6.3 Labels and Calculations



This section enables configuration of each labeled measurement individually.

Step 1: Select the appropriate package.

Step 2: Select the labeled measurement to customize.

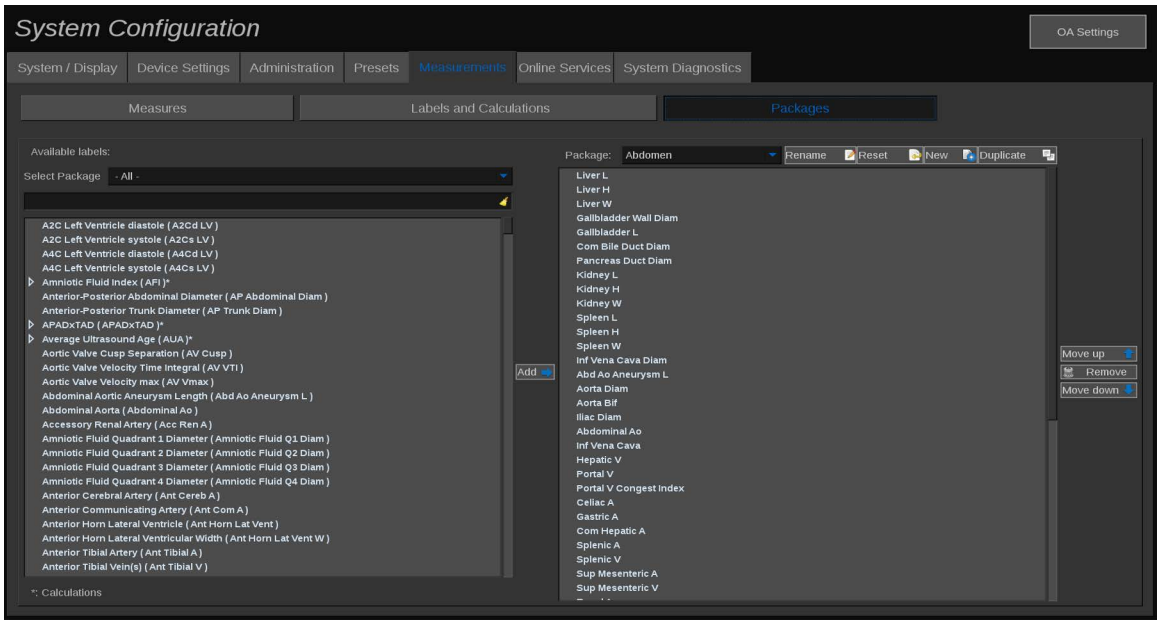
- Select the broom icon to erase the text in the search box.

The information and options related to this labeled measurement appear on the right.

Step 1: Modify the unit and the precision. Select the unit or the precision needed to modify and select the appropriate unit in the drop-down list.

Step 2: With the drop down, choose the measurements that are needed to be displayed on screen and/or included in the report.

16.6.4 Packages



This section enables configuration of the labeled measurements packages.

The left side box contains all the labels available on the Imagio® Breast Imaging System.

The right-side box contains the labels available for the selected application, as it appears on the main display when pressing Measurements on the system console.

Edit the labels that are available for a given application.

16.6.4.1 To add a labeled measurement to a package:

Step: 1 Select the package to modify on the right side of the screen.

Step 2: Select the package that contains the labeled measurement on the left side of the screen. Select All to see the labeled measurements available on the Imagio® Breast Imaging System.

Step 3: Select the labeled measurement to add from the left side list.

Step 4: Select Add.

16.6.4.2 To remove a labeled measurement from a package:

Step: 1 Select the package on the right side of the screen.

Step 2: Select the labeled measurement needed to delete from the right-side list.

Step 3: Select Remove.

16.6.4.3 To move a labeled measurement within the list in a package:

Step: 1 Select the package.

Step 2: Select the labeled measurement needed to move from the right-side list.

Step 3: Select Move up or Move down until it reaches the desired place.

16.6.4.4 To rename a package:

Step: 1 Select the package on the right side of the screen.

Step 2: Select Rename.

Step 3: Enter a new name in the pop-up window.

16.6.4.5 To reset a package to its default configuration:

Step: 1 Select the package on the right side of the screen.

Step 2: Select Reset.

16.6.4.6 To create a new package:

Step: 1 Select New.

Step 2: Enter a name in the pop-up window and select OK.

Step 3: Add labeled measurements to the new package. It will be available in the presets.

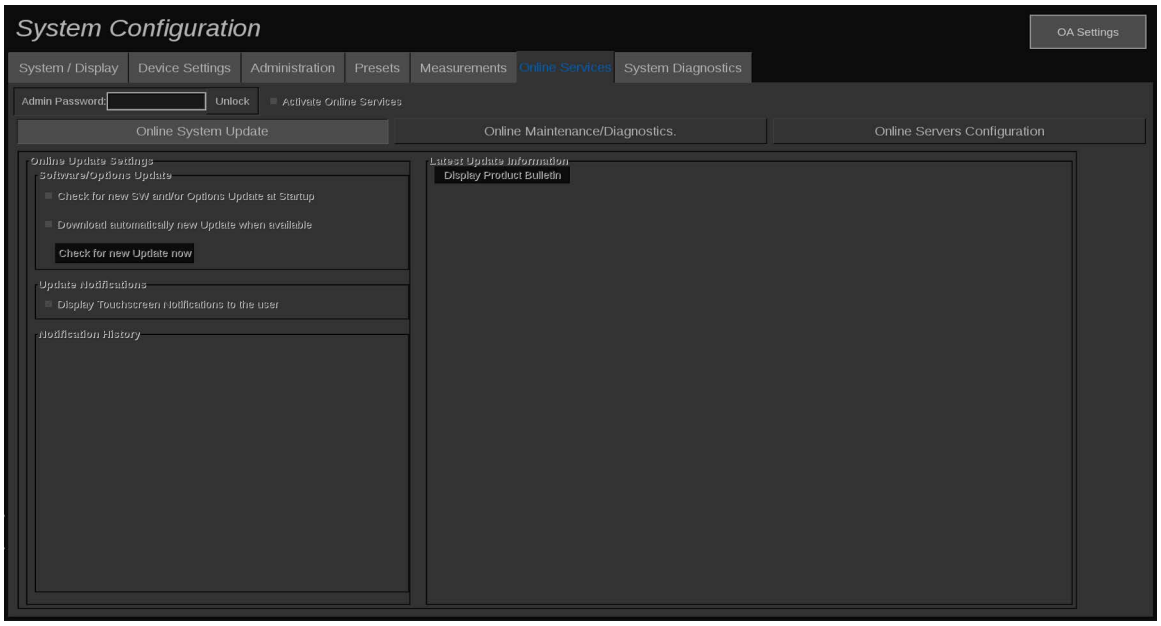
16.6.4.7 To duplicate a package:

Step: 1 Select Duplicate

Step 2: Enter a name in the pop-up window and select OK

A new package will be created with all the labeled measurements.

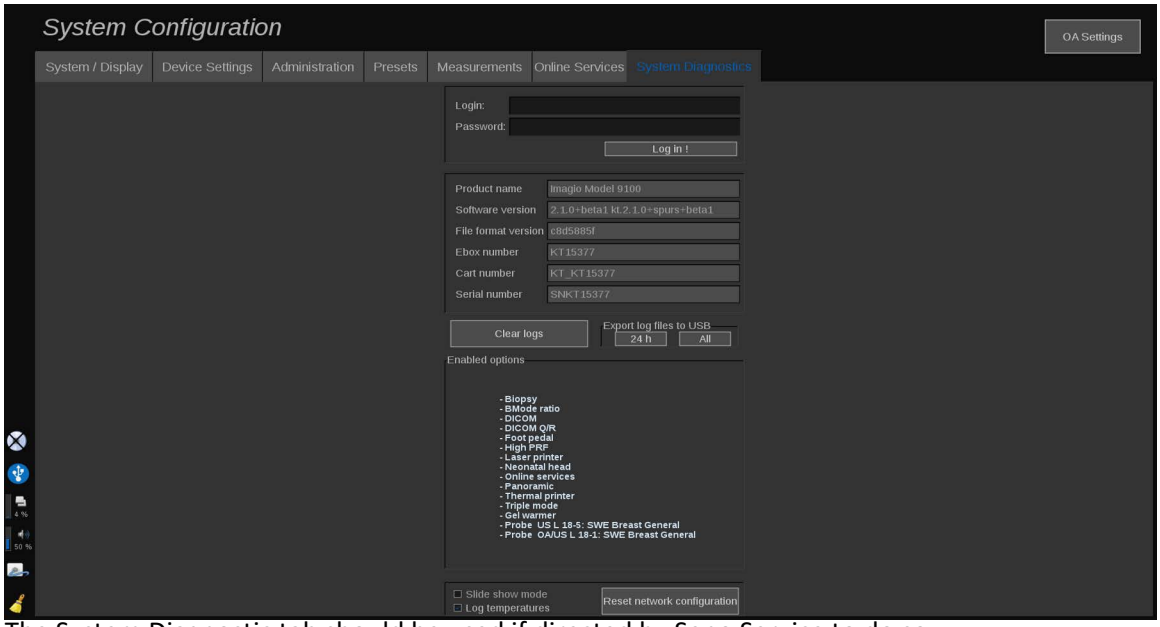
16.7 Online Services



The Online Services tab is intended to be accessed by service personnel only.

Password access to the some of the contents is required to configure the online services.

16.8 System Diagnostics



The System Diagnostic tab should be used if directed by Seno Service to do so.

Password access to the some of the contents is required to perform system diagnostic tests.

A password is not required to access some basic Imagio® Breast Imaging System information, as follows:

- Product name, Software version, File format version, Ebox number, Cart number, Serial number, List of enabled options

In addition, 3 buttons are available for log operations:

- Clear logs, 24 hr, and All: Export logs since installation or since logs were last cleared.

Note: OA logs are generated. See “Notifications Window” on page 110. for instructions for the second log export.

Reset network configuration is a password-controlled feature for Service personnel only.

16.9 Remote Support

The Remote Support feature allows service personnel to remotely access the system from an off-site support location through the Internet. The Remote Support feature:

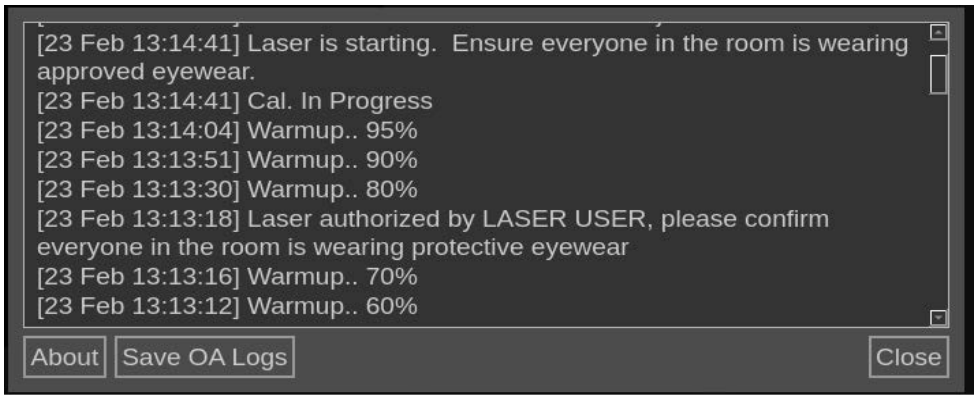
- Requires that the Imagio® be connected a network with Internet (speed >=1 Mbps) access
- Requires that the local user at the Imagio® site to initiate the connection
- Requires the local user to confirm that they are responsible for the system during the support session
- Requires the local user to provide a system-generated (random) Session ID to the support personnel through another communication channel; phone (888) 978-8835, email at service@senomedical.com
- Requires that the service personnel have credentials for the session
- Uses the Secure Shell (SSH) protocol to encrypt the connection
- Always displays an option for the local user to terminate the connection
- Will automatically terminate the connection if the session is inactive for one hour (no cursor movement detected)

- Does not allow the laser to be fired remotely

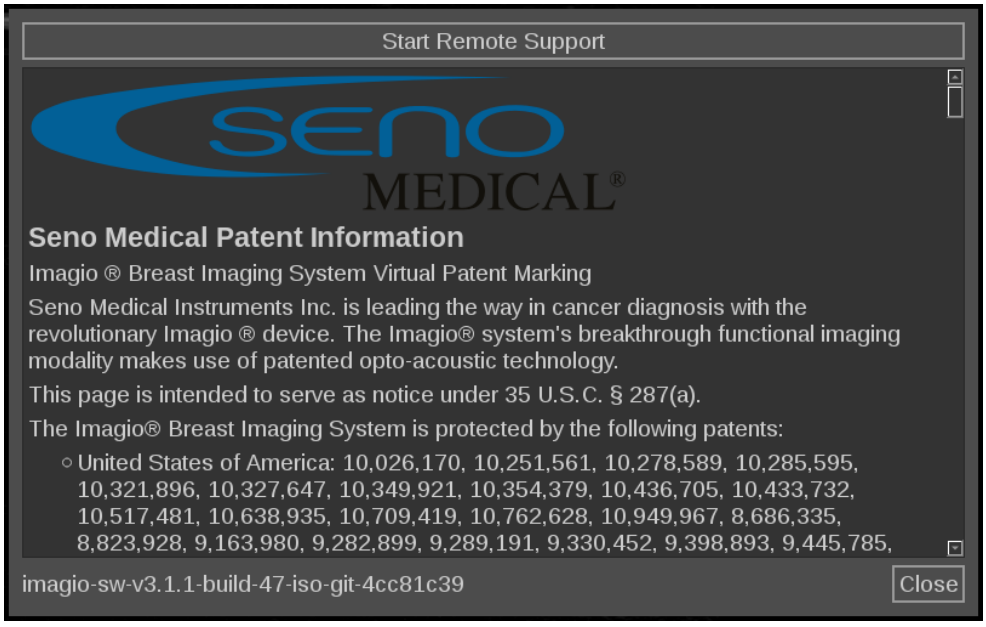
To begin a Remote Support session

Select Notifications:

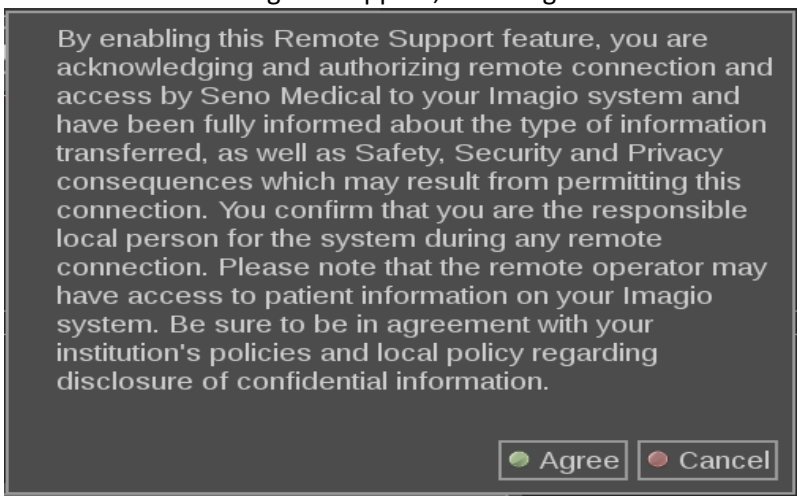
Select About:



Select Start Remote Support:

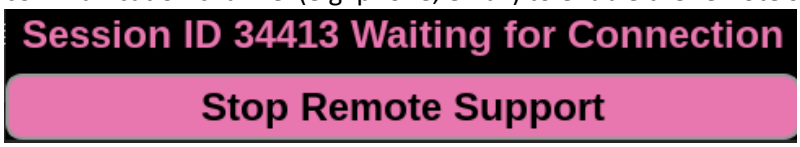


A Confirmation message will appear, Select Agree:

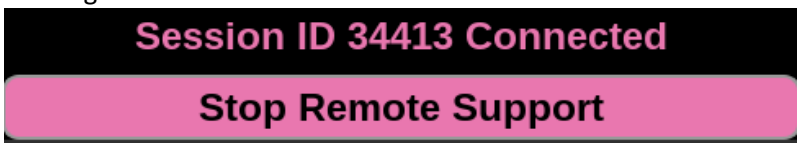


If the system successfully connects to the Remote Support server, several seconds after selecting Agree, a status area will appear at the top of the screen indicating the session is now in progress. Waiting for Connection means the remote support personnel has not yet connected, but the machine is open to a connection.

Waiting for Connection; Provide the Session ID number to the service personnel through another communication channel (e.g. phone, email) to enable the remote support connection:



When the service personnel successfully connects to the machine, the status area will change from Waiting for Connection to Connected.



The service personnel can now remotely access the machine. The local user may stop the session at any time by selecting Stop Remote Support otherwise the session will automatically stop if left idle (no cursor movement) for one hour.

Annex A Troubleshooting

A.1 Troubleshooting

If difficulties are encountered in the operation of the system, use the information in this section to help correct the problem.

If the problem is not covered here, call the Seno Service for assistance at (888) 978-8835.

The troubleshooting table below contains a list of symptoms and the action to take to correct the problem.

To avoid potential injury, never service or maintain the Imagio® Breast Imaging System while in use with the patient.

Symptom	Corrective action
System does not power on	Ensure that the system is plugged in to a functioning outlet, and that the circuit breaker on the rear power is set. Turn on power.
Image quality is poor	Adjust ambient light Optimize Technical Parameters Adjust gain, TGC and Auto TGC Adjust position of LCD screen to improve viewing angle If there is no change, call Seno Service for assistance at (888) 978-8835.
Error message appears on screen	Note the error and call Seno Service for assistance at (888) 978-8835.
System does not recognize the probe	Disconnect, reconnect and reselect the probe. If there is no change, call Seno Service for assistance at (888) 978-8835.
The system does not start, the fans do not spin	Ensure that the system is plugged in to a functioning outlet, and that the circuit breaker on the rear power is set. Turn on power. If there is no change, call Seno Service for assistance at (888) 978-8835.
The main monitor does not turn on (fans run, and system console is on)	Reboot If there is no change, call Seno Service for assistance at (888) 978-8835.
The Touch Screen display is off when the system is ready	Reboot if no change, call Seno Service for assistance at (888) 978-8835.
The system console is off	Reboot. If no change, call Seno Service for assistance at (888) 978-8835.
The system displays a banner indicating a HW problem	Reboot. If banner stay on, call Seno Service for assistance at (888) 978-8835.

Symptom	Corrective action
"GRUB error" is displayed at boot time.	Internal hard drive failure. Service is needed. Call Seno Service for assistance at (888) 978-8835.
Splash screen is up but the progress bar has not moved for more than 5 minutes	Operating system is damaged. Service is needed. Call Seno Service for assistance at (888) 978-8835.
A broom icon appears in the icon area of the screen	This icon appears once a month, it is to remind the operator to check the air filters. Stop the system and verify the filters are clean (refer to "Cleaning the Air Filter" on page 40) Select the icon A pop-up window appears Select yes on the pop-up window The icon disappears
Artifact, white cone(s) in the B Mode, and/or colored cone(s) on the color flow image, starting from the skin line	Reboot the system. If there is no change, call Seno Service for assistance at (888) 978-8835.

Annex B System Classification and Warning Labels

B.1 Laser Classification

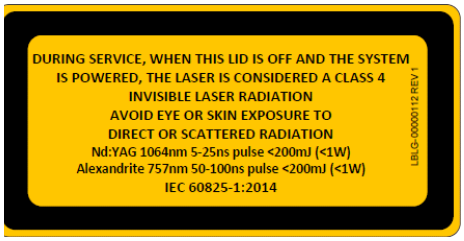
The Imagio® Breast Imaging System uses a 1064 nm 6-9 ns pulse and a 757 nm 80-90 ns pulse lasers. Both lasers operate at 85 mJ +/-20% that correspond to a max energy out of the probe =102 mJ (0.51W) per laser (wavelength). Nominal operation is at 85 mJ, and the max energy is 102 mJ, that correspond to 20% over the operational energy output.

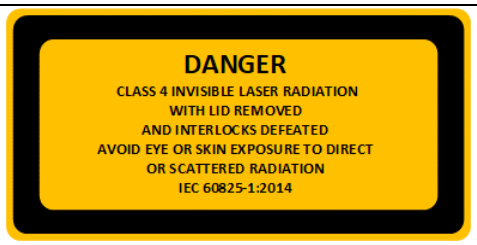
The Imagio® Breast Imaging System emitted laser beams are Class 3B eye hazards. The lasers operate at two different wavelengths. Any energy transmitted by the Imagio® Breast Imaging System that enters the eye may be focused directly on the retina. Direct absorption of laser energy by the retina may result in temporary clouded vision, retina lesion, long term scotoma and long-term photophobia.

The potential for loss of sight exists in any case of:

- Direct laser radiation
- Reflected laser radiation
- Diffused laser radiation

B.1.1 Laser Warning Labels

Label Name	Warning
System - Class 3B Laser	
Explanatory - Class 4 Laser	
High Voltage	

Label Name	Warning
Interlocked Laser Panel - Class 4 Laser	
Attention High Voltage	
Laser Beam	

B.1.2 The Imagio® Breast Imaging System and Output Specifications

Specified Parameter	Nd:YAG Flashlamp Pumped, QS SSL	Alexandrite Flashlamp Pumped, QS SSL
Wavelength (nm) (1)	1064	757
Beam Shape (cm^2) (2)	2x Rectangular 5.5 x 0.625	2x Rectangular 5.5 x 0.625
Laser Mode	Pulsed	Pulsed
Repetition Rate (Hz)	5	5
Pulse Energy (mJ) (3)	102	102
Average Power (W)	0.51	0.51
Pulse Width (ns)(4)	7.5 +/- 1.5	90 +/- 10
Beam Divergence (mrad)	33 x 13.8 degrees	33 x 13.8 degrees

- (1)(+/-10nm)
- (2)Contiguous output windows: Total Area 5.5cm x 1.25cm. Note that the actual area of the probe is 4.3 cm x 3.3 cm
- (3)Maximum Energy Probe Output (85mJ+/-20%): 102mJ
- (4) Minimum possible output is 6 ns and 60 ns respectively

Ocular Exposure		
Specified Parameter	**YAG Laser (1064nm)**	**Alexandrite Laser (757nm)**
Radiant Exposure @ 10 cm (J/cm^2)	3.59×10^{-3}	3.59×10^{-3}
MPE_Repetitive-Pulse (J/cm^2)	6.6×10^{-6}	0.83×10^{-6}
Energy/Pulse Thru 7mm Aperture (J)	1.38×10^{-3}	1.38×10^{-3}

Class 3B AEL (J)	150 x 10^{-3}	37.2 x 10^{-3}
Laser Class	3B	3B
Viewing Condition	Unaided Viewing	Unaided Viewing
Necessary OD @ 10cm Viewer Distance	2.73	3.64
Nominal Ocular Hazard Distance (m)	2.66	7.48
Skin Exposure		
Specified Parameter	**YAG Laser (1064nm)**	**Alexandrite Laser (757nm)**
MPE Skin (mJ/cm^2)	100	24.8
Seno Level Radiant Exposure @ 0cm (mJ/cm^2) (5)	14.8	14.8
Necessary skin OD	None	None

- (5) Skin Exposure at the output of the Probe with Uniform Energy Distribution

B.1.3 General information

Electrostatic discharge (ESD)

ESD or static shock is a natural phenomenon. Static shock is a discharge of electrical energy that can be transferred to file cabinets, computer equipment, metal door knobs and other individuals. Static shock occurs most often during low humidity conditions that can be brought on by heating or air conditioning. To avoid damage to the system or probes resulting from an electrical energy discharge from a system operator or patient, the use of anti-static mats, anti-static sprays or a ground wire connection between the system and the patient table are recommended.

Electromagnetic compatibility (EMC)

Medical electrical equipment needs special precautions regarding EMC and need to be installed and put into service according to the EMC information. The Imagio® Breast Imaging System must be installed only by Seno authorized personnel. This equipment has been tested and found to comply within the limits for medical devices in IEC 60601-1-2 Class A. These limits are designed to provide reasonable protection against harmful interference in a typical medical institution. This equipment can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may interfere with other devices in the vicinity. Powering the system Off and On can determine if the problem is caused by this unit. In addition, electromagnetic fields from fixed transmitters such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast may interfere with the use of this device. Portable and mobile RF communications equipment can affect the device. These fields may cause degradation of the image quality of the device. Sources of electromagnetic interference cannot be predicted theoretically with accuracy.

If this system causes harmful interference to other devices, or the system demonstrates an interference pattern on the image, the operator is encouraged to try to correct the interference by:

- Increasing the distance separating the pieces of equipment
- Ensuring the system is not connected to the same outlet as the other device(s)
- Using only shielded cabling when connecting the device to networks and peripherals. The specified Ethernet cable is shielded.
- Reorienting the device
- Consulting the manufacturer or field service representative for help

If abnormal performance persists, additional measures may be necessary, such as relocating the system.

B.1.4 Recommended separation distances between portable and mobile RF communications equipment and Imagio® Breast Imaging System

The Imagio® Breast Imaging System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the operator of the Imagio® Breast Imaging System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Imagio® Breast Imaging System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz $d = 35\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	35	0.12	0.23
0.1	11	0.40	0.73
1	35	1.2	2.3
10	111	3.8	7.3
100	350	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Imagio® Breast Imaging System is provided with the following cables:

- Power supply cable
- Probe cables
- Ethernet cable

Imagio® Breast Imaging System has been EMC tested with the following accessories:

- Seno OA/US L18-1 Probe
- Seno US L18-5 Linear Probe
- Ethernet cable, CAT6a SSTP (PIMF) 500Mhz (shielded) AWG26/7, meets standards EIA/TIA 568 B2-ISO/IEC11801

B.1.5 Declaration of Electromagnetic Emission

Imagio® Breast Imaging System is suitable for use in the following environment. The operator must assure that it is used only in the electromagnetic environment as specified.

Emission test	Compliance	Electromagnetic environment - guidance
RF Emission CISPR 11	Group 1	Imagio® Breast Imaging 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 Emission CISPR 11	Class A	Imagio® Breast Imaging System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission IEC 61000-3-2	Class A	
Voltage fluctuation/Flicker emissions IEC 61000-3-3	Complies	

All patient-contact devices, such as probes, and ECG leads not specifically indicated as defibrillation-proof must be removed from patient contact before application of a high-voltage defibrillation pulse.

B.1.6 Declaration of Immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	± 4 kV contact ± 8 kV air	Floors shall be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity shall be at least 30%
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply line ±1 kV for input/output lines	±2 kV for power supply line ±1 kV for input/output lines	Main power quality shall be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Main power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Voltage dips, short interruptions and voltage variations on power supply input line IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Main power quality should be that of a typical commercial or hospital environment. If the operator of the Imagio® Breast Imaging System requires continued operation during power mains interruptions, it is recommended that the Imagio® Breast Imaging System be powered from an uninterruptible power supply.
Power frequency (50/ 60Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the AC main voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
Imagio® Breast Imaging System is suitable for use in the following environment. The operator must assure that the system is used according to the specified guidance and only in the electromagnetic environment listed in the electromagnetic environment as specified.			
Immunity Test	**IEC 60601 Test**	**Compliance Level**	**Electromagnetic Environment Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	0.10 Vrms 3.0 V/m	Potable and mobile RF communications equipment should be used no closer to any part of Imagio® Breast Imaging System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 35\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: 

Note: At 80 MHz and 800 MHz, the higher frequency range applies

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Imagio® Breast Imaging System is used exceeds the applicable RF compliance level above, Imagio® Breast Imaging System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Imagio® Breast Imaging System.
- Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [VI] V/m.

B.2 Electromagnetic Compatibility Compliance

This section describes the Imagio® Breast Imaging System EMC compliance and Special EMC Precautions.

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this section and Guidance and Manufacturer's

Declaration. Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.

B.2.1 Electromagnetic Interference Testing

The Imagio® Breast Imaging System has undergone Electromagnetic Interference (EMI) testing and has been found to comply with the Electromagnetic Compatibility (EMC) Class A limits of IEC/EN 60601-1-2.

The Imagio® Breast Imaging System can radiate radio frequency energy and may cause interference with other equipment in the same area.

B.2.2 Special EMC Precautions

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment.

- The Imagio® Breast Imaging System complies with IEC/EN 60601-1-2. The Imagio® Breast Imaging System is intended only to be installed in professional medical environments, such as a hospital, clinic or imaging center.
- The Imagio® Breast Imaging System complies with all applicable and required standards for electromagnetic interference.
- The Imagio® Breast Imaging System does not affect nearby equipment and devices and it is not normally affected by nearby equipment and devices. It is good practice to avoid using the Imagio® Breast Imaging System near other electronic equipment.

B.2.3 Interference from Other Devices

Portable and mobile RF communications equipment can affect the Medical Electrical Equipment. The quality of the Imagio® Breast Imaging System scan results can be negatively affected by interference from external electromagnetic fields generated by other electrical devices installed in proximity. These devices include portable and mobile RF communication devices. Take all necessary precautions to preclude EMI interference from other devices.

B.2.4 Separation Distances

The Imagio® Breast Imaging System is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or operator of the Imagio® Breast Imaging System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the Imagio® Breast Imaging System as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	**Separation (m) 150kHz to 80MHz D=(3.5/V1)(Sqrt P)**	**Separation (m) 80 to 800MHz D=(3.5/E1)(Sqrt P)**	**Separation (m) 800MHz to 2.5GHz D=(7/E1)(Sqrt P)**
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.333

Annex C Product Specifications

C.1 Specifications

Testing performed with a laser emission duty cycle of 5 minutes on and 10 minutes off.

System Cabinet	
Size (not including monitors)	79 cm x 104 cm x 135 - 170 cm (31" x 41" x 53 - 67")
Maximum Weight	500 pounds (227kg)
Power Requirements	208-240 VAC, 50-60 Hz, 10 A
Warm-up Time	Up to 15 minutes
Environmental Requirements: Operational Temperature and Humidity	Ambient temperature 15 °C to 30 °C (59 °F to 86 °F), relative humidity 30% - 70% non-condensing
Environmental Requirements: Storage/ Transport Temperature and Humidity	Ambient temperature 4 °C to 50 °C (39 °F to 122 °F), relative humidity 30% to 80% non-condensing
Acoustic Noise	<80 dB
Generated Heat	2200 Watts (8530 BTUs)
Mode of Operation	OA duty cycle: 5 minutes ON / 10 minutes OFF
Ingress	IP20 cabinet IPX8 foot switch
Monitor	23 Inches (58.4 cm) measured diagonally (resolution 1920x1080)
Operator Interface	Flat 23-inch Full HD monitor with handle Full HD Touchscreen (resolution 1920x1080) Multitouch Touchpad Brightness of Touchscreen and Console adjustable by the user Multi-button console Easy to adjust the console height Footswitch
Mobility	Wheels and locking casters

Laser System	
Laser Types	Alexandrite, Nd:YAG
Wavelengths	757 +/- 10 nm (Alexandrite); 1064 +/- 10 nm (Nd:YAG)
Maximum System Output Power	0.51 W (5 Hz) (Alexandrite); 0.51 W (5 Hz) (Nd:YAG). 1.02 W Combined Power (10 Hz)
Nominal System Nominal Output Energy	85 mJ +/- 20% (Alexandrite); 85 mJ +/- 20% (Nd:YAG)
System Output Fluence	< 20 mJ / cm^2
Pulse Width	80 ns nominal +/- 10 ns (Alexandrite); 7.5 ns nominal +/- 1.5 ns (Nd:YAG)
Repetition Rate	5 Hz per wavelength or 10 Hz “interlaced” operation. Both wavelengths are always selected during OA operation.
Laser Classification	Class 3B (out of the probe, external), Class 4 (internal laser source), IEC 60825 standard.

Laser System	
Activation	Laser Authorization Card, Interlock, Foot Switch
Cooling System	1.0 L of Distilled water required

OA/US L18-1 Probe	
Number of Elements	256
Type	Linear array (50 mm Linear Array)
Biocompatibility	Parts intended for patient contact made of biocompatible materials; not made with natural rubber latex
Cable Length	1.88 m (74.0 in)
Minimum Cable Bend Radius	5 cm (2”)
Mechanical Focal Length	21 ± 2 mm
Ultrasound Connector Type	Zero Insertion Force (ZIF)
Laser Connector Type	Seno custom
Probe Fluence	Skin Exposure <20 mJ / cm^2
Ingress	IPX1

US L18-5 Linear Probe	
Number of Elements	256
Type	L18-5 (50 mm Linear Array)
Biocompatibility	Parts intended for patient contact made of biocompatible materials; not made with natural rubber latex
Cable Length	2.10 m (82.7 in)
Mechanical Focal Length (Focal Depth)	21 ± 2 mm
Ultrasound Connector Type	Zero Insertion Force (ZIF)
Ingress	IPX1

Imaging/Data Acquisition	
Imaging Modes	B Mode OA co-registered with B Mode (OA/US) Color Doppler: Color Flow (CFI), Color Power (CPI) Direction Color Power (dCPI) Pulsed Wave Doppler (PW) ShearWave™ Elastography (SWE™)

Imaging/Data Acquisition	
Imaging Features	Panoramic Imaging Simultaneous Doppler (Duplex and Triplex) Wide Sector Imaging (Trapezoid) Tissue Harmonic Imaging SuperCompound (Spatial Compounding) SuperRes (Adaptive Filtering) TissueTuner (Speed of Sound control) B Mode PRF (Reverberation Reduction)
Workflow	Clip Capture DICOM 3.0 compatible
OA Mode Features	Maximum 40 mm imaging depth

C.2 Essential Requirements

List of ESSENTIAL PERFORMANCE functions

1. The system shall display co-registered structural and functional images typically used to assist in diagnosing breast abnormalities.
2. The system shall produce images that enable the operator to assess vessels in the internal zone of a breast anomaly.
3. The system shall produce images that enable the operator to assess blush in the internal zone of a breast anomaly.
4. The system shall produce images that enable the operator to assess total hemoglobin in the internal zone of a breast anomaly.
5. The system shall produce images that enable the operator to assess vessels in the external peripheral zone of a breast anomaly.
6. The system shall produce images that enable the operator to assess vessels in the external boundary zone of a breast anomaly.
7. The system shall allow the operator to adjust the following imaging parameters for differences in anatomy: gain, TGC, focus zones, fundamental frequency, tissue harmonic frequency, gray scale, dynamic range, persistence, and depth.
8. The system shall have an auto-optimization capability for gain and TGC for US Modes with and without OA
9. The system shall provide the ability to assign OA/US and US imaging feature scores and provide a suggested POM and BI-RADS category via separately packaged software (e.g. Online form).
10. The system shall be free from noise on a waveform or artifact or distortion in an image or error of displayed numerical value which cannot be attributed to a physiological effect and which may alter the diagnosis.
11. The system shall be free from the display of incorrect numerical values associated with the diagnosis to be performed.[1]
12. The system shall be free from the display of incorrect safety-related indications.[1]

1. "incorrect" in the sense that the displayed value differs from what is calculated (having been altered during data transfer), or the calculation itself is incorrect.

13. The system shall be free from the production of unintended or excessive ultrasound output.
14. The system shall be free from the production of unintended or excessive TRANSDUCER ASSEMBLY surface temperature.

Supplementary Information:

ESSENTIAL PERFORMANCE is performance, the absence or degradation of which, would result in an unacceptable risk.

Annex D Probe Ranges, Accuracies, and Precision

D.1 Transducer information

Probe name	Geometry	Nominal center frequency	US Imaging frequency range
US L18-5	Linear	8.5 MHz	4.0 - 15 MHz
OA/US L18-1	Linear	8.5 MHz	4.0 - 15 MHz

D.2 Measurements

D.2.1 2D Measurements

The table below shows the measurement accuracy and range for the 2D measurements available on the Imagio® Breast Imaging System. Measurements were performed using both the US L18-5 and OA/US L18-1 linear probes.

Measurement type	Accuracy	Range	Notes
Axial distance	+/- 5% or 1mm	0.01 to 25 cm	Whichever is larger
Lateral distance	+/- 5% or 2mm	0.01 to 20 cm	Whichever is larger
Area	+/- 5% or 25mm^2	0.01 to 1000 cm^2	Whichever is larger (1,2)

Note 1: Distance and area measurement accuracy test is performed using the CIRS Model 040GSE phantom.

Note 2: Continuous trace accuracy depends on operator.

Note: The tolerances specified apply only to measurements made in a homogeneous medium with a speed of sound of 1540 m/s and with non-refractive surface and with insonification angle of 90 degrees relative to the surface of the probe.

D.2.2 Panoramic distance measurements

Panoramic distance accuracy is tested using an ATS 551 Small Parts phantom. A panoramic sweep is performed by translating the probe horizontally at the surface of the Phantom. Distance is measured between the first and last target structure of the Phantom in the panoramic image. Individual non-panoramic images are collected spanning the total area in the panoramic image are collected. Distance measurements are performed in the non-panoramic images and totaled. Panoramic distance measurement accuracy is the difference between the total distance measured in the individual images and the distance measured in the panoramic image.

Metric	Specification	Test level	Notes
Probe name / preset	US L18-5 Linear Probe/General	I	1
Panoramic distance measurement accuracy	+/- 10%	M	2
Metric	**Specification**	**Test level**	**Notes**
Probe name / preset	OA/US L18-1 Linear Probe/General	I	1
Panoramic distance measurement accuracy	+/- 10%	M	2

Test Level I: Verified by inspection or qualitative analysis.

Test Level M: Verified by measurement.

Note 1: Specification is for information purposes only and is not a testable requirement at the system level.

Note 2: Specification refers to the ultrasound pulses used in the imaging part of the B Mode sequence.

D.2.3 B Mode spatial resolution measurements

Spatial resolution test is measured using a wire target at the elevational focal depth of the probe with the focal zone set as close as possible to the targets. The probe is placed across the wire targets such that

they appear as points. The minimum distance at which the targets are individually distinguishable is the spatial resolution. Axial resolution is measured along the axis beam axis (vertically spaced targets), lateral resolution is perpendicular to the beam axis (horizontally spaced targets).

Metric	Specification	Test level	Notes
Probe name / preset	US L18-5 Linear Probe/General	I	1
Maximum Axial Resolution	1 mm	M	2
Maximum Lateral Resolution	1.5 mm	M	2
Metric	**Specification**	**Test level**	**Notes**
Probe name / preset	OA/US L18-1 Linear Probe/General	I	1
Maximum Axial Resolution	1 mm	M	2
Maximum Lateral Resolution	1.5 mm	M	2

Test Level I: Verified by inspection or qualitative analysis.

Test Level M: Verified by measurement.

Note 1: Specification is for information purposes only and is not a testable requirement at the system level.

Note 2: Measured using a custom wire phantom in water with two a pair of wires sloping towards each other at the focal point of the probe. The wires are vertically spaced for axial resolution measurement and horizontally spaced for lateral resolution measurement. The probe is placed orthogonal to the wires such that the appear as point targets. The probe is translated along the wire until the point targets are no longer individually discernible. Measurement may also be performed using a Phantom with fixed target spacing such as the ATS 551 Small Parts Phantom.

D.2.4 Doppler Accuracy and Sensitivity Summary

Doppler measurement calipers are positioned on a single pixel in a desired location. Velocity measurements are displayed in units of cm/s or m/s with at least 1 digit past the decimal point. The tables below show the measurement accuracy, range, and tolerance for the Doppler measurements on the ultrasound system in combination with the transducer.

Metric	Specification	Test level	Notes
Probe name / preset	US L18-5 / Breast	I	1
PW Doppler spectral velocity accuracy	=15% error	M	2
PW Doppler minimum penetration depth	55 mm	M	3
Metric	**Specification**	**Test level**	**Notes**
Probe name / preset	OA/US L18-1 / Breast	I	1
PW Doppler spectral velocity accuracy	=15% error	M	2
PW Doppler minimum penetration depth	55 mm	M	3

Test Level I: verified by inspection or analysis

Test Level M: verified by measurement

Note 1: Transmitter center frequencies for grayscale imaging

Note 2: Using CIRS 043 Doppler String Phantom

Note 3: Using Gammex 403TM Flow Phantom. PW gain is adjusted to the noise level ~1%. The depth limit value above which the vessel is poorly represented on the PW spectrum display is the penetration depth.

D.2.5 Color Flow Doppler Sensitivity

The purpose of this test is to measure the penetration of color flow imaging performance. Each probe is placed in Color Flow Imaging mode. The Color Flow Doppler Phantom (Gammex 403^{TM}) is equipped with a 5 mm diameter sloping cylindricalvessel is imaged to measure the Color Doppler Sensitivity in centimeters. The flow pump is set to keep a flow rate at 7.5 ml/s and color gain is set to the noise level ~1%. The maximal depth (penetration) at which the Doppler signal can be detected on the display is

measured using the calipers with one caliper at skin line and the other where the color flow signal starts to show dropouts.

Metric	Specification	Test level	Notes
Probe name / preset	US L18-5 / Breast	I	1
Color penetration	60 mm	M	2
Metric	**Specification**	**Test level**	**Notes**
Probe name / preset	OA/US L18-1 / Breast	I	1
Color Penetration	60 mm	M	2

Test Level I: verified by inspection or analysis

Test Level M: verified by measurement

Note 1: Transmitter center frequencies for grayscale imaging

Note 2: Using CIRS 043 Doppler String Phantom

D.2.6 Elastography Measurements

D.2.6.1 SWE™ Penetration and Spatial Resolution

The tables below document the SWE™ elasticity estimation accuracy, SWE™ penetration depth, and SWE™ spatial resolution specifications for all probes where the SWE™ Mode is available.

Metric (notes)	Specification	Test level	Notes
Probe name / preset	US L18-5 Linear Probe/ General	I	1
Elasticity Estimation Accuracy	± 30% or 3 kPa (whichever is greater)	M	2
SWE™ penetration depth range	30 mm	M	3
SWE™ spatial resolution	1.58 mm - 2.53 mm	M	4
Metric (notes)	**Specification**	**Test level**	**Notes**
Probe name / preset	OA/US L18-1 Linear Probe/ General	I	1
Elasticity Estimation Accuracy	± 30% or 3 kPa (whichever is greater)	M	2
SWE™ penetration depth range	30 mm	M	3
SWE™ spatial resolution	1.58 mm - 2.53 mm	M	4

Note: If the operator considers the ShearWave™ velocity measurement, the error of 15% or 1 m/s whichever is greater should be considered.

Note: If the operator considers the Young's modulus measurement, the error of 30% or 3 kPa whichever is greater should be considered.

Test Level I: Verified by inspection or analysis

Test Level M: Verified by measurement

Note 1: Specification is for information purposes only and is not a testable requirement at the system level.

Note 2: SWE elasticity estimation accuracy is defined as the difference between the SWE™-based elasticity measurement from a given phantom target and the reference elasticity for this target provided by the phantom manufacturer. The elasticity estimation accuracy specifications were derived from SWE™ measurements on the four spherical targets (reference elasticities equal to 5.4, 7.8, 24.8, and 52.8 kPa) and the uniform-elasticity background (reference elasticity equal to 16.3 kPa) contained in the CIRS 049 Quality Assurance Elasticity phantom.

Note 3: SWE™ penetration is defined as the maximum depth for which the SWE image exhibits good color filling and minimal noise. The SWE™ penetration specifications were derived by scanning regions of uniform-elasticity background material of the CIRS 040GSE Multi-Purpose Multi-Tissue Ultrasound Phantom.

Note 4: SWE™ spatial resolution range is measured using the CIRS 049A phantom. The smallest detectable inclusion corresponding to the highest elastic contrast (background vs type IV) is imaged. The procedure is to scan Type IV inclusions from largest size to smallest size until the inclusion cannot be detected on the elasticity map. The list of inclusion sizes is 16.668 mm, 10.404 mm, 6.49 mm, 4.05 mm, 2.53 mm, and 1.53 mm. The result is an interval for the resolution (smallest detected size < x < next smallest detected size).

Annex E Acoustic Output Tables

E.1 Maximal Temperature Data

Transducer Name	Maximal Temperature Increase	Test Method
OA/US L18-1	21.6°C	Still Air
US L18-5	21.6°C	Still Air

E.2 OA/US L18-1 & US L18-5 Linear Probe B Mode

Index Label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum Index Value		**1.5**	**0.99**		**1.28**		**1.28**
Index Component Value			0.99	0.99	1.28	0.99	
Associated Acoustic Parameters	pr.a@zMI (Mpa)	2.8					
	W0 (mW)		52.16		52.16		52.2
	W1x1 (mW)		3.43		3.43		
	ZS (cm)			0.2			
	zb (cm)					0.5	
	zMI (cm)	1.6					
	zpii.a (cm)	1.6					
	fawf (MHz)	3.75	4.25		4.25		4.25
Other Information	prr (Hz)	690					
	srr (Hz)	69					
	npps	10					
	Ipa.a@zpii.a (W/cm^2)	--					
	Ispta.a@zpii.a (mW/cm^2)	56.5					
	Ispta@zpii (mW/cm^2)	84.82					
	pr@zpii (Mpa)	3.49					
Operating control conditions	Condition 1	MI					
	Condition 2		TIS		TIB		TIC
	Condition 3						
	Condition 4						
Condition 1: B: General, B mode THI, Focal zone 37 mm, PEN, SuperCompound on, Acoustic Power 0 dB							
Condition 2: B: Thyroid, B mode Fundamental, Focal zone 4 mm, PEN, SuperCompound off, Acoustic Power 0 dB							

E.3 US L18-5 Linear Probe Color Doppler

Index Label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum Index Value		**0,7**	**0,27**		**0,27**		**0,11**
Index Component Value			0,27	0,27	0,15	0,27	
Associated Acoustic Parameters	pr,a@zMI (Mpa)	1,8					
	W0 (mW)		6,57		6,57		5,1
	W1x1 (mW)		0,29		0,29		
	zs (cm)			0,61			
	zb (cm)					0,59	
	zMI (cm)	1,8					
	zpii,a (cm)	2,0					
	fawf (MHz)	9,6	9,625		9,625		9,625
Other Information	prr (Hz)	135					
	srr (Hz)	135					
	npps	1					
	Ipa,a@zpii,a (W/cm2)	124,9					
	Ispta,a@zpii,a (mW/cm2)	54,11					
	Ispta@zpii (mW/cm2)	105,88					
	pr@zpii (Mpa)	2,91					
Operating control conditions	Condition 1	MI	TIS		TIB		TIC
	Condition 2						
	Condition 3						
	Condition 4						

Condition 1: B: Thyroid, B mode Harmonic, Focal zone 14 mm, PEN, SuperCompound on, Acoustic Power 0 dB

E.4 US L18-5 Linear Probe Shear Wave Elastography

Index Label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum Index Value		**1,9**	**0,86**		**2,81**		**1,40**
Index Component Value			0,86	0,51	1,00	2,81	
Associated Acoustic Parameters	pr,a@zMI (Mpa)	4,1					
	W0 (mW)		39,52		43,92		28,8
	W1x1 (mW)		39,52		43,92		
	zs (cm)			1,59			
	zb (cm)					2,7	
	zMI (cm)	1,3					
	zpii,a (cm)	1,6					
	fawf (MHz)	4,5	4,5		4,5		4,5
Other Information	prr (Hz)	19					
	srr (Hz)	1					
	npps	19,1,109					
	Ipa,a@zpii,a (W/cm2)	367,7					
	Ispta,a@zpii,a (mW/cm2)	4,36					
	Ispta@zpii (mW/cm2)	0,00					
	pr@zpii (Mpa)	4,67					
Operating control conditions	Condition 1	MI					
	Condition 2		TIS		TIB		TIC
	Condition 3						
	Condition 4						

Condition 1: Breast, SWE Box position 20 mm, Bmode: Thyroid, B mode Harmonic, Focal zone 14 mm, PEN, SuperCompound on, Acoustic Power 0 dB

Condition 2: Breast, SWE Box position 45 mm, Bmode: Thyroid, B mode Harmonic, Focal zone 14 mm, PEN, SuperCompound on, Acoustic Power 0 dB

E.5 US L18-5 Linear Probe Pulsed Wave Doppler

Index Label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum Index Value		**0,7**	**0,09**		**0,30**		**1,42**
Index Component Value			0,09	0,07	0,17	0,30	
Associated Acoustic Parameters	pr,a@zMI (Mpa)	1,5					
	W0 (mW)		3,70		3,70		3,7
	W1x1 (mW)		3,70		3,70		
	zs (cm)			0,81			
	zb (cm)					1,2	
	zMI (cm)	1,2					
	zpii,a (cm)	1,3					
	fawf (MHz)	5,0	5		5		5
Other Information	prr (Hz)	805					
	srr (Hz)	N/A					
	npps	1					
	Ipa,a@zpii,a (W/cm2)	59,9					
	Ispta,a@zpii,a (mW/cm2)	112,00					
	Ispta@zpii (mW/cm2)	174,25					
	pr@zpii (Mpa)	1,75					
Operating control conditions	Condition 1	MI					
	Condition 2		TIS		TIB		
	Condition 3						TIC
	Condition 4						

Condition 1: General, Focal zone 22 mm, SV 1 mm, Scale 8 cm/s, Acoustic Power 0 dB

Condition 2: General, Focal zone 68 mm, SV 0.5 mm, Scale 110 cm/s, Acoustic Power 0 dB

Condition 3: General, Focal zone 2 mm, SV 1.5 mm, Scale 190 cm/s, Acoustic Power 0 dB

E.6 OA/US L18-1 B Mode Elastography

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At surface	At surface	Below surface	At surface	At surface	Below surface	At surface	At surface
Maximum Index Value			1.56		1.21			1.57		1.42	
Index Component Value			B : 1.56 P : 1.17 F : 1.17	--	B : 1.03 P : 0.05 F : 0.13	B : 1.03 P : 0.04 F : 0.04	--	B : 1.29 P : 0.07 F : 0.06	B : 1.29 P : 0.23 F : 0.03	--	B : 1.29 P : 0.07 F : 0.06
Associated Acoustic Parameters	pr,a@zMI (Mpa)		B : 3.17 P : 2.48 F : 2.54								
	W0 (mW)			--	B : 52.21 P : 2.54 F : 4.33		--	B : 52.21 P : 2.54 F : 4.33		--	B : 52.21 P : 2.54 F : 4.33
	W1x1 (mW)			--	B : 52.21 P : 2.54 F : 4.33		--	B : 52.21 P : 2.54 F : 4.33			
	minP,I (mW)					B : -- P : 1.09 F : 0.02					
	zs (cm)					B : -- P : 1.34 F : 2.7					
	zbp (cm)					B : -- P : 1.34 F : 2.7			B : -- P : 1.34 F : 2.7		
	zb (cm)								B : -- P : 1.54 F : 2.7		
	zpii (cm)		B : 1.27 P : 2.96 F : 1.53			B : -- P : 2.31 F : 1.53			B : -- P : 2.31 F : 1.53		
	zMI (cm)		B : 1.18 P : 2.89 F : 1.38			B : -- P : 1.65 F : 1.38					
	deq@zb (cm)								B : -- P : 0.16 F : 1.08		
	fawf (MHz)		B : 4.13 P : 4.5 F : 6.25	--	B : 4.13 P : 4.5 F : 6.25		--	B : 4.13 P : 4.5 F : 6.25		--	B : 4.13 P : 4.5 F : 6.25
	Dim of Aaprt	X (cm)		--	B : 1.62 P : 1.26 F : 5.12		--	B : 1.62 P : 1.26 F : 5.12		--	B : 1.62 P : 1.26 F : 5.12
		Y (cm)		--	B : 0.05 P : 0.05 F : 0.05		--	B : 0.05 P : 0.05 F : 0.05		--	B : 0.05 P : 0.05 F : 0.05
Other Information	td (us)		B : 0.41 P : 675.96 F : 0.52								
	prr (Hz)		B : 690 P : 0.6 F : 25.2								
	srr (Hz)		B : 69 P : 0.6 F : 0.6								
	pr@zpii (Mpa)		B : 3.75 P : 3.8 F : 3.32								
	deq@zpii (cm)								B : -- P : 0.14 F : 0.81		
	Ipa,a@zpii,a (W/cm2)		B : 356.54 P : 157 F : 174.75								
	Focal Length	FLx (cm)	B : 0.24 P : 0.24 F : 5.2			B : -- P : 0.12 F : 5.2			B : -- P : 0.12 F : 5.2		
		Fly (cm)	B : 0.21 P : 0.3 F : 0.18			B : -- P : 0.24 F : 0.18			B : -- P : 0.24 F : 0.18		

Index Label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum Index Value		1.56	1.21		1.57		1.42
Index Component Value			B : 1.03 P : 0.05 F : 0.13	B : 1.03 P : 0.04 F : 0.04	B : 1.29 P : 0.07 F : 0.06	B : 1.03 P : 0.23 F : 0.03	
Associated Acoustic Parameters	pr,a@zMI (Mpa)	B : 3.2 P : 2.5 F : 2.5					
	W0 (mW)		B : 52.21 P : 2.54 F : 4.33		B : 52.21 P : 2.54 F : 4.33		B : 52.21 P : 2.54 F : 4.33
	W1x1 (mW)		B : 52.21 P : 2.54 F : 4.33		B : 52.21 P : 2.54 F : 4.33		
	zs (cm)			B : -- P : 1.341 F : 2.703			
	zb (cm)					B : -- P : 1.544 F : 2.703	
	zMI (cm)	B : 1.2 P : 2.9 F : 1.4					
	zpii,a (cm)	B : 1.2 P : 2.9 F : 1.4					
	fawf (MHz)	B : 4.1 P : 4.5 F : 6.3	B : 4.13 P : 4.5 F : 6.25		B : 4.13 P : 4.5 F : 6.25		B : 4.13 P : 4.5 F : 6.25
Other Information	prr (Hz)	B : 690 P : 0.6 F : 25					
	srr (Hz)	B : 69 P : 0.6 F : 1					
	npps	B : 10 P : 1 F : 42					
	Ipa,a@zpii,a (W/cm2)	B : 356.5 P : 157 F : 174.8					
	Ispta,a@zpii,a (mW/cm2)	B : 262.2 P : 73.7 F : 2.3					
	Ispta@zpii (mW/cm2)	B : 373.6 P : 182.6 F : 4.3					
	pr@zpii (Mpa)	B : 3.8 P : 3.8 F : 3.3					
Operating control Conditions	Condition 1	MI					
	Condition 2		TIS		TIB		
	Condition 3						TIC

Condition 1 :
B : Breast preset ; Harmonic ; Optimization = Pen ; focal position 22 mm ; Acoustic Power 0 dB
P + F : Breast preset ; Optimization = Res ; SWE box position 4 mm ; Acoustic Power 0 dB

Condition 2 :
B : Breast preset ; Harmonic ; Optimization = Pen ; focal position 52 mm ; Acoustic Power 0 dB
P + F : Breast preset ; Optimization = Std ; SWE box position 30 mm ; Acoustic Power 0 dB

Condition 3 :
B : Breast preset ; Harmonic ; Optimization = Pen ; focal position 52 mm ; Acoustic Power 0 dB
P + F : Breast preset ; Optimization = Pen ; SWE box position 30 mm ; Acoustic Power 0 dB

E.7 OA/US L18-1 B Mode Color Doppler

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At surface	At surface	Below surface	At surface	At surface	Below surface	At surface	At surface
Maximum Index Value			1.56		1.30			1.42			1.42
Index Component Value			B : 1.56 C : 1.42	B : 1.03 C : 0.27	--	--	B : 1.29 C : 0.14	--	--	B : 1.29 C : 0.14	--
Associated Acoustic Parameters	pr,a@zMI (Mpa)		B : 3.17 C : 1.73								
	W0 (mW)			B : 52.21 C : 6.65	--		B : 52.21 C : 6.65	--		B : 52.21 C : 6.65	--
	W1x1 (mW)			B : 52.21 C : 6.65	--		B : 52.21 C : 6.65	--			
	minP,I (mW)					--					
	zs (cm)					--					
	zbp (cm)					--			--		
	zb (cm)								--		
	zpii (cm)		B : 1.27 C : 1.91			--			--		
	zMI (cm)		B : 1.18 C : 1.75			--					
	deq@zb (cm)								--		
	fawf (MHz)		B : 4.13 C : 8.88	B : 4.13 C : 8.63	--		B : 4.13 C : 8.63	--		B : 4.13 C : 8.63	--
	Dim of Aaprt	X (cm)		B : 1.62 C : 2.26	--		B : 1.62 C : 2.26	--		B : 1.62 C : 2.26	--
		Y (cm)		B : 0.05 C : 0.05	--		B : 0.05 C : 0.05	--		B : 0.05 C : 0.05	--
Other Information	td (us)		B : 0.41 C : 0.39								
	prr (Hz)		B : 690 C : 290.32								
	srr (Hz)		B : 356.54 C : 26.39								
	pr@zpii (Mpa)		B : 3.75 C : 2.7								
	deq@zpii (cm)								--		
	Ipa,a@zpii,a (W/cm2)		B : 356.54 C : 99.84								
	Focal Length	FLx (cm)	B : 0.24 C : 0.12			--			--		
		Fly (cm)	B : 0.21 C : 0.16			--			--		

Index Label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum Index Value		1.56	1.30		1.56		1.42
Index Component Value			B : 1.03 C : 0.27	B : 1.03 C : 0.27	B : 1.29 C : 0.14	B : 1.03 C : 0.27	
Associated Acoustic Parameters	pr.a@zMI (Mpa)	B : 3.2 C : 1.7					
	W0 (mW)		B : 52.21 C : 6.65		B : 52.21 C : 6.65		B : 52.21 C : 6.65
	W1x1 (mW)		B : 52.21 C : 6.65		B : 52.21 C : 6.65		
	zs (cm)			--			
	zb (cm)					--	
	zMI (cm)	B : 1.2 C : 1.8					
	zpii,a (cm)	B : 1.2 C : 1.8					
	fawf (MHz)	B : 4.1 C : 8.9	B : 4.13 C : 8.63		B : 4.13 C : 8.63		B : 4.13 C : 8.63
Other Information	prr (Hz)	B : 690 C : 290.3					
	srr (Hz)	B : 69 C : 26.4					
	npps	B : 10 C : 11					
	Ipa,a@zpii,a (W/cm2)	B : 356.5 C : 99.8					
	Ispta,a@zpii,a (mW/cm2)	B : 262.2 C : 14.8					
	Ispta@zpii (mW/cm2)	B : 373.6 C : 42.5					
	pr@zpii (Mpa)	B : 3.8 C : 2.7					
Operating control Conditions	Condition 1	MI					
	Condition 2		TIS		TIB		
	Condition 3						TIC

Condition 1 :
B : Breast preset ; Harmonic ; Optimization = Pen ; focal position 22 mm ; Acoustic Power 0 dB
C : Breast preset ; Optimization = Res ; Boost = High Definition ; Color box position 22 mm ; scale 4 cm/s

Condition 2 :
B : Breast preset ; Harmonic ; Optimization = Pen ; focal position 52 mm ; Acoustic Power 0
C : Breast preset ; Optimization = Res ; Boost = High Definition ; Color box position 68 mm ; scale 18 cm/s

Condition 3 :
B : Breast preset ; Harmonic ; Optimization = Pen ; focal position 52 mm ; Acoustic Power 0
C : Breast preset ; Optimization = Gen ; Boost = High Definition ; Color box position 65 mm ; scale 21 cm/s

E.8 OA/US L18-1 B Mode Pulsed Wave Doppler

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At surface	At surface	Below surface	At surface	At surface	Below surface	At surface	At surface
Maximum Index Value			1.18		1.01			2.50			1.43
Index Component Value			1.18	--	1.01	0.71	--	1.36	2.50	--	1.43
Associated Acoustic Parameters	pr,a@zMI (Mpa)		2.63								
	W0 (mW)			--	42.45		--	40.23		--	42.45
	W1x1 (mW)			--	42.45		--	40.23			
	minP,I (mW)					0.01					
	zs (cm)					1.11					
	zbp (cm)					1.11			1.11		
	zb (cm)								1.41		
	zpii (cm)		1.49			2.05			1.74		
	zMI (cm)		1.38			1.50					
	deq@zb (cm)								0.23		
	fawf (MHz)		5.00	--	5.00		--	5.00		--	5.00
	Dim of Aaprt	X (cm)		--	0.86		--	0.86		--	0.86
		Y (cm)		--	0.05		--	0.05		--	0.05
Other Information	td (us)		0.85								
	prr (Hz)		1392								
	srr (Hz)		1392								
	pr@zpii (Mpa)		3.15								
	deq@zpii (cm)								0.22		
	Ipa,a@zpii,a (W/cm2)		271.61								
	Focal Length	FLx (cm)	0.22			0.30			0.30		
		Fly (cm)	0.20			0.20			0.20		

Index Label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
Maximum Index Value		**1.18**	**1.01**		**2.50**		**1.43**
Index Component Value			1.01	0.71	1.36	2.50	
Associated Acoustic Parameters	pr,a@zMI (Mpa)	2.6					
	W0 (mW)		42.45		40.23		42.45
	W1x1 (mW)		42.45		40.23		
	zs (cm)			1.108			
	zb (cm)					1.407	
	zMI (cm)	1.4					
	zpii,a (cm)	1.4					
	fawf (MHz)	5.0	5		5		5
Other Information	prr (Hz)	1392					
	srr (Hz)	1392					
	npps	1					
	Ipa,a@zpii,a (W/cm2)	271.6					
	Ispta,a@zpii,a (mW/cm2)	500.5					
	Ispta@zpii (mW/cm2)	838.2					
	pr@zpii (Mpa)	3.1					
Operating control Conditions	Condition 1	MI					
	Condition 2		TIS				TIC
	Condition 3				TIB		

Condition 1 : Breast preset ; Sample volume position 30 mm ; Sample volume size 1.5 mm ; Scale 10.3 cm/s
Condition 2 : Breast preset ; Sample volume position 52 mm ; Sample volume size 20 mm ; Scale 30.8 cm/s
Condition 3 : Breast preset ; Sample volume position 52 mm ; Sample volume size 20 mm ; Scale 15.4 cm/s

Annex F Risk Benefit Analysis

F.1 Risk Benefit Analysis

Seno Medical assessed that the medical benefits of the device outweigh the residual risk associated with the potential for incorrect diagnosis of false positives/negatives and the other warnings documented in the Operator Manual as outlined in ISO 14971:2019 Medical devices – Application of risk management to medical devices.

Annex G Guidelines for OA/US Scanning

G.1 OA/US Instrumentation and Scan Technique

The following image guidelines are for OA/US imaging and should not be used as a replacement for standalone ultrasound imaging clinical procedures and practices. The operator should minimally perform the OA/US captures listed for each application.

Important: Always refer to OA feature training resources for the complete range of reassuring to highly suspicious OA features.

OA provides information consistent with conventional diagnostic ultrasound and interleaves the Ultrasound (US) frames with OA frames containing functional data from the mass of interest. Our scan procedures are created in accordance with The American College of Radiology and the European Society of Breast Imaging Practice Guidelines.

G.1.1 Optimize technical factors and scanning techniques for OA/US

- Adjust the Optimization Setting (Frequency) to the highest available (Resolution) and optionally interrogating with harmonics optimizes the detail and contrast resolution of the OA/US image
- Apply just enough gel to wet the skin surface to optimize OA/US transmission and reception. Too much gel may introduce a gel standoff, air gaps or air bubbles, which will all negatively effecting light transmission.
- Apply normal to light probe pressure optimizes OA/US L18-1 Probe face skin contact.
- Adjust the Time Gain Compensation (TGC) so there is uniform gray scale from superficial to deep optimizes spatial brightness uniformity of the OA/US image. Press Auto TGC as the tissue profile changes. Press the Touchscreen TGC button then slide your finger on the touchscreen TGC curve to increase or decrease brightness at specific depths.
- Adjust depth so the field of view contains the entire area of breast tissue while capturing only the first few millimeters of non-breast structures deep to the area of interest (i.e. chest wall, implants).
- Adjust the gray scale focus to match the Depth of the field of view to optimize lateral resolution.

G.1.1.1 Recommended Parameter Values for B Mode and OA Mode

The following are baseline optimized instrumentation settings which may be saved as an Imaging Preset. Refer to “Imaging Presets” on page 151

- Optimization - Resolution
- TissueTuner™ - 1480 m/s
- Dynamic Range - 70 dB
- 2D Map - 10
- Sector - Large
- PRF - Max
- Persistence - Low
- AutoTGC offset - 0 dB

- SuperRes™ - 4
- Acoustic Power - 0.0 dB
- SuperCompound™ - On

G.1.2 How to Hold the OA/US L18-1 Probe

The technique for holding the OA/US L18-1 Probe is an Operator preference; however, the following conditions must be met:

The face of the OA/US L18-1 Probe must be perpendicular to the tissue on which it is placed so that uniform pressure is applied to the tissue across the entire surface of the OA/US L18-1 Probe face.

The amount of pressure should be just enough to make full contact with the tissue across full surface of the OA/US L18-1 Probe face and in accordance with established guidelines for Ultrasound imaging.

If too much pressure is applied to the skin tissue, the underlying blood vessels may be compressed causing diminished blood volume within those vessels resulting in poor imaging.

If too little pressure is applied to the skin tissue, the risk of accidental laser light emissions may occur in addition to poor image quality.

Note: Any gaps between probe face and skin and surface air gaps or gel stand-off may negatively affect OA image quality. Every attempt should be made to keep the entire OA/US L18-1 Probe face in full contact with skin to obtain maximum light transmission from the probe into the skin and tissue. If full contact cannot be maintained, for example around the areola or axilla, the operator can attempt to scan in different scan planes or use slight probe angulation to maximize contact and light transmission.

G.2 OA/US Breast Imaging

G.2.1 Interrogation

Some critical Opto-acoustic findings occur within the tissues that surround the primary breast mass. Therefore, it is important for the operator to interrogate the tissues and structures around the main portion of the lesion and to capture images and clips that will best demonstrate things such as vascular supply and other structures in the peri-tumoral bed. This does not necessarily need to be in strict radial or anti-radial and transverse and long scan planes but should be in two orthogonal scan planes that best demonstrates both boundary and peripheral zone structures.

Important: The feature score for each of the individual 5 OA characteristics internal (Vessels, Blush, Hemoglobin) and external (Boundary Zone Vessels, Peripheral Zone Vessels), is based on the internal and external features of the entire three-dimensional mass/tissue volume. Therefore, it is very important to make a mental note of the color, number and orientation of the individual features while interrogating the entire mass and surrounding tissue. This will assist in choosing a representative clip frame in which to draw a region of interest (ROI) to segment between the internal zone, boundary zone, peripheral zone.

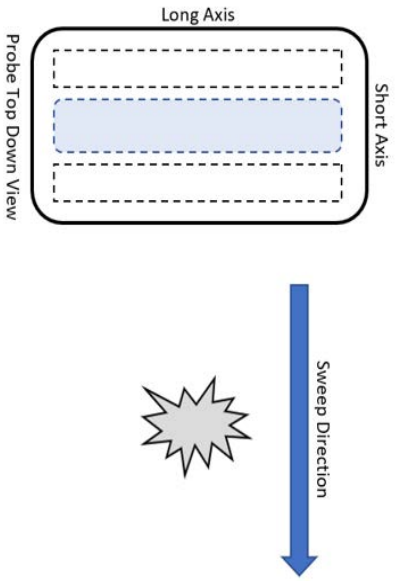
G.2.2 Breast OA/US Imaging and Recording

To capture a region of interest (ROI), tissue, palpable area, mass or structure, a scan technique that utilizes probe motion or “sweep” is used. As the probe is swept, a clip is captured of the region of interest and surrounding volume of tissue. The clip is saved and can later be viewed in real time or frame by frame in order to analyze the opto-acoustic signals within the region of interest.

G.2.2.1 SAX or Short Axis Video Sweep

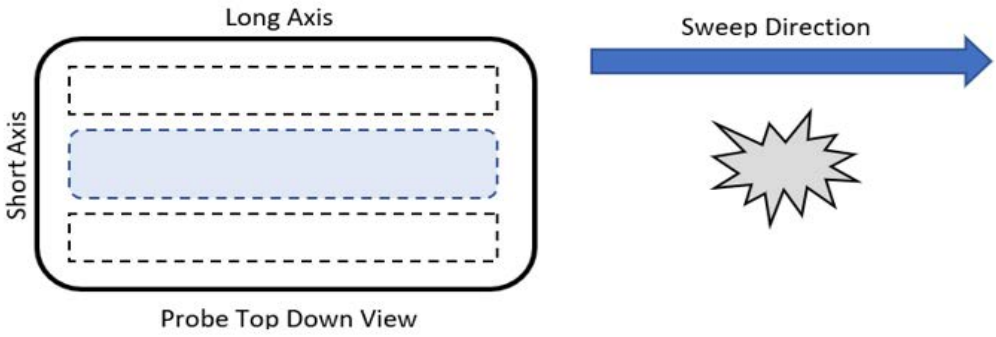
This technique is called a Short Axis Video sweep or SAX. It is created as follows: press unfreeze, position the probe approximately 2cm outside of the ROI, press freeze then unfreeze, (press the foot switch to

emit laser in OA Mode), then move the probe in one direction along an imaginary line that parallels the short axis of the transducer until the probe has reached 2 cm outside the ROI on the opposite side, press freeze, and finally press save clip. This should take a maximum of 10 seconds depending on the size of the ROI moving the probe no greater than 5 mm per second.



G.2.2.2 LAX or Long Axis Video Sweep

This technique is called a Long Axis Video Sweep or LAX. It is created as follows: press unfreeze, position the probe in a plane midway through the mass and offset right or left so the mass is seen on one side of the field of view, press freeze then unfreeze, (press the foot switch to emit laser in OA Mode), then move the probe in one direction along an imaginary line that parallels the long axis of the transducer until the mass is visualized on the opposite side of the field of view, press freeze, and finally press save clip. This should take a maximum of 10 seconds depending on the size of the ROI moving the probe no greater than 5 mm per second.



Note: To capture off axis or obliquely oriented OA/US features or avoid nipple or other artifacts, orthogonal scan planes other than true radial and anti-radial can be selected. Annotate either oblique radial or oblique anti-radial

Note: To obtain a high-quality OA/US signal, use light probe pressure to avoid compressing small vessels but maintain contact so there is no signal drop out or gel standoff

Note: Transverse and longitudinal scan planes may be used in place of radial and anti-radial scan planes

G.2.2.3 B Mode - Imagio® Breast Imaging System (Minimum) Recommended Clips:

Step: 1 One radial scan plane SAX

Step: 2 One anti-radial scan plane SAX

For a mass with a partial thin capsule present on anterior and posterior surfaces, but not seen on sides, a complete thin capsule can be imaged by capturing a LAX.

G.2.2.4 OA Mode - Imagio® Breast Imaging System (Minimum) Recommended Clips:

Step: 1 One radial scan plane SAX

Step: 2 One anti-radial scan plane SAX

- For a mass with a partial thin capsule present on anterior and posterior surfaces, but not seen on sides, a complete thin capsule can be imaged by capturing a LAX.

G.2.3 Benign Appearing OA/US Features:

- The vessels feeding and draining hemoglobin in benign masses tend to be oriented parallel to the mass wall
- The vessels tend to be a parallel paired feeding artery and draining vein
- Benign masses are usually supplied and drained by no more than 2 vessels
- The feeding vessel(s) are typically oxygenated and appear green in OA, but may be red because in OA, colorization is relative

G.2.4 Malignant Appearing OA/US Features:

- The peripheral zone vessels and boundary zone neo-vessels in malignant masses tend to be oriented and enter or exit perpendicular to the mass wall.
- The polymorphic and tortuous neo-vascularity of malignant masses may appear in a dot-dash pattern on a static image
- The polymorphic and tortuous neo-vascularity of malignant masses tend to be de-oxygenated and appear red, but may be green in part because in OA, colorization is relative
- The neo-vascularity (supply and drain) of malignant masses tend to be unevenly distributed in the boundary zone
- The distribution and corresponding higher density of vessels may occur in one or a combination of areas around the lesion’s capsule. Additionally, these vessels are usually polymorphic and tortuous (vary in size, shape, and orientation)
- The neo-vessels tend to be oriented and course in a “snake like” pattern, therefore it is highly recommended that all three areas; the internal zone, the boundary zone, and the peri-tumoral area be thoroughly interrogated when performing an OA/US scan
- OA colorization is relative, meaning the OA colorized signal from oxy and deoxy hemoglobin in vessels is determined by different light absorption characteristics of each slice of tissue, and some out of plane tissue/light interactions. Additionally, the generated ultrasound from the Opto-

acoustic effect in tissues is susceptible to and is affected in the same manner as returning conventional diagnostic ultrasound. Therefore, a malignant masses vascularity may not always be colorized red and benign vessels may not always be colorized green

Note: Neo-vessels in the boundary zone and radiating vessels in the peripheral zone of malignant appearing masses have unique OA features. First, while interrogating, it is important to make a mental note of the number, location and orientation of vessels in the external zone. External OA features can be identified by the Relative and Total Hemoglobin map. Secondly, assess their relative color. Finally, note the OA features found in the Internal zone. Observing and noting malignant appearing OA features from the external zone first, then the internal zone, will assist in choosing a representative clip frame in which to draw regions of interest (ROI) to segment between the internal zone, boundary zone, and peripheral zone.

G.2.4.1 Example: Highly Suspicious Breast Mass OA Features

External

- Multiple boundary zone red (deoxygenated) perpendicular polymorphic neo-vessels or red blush
- More than 2 peripheral zone radiating vessels on more than one side of the mass

Internal

- Red (deoxygenated) blush
- Many large and heterogenous vessels almost filling mass
- Multiple red (deoxygenated) vessels

G.3 Region of Interest (ROI)

Choose a single OA Mode image or video frame of a mass that is representative of the overall OA features, draw two ROI. One ROI is drawn on the border between Peripheral Zone and Boundary Zone and one ROI is drawn on the border between the Boundary Zone and Internal Zone. The ROIs can be drawn on a frozen or previously saved image or video frame.

G.4 Axillary Lymph Node OA/US Scanning

- The most frequent site of breast cancer metastasis are lymph nodes; so it is important to explore internal mammary lymph nodes and axillary lymph nodes when a breast mass is identified.

G.4.1 Axillary Lymph Node OA/US Imaging and Recording

Begin scanning in the inferior medial axillary tail (Tail of Spence) and move the probe superiorly to identify the Sentinel Node(s) (first node(s) “downstream” from the cancer in the lymph circulatory system).

G.4.1.1 Imagio® Breast Imaging System OA (Minimum) Recommended Clips for Lymph Nodes:

Step: 1 SAX transverse *or* long scan plane.
Step: 2 LAX in the same plane as SAX

G.4.1.2 Example: Highly Suspicious Lymph Node OA Features

Internal

- Red (de-oxygenated) blush
- Multiple tortuous vessels

External

- Non-hilar trans capsular vessels – red or green

Annex H OA Imaging Performance

Test	Purpose	Acceptance Criteria	Results
1. Spatial Resolution	Evaluate and quantify in-plane (axial, lateral), and out-of-plane (elevational) spatial resolution of OA images	None	Axial resolution, short wavelength = 0.58 ± 0.10 mm Axial resolution, long wavelength = 0.54 ± 0.10 mm Lateral resolution, short wavelength= 1.12 ± 0.35 mm Lateral resolution, long wavelength= 1.09 ± 0.25 mm Elevational resolution, short wavelength = 2.7 ± 0.4 mm (at ~4.5 mm depth), 5.6 ± 0.2 mm (at ~34 mm depth), respectively Elevational resolution, long wavelength = 2.7 ± 0.4 mm (at ~4.5 mm depth), 5.4 ± 0.5 mm (~34.5 mm depth), respectively
2. Geometric Accuracy and Precision	Evaluate accuracy of measured 1D distances and 2D areas in OA images. Assess OA image precision with repeated acquisitions.	None	Worst-case horizontal error = +0.81/-0.54 mm, std. deviation = 0.33 mm (over both wavelengths) Worst-case vertical error = +0.19/-0.36 mm, std. deviation = 0.13 mm (over both wavelengths) Worst-case Image precision = +0.23 mm/-0.90 mm (over both wavelengths) Average percent errors of drawn ellipses were 0.4% in diameter, 0.7% in area, and 0.3% in circumference.
3. OA/US Co-Registration	Evaluate co-alignment of fused OA, US images	None	Worst-case horizontal error, -0.94/ +0.85 mm, std. deviation = 0.33 mm Worst-case vertical error = -0.17/ +0.21 mm, std. deviation = 0.09 mm (over both wavelengths)
4. Image uniformity	Quantify horizontal and vertical signal uniformity	None	With clinical contrast settings, Horizontal variation <2 dB (near-field) or <6 dB (far-field). Vertical uniformity < 31 dB (near-field), < 35 dB (far-field) due to expected effect of optical attenuation vs. depth.
5. Depth detection	Quantify the maximum penetration depth of OA imaging	None	Max imaging depth > 4 cm for OA Short and OA Long for detecting de-oxygenated and oxygenated vessels, respectively.
6. Sensitivity-linearity	Evaluate and quantify OA sensitivity to and linearity vs. optical absorption	None	OA signal is highly linear vs. changes in target absorption coefficient using fixed contrast settings (R^2 > 0.986). Sensitivity = 0.046 cm^{-1} / grayscale for OA Short, 0.0343 cm^{-1}/grayscale for OA Long using fixed contrast settings. Clinical contrast settings can result in saturation effects, as expected.

7. OA Dynamic Range	Evaluate and quantify the OA	None	OA dynamic range (OA Short): 9.079-22.976 dB OA dynamic range (OA Long): 10.015-23.923 dB
8. Accuracy of vessel diameters for simulated blood vessels	Evaluate accuracy of measuring tube diameters with the Imagio® OA imaging	None	Device detects differences in vessel diameters correlated with known diameters, although measured diameter values are overestimated.
9. Oxygen saturation variation	Quantify the ability of the Imagio® system to depict and resolve differences in blood oxygen saturation	None	Device can detect SO_2 differences of ~3.5% ± 2.3% for targets near 100% SO_2, ~11% ± 15% for targets near 50% SO_2.
10. Out-of-plane absorber effects	Evaluate and quantify the effects of out-of-plane absorbers on the OA colorization	None	Out-of-plane absorber artifacts can potentially affect OA image colorization. Effects are stronger when out-of-plane target has similar SO_2 and smaller vessel diameter relative to in-plane target.
11.Dual wavelength laser energy variation	Quantify the effects of varying laser energy on image quality	None	Device maintains accurate colorization even with reduced laser energy beyond allowable tolerances for operation.

Annex I Clinical Study Summary

Reader-02 was a single arm, sequentially read, controlled, blinded, multi-reader, multi-case (MRMC) pivotal study to establish a reasonable assurance of Imagio® Breast Imaging System safety and effectiveness. The primary goal of the Reader-02 was to demonstrate that readers using the full functionality of Imagio® Breast Imaging System (IUS+OA) performed better compared to when using IUS alone in terms of specificity at a fixed sensitivity of 98%. The images used in Reader-02 were a subset of the images acquired in a previous study called the PIONEER Study. PIONEER Study data collection is described next. The Reader-02 Pivotal Study's endpoints were as follows:

Primary endpoint: Evaluate reader specificity with IUS alone at 98% sensitivity versus Imagio® Breast Imaging System (IUS+OA) at the same sensitivity.

Secondary endpoints: Evaluate the following for IUS alone versus Imagio® Breast Imaging System (IUS+OA):

a) Negative Likelihood Ratio (NLR) defined as ((1-sensitivity)/specificity)

b) Positive Likelihood Ratio (PLR) defined as (sensitivity/(1-specificity))

c) Partial ROC AUC (pAUC) corresponding to 95-100% sensitivity

Sensitivity and specificity for the secondary endpoints were based on reader's probability of malignancy (POM) scores with a positivity threshold of POM of 2%, i.e., POM>2% was considered a positive read (positive result) and POM≤2% was considered a negative read (negative result).

The evaluation used a sequential hierarchical approach for hypothesis testing, with secondary endpoints tested in the order NLR, PLR, and pAUC. Corresponding Hypothesis testing were as follow:

Primary hypothesis test:

H_0: $S_{Imagio®} = S_{IUS}$ (no specificity [at 98% sensitivity] difference)

H_1: $S_{Imagio®} \neq S_{IUS}$ (superior specificity [at 98% sensitivity])

where $S_{Imagio®}$ and S_{IUS} represent specificity [at 98% sensitivity], values associated with Imagio® Breast Imaging System (IUS + OA) and IUS, respectively.

Secondary hypothesis tests:

A 2% Probability of Malignancy (POM) cutoff was used as the positivity threshold. Specificity was defined as the proportion with a negative result (POM ≤2%) among all benign+TPB (truth panel benign) masses (to include all high-risk masses). Please refer to the description below for the definition of TPB and high-risk masses. Sensitivity was defined as the proportion with a positive result (POM >2%) among all malignant masses.

a. NLR:

H_0: $NLR_{IUS} = NLR_{Imagio®}$ vs

H_A: $NLR_{IUS} \neq NLR_{Imagio®}$ representing a reduction (improvement in NLR)

b. PLR:

H_0: $PLR_{IUS} = PLR_{Imagio®}$ vs

H_A: $PLR_{IUS} \neq PLR_{Imagio®}$ representing an increase (improvement in PLR)

c.Partial ROC AUC:

H_0: $pAUC_{IUS} = pAUC_{Imagio®}$ vs

H_A: $pAUC_{IUS} \neq pAUC_{Imagio®}$ representing an increase (improvement in partial ROC AUC)

A sequential hierarchical approach for hypothesis testing was applied.

PIONEER Study Data Collection

The subjects for PIONEER Study were selected from women referred for a diagnostic breast ultrasound work-up who had a suspicious finding within the previous 45 business days, by palpation or by a screening mammogram or diagnostic methodology other than ultrasound, who were scheduled to undergo or already had a Clinical Diagnostic Ultrasound (CDU). The CDU at the time of Study enrollment was used to classify subjects as NDU (Negative Diagnostic Ultrasound) (CDU BI-RADS 3) or PDU (Positive Diagnostic Ultrasound) (CDU BI-RADS ≥4a) to determine if follow-up (NDU patients) or biopsy (PDU patients) was required.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the PIONEER study was limited to patients who met the following inclusion criteria (all conditions are to be met to be included in the study):

a) Has signed and dated informed consent, prior to initiation of any Study activities.

b) Has had an undiagnosed suspicious finding within the previous 45 business days, by palpation or by a screening or diagnostic methodology other than ultrasound; this may have included more than one suspicious mass.

c) Has at least 1 or up to 3 pre-selected and undiagnosed breast masses including suspicious solid masses and/or complex cystic and solid masses that the investigator had characterized as either BI-RADS 3, BI-RADS 4, or BI-RADS 5 that have been scheduled for either biopsy or follow-up.

d) Has at least one undiagnosed breast mass that was detected by one of the following 4 methodologies within 45 business days prior to enrollment with imaging results available for Study utilization:

- Call backs for additional evaluation of suspicious area(s) identified by imaging other than ultrasound.
- Diagnostic referral to assess focal physical symptoms and/or signs that were either a chief complaint of the subject or were elicited by the healthcare practitioner (excluding focal breast pain in the absence of other positive clinical findings).
- Interval clinical problems (symptoms or physical findings, excluding isolated focal breast pain, that had developed between yearly mammograms).
- Other referrals to CDU including subjects younger than 30 years old for a clinically suspicious area, or subjects referred from a screening MRI because of an abnormality.

e) Is at least 18 years of age.

f) Has received a recommendation to either biopsy or not biopsy.

g) Is willing and able to comply with protocol required procedures.

Patients were not permitted to enroll in the PIONEER study if they met any of the following exclusion criteria (any condition by itself is sufficient to exclude a subject):

a) Subject is male.

b) Has a condition or impediment which could interfere with the intended field-of- view (i.e., breast implants within the previous 12 months, or tattoos).

c) Has or has had cancer in the ipsilateral breast or prior breast surgeries in the same quadrant of the ipsilateral breast that would have interfered with the ability to capture or interpret images.

d) Prior benign excisional breast biopsy within the immediate vicinity of the currently evaluated suspicious mass within the past 18 months (benign excisional biopsy not within immediate Imagio® Breast Imaging System field-of-view will not exclude the subject from the Study).

e) Has greater than 3 suspicious masses.

f) Mass(es) of interest is greater than 4 cm.

h) Has all mass(es) characterized as BI-RADS 1 and/or 2 as determined using a CDU.

i) Currently has mastitis.

j) Has focal pain without thickening or mass.

k) Is pregnant or lactating.

l) Has open sores including insect bites, rash, poison ivy, and chafing on the skin of the ipsilateral breast.

m) Has an acute or a chronic hematoma and/or acute ecchymosis of the ipsilateral breast.

n) Is experiencing photo-toxicity associated with currently taking, or having taken, photosensitizing agents within the previous 72 hours such as sulfonamides, ampicillin, tetracycline. Is currently undergoing phototherapy.

o) Has a history of any photosensitive disease (e.g., porphyria, lupus erythematosus) or undergoing treatment for a photosensitive disease and was experiencing photosensitivity.

p) Concurrent neoadjuvant therapy prior to the Imagio® Breast Imaging System evaluation or the biopsy.

q) Has previously had image guided core biopsy, image guided DVAB, or surgical biopsy of the mass of interest.

r) Has nipple rings that cannot be removed or are not removed during Imagio® Breast Imaging System evaluation.

2. Methodology

Subjects were prospectively enrolled upon confirmation of being BI-RADS 3, BI-RADS 4, or BI-RADS 5, as confirmed by CDU evaluation of the suspicious mass(es). Subjects who had all mass(es) characterized as BI-RADS 1 and/or 2 as determined using a CDU were regarded as screen failures. Of the remaining subjects who consented (n=2105), 23 were considered as enrollment failures because (1) mass was too deep for Imagio® Breast Imaging System to visualize, or (2) device malfunctioned prior to or during the

scanning procedure, or (3) subject was withdrawn prior to scanning procedure initiated. Remaining subjects (n=2082) were exposed to OA.

The first 10 subjects scanned at the Cancer Therapy and Research Center (CTRC) and the next 100 subjects enrolled as pilot cases for the study were excluded from the Safety Population of the study. The PIONEER Safety Population thus consisted to 1972 subjects.

Subjects were scheduled for an Imagio® Breast Imaging System procedure after the decision whether to biopsy was made, but prior to any biopsy. The subjects must have had the Imagio® Breast Imaging System procedure within 10 days of the enrollment visit and within 45 business days before the biopsy. Subjects in the NDU group who opted not to undergo a biopsy were to have second Imagio® Breast Imaging System procedure 12 months (±30 days) after the initial imaging procedure.

All images, both OA and IUS, were to undergo QA review by the quality assurance radiologists (QARs). To ensure image reading consistency, the assessment of all Study imaging, including OA, was managed by an independent Imaging Core Laboratory (ICL).

Starting with the PIONEER Safety Population, 233 subjects were excluded from the PIONEER Intent-to-Diagnose (ITD) Population for the following reasons: QA failure of images, technical failures, PDU with no biopsy, NDU with no truth panel review, and protocol deviations.

3. Ground Truth Determination

For masses that underwent biopsy, the final diagnosis depended on the histopathological examination of the biopsy data from the suspected mass by an independent central histopathologist. Samples determined by the central histopathologist to be high-risk (HR), such as atypical ductal hyperplasia, atypical lobular neoplasia, and lobular carcinoma in situ were considered to be benign in the study effectiveness analysis. A Truth Panel was established to review and/or adjudicate NDU cases with follow-up at 12 months (≥11 months) to determine if the cases were True Negative (Truth Panel Benign [TPB]). TPB was determined for subjects who had masses classified as BI-RADS 3 with CDU by site investigators that were not biopsied and had ≤20% increase in max diameter and no change in BI-RADS classification from 3 to 4a+ at the 12-month follow up. Panel members evaluated available imaging modalities in the following order: CDU, mammography, MRI and IUS. OA was not utilized for this determination. NDU subjects who were not biopsied within the 12-month follow-up window and showed an increase in mass size (>20%) or a BI-RADS change to >3 were classified as truth panel change (TPC) masses by the Truth Panel. There were 8 such TPC masses, all of which were BI-RADS 3 by CDU at 12-month follow-up; none were recommended for biopsy by site investigators. The PIONEER ITD Population included 1739 subjects with a total of 652 biopsied cancer, 41 biopsied high risk, and 848 biopsied benign, 190 non-biopsied TPB and 8 non-biopsied “other” (truth panel change or

TPC) masses. PIONEER ITD analysis population excluded the 8 TPC cases because they could not be classified as TPB, high-risk, or cancer.

Case selection for Reader-02 Pivotal Study

Reader-02 Pivotal Study used a subset of the images acquired for the PIONEER Pivotal Study. No new subjects were enrolled for Reader-02 Study. The patient population for Reader-02 Study is described in the following.

Masses were selected at random for the Reader-02 Study in proportion to the original assignment distribution of BI-RADS classifications among subjects in the PIONEER Study by conventional diagnostic ultrasound (CDU). Masses selected from the PIONEER ITD analysis population for the Reader-02 Study could include up to 7 blocks of 120 images. The Reader-02 Pivotal Study was planned to consist of between 480 to 840 masses with complete imaging read sets from the original PIONEER ITD analysis

population. The data were organized and presented to readers in blocks of 120 masses, each consisting of 72 benign plus 3 high risk (to be categorized as benign) and 45 malignant masses (reflecting a similar prevalence of cancer as the overall PIONEER ITD analysis population, approximately 38%). To facilitate the alignment of the PIONEER Pivotal Study data with the Reader-02 Pivotal Study data in terms of mammogram availability, the mass image set sampling plan selected a benign mass proportion with and without mammograms depending on availability of the mammograms to be the same as in PIONEER; this stratification did not apply for malignant masses where nearly all masses were previously evaluated using mammography. Sample size was assessed at a blinded interim analysis after the first 360 reads and could be adjusted as necessary based on inter- and intra- reader variance up to a maximum of 840 reads.

The dataset determined by the radiologists in the MRMC Study consisted of 480 (four blocks of 120 read sets each), and masses in total, comprised of the following:

- 180 malignant masses
- 300 benign masses (288 benign, 12 high risk defined as atypical ductal hyperplasia, atypical lobular neoplasia, and lobular carcinoma in situ, etc.)

To avoid any potential for bias, all four blocks had been read by all readers in advance of the database lock for the pre-planned interim analysis.

Mass Inclusion and Exclusion Criteria

The mass inclusion criteria for the Reader-02 Pivotal Study were as follows:

a) One analyzable mass per patient: BI-RADS 3, 4a, 4b, 4c and 5 masses as declared by clinical site investigator via PIONEER study inclusion criteria and categorized as BI-RADS 3, 4a, 4b, 4c, and 5 by CDU

b) Masses declared to be in the PIONEER ITD analysis population, including high risk cases per original PIONEER protocol

c) Patient age, indication for study entry and available medical history

d) Evaluable mammograms (when available) and IUS and OA video loops and still images for each mass

The mass Exclusion criteria for the Reader-02 Pivotal Study were as follows:

a) Critical missing IUS or OA still image and/or video loop views or incorrect IUS or OA stills and video loops that would preclude a case from being evaluated by readers

b) Reader-02 proficiency test and training cases

c) Failure of quality assurance review, as described below.

Quality Assurance Review

The quality assurance radiologists (QARs) were two physicians selected by Seno Medical with knowledge and experience in breast imaging. In addition to exam quality checks, the QAR's role was to identify and label, with guidance from limited medical history data and breast MRI and CDU exams, the appropriate intent-to-diagnose mass on mammogram and IUS and Imagio® Breast Imaging System (IUS+OA) exams to be read and scored by the 15 independent readers on this study.

Reader Qualifications and Training

The study included 15 readers with an additional 5 back-up readers depending on qualifications and availability. Readers that participated in any previous study were not eligible to participate as independent readers in this Reader-02 Pivotal Study. The readers were required to undergo training before they were permitted to participate in the Reader-02 Pivotal Study.

Training consisted of three modules: Didactic training, interactive reading, and test. Didactic training included fundamentals of OA, OA feature scoring, correlation of OA features with core biopsy histopathology, OA artifacts, IUS feature scoring, Seno learnings from previous studies, and the use of the SenoGram®. In the interactive reading module, the readers read and scored a mixture of up to 30 malignant and benign cases after being trained on how to use a reading station, draw regions of interest (ROIs), score IUS and OA features, use the SenoGram® to aid in predicting OA POM and BI-RADS category. In the test module, the readers had to pass a proficiency test involving the scoring and interpretation of 30 cases before starting their study reads.

Image Interpretation

Interpretation of each case consisted of two consecutive reads: Read 1, immediately followed by Read 2 within the same reading session. In both Read 1 and Read 2, the radiologist provided a POM rating between 0 and 100 using a custom graphical interface with zoomed-in gradations at low probabilities (POM<2%), and a corresponding BI-RADS score (BI-RADS 2, 3, 4a, 4b, 4c or 5).

Read 1 reflected the typical information available to a radiologist when evaluating standard ultrasound images, taking into consideration the mass, patient history and assessing mammogram BI-RADS results, when available. Read 1 (IUS reads) served as the control representing current clinical practice.

- Read 1:
  - Data provided for the reader: Patient History (age) + Mammogram (if available) + IUS (stills and videos provided).
  - Reader output: IUS Probability of Malignancy (POM) and BI-RADS category assigned in the data form, then locked.

Read 2 displayed the OA images in addition to the data provided in Read 1. Each reader entered 5 feature scores for IUS, 5 feature scores for OA, and four other features (patient age, mass size, depth to the posterior aspect of the mass and mammographic BI-RADS classification) into the SenoGram® report form. Based on this information, the SenoGram® displayed a predicted Likelihood of Malignancy (LOM) computed from reader input. Each reader then assigned final POM and BI-RADS scores.

- Read 2:
  - Data initially provided for the reader: Patient History (age) + Mammogram (if available) + IUS (stills and videos provided), and Imagio® Breast Imaging System (IUS+OA) (stills and videos provided).
  - Input provided by the reader to SenoGram®: 5 feature scores for IUS, 5 feature scores for OA, and four other features.
  - Reader output: Imagio® Breast Imaging System (IUS+OA) POM and BI-RADS category after viewing the SenoGram® output. The data form is then locked.

Study Population

Of the 480 masses read in the Reader-02 study, the overall mean age was 49.9±14.4 years; in the benign+TPB+High Risk (HR) group, the mean was 44.2±12.5 years, and in the malignant group it was 59.4±12.2 years, consistent with the age distribution of cancer diagnosis in the population.

Almost ninety percent (89.6%) of subjects had available mammography, of which 84.0% were benign+TPB+HR subjects and 98.9% were cancer subjects.

In the overall Intent to Diagnose (ITD) population, two (0.4%) had CDU BI-RADS scores of 2; 74 (15.4%) were score 3; 129 (26.9%) were score 4a, 84 (17.5%) were score 4b, 87 (18.1%) were score 4c, and 102 (21.3%) were score 5. As expected, a greater proportion of subjects in the

malignant group were scored BI-RADS 5 (96, 53.3%). Almost three-quarters of the masses (355, 74%) had a mammographic breast density of 2 or 3; 210 masses (43.8%) were palpable, and 199

masses (41.5%) were not. Almost half the subjects (219, 45.6%) were post-menopausal, and 14 (2.9%) had breast implants.

Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the PIONEER Safety cohort of 1972 patients. Summary of the adverse effects that occurred in the PMA clinical study is as following:

Overall, 52 subjects (2.6%) in the PIONEER Safety Population experienced an Adverse Event (AE). Forty subjects (2.0%) experienced at least one AE assessed as mild and 11 subjects (0.6%) experienced at least one AE assessed as moderate in severity. One subject (0.1%) reported two AEs assessed as severe and serious. This subject experienced atrial fibrillation and congestive heart failure, both assessed as serious, severe, and not related to the procedure. The event of atrial fibrillation was attributed to renal failure and the event of congestive heart failure was attributed to atrial fibrillation.

The most common AEs by system organ class were injury, poisoning, and procedural complications (21 events) followed by nervous system disorders (16 events). The most common events by preferred term (PT) were paresthesia (10 events) and post procedural hematoma (all post-biopsy; 5 events). Twenty-five events, including 10 events of paresthesia, had a start date of the same day as the OA procedure.

Of the Serious Adverse Events (SAE)s reported in 5 subjects, none were considered related to the OA procedure. There were no serious adverse device effects (SADEs), unanticipated adverse device effects (UADEs) or deaths reported during the Study.

Of the 52 subjects with AEs, 10 subjects (0.5%) reported 11 events that were considered related (possibly, probably, likely) to the OA procedure. All 11 procedure-related AEs were considered mild.

A single event of “burns second degree” occurred. This patient had a moderate skin rash of undetermined origin. This was deemed by the sponsor to be more likely due to contact dermatitis with post-biopsy tape than a photothermal skin injury due to laser exposure.

2. Effectiveness Results

The following conclusions are based upon the results of the pivotal study:

The Reader-02 Pivotal Study met its primary endpoint and demonstrated that Imagio® Breast Imaging System has better specificity than IUS at fixed sensitivity of 98%. Specificity at a fixed sensitivity of 98% (fSp) and partial area under the ROC curve (pAUC) between sensitivities of 95% and 100% are metrics that assess the part of the ROC curve where the clinical decisions are actually made. Diagnostic likelihood ratios (DLR) can be calculated from sensitivity and specificity based on POM scores and can be useful in comparing technologies in breast imaging.

Specificity at a fixed sensitivity of 98% was analyzed using MRMC analysis. Mean (average over all readers) fSp was found to be higher with statistical significance (two-sided p=0.027) for IUS+OA (47.2%, 95% CI=[35.9%,58.5%]) compared to IUS alone (38.2%, 95% CI= [24.9%, 51.6%]), with a difference in fSp of 9.0% with 95% CI=[1.0%, 17.0%]. Thus, IUS+OA achieved the primary endpoint in the Reader-02 Pivotal Study. When the empirical ROC curve is used, interpolation is typically required to estimate fSp because 98% sensitivity may not fall onto the intrinsic grid for the empirical ROC curve.

The observed mean NLR was 0.047 (95% CI: 0.032, 0.062) for IUS+OA suggesting that averaging over all 15 readers in the study a negative test read (POM ≤2%) was observed about 21 (i.e., 1/0.047) times more often among non-cancer cases, compared to those with cancer, and the observed mean NLR was 0.053

(95% CI: 0.037, 0.070) for IUS alone suggesting that averaging over all 15 readers in the study a negative read (POM≤2%) was observed about 19 (i.e., 1/0.053) times more often among non-cancer cases, compared to those with cancer. The decrease (i.e., improvement with IUS+OA compared to IUS alone) in NLR could not be established with statistical significance because the observed relative NLR (the ratio in NLR for IUS+OA and IUS) was 0.896 with a 95% CI= (0.693, 1.11) which included 1 indicating that no evidence of a difference in NLR was found. The confidence intervals above for NLR and the relative NLR do not take into consideration the variability in the reader population and are therefore applicable only to the set of radiologists who took part in the reader study. Since a sequential hierarchical testing to control the study type I error rate was pre-specified, and this was the second hypothesis test in the sequence, and decrease in NLR was not met (i.e., an improvement in NLR for IUS+OA compared to IUS alone could not be shown), not only improvement in NLR for IUS+OA compared to IUS alone cannot be claimed, but hypotheses test results from subsequent hypotheses (for the remaining secondary endpoints of PLR and partial ROC AUC) are not reported. The results reported below for PLR and Partial ROC AUC are considered descriptive or non-confirmatory.

Based on descriptive statistics that do not control type I error and that cannot be generalized outside this particular study, the observed mean PLR was 1.959 (95% CI: 1.870, 2.051) for IUS+OA (only as a descriptive result this suggests that averaging over all 15 readers in the study a positive test read (POM>2%) was observed about 2 times more often among cases with cancer, compared to those without cancer), and the mean PLR was reported as 1.548 (95% CI: 1.498, 1.597) for IUS alone (only as a descriptive result this suggests that averaging over all 15 readers in the study a positive test read (POM>2%) was observed about 1.5 times more often among cases with cancer, compared to those without cancer). The descriptive observed relative PLR was 1.281 (95% CI: 1.231, 1.298). The confidence intervals above for PLR and the relative PLR do not take into consideration the variability in the reader population and are therefore applicable only to the set of radiologists who took part in the reader study.

pAUC was lower in the hierarchical test order than NLR, which failed to achieve significance. Consequently, pAUC results are not part of the claim structure and are reported as descriptive statistics. The mean unscaled pAUC was 0.0244 (95% CI: 0.0230, 0.0258) for IUS+OA and 0.0205 (95% CI: 0.0191, 0.219) for IUS alone, a difference of 0.0039. All readers had a larger point estimate of pAUC for IUS+OA than for IUS alone.

The following results are not part of the claim structure and are reported as only descriptive and non-confirmatory results. POM scores were analyzed by computing the mean score among the 15 readers for a given mass with IUS only or with IUS+OA. For IUS+OA, the mean POM for malignant masses was 70.7 (95% CI: 66.86, 73,28) whereas the mean POM for benign masses was 15.90 (95% CI: 13.65, 18.15). For IUS alone, the mean POM for malignant masses was 65.23 (95% CI: 62.38, 68.08) whereas the mean POM for benign masses was 16.41 (95% CI: 14.54, 18.28). The confidence intervals provided above apply only to the average POM score of the 15 readers who participated in the study, and do not generalize to the average POM scores of other readers or the POM scores of individual readers.

SenoGram® classification performance was assessed with descriptive (non-confirmatory) ROC metrics (fSp, pAUC) and classification metrics (sensitivity and specificity) observed on the Reader-02 dataset. fSp and pAUC were assessed based on the SenoGram® inputs assigned by each reader in Reader02, and then averaged over the 15 readers. Sensitivity and specificity were assessed for each reader at a threshold of 2% for the SenoGram® POM output and then averaged. Using endpoint interpolation, the average fSp was 44.1% (95% CI: 38.4%, 49.8%) and the average pAUC was 0.0232 (95% CI: 0.0215, 0.0249). The average SenoGram® sensitivity and specificity were 97.0% (95% CI: 96.0%, 97.9%) and 50.9% (95% CI: 46.0%, 55.8%), respectively.

The binary agreement between readers and SenoGram® predictions was measured by comparing results for each case. Reader and SenoGram® results agree if both predict positive (cancer) or both predict

negative (benign). Readers agreed with the SenoGram® results in 98.8% (2667/2700) of cancer cases, 93.3% (4197/4500) of benign+TPB+HR cases, and 95.3% (6864/7200) overall.