Imagio® Breast Imaging System

Seno Medical Instruments™

Imagio Breast Imaging System User Manual

SID-0000003235

CE 2797

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

EC REP

Authorized European Representative
Emergo Europe B.V.
Prinsessegracht 20
The Hague 2514 AP
Netherlands

The Imagio® Breast Imaging System complies with the regulatory requirements of European Directive 93/42/EEC concerning medical devices.

CE 2797

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

Tel: 210-615-6501
www.senomedical.com
https://senomedical.com/patents/

To access the latest version of the Imagio® Breast Imaging System User Manual, please go to:
https://senomedical.com/manuals/current

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.

TRAINING STATEMENT

Seno Medical provides a training program accessible online at Seno University https://senouniversity.com/ for new users. Users can arrange to participate by notifying Seno Medical. In addition, Seno Medical provides 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 users.

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 a Seno authorized service provider. All parts that are replaced become the property of Seno. The user 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 users, all service work must be performed by an authorized service representative. Call the local service provider.

SAFETY

This manual uses the following safety descriptors:

⚠WARNING*:*	Warning statements inform the User of safety alerts that must be followed carefully to avoid bodily injury.

⚠***CAUTION:***	Caution statements inform the User of safety alerts that must be observed to avoid damage to your equipment.

SAFETY ALERTS - WARNINGS

The following list of warnings alert the user to possible injury or other serious adverse reactions associated with the use or misuse of the Imagio Breast Imaging System.

⚠***WARNING:*** CAUTION - Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

⚠***WARNING:*** Invisible laser light is emitted from the OA/US Probe. Reflected and/or misdirected laser light may damage eyes.

- Never use any controls or adjustments or performance settings other than those specified herein.
- The Patient, the Imagio Breast Imaging System User, 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 OA/US Probe is out of its holder. Refer to **Error! Reference source not found. Error! Reference source not found.**. 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 Probe, and calibrating laser energies or any other time the Imagio Breast Imaging System is powered on and the OA/US Probe is removed from the probe holder.
- Never look directly at the laser beam even when laser protective eyewear is being worn.
- Never 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 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 Probe from the skin or holder/sheath.
- Always follow the laser safety precautions prior to laser emitting to protect the Patient, User, and Observers.
- Always place the OA/US Probe in the OA/US Probe holder when not in use. This OA/US Probe holder is designed to minimize the release of laser light due to an unintentional activation of the foot switch.

⚠***WARNING:*** Unapproved accessories are NOT permitted and may cause tissue damage.

- Always use Seno approved accessories.

⚠***WARNING:*** Operation of the Imagio Breast Imaging System by untrained individuals may result in harm to patient and/or user.

- Never allow the Patient to touch the Imagio Breast Imaging System Console.

- Never share your password with anyone. Only trained users can use the Imagio Breast Imaging System.
- Always disable the laser by pressing the touch screen Laser Control button when the Imagio Breast Imaging System will be left unattended.

⚠***WARNING:*** There is a low possibility of a photosensitive reaction to the laser light used in the Imagio® Breast Imaging System.

- Inform patients who are experiencing photo-toxicity associated with currently taking, or having taken, photosensitizing agents within the previous 72 hours. Refer to **Error! Reference source not found.Error! Reference source not found.**. Recommend temporary discontinuation of such medications until after the procedure is completed unless continuation of the medication is indicated for other medical reasons.

⚠***WARNING:*** The Imagio Breast Imaging System contains dangerous voltages that are capable of permanent impairment or life-threatening injury.

- If any defects are observed or malfunctions occur, stop operating the Imagio Breast Imaging System. Call the local service provider. Always connect the Imagio Breast Imaging System to approved supply mains with protective earth.
- Always use the Seno approved power cable and connector.
- Never touch the Patient and any exposed connector simultaneously.
- Never touch any exposed connector when a probe is in contact with the Patient.
- Never attempt to operate the Imagio Breast Imaging System if panels are removed or not properly attached.
- Never clean the power cord while it is plugged in to the mains power outlet or the Imagio Breast Imaging System.
- Never share the power outlet with other types of equipment.
- Never use an adaptor or converter to connect with a power source plug (three prongs to two- prong converter).

⚠***WARNING:*** The detachable power supply cord is located at the back of the Imagio Breast Imaging System. Injury may occur if the Imagio Breast Imaging System is not positioned to allow access to the power cord.

- Always position the Imagio Breast Imaging System away from the wall to allow quick access.
- Check power cables and plug for damage on a regular basis.
- Never detach the power supply cord by pulling on the cable. Only pull the IEC connecter to detach the power supply cord.

⚠***WARNING:*** The Imagio Breast Imaging System allows users to configure User-defined Measurements, Calculations and Tables for diagnostic purposes, errors may lead to misdiagnosis or delay in treatment.

- Seno does not endorse user-defined Measurements, Calculations or Tables. These are utilized at the User's discretion and risk only.

⚠***WARNING:*** The Enable Unassigned Exam functionality allows exams to be conducted without patient identifier input. However, saving exams without patient identifier input can lead to identification errors which could result in an incorrect diagnosis or delay in treatment.

- When using this feature always add patient identifier input before saving data. Individuals or organizations that enable the Enable Unassigned Exam feature are assuming all liability and risks associated with use of this option.

⚠***WARNING:*** Laser emission in the presence of flammable materials may cause fire or explosion.

- Never 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)

SAFETY ALERTS - CAUTIONS

The following list of cautions alert the user to the possibility of a problem with the Imagio Breast Imaging System associated with its use or misuse.

⚠***CAUTION:*** The Imagio Breast Imaging System requires uninterrupted airflow through the right-side cooling intake. Any obstruction to airflow may cause overheating and system power down.

- Always position the exam table with a minimal distance of 31 cm (12”) between the exam table and the Imagio Breast Imaging System.

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

- Never 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 the local service provider.

⚠***CAUTION:*** Unauthorized installation or service may cause damage to the Imagio Breast Imaging System components and operation.

- Users should never modify or attempt to service the Imagio Breast Imaging System equipment. Only Seno Medical personnel and/or their authorized third-party Service companies are to install and service the Imagio Breast Imaging System equipment.

⚠***CAUTION:*** Liquids stored or placed on the Imagio Breast Imaging System may spill and damage the Imagio Breast Imaging System components rendering the device unusable.

- Never place cups, drinks, or other fluid containers on the Imagio Breast Imaging System.

⚠***CAUTION:*** The Imagio Breast Imaging System is designed for use with the Imagio Breast Imaging System OA-16-1S Opto-acoustic (OA/US) and US/L-14-5 Linear Probes only. Other Probes will not be recognized or usable and may damage the system.

- Never attempt to attach any other probe to the Imagio Breast Imaging System.

⚠***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 equipment or system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

⚠***CAUTION:*** When connected to a network, the Imagio Breast Imaging System is susceptible to cybersecurity compromise and 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 user.
- Never operate the Imagio Breast Imaging System without a firewall or anti-virus software. Organizations that elect to configure/use the networking functionality provided by Seno are assuming all liabilities and risks associated with that decision.
- Do not install Seno unauthorized software or hardware on the Imagio Breast Imaging System.
- Always call the local service provider for cybersecurity compromise on the Imagio Breast Imaging System.
- Always maintain configuration and data backups for the Imagio Breast Imaging System.

⚠***CAUTION:*** The OA/US and Ultrasound probes are sensitive medical devices and may be easily damaged by misuse.

- Never use a damaged probe. Call the local service provider if the probe face is damaged or the probe is dropped.
- Never sterilize the probe with sterilization techniques such as autoclave, ultraviolet, gamma radiation, gas, steam, or heat sterilization techniques. Severe damage will result using the above sterilization techniques.
- Never use chemicals such as phenol, benzethonium chloride, Phisohex, benzoyl peroxide, hydrogen peroxide, antibacterial skin cleaners or lotions which are commonly found in clinic and hospital settings.
- Never have strong solvents such as acetone, Freon and other industrial cleansers contact the probe.
- Never contact the probe face with any other surfaces, including non-barrier protected bare hands.
- Never wipe the glass windows of the OA/US Probe or acoustic lens of the OA/US or Ultrasound probes with paper towels or any other material that may damage the surface of the probe face.
- Only use Seno approved gel and cleaner disinfectant on the surface of the probe face.
- Do not get any cleaner disinfectant on probe connectors and contacts.
- Always clean the probes before each patient scan and at the end of each scanning day.
- Never touch or contact the end of the fiber optic cable.

⚠***CAUTION:*** The Imagio Breast Imaging System is a sensitive electronic instrument and may be damaged or data may be lost by improper use or misuse.

- Never disconnect the OA/US Probe during live imaging.
- Never position the Key to the OFF position while scanning.
- Never use the Circuit breaker or main power for regular shutdowns.
- Always perform an orderly shutdown of the Imagio Breast Imaging System.

SAFETY ALERTS, WARNINGS AND CAUTIONS

⚠***CAUTION:*** The Imagio Breast Imaging System is a sensitive medical device and may be easily damaged by misuse of unapproved cleaning agents and solvents.

- Never spill or spray water or cleaning solution on the controls or probe ports.
- Never pour cleaning solutions directly onto any surface of the Imagio Breast Imaging System including probe holder, power cord, and foot switch.
- Never pour cleaning solutions directly onto any surface of the Display Monitor or the touch screen.
- Computer wipes may be used only if they specifically state they are designed for Display Monitors.
- Never scratch the Display Monitor or the Touch Screen.
- Never use paper towels to clean the Display Monitor or the Touch Screen as they may cause damage and scratches.
- NEVER use unapproved cleaning products containing any of the following on the system surfaces or screens:
    - Abrasives
    - Acetone
    - Alcohol (Ethanol, Methanol or Isopropyl)
    - Hydrogen Peroxide
    - Iodine
    - Ammonia
    - Benzene and Benzol
    - Solvents and Thinners
    - Wax

⚠***CAUTION:*** The Imagio Breast Imaging System laser protective eyewear has delicate lenses which may be easily damaged by misuse of unapproved cleaning agents and solvents.

- Never use cleaning solvents on the laser protective eyewear.
- Only use water and a soft cloth or approved lens cleaning towelettes.

⚠***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.

- Fill the refill bottle away from the Imagio Breast Imaging System.
- 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 microbiology contamination of the cooling system. Use only distilled water when filling the laser coolant reservoir.

⚠***CAUTION:*** The OA/US Probe and OA/US Probe cable contain delicate fiber-optic cables that can be easily damaged if not handled carefully. If the fiber-optic cables are damaged, the OA/US Probe may not emit the proper amount of laser light and the exam results may be degraded. Never use cleaning solvents on the laser protective eyewear.

- Only use water and a soft cloth or approved lens cleaning towelettes.

- Always store the OA/US Probe in the OA/US Probe holder when not in use.
- Never allow the OA/US Probe cable to be crushed (for example: between equipment or stepped on.)
- Never allow the cable to become crimped.
- The minimum bend radius for the fiber optic cable is 5.08 cm (2”); therefore, the cable should not be wrapped tighter than an 11 cm (4”) diameter.

⚠***CAUTION:*** The OA/US Probe may be damaged if exposed to temperatures outside of the stated range.

- Only use water and a soft cloth or approved lens cleaning towelettes.
- Do not store the OA/US probe in environments beyond 4° C - 50° C or 30% to 80% relative humidity, as this was the range tested and verified by Seno Medical.
- Do not operate the OA/US probe in environments beyond 10° C, - 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 local service provider.

QUICK REFERENCE

This quick reference does not substitute the information found in the Imagio Breast Imaging System User Manual. Trained and authorized users should always refer to expanded text in the Imagio Breast Imaging System User Manual for a detailed explanation of the Imagio Breast Imaging System safety and operation.

Figure 1: The Imagio Breast Imaging System

Scan Room and the Imagio Breast Imaging System Preparation

<u>Maintain minimum distances from the Imagio Breast Imaging System for proper airflow:</u>

- 31 cm (12”) from Probe Holder side of the Imagio Breast Imaging System
- 92 cm (36”) from Key Switch side of the Imagio Breast Imaging System

Ensure signs and safety labeling are used and meet institutional regulatory requirements.

QUICK REFERENCE

User Activities

- Prior to removing the OA/US Probe from its holder ensure all individuals are wearing Seno approved laser protective eyewear. All persons in the scan room must wear the laser protective eyewear provided by Seno to filter out laser light that may be released during scans. Laser protective eyewear of OD4 or greater provides protection for the 1064 nm wavelength and OD5 or greater for the 757 nm wavelength.
- Inspect the probe and probe face.
- Power on the Imagio Breast Imaging System using the on/off key switch.
- Add Coolant and Calibrate Laser Energies if messages appear on display.
- Optional: Perform the Machine Check to verify a diagnostic quality, Opto-acoustic image.

Figure 2: OA System Console

Patient scanning may proceed only when the Imagio Breast Imaging System meets operational conditions located in Appendix E: Product Specifications.

OA Imaging, Preparing to Scan, and OA Scan Overview

OA Imaging

Opto-acoustic (OA) provides the ability to visualize blood accumulations such as in veins, arteries, and micro-vasculature associated with lesions. Therefore, when a suspected lesion is located by normal sweeping patterns of the OA/US Probe, it is then recommended to hold the OA/US Probe stationary over the suspected lesion and rotate the face of the OA/US Probe (along its long axis) to attempt to locate veins and arteries of interest. For example, an artery initially appearing as a dot may gradually appear as a line when the OA/US Probe head is rotated to align it parallel to the artery.

QUICK REFERENCE

Record functional OA images that include:

(1) Veins and arteries

- In the lesion
- Immediately adjacent to the lesion

(2) Concentrations of blood/ blood pools

- In the lesion
- Immediately adjacent to the lesion

IMPORTANT: ***OA includes a colorization algorithm that places color where there are various amounts of laser energy absorbed by blood components within the image. The various colors and intensities are calculated with only a portion of the total image. That portion is a horizontal band from 5mm deep to 35mm deep across the full width of the OA image. If there is a significant, concentrated area of blood presence within the band, such as a large vein or artery, the colorization may be skewed by these "dominant sources." These will show up as a bright red or green spot on the screen or dominant source artifacts.***

WARNING

Laser Hazard

All persons in the scan room must wear the laser protective eyewear provided by Seno to filter out laser light that may be released during scans.

Figure 3: Laser Hazard Reminder

Preparing to Scan

Preparing for Laser Emission

Safeguards have been designed into the Imagio Breast Imaging System to protect the User and the Patient from laser energy; however, it is the responsibility of the User to follow all Warnings and Cautions outlined in this manual. Refer to the safety alerts on page 4.

When the Imagio Breast Imaging System is first powered up, the OA/US Probe is in standby mode and is not emitting laser power.

All Three (3) conditions must be met to enable laser emission from the OA/US Probe:

(1) The System must be in OA mode.

(2) The User must have entered the Laser Control password (Laser ENABLED).

(3) The foot switch must be pressed.

⚠***WARNING:*** Invisible laser light is emitted from the OA/US Probe. Reflected and/or misdirected laser light may damage eyes.

- Never use any controls or adjustments or performance settings other than those specified herein.
- The Patient, the Imagio Breast Imaging System User, 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 OA/US Probe is out of its holder. Refer to Chapter 2.4.12 Laser Protective Eyewear. 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 Probe, and calibrating laser energies or any other time the Imagio Breast Imaging System is powered on and the OA/US Probe is removed from the probe holder.
- Never look directly at the laser beam even when laser protective eyewear is being worn.
- Never 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 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 Probe from the skin or holder/sheath.
- Always follow the laser safety precautions prior to laser emitting to protect the Patient, User, and Observers.
- Always place the OA/US Probe in the OA/US Probe holder when not in use. This OA/US Probe holder is designed to minimize the release of laser light due to an unintentional activation of the foot switch.

QUICK REFERENCE

General Instructions

(1) Ensure there is laser protective eyewear for each person in the scan room. If there will not be enough pairs of Seno approved laser protective eyewear for each person in the scan room during the scan, you must ask unprotected personnel to leave the scan room during the scan.

(2) Inspect the OA/US Probe cables and connections for damage before use.

(3) Inspect the face of the OA/US Probe before use to ensure the glass windows are not scratched or broken and there is no visible damage to the acoustic lens.

(4) Never allow the Patient to touch the Imagio Breast Imaging System Console at any time.

(5) Avoid ink marks on the skin (ink may interfere with imaging).

(6) Do not use the OA/US Probe on area(s) with open wounds.

(7) The Imagio Breast Imaging System OA/US Probe face is larger than standard Grayscale Ultrasound Probes, so it is important to maintain complete surface contact of the OA/US Probe face against the skin while acquiring images, keeping the Patient's comfort in mind always.

Reloading Presets

The Imagio Breast Imaging System is preloaded with parameters optimized for breast imaging.

To Reload the Imagio Breast Imaging System Breast Imaging Presets

- On the touch screen, press Presets → Breast Imaging → General

Prepare the Exam Table

⚠***WARNING:*** Operation of the Imagio Breast Imaging System can only be performed by trained users. Unauthorized use may cause injury.

- Never allow the Patient to touch the Imagio Breast Imaging System Console.
- Never share your password with anyone. Only trained users can use the Imagio Breast Imaging System.
- Always disable the laser by pressing the touch screen Laser Control button when the Imagio Breast Imaging System will be left unattended.

Preparing Patient for Scan

(1) Instruct the Patient and everyone in the scan room to wear the provided Seno approved laser protective eyewear and to keep them on until told otherwise.

(2) Inform the patient and everyone in the scan room that there will be potentially harmful laser radiation emitting from the OA/US Probe.

(3) Assist the Patient onto the exam table.

(4) Ensure that the Patient is wearing the Seno approved laser protective eyewear for the Patient.

(5) Enable the Laser by pressing the Laser Control button on the touch screen and entering the password.

(6) Apply the Seno approved exam gel to the Patient.

OA Scan Overview

(1) View the Monitor Six-Up OA image display:

Note: *Upon initial entry into OA Mode, the OA imaging areas will be blank until the foot switch is pressed and OA images are acquired.*

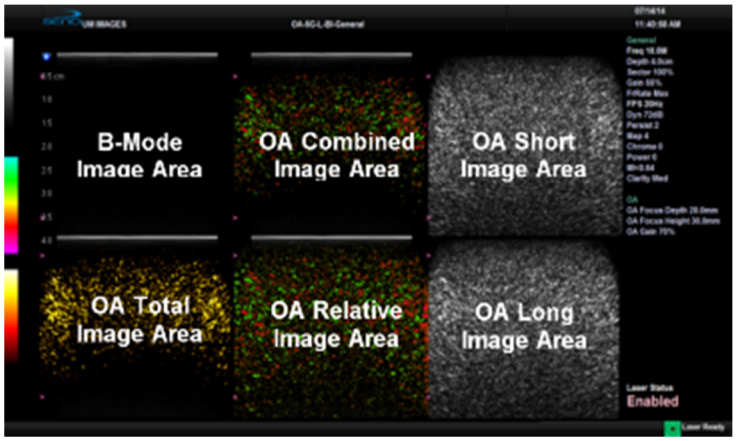


Figure 4: Six-Up Display

(2) View the "B-Mode Image Area" and locate the lesion by observing the B-Mode image.

(3) As a secondary check to ensure the laser has been enabled, verify that the ***Laser Ready*** icon appears on the Display Monitor.

(4) Ensure that the OA/US Probe is in full contact with the patient's skin at the suspected lesion location ensuring that a small but sufficient amount of exam gel has been applied to allow smooth OA/US Probe movement.

(5) Press the foot switch completely and fully to the floor to initiate the OA scan.

The following occurs:

(6) OA/US Probe emits pulses of laser energy that are applied directly to the tissue.

(7) Laser emission intermittent tone sounds.

(8) Laser Ready icon changes to Laser Emitting icon.

(9) Laser Emitting LED on the upper display bezel is illuminated.

(10) Live OA image(s) appear on the Display Monitor.

IMPORTANT: ***Only apply enough gel to obtain a diagnostic quality image. Avoid gel stand-off.***

IMPORTANT: ***The User should apply standard pressure while performing OA imaging in accordance with established imaging guidelines.***

IMPORTANT: ***If too much pressure is applied to the skin, the underlying blood vessels may be compressed causing diminished blood volume within those vessels resulting in poor imaging.***

IMPORTANT: ***If too little pressure is applied, poor image quality may result***

IMPORTANT: ***During live imaging, move the OA/US Probe slowly in a manner similar to customary Greyscale Probe movement to avoid potential misregistration of the OA colorization and ultrasound greyscale display.***

(11) Slowly move the OA/US Probe over the suspected lesion area while viewing the OA image on the Display Monitor. Move the OA/US Probe in a manner similar to customary Greyscale

Probe movement. Refer to Appendix I: General Guidelines for OA/US Scanning for specific recommended scan technique and captures.

(12) To minimize dominant source and out-of-plane laser absorber effects, if necessary, do the following:

- Attempt to move the OA/US Probe in such a way that any dominant sources are outside of the image area.
- If necessary, adjust the upper and lower OA focus lines on the image area using the OA Focus Line mode.

(13) When OA/US Probe movement is stopped, and the image is frozen, identify and annotate the region of interest.

(14) To stop image updating, press the ***System Console*** ❄ ***Freeze button***. Press the ***System Console*** ❄ ***Freeze button*** again to toggle back to live imaging.

(15) To record and image and save it to the patient's file, press the ***1 button*** on the System Console.

To Stop OA

⚠***WARNING:*** Invisible laser light is emitted from the OA/US Probe and reflected and/or misdirected laser light may damage eyes.

- Always release the foot switch before removing the OA/US Probe from the skin or holder/sheath.

---

(1) The foot switch may be released at any time to pause during the scan. This will also stop the laser light emission from the OA/US Probe. The last OA image displayed will remain displayed.

(2) Place the OA/US Probe securely in the OA/US Probe holder. End the Exam if Patient Data was entered.

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

Introduction

Overview

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

This manual contains:

- Quick Reference
- Intended Use
- Online Access to Imagio Breast Imaging System User Manual on the Imagio® Breast Imaging System.
- 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 power calibration and optional machine checks

Who Should Use This Manual

This user manual is a reference for users 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. The Imagio Breast Imaging System is restricted for use by individuals who have completed formal training. Each trained and authorized Imagio Breast Imaging System user receives a certificate, located in Appendix E: Product Specifications, upon successful completion of the Imagio® Breast Imaging System Training Program.

Formal System training from Seno personnel or their agents combined with the information in this manual contain necessary and sufficient 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. Pay special attention to the information in the Alerts Safety section. Keep this manual with the equipment at all times. Periodically review the procedures for operation and safety precautions.

INTRODUCTION

Permissible/Impermissible Impairments for users of the system

Permissible impairments include:

- Latex allergy

Impermissible impairments include:

- Vision impaired persons without corrections.
- Persons unable to firmly and steadily grip an OA/US Probe.
- Persons unable or unwilling to wear laser safety protective eye wear.
- Color blindness.
- Persons with difficulty standing.

Safety, EMC, and Regulatory Compliance

Laser Safety

The facility should check and abide by any country/state regulations as pertaining to our laser classifications noted below.

Laser Classification

The Imagio Breast Imaging System uses an Nd:YAG 1064 nm 5-25 ns pulse and an Alexandrite 757 nm 50-100 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 Class 3B laser beams emitted by the Imagio Breast Imaging System can cause loss of sight.
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

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)	Rectangular 4.3 x 1.6	Rectangular 4.3 x 1.6
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)	7	50
Beam Divergence (mrad)	560 x 980	560 x 980
Beam Diameter (cm) @ 10cm Viewer Distance	7.0 x 10.0	7.0 x 10.0

- (1) (+/-10nm)
- (2) Contiguous output windows: Total Area 4.3cm x 1.6cm. Note that the actual area of the probe is 4.3 cm x 3.3 cm
- (3) Maximum Energy Probe Output (85mJ+/-20%): 102mJ

Ocular Exposure		
Specified Parameter	Laser YAG (1064nm)	Laser Alexandrite (757nm)
Irradiance @ 10cm (mW/cm^2)	7.28	7.28
MPE_CW ($\mu W/cm^2$)	9.4	1.17
Radiant Exposure @ 10 cm (mJ/cm^2)	1.46	1.46
MPE_Repetitive-Pulse ($\mu J/cm^2$)	1.88	0.23
Energy/Pulse Thru 7mm Aperture(J)	560×10^{-6}	560×10^{-6}
Class 3B AEL (J)	62.5×10^{-3}	37.2×10^{-3}
Laser Class	3B	3B
Viewing Condition	Unaided Viewing	Unaided Viewing
Necessary OD @ 10cm Viewer Distance	2.9	3.8
Nominal Ocular Hazard Distance (m)	3.14	8.9
Skin Exposure		
Specified Parameter	YAG Laser (1064nm)	Alexandrite Laser (757nm)
MPE Skin (mJ/cm^2)	100	25.2
Seno Level Radiant Exposure @ 0cm (mJ/cm^2) (4)	14.8	14.8
Necessary OD	None	None

- (4) Skin Exposure at the output of the Probe with Uniform Energy Distribution

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.

Laser Cooling System

The laser cooling system is filled with distilled water. The 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. Refer to Figure 93: Adding Distilled water to Laser Coolant Reservoir.

Device Information Standards and References:

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
ISO 14971:2012	Medical devices – Application of risk management to medical devices.
IEC 62304	Medical device software - Software life cycle processes
EN ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
IEC 62366	Medical devices - Part 1: Application of usability engineering to medical devices
D4169-09	Standard Practice for Performance Testing of Shipping Containers and Systems
ISO 15223-1	Medical devices - Symbols to be used with medical device 15labels, labelling, and information to be supplied - Part 1: General requirements

ISO 15223-2	Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation
IEC 60878	Graphical symbols for electrical equipment in medical practice
EN 1041	Information supplied by the manufacturer of medical devices
EN 980	Symbols for medical device labelling
ISO 15459-2	Information technology -- Automatic identification and data capture techniques -- Unique identification -- Part 2: Registration procedures
ISO 15459-4	Information technology -- Automatic identification and data capture techniques -- Unique identification -- Part 4: Individual products and product packages
ISO 15459-6	Information technology -- Automatic identification and data capture techniques -- Unique identification -- Part 6: Groupings
EN 50419	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)
FDA Final Guidance 560	Marketing Clearance of Diagnostic Ultrasound Systems and Transducers Guidance for Industry and Food and Drug Administration Staff JUNE 2019

INTRODUCTION

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 B Applied Part: OA-16-1S Probe
  - Type BF Applied Part: US/L-14-5 Probe
  - Electrical Ratings: 220-230V~, 50/60Hz, 20A
  - OA duty cycle: 10 minutes ON / 10 minutes OFF
  - Laser Output energy accuracy: +/- 20%
  - Ingress Protection: The Imagio Breast Imaging System IP20
  - Ingress Protection: Footswitch: IPX6

Electrical Rating and Warnings

Electrical Rating: 220-230VAC, 50/60Hz, 20A

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

IMPORTANT: ***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.***

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 Appendix D: Guidance and Manufacturer's Declaration.

Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.

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 the IEC/EN 60601-1-2.

INTRODUCTION

The Imagio Breast Imaging System can radiate radio frequency energy and may cause interference with other equipment in the same area. Refer to Appendix D: Guidance and Manufacturer's Declaration.

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 is not to be connected directly to the public supply electrical network.
- 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.

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.

Emissions and Immunity Information

Please refer to Appendix D: Guidance and Manufacturer's Declaration for the Imagio Breast Imaging System emissions and immunity tables.

Environmental Requirements

Temperature

- 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

Decommissioning and Disposal

The Imagio Breast Imaging System must not be disposed of as unsorted municipal waste and must be collected separately. Please notify an authorized representative of Seno Medical for information concerning the decommissioning of your equipment.

Regulatory Requirements

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

INTRODUCTION

The facility's Laser Safety Officer is responsible for verifying and complying with local regulatory requirements concerning the use of lasers in the facility.

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 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

IMPORTANT: ***The MI and TI are displayed to the right of the image field. All thermal and mechanical indices are below 1.0 for the OA-16-1S Probe and below 1.06 for the US/L-14-5 for all device settings.***

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.

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

American Institute of Ultrasound in Medicine

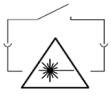
14750 Sweitzer Lane, Suite 100

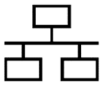
Laurel, Maryland 20707-5906

USA telephone: 1-800-638-5352 or 301-498-4100

Symbols and Markings Glossary

Table 1. Symbols and Markings Glossary

Symbol / Marking	Definition
	Manufacturer
	Date of Manufacture
	Authorized Representative in the European Community
	Catalogue number
	Serial number
	General warning sign
	Warning; Laser beam
	Emergency Laser Stop
	Refer to instruction manual/booklet
	Wear eye protection
	Type B applied part
	Type BF applied part
	Alternating current
	Optical fiber applicator
	Foot switch
	Remote interlock connector

Symbol / Marking	Definition
	**Equipotentiality**
	**Computer network**
	**"OFF" (power)**
	"ON" (power)
	**Filling**
	**Draining; emptying**
	**Valve; shut-off element**
	**Mass; weight**
IPN_1N_2	**Ingress Protection Mark**
	WEEE Mark 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 your equipment. Note: Only relevant for EU!
Rx Only	**Rx Only Mark**
CE 2797	**CE Conformity Mark**
	**ETL Mark**

Documentation Access

Users can access the Imagio Breast Imaging System User Manual via the Settings button.

IMPORTANT: ***Documentation will not open if a dialog box is open (e.g., Exam Management).***

To Access Documentation

(1) Ensure the main touch screen is visible and that all dialog boxes on the Display Monitor are closed.

(2) Press the Touch Screen Settings button.

(3) Select Documentation on the User Settings window.

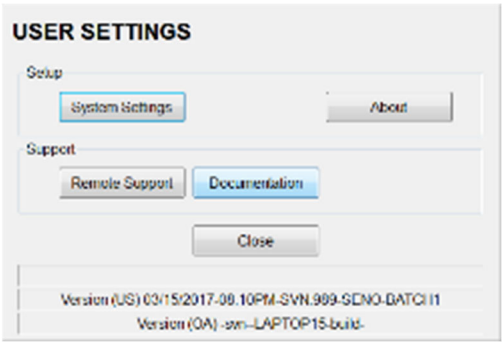


Figure 5: Documentation

To Close Documentation

(1) Select the "X" in the upper right corner of the viewer window.

(2) Select Close on the User Settings window.

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 Imagio 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 and subsequent BI-RADS category.

Chapter 2: Imagio® Breast Imaging System

2.1 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 users in assessing BI-RADS classifications.

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

2.2 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 women 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 user 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.

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

Table 2. Probe Intended Use and Indications

System	Imagio® Breast Imaging System						
Probe	OA-16-1S Probe						
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	M	PWD	CWD	Color/Power Doppler (CD/PD)	Combined	OA
Small Organ: Breast	Yes	No	Yes	No	Yes	Yes	Yes
Probe	US/L-14-5 Probe						
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	M	PWD	CWD	Color/Power Doppler (CD/PD)	Combined	OA
Small Organ: Breast	Yes	No	Yes	No	Yes	Yes	No

*Marketing Clearance of Diagnostic Ultrasound Systems and Transducers Guidance for Industry and Food and Drug Administration Staff Document issued on: June 27, 2019

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 (i.e., breast implants within the previous 12 months, or tattoos).
- 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 suspicious mass within the past 18 months (benign excisional biopsy not within immediate the Imagio® Breast Imaging System field-of-view will not exclude the patient). The benefits and risks of use of the system are always to be weighed by the treating physician, however: Should a patient have had a benign excisional breast biopsy within the immediate vicinity of the currently evaluated suspicious mass within the last 18 months, it is recommended that a physician weigh the benefits of the procedure against the possible risks of excessive scar tissue and acoustic noise on image(a benign excisional biopsy not within the immediate field-of-view of the Imagio Breast Imaging System may not exclude the patient).
- Has greater than three suspicious lesions.
- Lesion(s) of interest is greater than 4 cm.
- Currently has mastitis.
- Has focal pain without thickening or mass.
- Is pregnant or lactating.

- Has open sores including insect bites, rash, poison ivy, and 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 non removal nipple ring when the mass is <4cm from the nipple.
- Has applied fragrance or lotion on the skin where the probe will be applied.

2.2.1 Contraindications

Absolute contraindications are as follows:

- Is pregnant
- Has open sores including insect bites, rash, poison ivy, and 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.

2.3 The Imagio Breast Imaging System Weight and Dimensions

Refer to Appendix E: Product Specifications.

2.4 The Imagio Breast Imaging System Components

Opto-acoustic (OA) is an imaging modality that uses pulses of laser light to produce imaging data in a medical environment. The Imagio Breast Imaging System utilizes this new modality to create images of tissue and then present those images on a display as well as record them for future reference. The Imagio Breast Imaging System provides a tool with which Imagio Breast Imaging System users may gain additional information about not only the presence of lesions within the tissue of interest but also whether those lesions may be malignant or benign.

The displays of the Opto-acoustic images include the addition of colors to the images to show where the laser light energy has been absorbed by structures within the tissue of interest. The relative amounts of absorption of the laser light by the tissue components can be related to the amount of blood content in and around a lesion and can even be related to the oxygenation level of that blood. This information can be used to assist in determining the tissue characteristics.

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

Figure 6: The Imagio Breast Imaging System Components

See Appendix C: Supplies and Accessories for a list of Seno approved accessories.

2.4.1 Cart

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

2.4.2 Key Switch

A key switch is used to power the Imagio Breast Imaging System ON and OFF. The removable key switch is a feature to prevent unauthorized access to the Imagio Breast Imaging System. Remove the key from the switch when the Imagio Breast Imaging System is not scheduled for scans.

Figure 7: Key Switch

2.4.3 System Console

The System Console is the User interface for entering patient data, exam settings, and for performing the exam. The System Console, mounted on an adjustable arm, consists of a key switch, buttons, trackball, touch screen, two (2) USB ports. (The USB ports are for connecting a removable flash drive to transfer patient scan data), and a Laser Emergency Stop button (used for deactivating the lasers).

Figure 8: System Console

Figure 9: Key Switch & USB Ports

Figure 10: Emergency Stop

2.4.4 OA/US Probe

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

The laser radiation is produced in the Imagio Breast Imaging System Laser Head and exits via the fiber optic cable at the OA/US Probe through two parallel bundles of optical fibers.

The output of each laser resonator is coupled together through two combining mirrors so that both laser beams are co-registered. The beams are then projected through an aperture to ensure that the laser subsystem output beam diameter is correct. Laser then travels through fused fiber optics to the OA/US Probe port where the light is coupled, via the threaded OA/US Probe Connector, to the bundles of optical fibers in the fiber optic cable.

The output from the fiber bundles is coupled to a window with a Light Shaping Diffuser (LSD) to fill the area of a window interface to the skin. A fiber optic bundle is placed on each side of the ultrasound probe (the acoustic portion of the probe), and the OA/US Probe end surface is in direct contact with the skin surface. The combination of the LSD and total internal reflection of the laser light inside the glass windows produces two uniform, flat top rectangular shaped laser beams.

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

Figure 11: OA/US Probe

2.4.5 Display Monitor

The Display Monitor displays the Opto-acoustic (OA) images detected by the Imagio Breast Imaging System OA/US Probe during the exam. The Display Monitor is mounted on an adjustable arm.

Figure 12: Display Monitor

2.4.6 Foot Switch

The laser foot switch controls the emission of the Imagio Breast Imaging System laser. OA images will be displayed if the laser is enabled and the foot switch pressed.

Figure 13: Foot Switch

2.4.7 Laser Emergency Stop Button

Pushing the laser emergency stop button (E-Stop) deactivates the Imagio Breast Imaging System laser.

Figure 14: Emergency Stop

2.4.8 Power Cord

A 4.5 meter (15 foot) power cord is supplied with the Imagio Breast Imaging System.

2.4.9 Ethernet Cable

A 4.5 meter (15 foot) Ethernet cable is provided for connection to a site-provided RJ45 network connection jacks to enable Internet access for uploading the Imagio Breast Imaging System images to the site's Picture Archiving and Communication System (PACS).

2.4.10 Wheel Lock

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. Call the local service provider before moving the Imagio Breast Imaging System out of the scanning room.

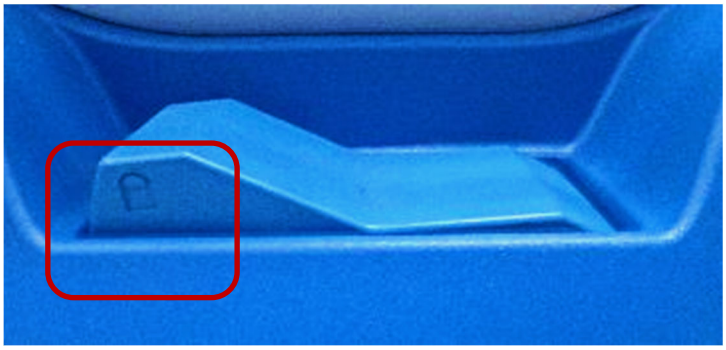


Figure 15: Wheel Lock – Locked and Not Moveable

Figure 16: Wheel Lock – Unlocked and Moveable

2.4.11 Flat Breast Phantom

The Phantom Box contains an Opto-acoustic (OA) Flat Breast Phantom used during the Imagio Breast Imaging System Machine Check optional procedure.

Call Seno Service with any Imagio Breast Imaging System image or performance concerns. Thus, Seno Service rather than the user will determine whether suboptimal performance is related to phantom degradation or suboptimal machine performance.

2.4.12 Laser Protective Eyewear

⚠***WARNING:*** Invisible laser light is emitted from the OA/US Probe. Reflected and/or misdirected laser light may damage eyes.

- Never use any controls or adjustments or performance settings other than those specified herein.
- The Patient, the Imagio Breast Imaging System User, 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 OA/US Probe is out of its holder. 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 Probe, and calibrating laser energies or any other time the Imagio Breast Imaging System is powered on and the OA/US Probe is removed from the probe holder.
- Never look directly at the laser beam even when laser protective eyewear is being worn.
- Never 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 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 Probe from the skin or holder/sheath.
- Always follow the laser safety precautions prior to laser emitting to protect the Patient, User, and Observers.
- Always place the OA/US Probe in the OA/US Probe holder when not in use. This OA/US Probe holder is designed to minimize the release of laser light due to an unintentional activation of the foot switch.

The Seno laser protective eyewear has been specifically selected for two main reasons:

(1) Designed to protect the User, Patient, and Observers from the specific wavelengths of the Imagio Breast Imaging System laser
(2) Designed to prevent interference with reading images

There are specific styles of eyewear only for the user 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.

IMPORTANT: ***Minimal laser protective eyewear of OD4 or greater provides protection for the 1064 nm wavelength and OD5 or greater for the 757 nm wavelength.***

IMPORTANT: ***Seno has designated the exact 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.***

2.4.13 Laser protective eyewear for the User and Observer

The four styles of laser protective eyewear are only for the User and Observers. There are three different frame styles to accommodate different facial dimensions and one for individuals wearing glasses.

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 the local service provider. It is recommended users always wear eyewear with clean lenses.

Direct Wear

For User and Observer Only

Laser Protective Eyewear

Over Framed RX

For User and Observer Only

Laser Protective Eyewear

Direct Wear / Patient, User, or Observer Can Wear This "*Goggle*" Style / Laser Protective Eyewear

Figure 17: User Laser Protective Eyewear

They provide protection against stray laser light during an Imagio Breast Imaging System scan and must be worn by each patient. 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 the local service provider.

IMPORTANT: ***The direct wear goggle style laser protective eyewear is only style permitted to be worn by the Patient.***

"*Goggle*" Style

Patient Only

Laser Protective Eyewear

Figure 18: Patient "*Goggle" style* Laser Protective Eyewear

2.4.14 US/L-14-5 Probe

An US/L-14-5 Probe or 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.

Table 3. US/L-14-5 Probe Specification

Frequency Range	14 – 5 MHz
Probe Category	Breast
Focal Range	2 - 9 cm
Image Field	16 mm

Figure 19: US/L-14-5 Probe

2.4.15 Keyboard

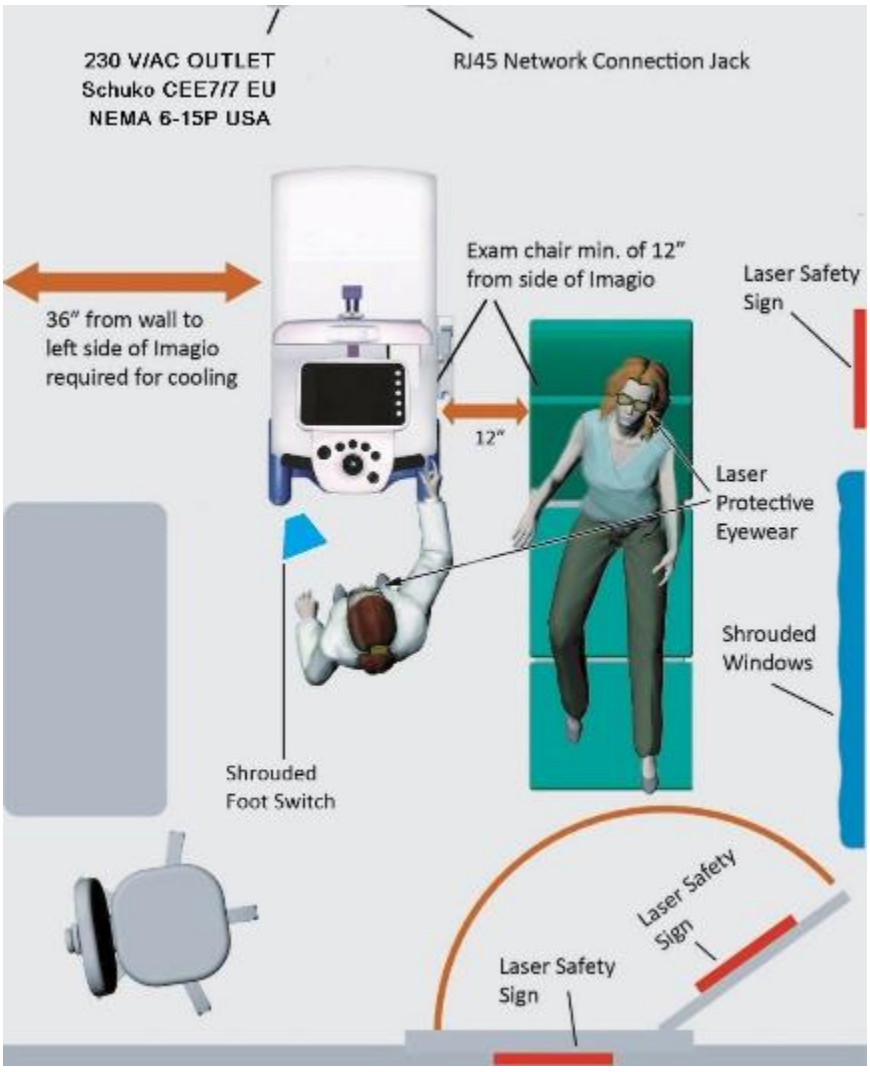
A physical keyboard is available if the user prefers a traditional tactile QWERTY keyboard. Notify a Seno Medical representative.

Figure 20: Keyboard

Chapter 3: Scan Room & The Imagio Breast Imaging System Preparation

It is recommended the user prepare the scan room and Imagio Breast Imaging System before the first scan of the day.

IMPORTANT: ***The Imagio Breast Imaging System lasers can take up to 14 minutes to reach operating temperature.***



WARNING
Laser Hazard

All persons in the scan room must wear the laser protective eyewear provided by Seno to filter out laser light that may be released during scans.

Figure 21: Example Scan Room Layout

SCAN ROOM & THE IMAGIO BREAST IMAGING SYSTEM

3.1 Positioning / Moving 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. Call the local service provider before moving the Imagio Breast Imaging System out of the scanning room.

3.1.1 Maintain minimum distances from the Imagio Breast Imaging System for proper airflow and patient comfort:

- 31 cm (12”) from Probe Holder side of the Imagio Breast Imaging System
- 92 cm (36”) from Key Switch side of the Imagio Breast Imaging System

3.2 Confirm Laser Safety Items

3.2.1 Signs, Safety Labeling, Notices, and Laser Protective Eyewear

- Verify that the Laser Warning Sign, provided by your Laser Safety Officer, and is affixed to the outside of each door leading into the scan room. This is to warn people not to enter the room without laser protective eyewear. Scattered laser radiation may be emitted from the OA/US Probe during an exam and cause potential harm to anyone not wearing designated laser protective eyewear.

Figure 22: Example of a Laser Warning Sign

- Verify that a Laser Warning Sign is also displayed near the Imagio Breast Imaging System and is visible to the System User and the Patient. This is to remind the Patient, User, and Observers of the hazards of lasers.
- Verify safety labeling and notices are in place on the Imagio Breast Imaging System.
- Verify that Seno provided laser protective eyewear is available for the Patient, User, and Observers. Everyone in the scan room must wear the Seno provided laser protective eyewear when the Imagio Breast Imaging System is powered on and the OA/US Probe is not in its holder.

IMPORTANT: ***Equipment safety labels and displaying laser warning signs are LASER SAFETY REQUIREMENTS.***

3.2 Ensure Proper Environmental Operating Conditions

IMPORTANT: ***The following environmental requirements are generally met to ensure the Imagio Breast Imaging System is being operated in conditions outside of required environmental conditions. Notify your Facility Engineer if there are environmental concerns.***

Table 4. Environmental Requirements

Operating Temperature Range	10 °C to 30 °C (50 °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

Chapter 4: OA-16-1S Probe and US/L-14-5 Probe

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 that would be the responsibility of the facility for repairs or replacement.

⚠***WARNING:*** Do not place an unclean and non-disinfected probe in its holder or any protective carrying case as cross-contamination may occur.

4.5.1 Exam Gel

AQUASONIC CLEAR® Acoustic Transmission Gel by Parker Labs is the approved exam gel to be used with the OA/US Probe.

4.5.2 Holding the OA/US Probe

The technique for holding the OA/US Probe is a User preference; however, the following conditions must be met:

- The face of the OA/US 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 Probe.
- The amount of pressure should be just enough to make full contact with the tissue across full surface of the OA/US Probe 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, the risk of accidental laser light emissions may occur in addition to poor image quality.

Location of Element #1

A protrusion indicates the side of the OA/US Probe where Channel/Element #1 is located. The protrusion assists the user in orienting the probe during scanning.

4.5.3 Avoid Emitting Stray Laser Beams

Handle the OA/US Probe cautiously always being aware of the direction of the face of the OA/US Probe where the laser light is emitted. For best practice, avoid aiming the OA/US Probe unnecessarily at the Patient, User, and Observers, and highly reflective surfaces that may reflect the laser light into someone's eyes. Exposure to laser beam reflections may be just as damaging as exposure to the primary beams.

4.6 OA/US Probe Holder

The OA/US Probe holder, located on the right side of the System Console, is specially designed with an OA/US Probe face cover to minimize accidental laser emission should the foot switch be unintentionally pressed. The OA/US Probe is stored in the OA/US Probe holder.

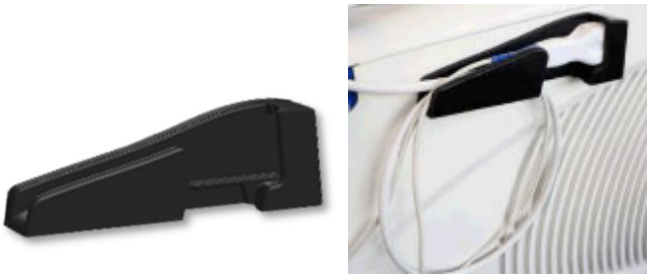


Figure 25: The Imagio Breast Imaging System OA/US Probe Holder and Probe/Cable Routing

4.7 US Probe Holder for the US/L-14-5 Probe

The US Probe holder is located on the front of the System Cart Handle and is designed to only accommodate the US Probe, provide a gel bottle holder, marker holder, OA/US Probe fiber optic cable guidance and US Probe cable storage features.

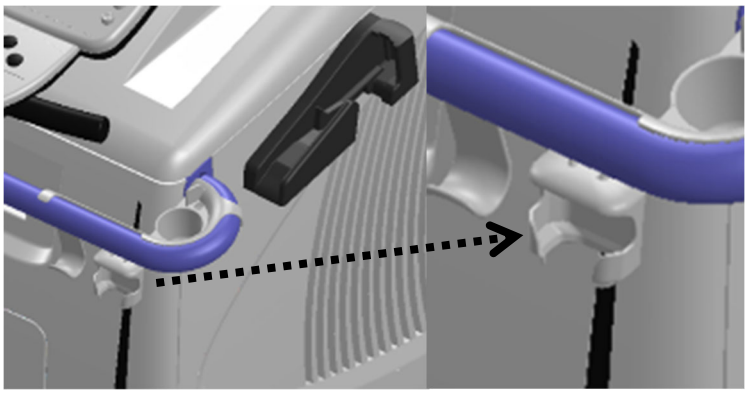


Figure 26: The Imagio Breast Imaging System US Probe Holder

Chapter 5: Cleaning System Components

The following cleaning and disinfectant agents have been tested by Seno. They are the only cleaners/ disinfectants approved by Seno to clean the probe holder, calibration port, OA/US calibration probe adapter, and clean and disinfect the probes.

> ⚠ ***CAUTION:*** The cleaning and disinfection instructions contained within are not suitable to remove blood from the surface of the probe/transducer.

For more detailed information, reference the manufacturer's directions for use labeling affixed to each cleaner/ disinfectant agent. **The following cleaning and disinfectant agents have been tested by Seno. Again, these are the only cleaner disinfectant approved by Seno to clean and disinfect :**

- Sani Cloth® AF3 is approved for use in the U.S.A only. http://pdihc.com .
- CaviWipes™ US is approved for use in the U.S.A only. http://www.metrex.com .
- CaviWipes™ EU is approved for use in the European Union only. http://www.metrex.com/EU/.

To order: Refer to Appendix C: Supplies and Accessories.

USE ONLY SENO APPROVED CLEANER DISINFECTANTS:

Figure 27: Cleaner/ Disinfectant for cleaning the probe holder, calibration port, OA/US calibration probe adapter, and to clean and disinfect the probes.

⚠*WARNING &* ⚠*CAUTION:*

Unapproved cleaner disinfectants are <u>NOT</u> permitted and may cause Imagio® Breast Imaging System damage.

- ***There are many cleaners and disinfectants available that may appear similar to Seno approved cleaner disinfectant.*** Use only Seno approved cleaners and cleaner disinfectant.

DO NOT USE UNAPPROVED CLEANER DISINFECTANTS

(examples of <u>unapproved</u> cleaner disinfectants):

Figure 28: Examples of Unapproved Cleaner Disinfectants

5.1 Inspecting, Cleaning, and Disinfecting, the OA/US and Ultrasound Probes

Use Seno approved cleaning and disinfecting agents only. Both the US and OA/US probe are sensitive and may easily be damaged by harsh cleaning agents, corrosive chemicals or mishandling. Always use care when handling the probes. See Chapter 0 4.3 Probe Care and Handling

The following generalized instructions for inspecting, cleaning, and disinfection are indicated for use with the probes. The definition of cleaning is the elimination of soil or other contaminants seen on the probe. The probe must be cleaned after each use for further disinfection. The definition of disinfection is the process of cleaning something, especially with a chemical, in order to destroy bacteria. It is recommended that between each patient, the probe is inspected, cleaned and disinfected.

The functional life of the probe has been robustly tested and its functionality is 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. Therefore, it is important that the face of the probe is thoroughly inspected for damage such as that mentioned in subchapter 5.1.1 Inspecting the Probe, step (2), below.

5.1.1 Inspecting the Probe

(1) **<u>Disable the laser</u> by pressing the touch screen Laser Control button 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 cart.***

(2) Examine the probe face for damage, especially breaks/chips in the acoustic lens and glass windows of the probe, as well as 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 the local service provider if damage is observed.

(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.

Figure 29: Examine Probe for Damage

Figure 30: Example of a Good OA/US and Ultrasound Probe Face

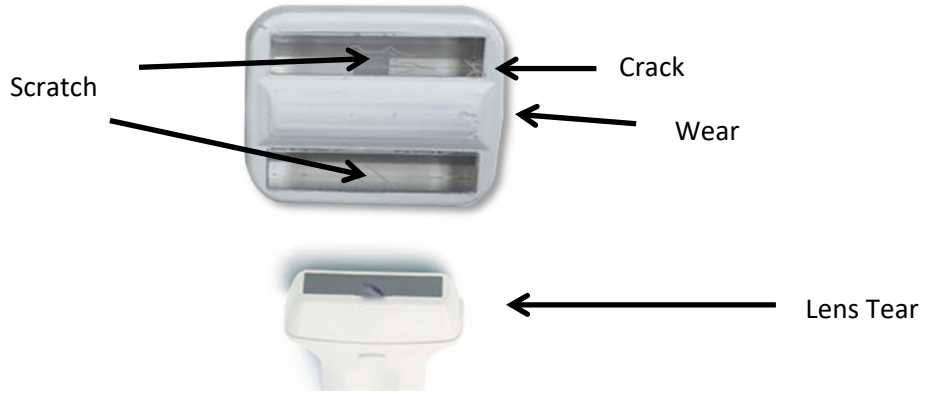


Figure 31: Example of a Bad OA/US and Ultrasound Probe Face

5.1.2 Manual Cleaning and Disinfecting the OA/US and Ultrasound Probes with Sani-Cloth® AF3 Germicidal Disposable Wipe

- **Sani Cloth® AF3 Germicidal Disposable Wipe is approved for use in the U.S.A only** http://pdihc.com. To order: Refer to Appendix C: Supplies and Accessories.

(1) Wear barrier protective gloves before using the Seno Medical-approved cleaner disinfectant.

(2) Remove the probe from the probe holder and place in a secure location to avoid accidentally damaging the probe.

(3) Wipe the internal surface of the probe holder and continue until all visible soil is removed using the Sani-Cloth® AF3 Germicidal Disposable Wipe.

5.1.2.1 Manual Cleaning Instructions

(4) Use Sani-Cloth® AF3 Germicidal Disposable Wipe to clean all surfaces of the probe.

(5) Wipe the probe cable using the Sani-Cloth® AF3 Germicidal Disposable Wipe. Avoid applying liquid to the electrical connection end.

(6) Wipe the external surface of the probe for a minimum of two (2) minutes and continue until all visible soil is removed. While wiping, give particular attention to crevices and hard-to-clean areas. Replace soiled towelettes as needed and use additional towelettes to ensure that all surfaces are uniformly cleaned.

(7) Visually inspect the probe for the absence or presence of remaining soil in a well-lit area. While inspecting, give particular attention to verifying soil has been removed from the hard-to-clean areas. If soil is present, then repeat the manual claening steps until all visible soil is removed.

5.1.2.2 Disinfection Instructions

(8) Use Sani-Cloth® AF3 Germicidal Disposable Wipe to disinfect the surfaces of the probe.

(9) Thoroughly wipe the the surfaces of the probe for two (2) minutes and then allow the surfaces to remain visibly wet for a minimum of three (3) minutes.

During the two (2) minute wipe time, use a disinfecting towelette to thoroughly wipe crevices and hard to disinfect areas.wipe the face of the probe and any other surface whih may have come into contact with the patient or caregiver. If needed use additional wipes to ensure the surfaces remain wet for the three (3) minute wet contact time.

(10) After disinfection, submerge and rinse the probe section with fresh sterile water for one (1) minute. Repeat rinse four (4) additional times using fresh sterile water for a total of five (5) rinses.

(11) Wipe the probe dry using lint free wipes.

(12) Visually inspect the probe to ensure all surfaces are dry. Do not use paper towels or other paper products on or near the face of the probe. Repeat the drying steps if any moisture is visible.

5.1.3 Manual Cleaning and Disinfecting the OA/US and Ultrasound Probes with CaviWipes™ Cleaner and Disinfectant Towelette

- **CaviWipes™ US Cleaner and Disinfectant Towelette is approved for use in the U.S.A only**. http://www.metrex.com. To order: Refer to Appendix C: Supplies and Accessories.
- **CaviWipes™ EU Cleaner and Disinfectant Towelette is approved for use in the European Union only**. http://www.metrex.com/EU/. To order: Refer to Appendix C: Supplies and Accessories.

(13) Wear barrier protective gloves before using the Seno Medical-approved cleaner disinfectant.

(14) Remove the probe from the probe holder and place in a secure location to avoid accidentally damaging the probe.

(15) Wipe the internal surface of the probe holder and continue until all visible soil is removed using the CaviWipes™ US Cleaner and Disinfectant Towelette.

5.1.3.1 Manual Cleaning Instructions

(16) Use Wipe the probe cable using the CaviWipes™ US Cleaner and Disinfectant Towelette. Avoid applying liquid to the electrical connection end.

(17) CaviWipes™ US Cleaner and Disinfectant Towelette to clean all surfaces of the probe.

(18) Wipe the external surface of the probe and continue until all visible soil is removed. While wiping, give particular attention to crevices and hard-to-clean areas. Replace soiled towelettes as needed and use additional towelettes to ensure that all surfaces are uniformly cleaned.

(19) Visually inspect the probe for the absence or presence of remaining soil in a well-lit area. While inspecting, give particular attention to verifying soil has been removed from the hard-to-clean areas. If soil is present, then repeat the manual cleaning steps until all visible soil is removed.

5.1.3.2 Disinfection Instructions

(20) Use CaviWipes™ US Cleaner and Disinfectant Towelette to disinfect the surfaces of the probe.

(21) Thoroughly wipe the the surfaces of the probe and allow the surfaces to remain visibly wet for a minimum of three (3) minutes. During the three (3) minute wipe time, use a disinfecting towelette to thoroughly wipe crevices and hard to disinfect areas. If needed use additional wipes to ensure the surfaces remain wet for the three (3) minute wet contact time.

(22) After disinfection, submerge and rinse the probe section with running water for five (5) minutes. Repeat rinse four (4) additional times using fresh sterile water for one (1) minute each for a total of five (5) rinses.

(23) Wipe the probe dry using lint free wipes.

(24) Visually inspect the probe to ensure all surfaces are dry. Do not use paper towels or other paper products on or near the face of the probe. Repeat the drying steps if any moisture is visible.

5.2 Laser Protective Eyewear

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 the local service provider. It is recommended users always wear eyewear with clean lenses.

Use only mild soap, warm water, and soft cloth (typically provided with eyewear), or approved lens cleaning towelette to clean laser protective eyewear:

- Pyramex LCT100. Refer to Appendix C: Supplies and Accessories.

⚠***CAUTION:*** The Imagio Breast Imaging System laser protective eyewear has delicate lenses which may be easily damaged by misuse of cleaning agents and solvents.

- Never use cleaning solvents on the laser protective eyewear.
- Only use water and a soft cloth or approved lens cleaning towelettes.

Direct Wear

For User and Observer Only

Laser Protective Eyewear

Over Framed RX

For User and Observer Only

Laser Protective Eyewear

Direct Wear / Patient, User, or Observer Can Wear This "*Goggle*" Style / Laser Protective Eyewear

Figure 32: Laser Protective Eyewear

5.3 Probe Holder

Figure 33: Clean Probe Holder only with Seno approved cleaning and disinfecting wipes.

The following cleaning and disinfectant agents have been tested by Seno. They are the only cleaner disinfectants approved by Seno to clean and disinfect the Probe Holder.

- Sani Cloth® AF3 is approved for use in the U.S.A only. http://pdihc.com.
- CaviWipes™ US is approved for use in the U.S.A only. http://www.metrex.com.
- CaviWipes™ EU is approved for use in the European Union only. http://www.metrex.com/EU/.

To order: Refer to Appendix C: Supplies and Accessories.

5.4 Calibration Port – Sensor Face

Figure 34: Clean Calibration Port – Sensor Face only with Seno approved cleaning and disinfecting wipes.

The following cleaning and disinfectant agents have been tested by Seno. They are the only cleaner disinfectants approved by Seno to clean and disinfect the Calibration Port.

- Sani Cloth® AF3 is approved for use in the U.S.A only. http://pdihc.com.
- CaviWipes™ US is approved for use in the U.S.A only. http://www.metrex.com.
- CaviWipes™ EU is approved for use in the European Union only. http://www.metrex.com/EU/.

To order: Refer to Appendix C: Supplies and Accessories.

5.5 OA/US Probe Calibration Adapter

Figure 35: Clean OA/US Probe Calibration Adapter only with Seno approved cleaning and disinfecting wipes.

The following cleaning and disinfectant agents have been tested by Seno. They are the only cleaner disinfectants approved by Seno to clean and disinfect the OA/US Probe Calibration Adapter.

- Sani Cloth® AF3 is approved for use in the U.S.A only. http://pdihc.com.
- CaviWipes™ US is approved for use in the U.S.A only. http://www.metrex.com.
- CaviWipes™ EU is approved for use in the European Union only. http://www.metrex.com/EU/.

To order: Refer to Appendix C: Supplies and Accessories.

5.6 The OA Flat Breast Phantom

The following cleaning agents have been tested by Seno. This is the only cleaner approved by Seno to clean the OA Flat Breast Phantom.

- Sani Cloth® AF3 is approved for use in the U.S.A only. http://pdihc.com.
- CaviWipes™ US is approved for use in the U.S.A only. http://www.metrex.com.
- CaviWipes™ EU is approved for use in the European Union only. http://www.metrex.com/EU/.

To order: Refer to Appendix C: Supplies and Accessories.

- Clean the gel from the Flat Breast Phantom using the Seno approved wipes.
- If the OA Flat Breast Phantom has been removed from its storage box, place the OA Flat Breast Phantom in it's storage box.
- Cover the OA Flat Breast Phantom and return it to the designated storage location.

5.7 The Imagio Breast Imaging System Cart

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

- Water
- Mild detergent (PH level at or near 7) and water solution.

5.8 Display Monitor

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.

5.9 Display Monitor Screen

Apply a small amount of water to a soft, non-abrasive cloth. Stroke the cloth across the display in one direction, moving from the top of the display to the bottom.

- Water

5.10 Touch Screen

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

- Water
- 1% isopropyl alcohol

5.11 System Console

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

- Water
- Mild detergent (PH level at or near 7) and water solution
- 1% isopropyl alcohol

5.12 Foot Switch

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

- Water
- 70% isopropyl alcohol

5.13 Power Cord

⚠***WARNING:*** The Imagio Breast Imaging System contains dangerous voltages that are capable of serious injury or death.

- If any defects are observed or malfunctions occur, stop operating the Imagio Breast Imaging System. Call the local service provider. There are no user serviceable components inside the Imagio Breast Imaging System cart.
- Always connect the Imagio Breast Imaging System to supply mains with protective earth.
- Never touch the Patient and any exposed connector simultaneously.
- Never touch any exposed connector when a probe is in contact with the Patient.
- Never attempt to operate the Imagio Breast Imaging System if panels are removed or not properly attached.

- Never clean the power cord while it is plugged in to the mains power outlet or the Imagio Breast Imaging System.
- When unplugging the power cord from the wall, use the IEC fastener, not the cable.

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

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

- Water
- Mild detergent (PH level at or near 7) and water solution

Chapter 6: System Power ON/OFF

6.1 Powering On the Imagio Breast Imaging System

To Power on the Imagio Breast Imaging System

(1) Ensure that the Imagio Breast Imaging System is plugged into the proper MAINS power outlet.

(2) Ensure that the IEC connector is plugged into the Imagio Breast Imaging System located on the back bottom of the Imagio Breast Imaging System.

Figure 36: IEC Connector

(3) Ensure that there are no air circulation restrictions.

(4) Turn the ***Key*** clockwise to the ***Start*** position.

IMPORTANT: ***If the Imagio Breast Imaging System was just turned on, it may take up to 14 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.***

Figure 37: Laser Heating Icon and Warmup Status Code

6.2 Powering Off the Imagio Breast Imaging System

6.3 Circuit Breaker

6.4 Power on Procedures when System is Unplugged

6.5 Procedures before Unplugging the Imagio Breast Imaging System

Chapter 7: System Console

The System Console contains a trackball, buttons, dials, and a touch screen that enables the User to perform exam management, scans, and adjustments of imaging parameters.

IMPORTANT: ***Active menus, modes, buttons, and tabs are colored Blue.***

7.1 All Controls on System Console

Figure 38: System Console

Figure 39: Shown with keyboard

7.1.2 Touch Screen Keyboard

Figure 40: Touch Screen Keyboard

Figure 41: Touch Screen Keyboard (half size)

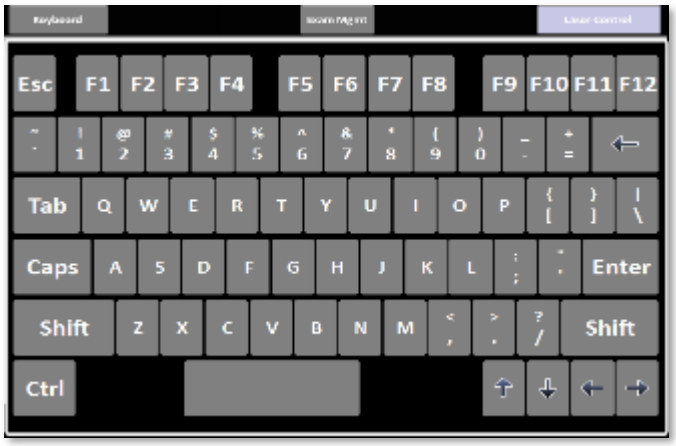


Figure 42: Touch Screen Keyboard (full size)

Table 5. Function Keys on the Imagio Breast Imaging System Keyboard

F1	Administrative Mode
F2	Freeze/Unfreeze
F3	User Settings Menu
F4	Exam Management
F5	Update Button
F6	Display Number
F7	Screen Capture
F8	Start DVR
F9	Stop DVR
F10	(No Function Assigned)
F11	Toggle Keyboard Size
F12	Laser Authorize/De-Authorize Control

SYSTEM CONSOLE

Table 6. System Console Controls and Buttons

Icon	*System Console Control*	*Functionality*
	Trackball	Used to position the onscreen arrow graphic, flashing text cursor, arrow cursor, calipers, etc.
	OA Button	Allows the User to enter/exit Opto-acoustic (OA) mode. When in OA mode, pressing the OA button will exit OA mode, place the laser in ***Standby***, and enter Ultrasound mode. This button is backlit orange when in OA Mode (***Ready***), and blue when in Ultrasound Mode (***Standby***).
	1 Button Image Recording	Save a Static Image of the Display Monitor to the selected Patient's file on the computer hard drive.
	2 Button Video Recording	Save a video of the Display Monitor to the selected Patient's file on the computer hard drive. Press to start recording. Press to stop recording.
	SELECT Button	Provides a wide variety of functions depending on the imaging state (e.g., selects onscreen menu items, etc.) as well as left-select mouse button functionality.
	UPDATE Button	Provides a wide variety of functions depending on the imaging state (e.g., toggle between B-Mode and Doppler Trace image fields, toggles the active caliper, etc., as well as right-select mouse button functionality.
	FREEZE Button	Pause (Orange Color) / Resume (Blue Color) a live image. Places Laser System in ***Laser Standby***.
	Dials	Five (5) dials that control the adjacent active (blue color) touch screen imaging parameter buttons (Dial function changes depending on the imaging mode). Once the touch screen imaging parameter button is pressed, (turns blue), turn the dial to make the relevant adjustments.

SYSTEM CONSOLE

Icon	*System Console Control*	*Functionality*
	Touch Screen Buttons	Displays touch screen menus and buttons which change depending on the imaging mode/state. **Active menus, modes, buttons, and tabs are colored Blue.**
	Touch Screen Display Mode Button	Alternates the OA display between 2 windows, 4 windows, or 6 windows displayed. B mode alternates between 1, 2, 4 windows.
	Touch Screen TGC Button	Depth dependent gain adjustment.
	Touch Screen Tab Buttons	Additional imaging parameter adjustments depending on mode in use. Blue tab is active.
	Touch Screen Keyboard Button	This button enables the use of the  Touch Screen QWERTY keyboard used for text entry (e.g., patient data, system setup, image text, etc.). Press F11 to alternate between half and full screen keyboards.
	Emergency Laser Stop Button	Instantly powers off the laser components of the Imagio Breast Imaging System.
	On/Off Key Switch	Power on/off the Imagio Breast Imaging System using the on/off key switch.
	USB Ports	There are 2 USB ports located on the left side of the System Console. Either port can be used for connecting a removable flash drive to transfer data.

Chapter 8: Enabling / Disabling the Laser

Use of the Imagio Breast Imaging System laser (and therefore performing OA scans) is restricted to use by trained and authorized users only. Trained and authorized users will be given a password to enable the laser. Upon successful password authentication, the ***Laser Enable*** remains in place on the display monitor until system enters the idle state after 15 minutes of inactivity, or the User presses the touch screen ***Laser Control*** button to disable the laser.

OA mode with laser access is the Imagio Breast Imaging System default mode; therefore, a password is required upon System start up. If the User does not successfully enter a password or if the Cancel button is selected other features of the System are still available (e.g. B-Mode) even though the laser is not enabled.

Safeguards have been designed into the Imagio Breast Imaging System to protect the User and the Patient from laser energy; however, it is the responsibility of the User to follow all Warnings and Cautions outlined in this manual. Refer to the safety alerts on page 4.

When the Imagio Breast Imaging System is first powered up, the OA/US Probe is in standby mode and is not emitting laser power.

All Three (3) conditions must be met to enable laser emission from the OA/US Probe:

(4) The System must be in OA mode.

(5) The User must have entered the Laser Control password (Laser ENABLED).

(6) The foot switch must be pressed.

⚠ ***WARNING:*** Invisible laser light is emitted from the OA/US Probe. Reflected and/or misdirected laser light may damage eyes.

- Never use any controls or adjustments or performance settings other than those specified herein.
- The Patient, the Imagio Breast Imaging System User, 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 OA/US Probe is out of its holder. Refer to Chapter 2.4.12 Laser Protective Eyewear. 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 Probe, and calibrating laser energies or any other time the Imagio Breast Imaging System is powered on and the OA/US Probe is removed from the probe holder.
- Never look directly at the laser beam even when laser protective eyewear is being worn.
- Never 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 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 Probe from the skin or holder/sheath.
- Always follow the laser safety precautions prior to laser emitting to protect the Patient, User, and Observers.

- Always place the OA/US Probe in the OA/US Probe holder when not in use. This OA/US Probe holder is designed to minimize the release of laser light due to an unintentional activation of the foot switch.

⚠ ***WARNING:*** Operation of the Imagio Breast Imaging System by untrained, unauthorized individuals may result in harm to patient and/or user.

- Never allow the Patient to touch the Imagio Breast Imaging System Console.
- Never share your password with anyone. Only trained and authorized personnel can use the Imagio Breast Imaging System.
- Always disable the laser by pressing the touch screen Laser Control button when the Imagio Breast Imaging System will be left unattended.

8.1 To Enable the Laser

(1) Confirm that the Display Monitor is displaying the message Laser Status Disabled on the imaging screen. Close dialog boxes (e.g., Exam Management) to view the imaging screen.

(2) Press the Touch Screen Keyboard button if not using the hardware keyboard.

(3) Press the Touch Screen Laser Control button. Enter your password in the password dialog box and select OK. If the password box is not displayed on the Display Monitor, press the touch screen Laser Control button to display the password dialog box.

Figure 43: Laser Control Button

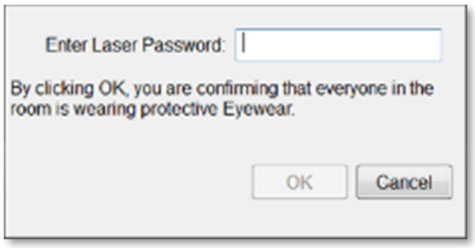


Figure 44: Login Screen

(4) Press the System Console ❄ Freeze button twice or freeze/unfreeze. If the laser is heated the Laser Ready Icon is displayed, 

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

.

Upon successful password authentication, the words Laser Status Enabled appear on the bottom right side of the Display Monitor and a message appears on the monitor bottom left reminding the users to check everyone in the scan room is wearing laser protective eyewear.

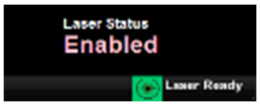


Figure 45: Laser Enabled Indication on Display Monitor

Laser Starting. Ensure Everyone In The Room Is Wearing Approved Eyewear.

IMPORTANT: ***If the Imagio Breast Imaging System was just turned on, it may take up to 14 minutes for the lasers to reach operating temperature and before an OA Scan can be performed. Always Press the System Console ❄ Freeze button twice or freeze/unfreeze after successfully entering the Laser Password.***

8.2 To Disable the Laser

(1) Confirm that the Display Monitor is displaying the message Laser Enabled on the imaging screen.

(2) Close dialog boxes (e.g., Exam Management) to view the imaging screen.

(3) Press the touch screen Laser Control.

(4) The words Laser Disabled appear on the right side of the Display Monitor.

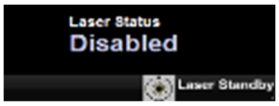


Figure 46: Laser Disabled Indication on Display Monitor

8.3 Laser Authentication and Heating Summary

Laser Password Authentication:

- Laser Status Enabled when correct password is entered. (User must press the freeze ❄ button twice or freeze then unfreeze to start the Laser Heating).
- Laser Status Disabled when the user presses the System Console Laser Control Button (refer to Figure 43) or there is no input activity for 15 minutes.
- The Imagio will remain in Laser Status Enabled if the user selects B-mode and the user keeps the system active.

Laser Heating:

- Laser Heating will take up to 14 minutes from a cold Imagio power on or laser sleep.
- Laser Heating will occur after successful laser password authentication and the freeze ❄ button is pressed twice freeze then unfreeze.
- Laser will discontinue heating and enter laser sleep if no user input is detected within 7 hours.
- To exit sleep, Laser Password Authentication must be performed to enter Laser Status Enabled.

Chapter 9: OA Mode

Safeguards have been designed into the Imagio Breast Imaging System to protect the User and the Patient from laser energy; however, it is the responsibility of the User to follow all Warnings and Cautions outlined in this manual. Refer to the safety alerts on page 4.

When the Imagio Breast Imaging System is first powered up, the OA/US Probe is in standby mode and is not emitting laser power.

All Three (3) conditions must be met to enable laser emission from the OA/US Probe:

(1) The System must be in OA mode.

(2) The User must have entered the Laser Control password (Laser ENABLED).

(3) The foot switch must be pressed.

⚠ ***WARNING:*** Invisible laser light is emitted from the OA/US Probe. Reflected and/or misdirected laser light may damage eyes.

- Never use any controls or adjustments or performance settings other than those specified herein.
- The Patient, the Imagio Breast Imaging System User, 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 OA/US Probe is out of its holder. Refer to Chapter 2.4.12 Laser Protective Eyewear. 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 Probe, and calibrating laser energies or any other time the Imagio Breast Imaging System is powered on and the OA/US Probe is removed from the probe holder.
- Never look directly at the laser beam even when laser protective eyewear is being worn.
- Never 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 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 Probe from the skin or holder/sheath.
- Always follow the laser safety precautions prior to laser emitting to protect the Patient, User, and Observers.
- Always place the OA/US Probe in the OA/US Probe holder when not in use. This OA/US Probe holder is designed to minimize the release of laser light due to an unintentional activation of the foot switch.

OA MODE

9.1 OA Mode

The Imagio Breast Imaging System defaults to OA Mode.

(1) To enter OA mode, press the System Console OA button or System Console Touchscreen OA button.

IMPORTANT: ***Laser Icons 0 and Status Codes 0 appear on the bottom right of the display monitor to communicate the laser state to the User.***

9.2 Laser Standby

Placing the Imagio Breast Imaging System in Laser Standby commands the Imagio Breast Imaging System Laser to stop all laser energy generation when it has been enabled.

Figure 47: Laser Enabled, Laser Standby

9.2.1 To Place the Imagio Breast Imaging System in Laser Standby

(1) Press the System Console Freeze button in OA-mode.

The following occurs:

- The backlit color of the ***System Console Freeze button*** changes from blue to orange.
- The laser state message icon changes to ***Laser Standby***.

9.2.2 To Exit Laser Standby

(1) Press the ***System Console Freeze button*** on the System Console.

The following occurs:

- The backlit color of the button changes from orange to blue.
- 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.
- The following message appears on the display monitor bottom left to remind the user to check that everyone in the scan room is wear laser protective eyewear.

  Laser Starting. Ensure Everyone In The Room Is Wearing Approved Eyewear.

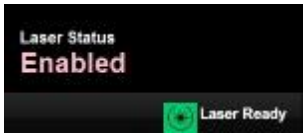


Figure 48: Laser Enabled, Laser Ready

9.2.3 Laser Heating

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

Figure 49: Laser Adjustment Period - Preparing

IMPORTANT: ***If the Imagio Breast Imaging System was just turned on, it may take up to 14 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.***

9.2.4 Laser Adjustment Period

The Laser Adjustment Period is designed to ensure that the laser has time to compensate for variations prior to OA/US 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. Sleep occurs when there is no user input in 7 hours.

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

- No laser energy will emit from the OA/US 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 user unfreezes the system (with or without the footswitch pressed)
- The laser status icon Preparing is shown on the bottom right of the display
- The laser emit light will illuminate during the Laser Adjustment Period
- No OA images will be displayed on the monitor until adjustment is complete
- It is acceptable to freeze the laser during the Laser Adjustment Period

Figure 50: Laser Adjustment Period - Preparing

Chapter 10: Foot Switch

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

IMPORTANT: ***If OA mode has been exited, the foot switch must be released before re-entering OA mode for proper system operation.***

- The Imagio Breast Imaging System needs to be in OA mode, the laser must be enabled, and the laser needs to be in a Ready state for the footswitch to be active. Laser Ready is indicated by the green laser ready icon on the lower right of the display. Un-freeze the image if the laser standby icon is indicated on the lower right of the display monitor.
- When in OA mode, pressing down on the foot switch completely and fully to the floor commands laser light to be emitted.
- The laser state message icon changes to laser emitting and the top Laser Emitting LED is lit.
- Releasing the foot switch stops laser emission and returns the laser icon to laser ready and turns off the Laser Emitting LED.
- When the foot switch is released, the last OA image acquired is frozen on the Display Monitor while the B-Mode image continues to update.

Figure 51: Foot Switch

10.1 How to Use the Foot Switch

(1) Press the Touch Screen OA button to enter OA mode.

(2) Enable the laser by pressing the Touch Screen Laser Control button, enter the password, and ensure the laser is in ready state as indicated by the green laser ready icon.

(3) Press the foot switch down completely and fully to the floor to engage and begin laser emission. The Laser Emitting LED illuminates and the laser state icon indicates laser emitting.

(4) Release the footswitch to stop laser emission. The Laser Emitting LED stops illuminating and the laser state icon indicates laser ready.

(5) Press the Laser Control Button to disable the laser.

Chapter 11: OA Main Touch Screen

The OA Main touch screen allows the User to:

- Activate OA imaging parameter dials (OA Focus Lines)
- Displays OA Focus Lines and gain parameter values
- Reload System Presets if adjustment have been made
- Access B-Mode controls
- End the current exam

IMPORTANT: ***Buttons colored blue display active modes, parameters, or tabs.***

11.1 OA Touch Screen Layout

(1) Press the Touch Screen Cancel or if a patient is selected, press the OK button while in the Exam Management screen to exit.

(2) Press the Touch Screen or System Console OA button to enter OA mode if not in OA mode.

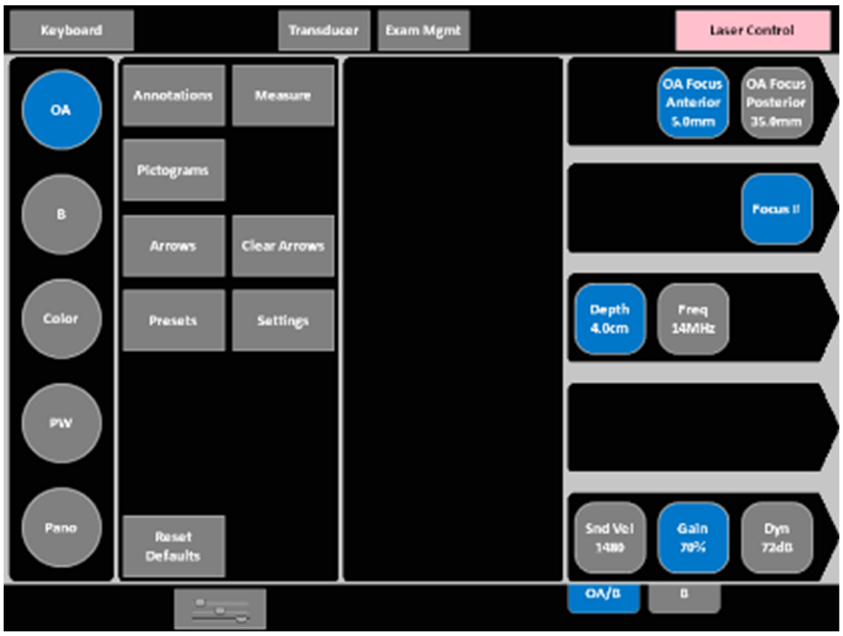


Figure 52: OA Touch Screen Layout Live

IMPORTANT: ***Once an image is frozen, some of the mode-specific touch screen options will be changed, for example Cine options will be available.***

11.2 OA Touch Screen – Frozen

(1) Press the System Console ❄ Freeze button will freeze the current images and the touch screen will change to the frozen layout.

(2) Press the System Console ❄ Freeze button while the display is static will return to live imaging.

IMPORTANT: ***The System Console ❄ Freeze button is a toggle button; press the System Console ❄ Freeze button to alternate between live imaging and frozen image.***

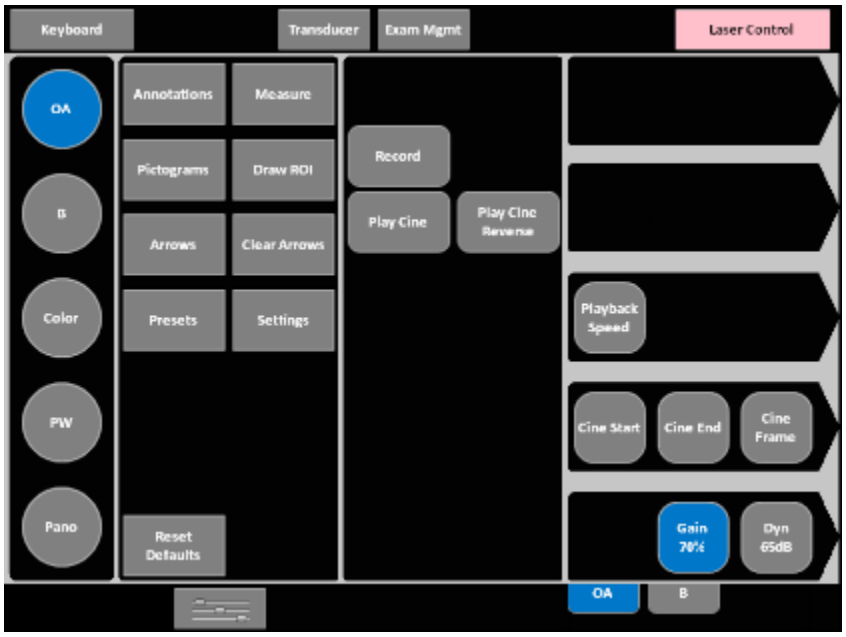


Figure 53: Layout of Frozen OA Touch Screen

Chapter 12: OA Display

When the Imagio Breast Imaging System power on initialization is complete, the System automatically enters OA Mode as the default mode and the exam management screen is displayed.

(1) Press cancel or if a patient is selected, press OK to enter OA Mode.

IMPORTANT: ***If the OA/US Probe is not attached, the initial screen displayed on the Display Monitor after System initialization will be the Exam Management screen. Attach the OA/US Probe and select Cancel so the System will recognize the OA/US Probe***

12.1 OA Display Description

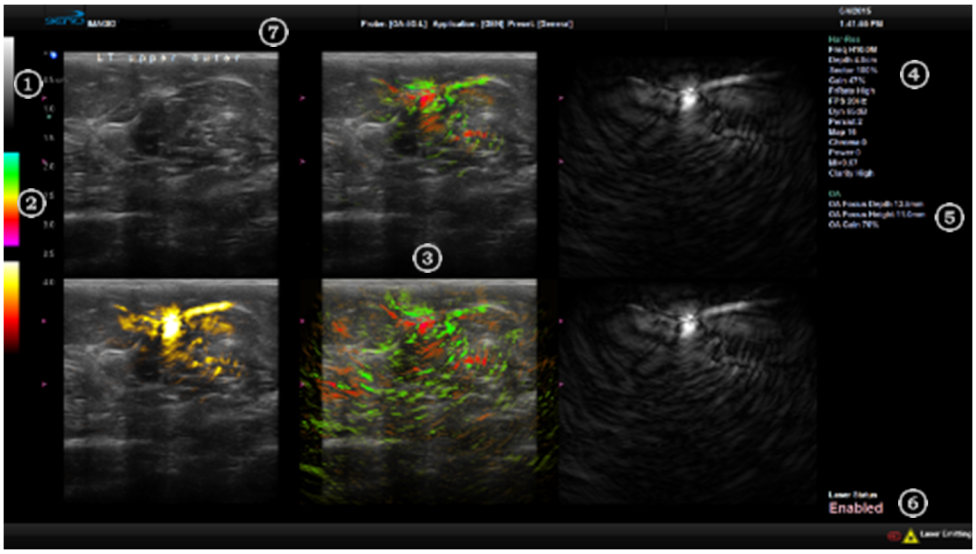


Figure 54: OA Display Monitor Area Description

OA DISPLAY

Table 7. Areas of the Display

1	**Grayscale**	The grayscale map applies only to the B-Mode image.
2	**Relative Absorption Color Scale**	Displays the order in which colors are used to depict relative levels of laser light absorption.
3	**Image area**	Displays greyscale and co-registered and temporally interleaved OA images.
4	**B-Mode Ultrasound Parameters**	Current B-Mode Ultrasound parameters.
5	**OA Parameters**	Current OA parameters such as: • OA Focus Height • OA Focus Depth
6	**Status Bar**	Displays status such as: • Laser state (e.g. Standby, Ready, Emitting)
7	**Exam Information**	Facility ID + Patient ID Patient Initials Probe Name-Imaging Mode Operator ID Date of Exam Time of Exam

12.2 OA Display

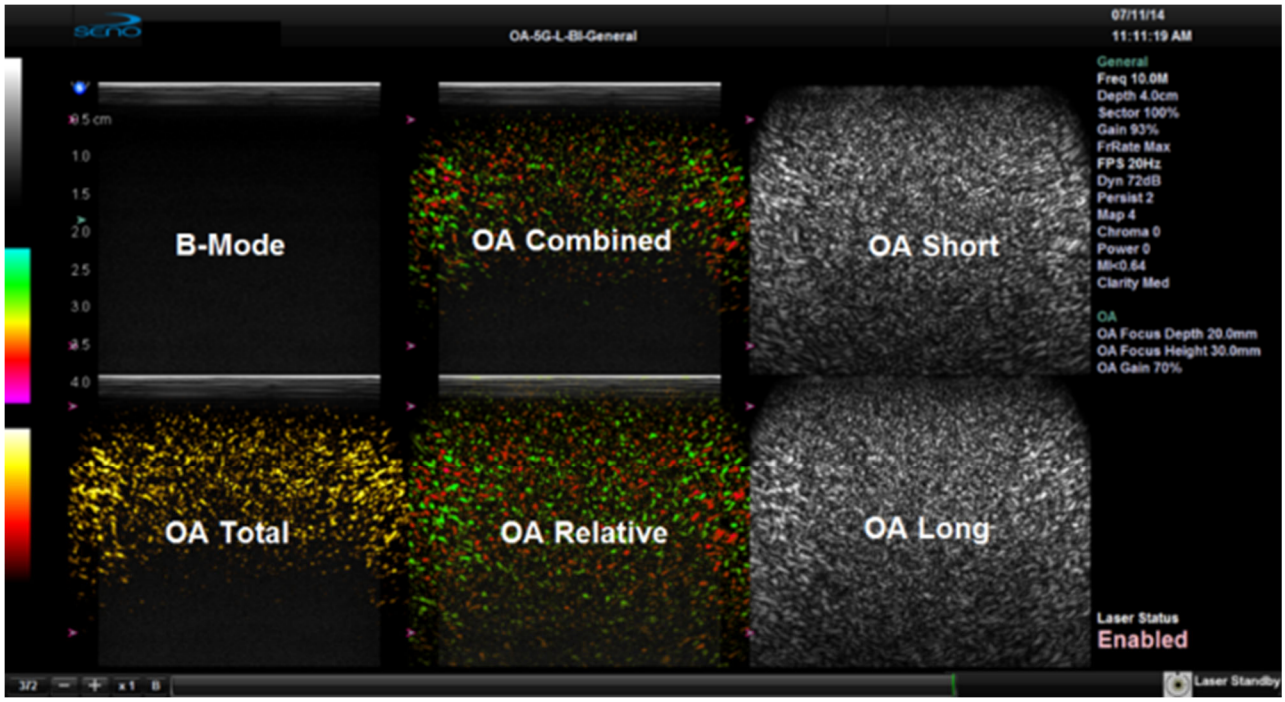


Figure 55: Display Monitor Screen (During OA Scan)

Table 8. Description of the OA Display

B-Mode	The B-Mode Ultrasound image is used 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

Chapter 13: OA Controls

⚠ ***WARNING:*** Invisible laser light is emitted from the OA/US Probe. Reflected and/or misdirected laser light may damage eyes.

- Never use any controls or adjustments or performance settings other than those specified herein.
- The Patient, the Imagio Breast Imaging System User, 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 OA/US Probe is out of its holder. Refer to Chapter 2.4.12 Laser Protective Eyewear. 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 Probe, and calibrating laser energies or any other time the Imagio Breast Imaging System is powered on and the OA/US Probe is removed from the probe holder.

OA colorization works best when the area in which the colorization calculations take place is relatively uniform in intensity. This area starts at 5mm depth and extends down to 35mm; it also extends fully from left to right across the image.

However, if the colorization produces small but intense spots of color (dominant sources) within this area, the calculations may be skewed, resulting in inaccurate colorization or dominant source artifacts. Therefore, these dominant sources of color should be excluded from the OA focus area. For instance, an artery will appear as a bright green area; a vein will appear as a bright red area. An attempt should be made to exclude dominant sources by changing the position of the OA/US Probe. However, if moving the OA/US Probe does not move the dominant source outside of the OA focus area, adjust the **OA Focus Lines** to attempt to exclude the dominant sources.

The goal of adjusting the OA focus lines is to exclude the dominant sources from the OA focus area. The **OA Focus Lines** mode gives the User the ability to exclude a dominant source that cannot be excluded by moving the OA/US Probe to a new location.

If the OA/US Probe is subsequently moved such that the dominant source is no longer a problem, the default settings for the **OA Focus Lines** should be restored by pressing the **Reset Defaults** button on the touch screen.

13.1 OA Focus Lines Adjustments

Adjusting the **OA Focus Lines** can be used to avoid dominant source artifacts if repositioning the OA/US Probe in an alternate scan plane does not eliminate the dominant source artifact. If no dominant source artifact is observed, leave the OA focus settings in their default value. See the below topic in this chapter “To Reset the OA Focus Depth and Height”.

The **OA Focus Lines** allows the User to specify the area used to calculate the mean OA signal by setting the **OA Focus anterior and posterior positions**. The **OA Focus anterior and posterior positions** can be adjusted to align the horizontal focus lines to an area of tissue outside the margins of the lesion. This procedure is used to avoid dominant source artifact, which can skew the mean value of OA colorization. Always maximize the **OA Focus Height** to include adjacent normal tissue while avoiding placement of

the **OA Focus Lines** directly over the lesion or on tissues other than the region of interest such as bone, air, and large vessels.

The above procedure is appropriate if the dominant source(s) is generally above or below the lesion. It is not intended to be used when the dominant source(s) is to the left or right of the lesion.

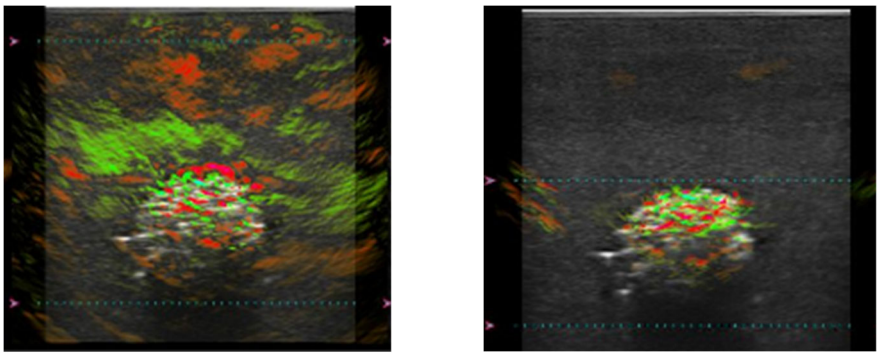


Figure 56: Dominant Source in Focus Area (left)
Dominant Source Excluded from Focus Area (right)

13.1.1.1 To Adjust OA Focus Lines

The OA anterior and posterior limits are indicated on the display by the red carets on the left side of each display.

The Anterior default is set to 5 mm. The Posterior default is set to 35 mm.

In OA Mode, the OA focus lines are always active, but not visible. Adjusting the OA focus lines causes dashed lines to appear that represent the superficial and deep limits of the OA focus area.

The dashed horizontal lines will disappear after 5 seconds of inactivity, but the red carets remain to indicate their depth.

IMPORTANT: ***Adjustments can be made to the anterior and posterior OA focus lines only when the image is unfrozen. If the image is frozen, press System Console ❄Freeze button to unfreeze the image.***

(1) Press the Touch Screen OA Focus Anterior button to activate the OA Focus and turn the adjacent dial to adjust the Anterior OA Focus line depth.

(2) Press the Touch Screen OA Focus Posterior button to activate the OA Focus and turn the adjacent dial to adjust the Posterior OA Focus line height.

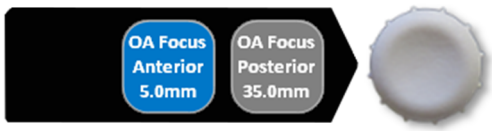


Figure 57: OA Focus Depth and Height Adjustment Dials

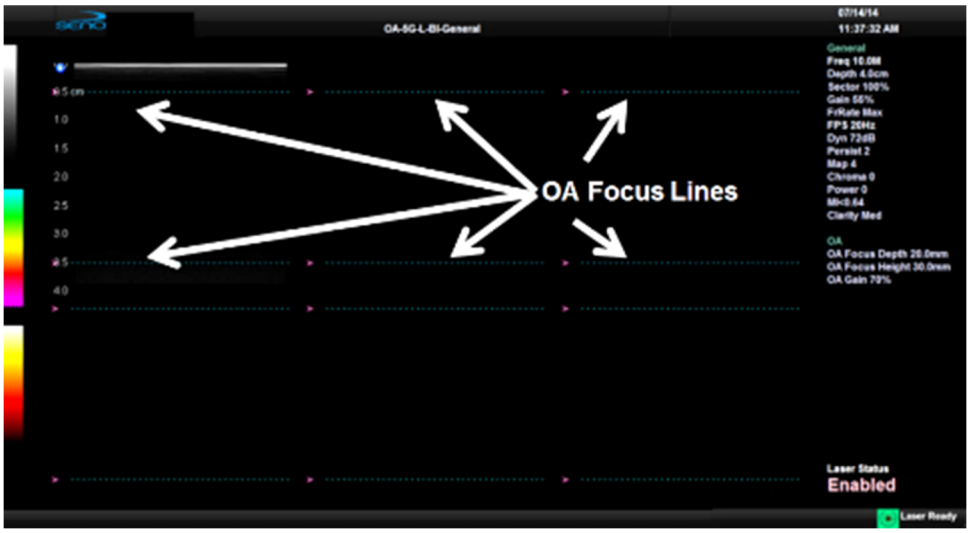


Figure 58: Focus Lines Displayed on Six-Up View

13.1.1.2 To Reset the OA Focus Lines to Default Depths

The Anterior default is set to 5 mm. The Posterior default is set to 35 mm.

(1) Press the Touch Screen Reset Defaults button.

(2) OA Focus Anterior and Posterior return to default settings.

IMPORTANT: ***Entering Cine mode on a frozen image allows the User to post process or re-adjust the OA focus line setting and record a new digital video recording with the re-adjusted focus line settings. Refer to chapter 14.3.2 Cine Options.***

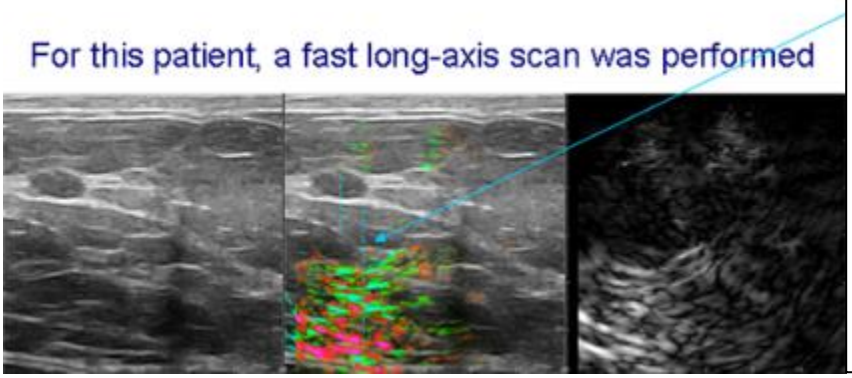
13.2 Image Quality and Optimization

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

13.2.1 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 this, users 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 greyscale 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.

Figure 59: Temporal Mis-registration

13.2.2 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-direction nature of the US acoustic signal compared to the uni-directional nature of the OA acoustic signal. The user 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.

13.2.3 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, users 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.

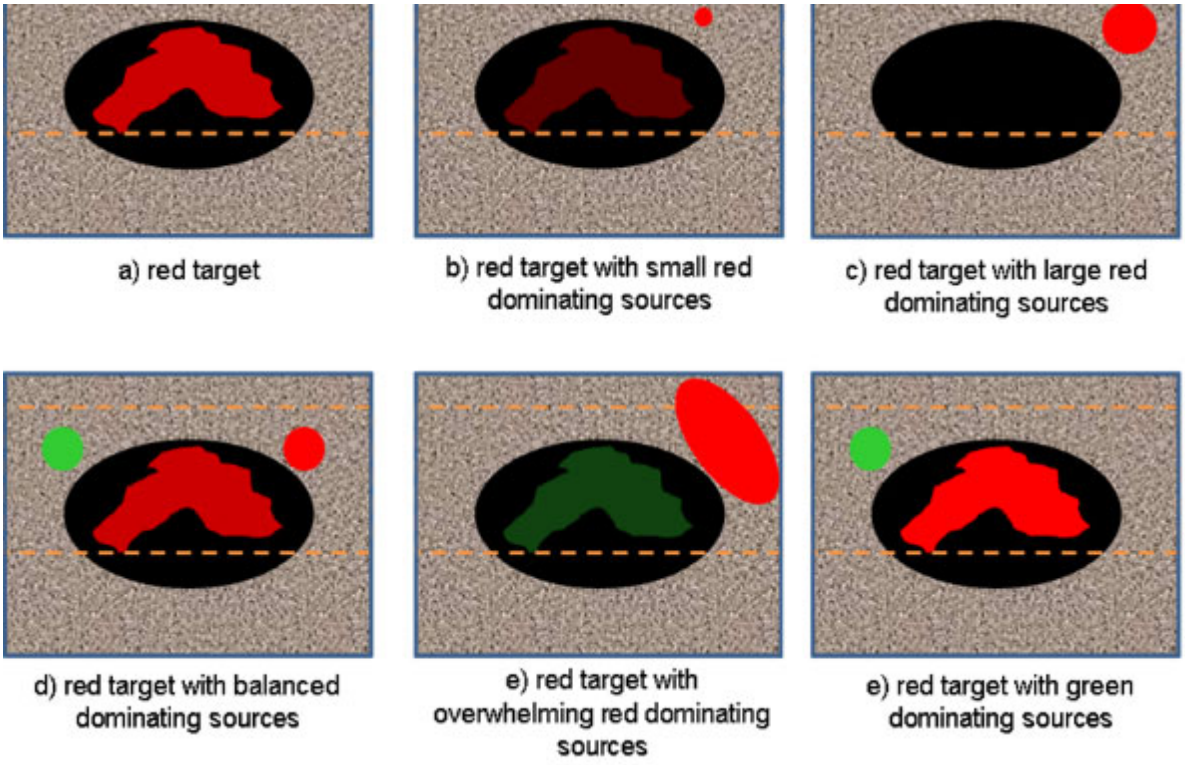


Figure 60: Dominant Source Artifact for Strongly Red Target

13.2.4 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.

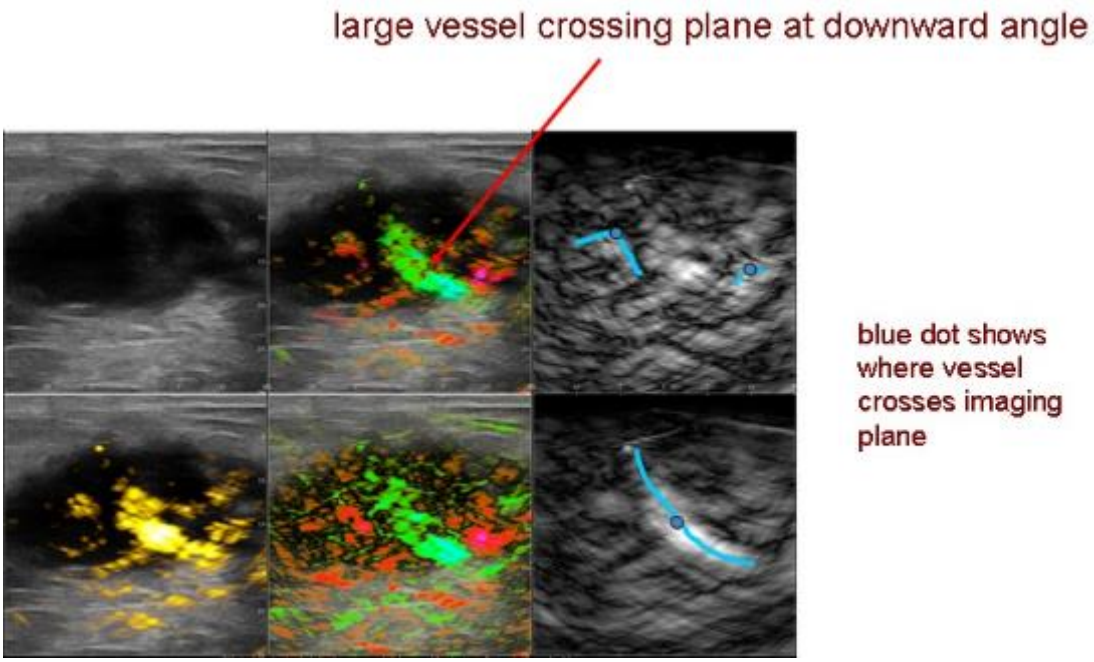


Figure 61: Tumor Exhibiting Out-Of-Plane Vessel Phenomenon

13.2.5 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. Users are advised to scan the target lesion from multiple directions and scanning planes to create a good understanding of the morphology of the lesion.

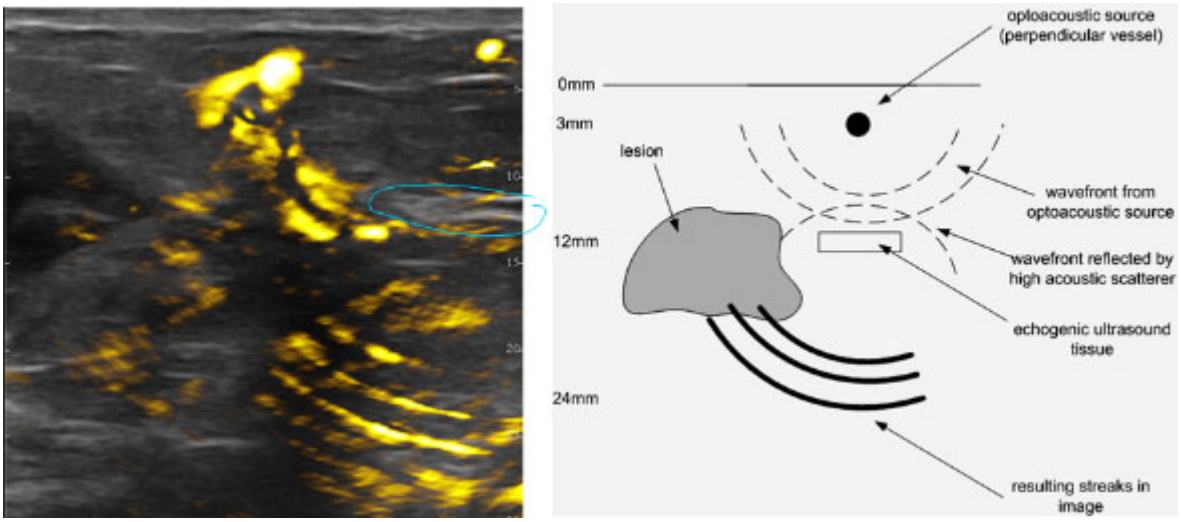


Figure 62: Streaks from Reflection and Reverberation Caused by Source Vessel

13.2.6 Ultrasound Artifacts

Because the OA return signal is an ultrasonic 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:

- Reverberation
- Comet Tail
- Ring-down
- Refraction
- Slice thickness
- Range ambiguity
- Grating lobe
- Mirror Image
- Speed error
- Speckle

Attenuation Artifacts:

- Enhancement
- Edge shadow
- Shadowing

For future reference, the RSNA supplies training on US artifacts at http://pubs.rsna.org/doi/full/10.1148/rg.294085199

13.2.7 Indicating a Region of Interest (ROI)

The User can document multiple regions of interest (ROI) on both B-Mode and OA images while the images are frozen or after they have been recorded. Freeform ROI loops can be drawn around an object of interest, and graphic arrows and text can be applied.

The ROI loop is blue when being drawn or modified, with small red boxes indicating vertices. When the ROI loop is closed, it turns green and the vertex indicators disappear.

Figure 63: Example of Multiple ROIs and Annotations, outlined in red in each of the 6 displays

13.3 To Draw a Freeform Loop around a Region of Interest

(1) If the image is live and not frozen, press the System Console Freeze button. Press the System Console Select button and press the Touch Screen Draw ROI button.

(2) Position the cursor by using the trackball.

(3) Press the System Console Select button to “drop” the cursor.

(4) Repeat steps 2 and 3 for each desired point of the loop. Note: Up to 20 points may be placed.

(5) To close the loop, press the Touch Screen Close ROI button or place the cursor over the first loop point (a circular indicator will appear when the cursor is over a point) and Press the System Console Select button. The loop will turn green.

(6) Add up to 20 points, adding more than 20 points to the ROI loop will close the loop.

(7) To modify, hover over the point to be moved and press the Touch Screen Select button to modify the vertices.

(8) Move the cursor to the new desired location and press the Touch Screen select button once more to place the vertices in the new position.

(9) Press the ***Touch Screen Draw ROI button*** or unfreeze to leave ROI mode.

IMPORTANT: ***Press Touch Screen Clear Last ROI or Clear All ROI button on the touch screen to remove ROI’s from the image on the display.***

Chapter 14: System Controls

14.1 Recording Images

Recording an image saves the current image displayed on the Display monitor. Multiple images can be recorded and saved to a patient's file.

When multiple images are saved, you can review the individual images to determine which images to permanently save and which images to delete.

IMPORTANT: ***In the steps below, the Imagio Breast Imaging System has been configured so that pressing the System Console 1 button will record the image.***

To Record an Image

(1) Press the System Console ❄ Freeze button.

(2) Press the System Console Image Record 1 button to save the image. The image appears on the image strip area.

14.2 Recording Video

14.3 Cine

Cine provides the ability to Record a series of sequential images that can be played back to appear as a movie.

14.3.1 Cine Frame Indicators

When an image is frozen, the Cine frame indicators appear at the bottom of the Display Monitor.

Figure 64: Cine Frame Indicators

Table 9. Cine Frame Indicators

1	***Cine Frame***	Marks the current ***Cine Frame*** (number coincides with green marker in 4).
2	***Cine Advance/Reverse***	Advances (+) or reverses (-) the ***Cine loop***, one frame at a time.
3	***Cine Play Speed***	Activates ***Cine Play Speed*** (⅛, ¼, ½, Full (1)).

4	***Cine Loop Slider***	Allows the User to select the: ***start frame*** ***end frame*** ***single (current) frame*** ***Cine loop*** start and end markers are gray, while the green marker denotes the current ***Cine frame*** (item **1** lists the corresponding frame number). Press the Touch Screen Select button to enable the cursor. Use the trackball to position the cursor over the grey start or end bar. Press the Touch Screen Select button to enable the grey start or end marker. Use the trackball to drag the start or end markers to define ***Cine loop*** limits. Press the Touch Screen Select button to set the position. IMPORTANT: ***When an image is frozen, the slider will always be set with the start/end markers to the far left/right with the green marker at the end of the loop (far right).***

14.3.2 Cine Options

When an image is frozen by pressing the ***System Console*** ❄ ***Freeze button***, the ***Cine*** touch screen tab becomes available.

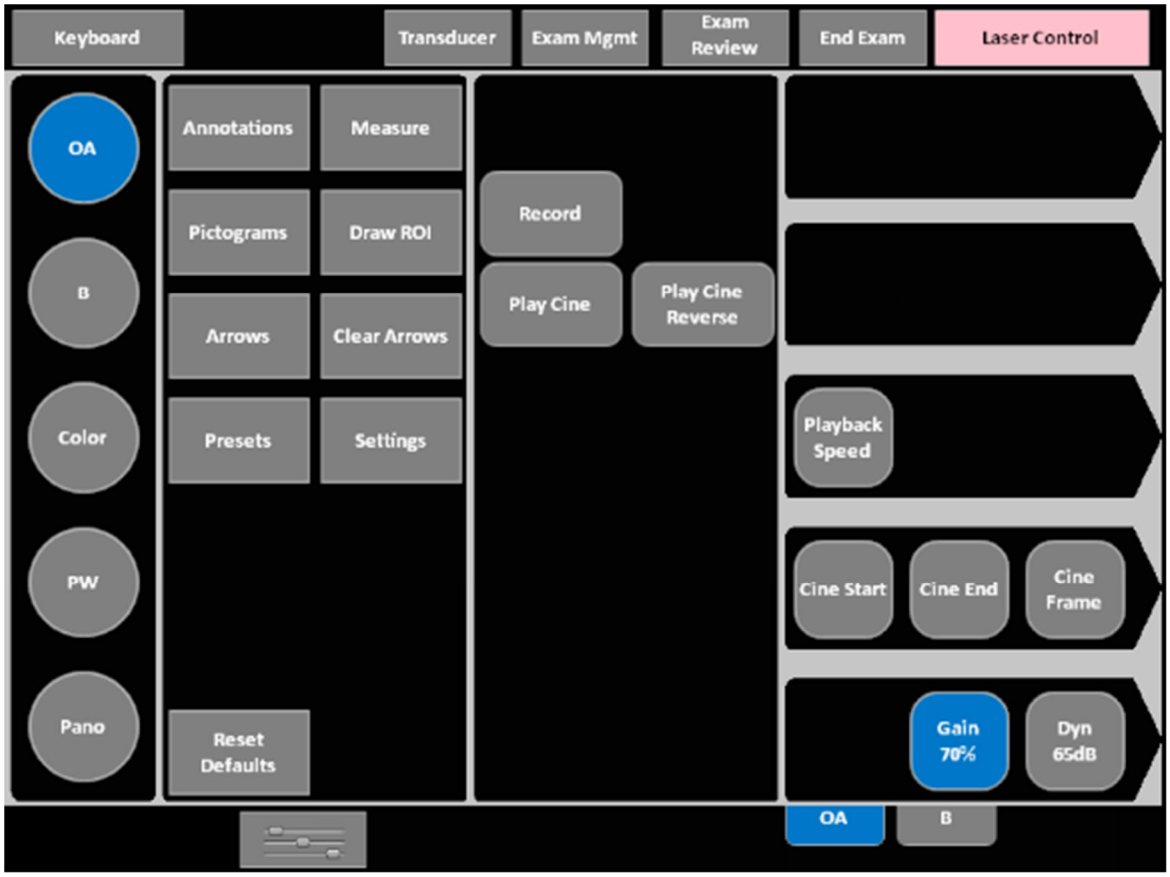


Figure 65: Frozen Touch Screen

Pressing the System Console ❄ Freeze button displays the Cine Controls on the Touch Screen.

Pressing the Touch Screen ***Play Cine button*** makes the OA focus lines controls visible.

Pressing ***Play Cine*** starts the cine video loop. While the cine loop is playing, the User can reposition the focus lines, press the ***Touch Screen Record button***, and record a new digital video recording.

Table 10. Cine Mode Action Buttons (press to activate)

End Exam	Press to end the current exam.
Play Cine Reverse	Select to play the available ***Cine*** frames in reverse.
Play Cine	Select to play the available ***Cine*** in the forward direction. ***OA Focus Lines button*** becomes active when the ***Play Cine button*** is pressed. The User may choose to reposition the focus lines and record a new digital video recording using the ***Record button***.
Stop Cine	Select to stop the ***Cine*** playback.
Record	Press to store the selected ***Cine*** frames to the system.

Table 11. Cine Imaging Parameters (press to activate, dial/press to adjust/trigger)

Cine Frame	Press to activate, then turn the adjacent dial to trigger the action: • ***Cine Frame*** selects the currently displayed frame and moves one (1) frame at a time.
Cine Start **Cine End**	When creating a ***Cine clip*** from a ***Cine loop***: • ***Cine Start/Cine End*** selects the start/end frame of the clip, moving one (1) frame at a time.
Cine Play Speed	Press to activate and turn the adjacent dial to select the ***Cine Play Speed*** (⅛, ¼, ½, Full (1)).

IMPORTANT: ***Changes made to Image Depth and Height may reset the number of frames available for review or storage***

IMPORTANT: ***Cine loop storage is a retrospective acquisition***

14.3.3 Recording a Cine Clip

(1) Ensure Live imaging by pressing the System Console ❄ Freeze button to unfreeze the image. Interrogate the area in and around the region of interest.

(2) Press the System Console ❄ Freeze button. The Cine controls appear on the touch screen.

(3) The Cine controls appear on the touch screen. Press the System Console Touch Screen Record Button to save the Cine. The Record button displays the video processing completion percentage.

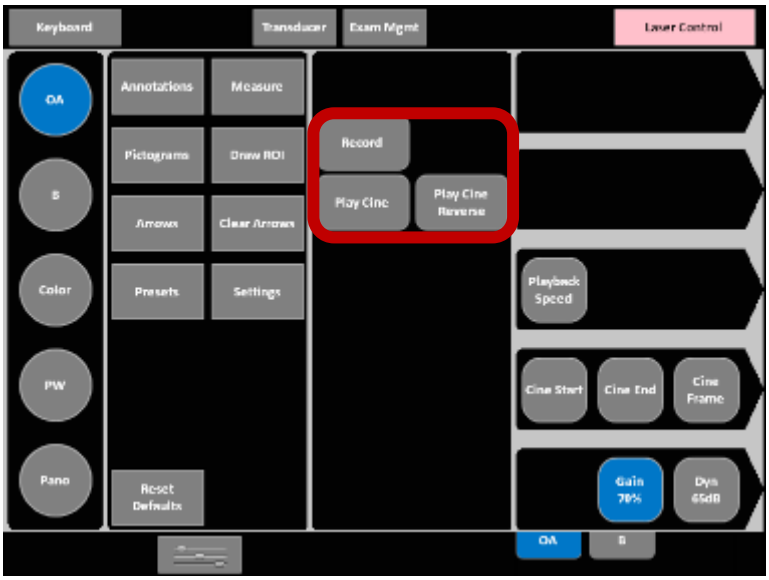


Figure 66: Cine Recording: Continue Scanning When Processing Has Completed and the Record Button is Displayed.

14.3.4 To Review the Cine Clip using Cine Controls

(1) With an image frozen, press the desired Cine start and end locations using the Touch Screen Cine Start and Cine End buttons if desired.

(2) Press the Touch Screen Play Cine button to start the cine video loop and makes visible the OA Focus Lines button. The user can reposition the focus lines depth and height to attempt to further optimize the OA signal.

(3) Press the Touch Screen Record button will record a new digital video recording and save a new video clip.

14.3.5 To Save a Cine Clip to a Patient Record

(1) With an image frozen, press the Touch Screen Record button. A thumbnail appears on the image strip area at the bottom of the Display Monitor identified with a small movie symbol and the cine is saved to the active patient record.

Stored Thumbnail Review

The ***Stored Thumbnail Review*** is displayed in the image strip area at the bottom of the Display Monitor.

IMPORTANT: ***Cine videos can also be accessed via the Exam Management Page Review button.***

14.3.6 To Review or Delete a Thumbnail Image/Cine Clip During an Exam

(1) Move the trackball arrow over the desired thumbnail and press the System Console Select button.

(2) The image is enlarged and displayed in the middle of the Display Monitor.

(3) Press System Console Select button again to return to imaging mode.

(4) Once the trackball arrow is over a thumbnail, a red X will be presented in the top right hand corner. Cursor over the X and press System Console Select button to delete the thumbnail.

14.4 To Type Text on the Image (Annotate)

14.4.1 To add custom text to the image

(1) Press the Touch Screen Annotation button to activate text entry and display Annotation buttons on the touch screen.

(2) Roll the Track Ball to position the cursor to an area where text will be entered.

(3) Press the Touch Screen Keyboard button and use the keyboard to type text on the image. If necessary, press the Touch Screen Delete Last button or keyboard back space to remove text letter by letter.

14.4.2 To add pre-programmed text to the image

(1) Press the Touch Screen Annotation button to activate text entry and display Annotation buttons on the touch screen.

(2) Press the part-specific text from the selection presented on the touch screen. If necessary, press the Touch Screen Delete Last button or keyboard backspace to remove text letter by letter.

IMPORTANT: ***Text can be entered on both live and frozen images. Recording the image will save all text.***

14.5 To Save User-Defined Presets

14.6 Measurements

The Measurements tools provide the User with the functionality to indicate measurements on the images to be recorded. Measurements range from simple measurements that calculate ***Length, Circumference, Area***, area ***Volume***, to ***Measurement Packages*** that use calculation formulas.

To access Measurement Packages, press the Touch Screen Measure button.

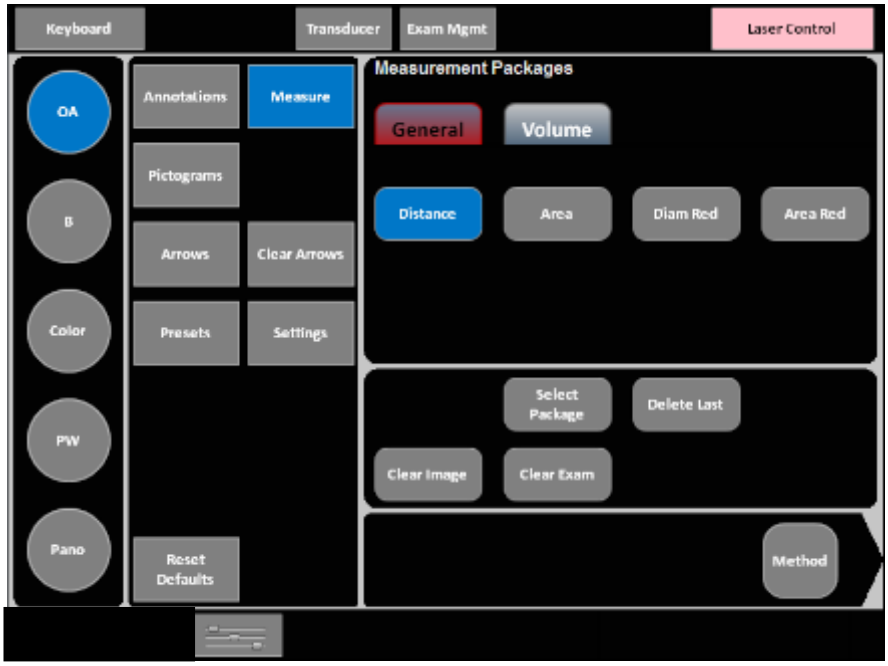


Figure 68: Measurement Packages Touch Screen

Table 12. System Console Measurement Buttons

	Selects, sets, and activates calipers, ellipse, etc.
	Toggles between the calipers prior to finalizing (setting) the measurement.

Table 13. Measurement Packages Touch Screen Controls

Clear Image Button	Press to ***Clear*** any measurements currently on the image.
Clear Exam Button	Press to ***Clear*** all measurements from both the ***Display Monitor***. IMPORTANT: ***Confirm this action when the message Clear Exam? Yes No is presented.***
Method Button	Press to change measurements types, e.g., from ***B Distance*** to ***Curved Distance***. Use the adjacent dial to advance to the desired measurement option. IMPORTANT: ***Not all measurements have more than one measurement option.***

14.6.1 Generic Measurements

During imaging, measurements are accessible by pressing the Touch Screen Measure button. The measurements default to the Touch Screen Distance button active.

Once the first measurement has been taken, the relevant touch screen button will be prefaced by (1). If additional measurements are taken, the number will increment accordingly.

Onscreen distance measurement labels are (ex. 1D, 2D) placed at the bottom right of the display. To avoid overlapping measurement labels, whenever possible, take care not to overlap measurement starting points.

14.6.2 Linear Measurement

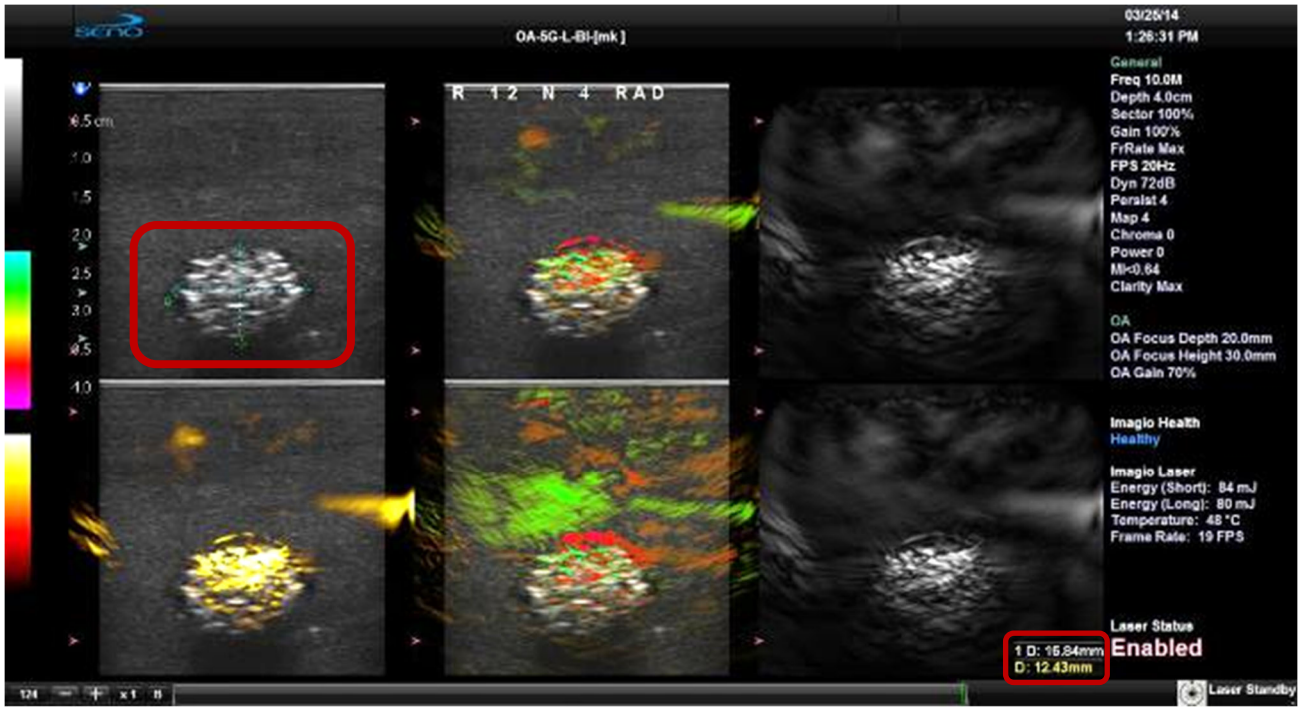


Figure 69: Image with Linear Measurement

14.6.2.1 To Perform a Linear Measurement

(1) Press the System console ❄ Freeze button to stop live imaging.

(2) Press the Touch Screen Measure button. (Defaults to Distance)

(3) Use the trackball to position the first caliper.

(4) Press the System Console ↖ Select button to set the first caliper and activate the second caliper.

(5) Use the trackball to position the second caliper.

(6) Press the System Console ↖ Select button to set the measurement.

IMPORTANT: ***Pressing the System Console ⟳ Update button will toggle control between the calipers enabling either or both to be repositioned prior to setting the measurement.***

IMPORTANT: ***To delete a measurement, press the Touch Screen Delete Last button.***

14.6.2.2 To Perform Curved Distance Measurement

(1) Press the System Console Freeze button to stop live imaging.
(2) Press the Touch Screen Measure button.
(3) Press the Touch Screen Method button and turn the adjacent dial to select - Distance set to 'Curved Distance'.
(4) Use the trackball to position the first caliper.
(5) Press the System Console Select button to set the first caliper and activate the second caliper.
(6) Use the trackball to trace the caliper to the desired position.
(7) Press the System Console Select button to set the measurement.

IMPORTANT: ***Pressing the System Console Update button will toggle control between the calipers enabling either or both to be repositioned prior to setting the measurement.***

IMPORTANT: ***To delete a measurement, press the Touch Screen Delete Last button.***

14.6.3 Area or Circumference Measurement

There are four (4) Generic methods of performing the **Area/Circumference** measurement: **Ellipse, Continual, Point by Point** and **Cross**.

14.6.3.1 Ellipse Method Area or Circumference Measurement

(1) Press the System Console Freeze button to stop live imaging.
(2) Press the Touch Screen Measure button.
(3) Press the Touch Screen Area button.
(4) Press the Method button and turn the adjacent dial to select Measurements Area set to 'Ellipse'.
(5) Use the trackball to position the first caliper.
(6) Press the System Console Select button to set the first caliper and activate the second caliper.
(7) Use the trackball to position the second caliper.
(8) Press the System Console Select button to set the second caliper position and activate the Ellipse sides.
(9) Use the trackball to increase/decrease the sides of the Ellipse.
(10) Press the System Console Select button to set the final caliper position.

IMPORTANT: ***Pressing System Console Update button will toggle control between the calipers enabling either or both to be repositioned prior to setting the measurement.***

IMPORTANT: ***The Area and Circumference values are presented on the bottom right of the Display Monitor.***

14.6.3.2 Continual Method Area or Circumference Measurement

(1) Press the System Console Freeze button to stop live imaging.

(2) Press the Touch Screen Measure button.

(3) Press the Touch Screen Area button.

(4) Press the Touch Screen Method button and turn the adjacent dial to select Measurements Area set to 'Continual'.

(5) Use the trackball to position the first caliper.

(6) Press the System Console Select button to set the first caliper.

(7) Use the trackball to trace the caliper around the desired area.

(8) Press the System Console Select button to set the final caliper position.

IMPORTANT: ***If the traced Area is not closed (i.e., the caliper start and end positions are not at the same point), the system will automatically fill in the space with a straight line in order to be able to calculate Area and Circumference when you set the last point with the System Console Select button.***

IMPORTANT: ***To delete a measurement, press the Touch Screen Delete Last button.***

14.6.3.3 Point by Point Area or Circumference Measurement

(1) Press the System Console Freeze button to stop live imaging.

(2) Press the Touch Screen Measure button.

(3) Press the Touch Screen Area button (under the General tab).

(4) Press Touch Screen Method button and turn the adjacent dial to select the Imagio Breast Imaging System Calcs-Area set to 'Point by Point'.

(5) Use the trackball to position the first caliper.

(6) Press the System Console Select button to set the first caliper.

(7) Use the trackball to position the second caliper.

(8) Press the System Console Select button to set the second caliper.

(9) Use the trackball to position the third caliper.

(10) Press the System Console Select button to set the final caliper.

(11) The system will automatically join the first and last caliper positions in order to calculate the Area and Circumference.

IMPORTANT: ***To delete a measurement, press the Touch Screen Delete Last button.***

14.6.3.4 Cross Area or Circumference Measurement

(1) Press the System Console Freeze button to stop live imaging.

(2) Press the Touch Screen Measure button.

(3) Press the Touch Screen Area button.

(4) Press the Touch Screen Method button and turn the adjacent dial to select Measurements Area set to 'Cross'.

(5) Use the trackball to position the first caliper.

(6) Press the System Console Select button to set the first caliper.

(7) Use the trackball to position the second caliper.

(8) Press the System Console Select button to set the second caliper.

(9) Use the trackball to position the third caliper.

(10) Press the System Console Select button to set the third caliper.

(11) Use the trackball to position the fourth caliper.

(12) Press the System Console Select button to set the final caliper.

IMPORTANT: ***To delete a measurement, press the Touch Screen Delete Last button.***

IMPORTANT: ***Pressing the System Console Update button will toggle control between the calipers enabling either or both to be repositioned.***

IMPORTANT: ***L (Length) measurements can be performed using either linear (B) or Curved Distance.***

IMPORTANT: ***All three (3) measurements must be completed to calculate the Volume.***

14.6.4 Percent Diameter Reduction Calculation (% Diam Red)

(1) Press the System Console Freeze button to stop live imaging.

(2) Press the Touch Screen Measure button.

(3) Press Touch Screen Diam Red button.

(4) Use the trackball to position the first caliper of the outer measurement.

(5) Press the System Console Select button to set the caliper position and activate the second caliper of the outer measurement.

(6) Use the trackball to position the second caliper of the outer measurement.

(7) Press the System Console Select button to set the second caliper.

(8) Use the trackball to position the first caliper of the inner measurement.

(9) Press the System Console Select button to set the caliper position and activate the second caliper of the inner measurement.

(10) Use the trackball to position the second caliper of the inner measurement.

(11) Press the System Console Select button to set the second caliper. The resulting % Diameter Reduction is presented on the bottom right of the Display Monitor along with the inner (I) and outer (O) diameter measurements that were used in the calculation.

IMPORTANT: ***To delete a measurement, press the Touch Screen Delete Last button.***

14.6.5 Percent Area Reduction Calculation (% Area Red)

When combined, the two (2) methods of performing the outer and inner Area Reduction measurements—Ellipse and Continual—result in a total of three (3) options.

IMPORTANT: ***The first caliper set is used for the outer measurement of the Area Reduction and the second caliper set is used for the inner measurement.***

Table 14. Percent Area Reduction Calculation Methods

Ellipse/Ellipse	Uses the ***Ellipse*** method for both outer and inner measurements.
Ellipse/Continual	Uses the ***Ellipse*** method for the outer measurement and the Trace method for the inner measurement.
Trace/Continual	Uses the ***Trace*** method for both outer and inner measurements.

14.6.5.1 Ellipse/Ellipse Method of Area Reduction Calculation

(1) Press the System Console Freeze button to stop live imaging.

(2) Press the Touch Screen Measure button.

(3) Press the Touch Screen Area Red button.

(4) Press the Touch Screen Method button and turn the adjacent dial to select Measurements Area Red set to 'Area Reduction Ellipse/Ellipse'.

(5) Use the trackball to position the first caliper of the outer Ellipse.

(6) Press the System Console Select button to set the caliper position and activate the second caliper of the outer Ellipse.

(7) Use the trackball to position the second caliper.

(8) Press the System Console Select button to set the second caliper position and activate the outer Ellipse sides.

(9) Use the trackball to increase/decrease the sides of the outer Ellipse.

(10) Press the System Console Select button to complete the outer measurement.

(11) Use the trackball to position the first caliper of the inner Ellipse.

(12) Press the System Console Select button to set the caliper position and activate the second caliper of the inner Ellipse.

(13) Use the trackball to position the second caliper.

(14) Press the System Console Select button to set the second caliper position and activate the inner Ellipse sides.

(15) Use the trackball to increase/decrease the sides of the inner Ellipse.

(16) Press the System Console Select button to complete the inner measurement.

IMPORTANT: ***The resulting % Area Reduction is presented on the bottom right of the Display Monitor along with the inner (I) and outer (O) measurements that were used in the calculation.***

14.6.5.2 Pressing will toggle control between the calipers enabling either or both to be repositioned. Ellipse/Continual Method of Percent Area Reduction Calculation

(1) Press the System Console Freeze button to stop live imaging.

(2) Press the Touch Screen Measure button.

(3) Press the Touch Screen Area Red button.

(4) Press the Touch Screen Method button and turn the adjacent dial to select the Imagio Breast Imaging System Calcs -–Area Red set to 'Area Reduction Ellipse/Trace'.

(5) Use the trackball to position the first caliper of the outer Ellipse.

(6) Press the System Console Select button to set the caliper position and activate the second caliper of the outer Ellipse.

(7) Use the trackball to position the second caliper.

(8) Press the System Console Select button to set the second caliper position and activate the outer Ellipse sides.

(9) Use the trackball to increase/decrease the sides of the outer Ellipse.

(10) Press the System Console Select button to complete the outer measurement.

(11) Use the trackball to position the caliper at the start position of the inner Trace measurement.

(12) Press the System Console Select button to set the second caliper.

(13) Use the trackball to trace the caliper around the desired area.

(14) Press the System Console Select button to set the second caliper position.

IMPORTANT: ***The resulting % Area Reduction is presented on the bottom right of the Display Monitor along with the inner (I) and outer (O) measurements that were used in the calculation.***

14.6.5.3 Pressing the System Console Update button will toggle control between the calipers enabling either or both to be repositioned. Continual/Trace Method of Percent Area Reduction Calculation

To Perform a Continual/Trace Method Area Reduction

(1) Press the System Console Freeze button to stop live imaging.

(2) Press the Touch Screen Measure button.

(3) Press the Touch Screen Area Red button.

(4) Press the Touch Screen Method button and turn the adjacent dial to select the Imagio Breast Imaging System Calcs - Area Red set to 'Area Reduction Trace/Trace'.

(5) Use the trackball to position the first caliper at the start position of the outer Trace measurement.

(6) Press the System Console Select button to set the first caliper.

(7) Use the trackball to trace the circumference around the desired area.

(8) Press the System Console Select button to set the Trace.

(9) Use the trackball to position the second caliper at the start position of the inner Trace measurement.

(10) Press the System Console Select button to set the second caliper.

(11) Use the trackball to trace the circumference the area of interest.

(12) Press the System Console Select button to set the second caliper position.

IMPORTANT: ***To delete a measurement, press the Touch Screen Delete Last button***

IMPORTANT: ***The resulting % Area Reduction is presented on the bottom right of the Display Monitor along with the inner (I) and outer (O) measurements that were used in the calculation.***

14.6.6 PW Doppler Measurements

14.6.6.1 Velocity Measurements

To Perform a Single Caliper Velocity Measurement

(1) Press the System Console Freeze button to stop live imaging.

(2) With a frozen Doppler Trace, press the Touch Screen Measure button.

(3) Press the Touch Screen Velocity button.

(4) Press the Touch Screen Method button and turn the adjacent dial to select Velocity set to '1 Cal. Velocity'.

(5) Use the trackball to position caliper.

(6) Press the System Console Select button to set the caliper.

IMPORTANT: ***Velocity values are presented on the bottom right of the display.***

To Perform a Double Caliper Velocity Measurement

(1) Press the System Console Freeze button to stop live imaging.

(2) With a frozen Doppler Trace, press the Touch Screen Measure button.

(3) Press the Touch Screen Velocity button.

(4) Press the Touch Screen Method button and turn the adjacent dial to select Velocity set to '2 Cal. Velocity'.

(5) Use the trackball to position the caliper to the peak velocity.

IMPORTANT: ***A Peak Systolic Velocity (PSV) value is presented on the display.***

(6) Press the System Console Select button to set the first caliper and activate a second caliper.

(7) Use the trackball to position the second caliper.

(8) Press the System Console Select button to set the second caliper.

IMPORTANT: ***An End Diastolic Velocity (EDV) value with associated Resistive Index (RI) and Systolic/Diastolic Ratio (SD) is presented on the bottom right of the display.***

14.6.6.2 Doppler Manual Trace Measurement – Continual Method

IMPORTANT: ***To ensure the most accurate results, position the first caliper at the start of the waveform and set the last caliper at end diastole for manual Doppler Traces***

To Perform a Manual Doppler Trace, Using the Continual Method:

(1) Press the System Console Freeze button to stop live imaging.
(2) With a frozen Doppler Trace, press the Touch Screen Measure button.
(3) Press the Touch Screen Trace button.
(4) Press the Touch Screen Method button and turn the adjacent dial to select Trace set to 'Spectrum Continual'.
(5) Use the trackball to position the first caliper at the start of the desired Doppler Waveform.
(6) Press the System Console Select button to set the start position. Use the trackball to draw the trace along the desired Waveform right up to the point of end diastole.
(7) Press the System Console Select button to end and set the Trace.

IMPORTANT: ***The Trace values are presented on the display.***

IMPORTANT: ***To modify an already set trace, move the trackball to position the cursor over the final set point. Press the System Console Update button. Use the Trackball to reposition the trace.***

14.6.6.3 Doppler Manual Trace Measurement – Point by Point Method

To Perform a Manual Doppler Trace, Using the Point by Point Method:

(1) Press the System Console Freeze button to stop live imaging.
(2) With a frozen Doppler Trace, press the Touch Screen Measure button.
(3) Press the Touch Screen Trace button.
(4) Press Method and turn the adjacent dial to select Trace set to 'Spectrum Point by Point'.
(5) Use the trackball to position the first caliper at the start of the desired Doppler Waveform.
(6) Press the System Console Select button to set the first caliper and activate the second.
(7) Use the trackball to position the next trace position.
(8) Press the System Console Select button to set the second caliper and activate the third.
(9) Use the trackball to position the third caliper at the last trace position.
(10) Press the System Console Select button to end and set the Trace.

IMPORTANT: ***The Doppler Trace values are presented on the display.***

IMPORTANT: ***To modify an already set trace, move the trackball to position the cursor over the final set point. Press the System Console Update button. Use the Trackball to reposition the trace.***

14.6.6.4 Doppler Auto-Trace Measurement (Spectrum Range)

To Perform an Auto Doppler Trace (D-Range):

(1) Press the System Console Freeze button to stop live imaging.

(2) With a frozen Doppler Trace, press the Touch Screen Measure button.

(3) Press the Touch Screen Trace button.

(4) Press the Touch Screen Method button and turn the adjacent dial to select Trace set to 'Spectrum Range'.

(5) Use the trackball to position the first caliper.

(6) Press the System Console Select button to set the first caliper and activate the second.

(7) Use the trackball to position the second caliper.

(8) Press the System Console Select button to set it.

IMPORTANT: ***Pressing the System Console Update button will control between the calipers enabling either or both to be repositioned.***

14.7 To Apply Directional Arrow(s) on the Image

14.8 To Apply Pictogram on the Image

14.9 Switching Probes

Chapter 15: MODES: B Mode, Color/Power Doppler Mode, Pulse Wave (PW), Triplex Mode and Panoramic Mode

15.1 Layout of Main Touch Screen (B-Mode Example) - Live

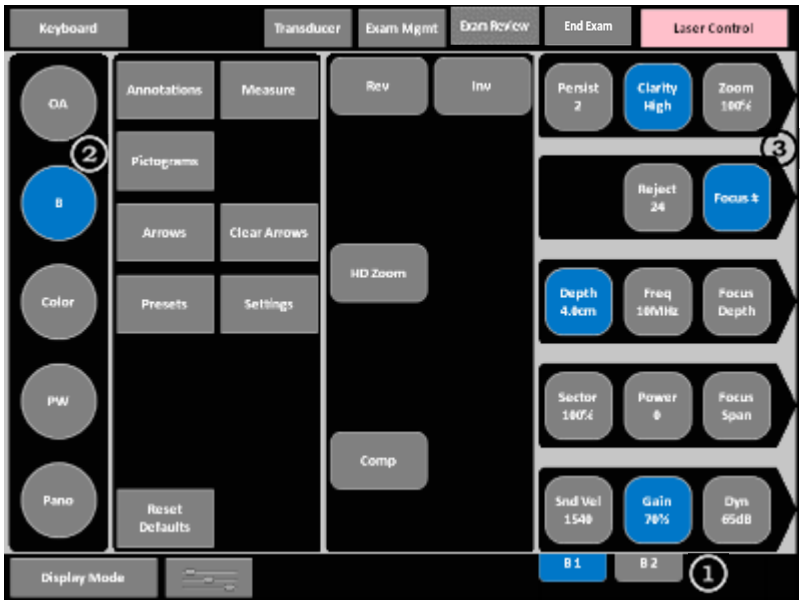


Figure 72: Layout of Main Touch Screen (B-Mode Example with Patient Data Previously Entered)

Table 15. Touch Screen Controls

1	***Touch Screen Tabs***	Press to access additional options. ***IMPORTANT: Tab availability depends on the current imaging mode***
2	***Imaging Mode Buttons***	Imaging Mode buttons activate and deactivate individual imaging modalities.
3	***Imaging Parameter Buttons***	Enable adjustments to be made to the available imaging parameters for the selected mode. Turn/press the adjacent touch screen dial to adjust an active imaging parameter.

15.1.1 Main Touch Screen – Frozen

Once an image has been acquired and frozen, the touch screen will be updated.

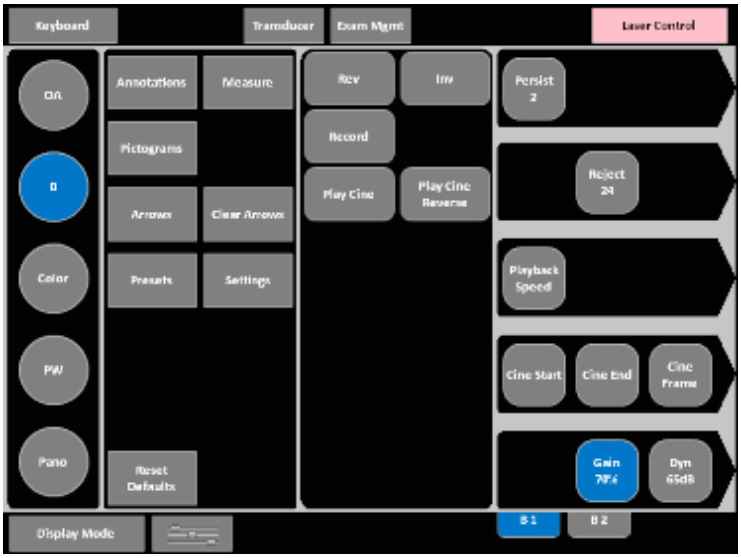


Figure 73: Layout of Main Touch Screen – Frozen (B-Mode Example)

B-Mode and Color Doppler may be used to assist in locating suspected lesions.

15.2 B-Mode Imaging

The B-Mode button is located on the Touch Screen.

15.2.1 Basic Imaging

Any time a User exits OA mode via the System Console OA button the system will go to B-Mode.

The Imagio Breast Imaging System probes provides a range of imaging Frequencies:

- Harmonics: artifact reduction
- Resolution: highest frequency
- General: standard imaging frequency
- Penetration: lowest frequency

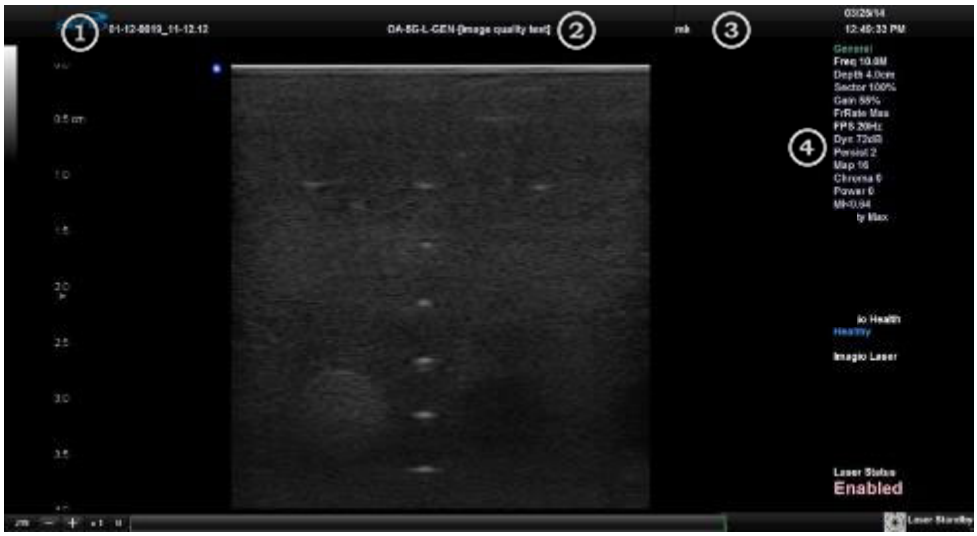


Figure 74: B-Mode

Table 16. B-Mode Field Locations during Imaging

1	Patient Name and ID
2	Application Preset
3	Operator ID
4	B-Mode Imaging Parameters

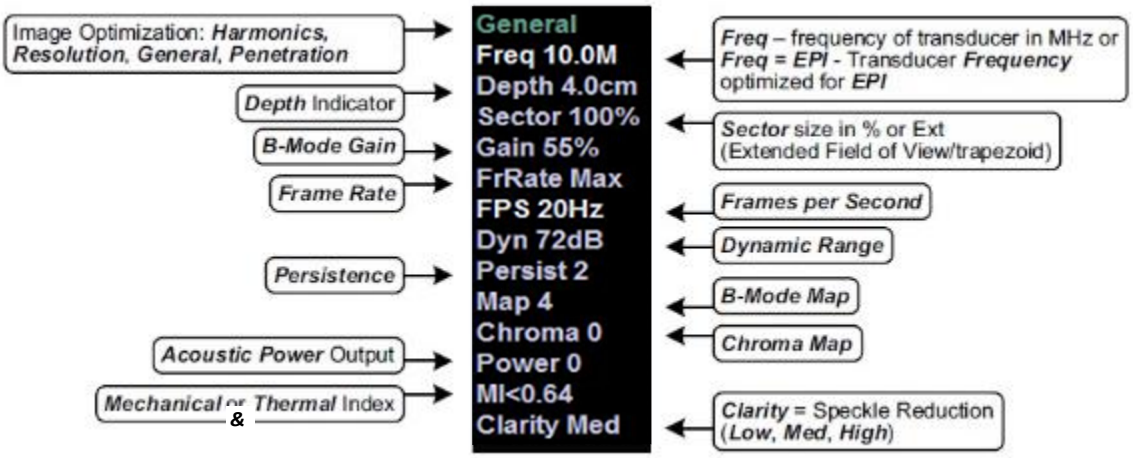


Figure 75: B-Mode Onscreen Imaging Parameters

Table 17. B-Mode Imaging Console Controls

Refer to Appendix A: Touch Screen Mode Action and Imaging Parameters for the description and function of all buttons.

	Used to exit other imaging modes and return to grey scale imaging.
	The TGC on the Touch Screen are used to adjust the Time Gain Compensation.
	Adjust the Probe Frequency: Penetration, General, Resolution, and Harmonics.
	Used to HD Zoom the image in or out.
	Adjust the imaging Depth up or down.
	Adjust the number of (focus), focal zones.
	Display Mode -–Activates Dual and twice to activate 4 up imaging.
	Used in B-Mode to steer the beam on linear probes.
	Used to adjust Acoustic Power. Important: Pressing the dial will not affect the Index setting.

IMPORTANT: ***Press the B-Mode button to exit other imaging modes (Color/Doppler) at any time during the imaging session and return to B-Mode imaging.***

IMPORTANT: ***Additional B-Mode imaging parameters are available on the touch screen under the B-Mode tab.***

15.2.1.1 To Select/Adjust Touch Screen B-Mode Imaging Parameters (Focus Example)

(1) Press the B-Mode Touch Screen B-Mode Tab. Active Tab changes to blue color.

(2) Press the desired imaging parameter button on the touch screen, (e.g., Focus). Button Changes to Blue.

(3) Turn the associated touch screen dial to adjust the imaging parameter. Turning Focus # increases or decreases the number of focal zones. Focus is indicated by the green caret on greyscale the depth scale on the left. When one or more foci are displayed, the focal depth and focal span touch screen buttons appear.

15.2.1.2 To Adjust the Imaging Frequency (Image Optimization)

(1) Press the Touch Screen Frequency button. To adjust the Frequency from General, turn the adjacent dial.

15.2.2 Clarity (Speckle Reduction)

Clarity imaging mode enhances the B-Mode image by performing adaptive filtering of the image. It provides improved visibility of real structures with various levels of speckle reduction.

To Adjust the Clarity (Speckle Reduction) Imaging Mode

(1) Press the B-Mode Touch Screen button.

(2) Press the Touch Screen Clarity button.

(3) Turn the associated touch screen dial to adjust the level of speckle reduction.

15.2.3 Spatial Compound Imaging

To Activate Spatial Compound Imaging

(1) Press the Touch Screen Comp button.

IMPORTANT: ***Spatial Compound imaging is not available during Color imaging. If another mode(s) is selected while in Compound imaging (e.g., Color Mode), when exiting that mode(s), the User will be returned to Compound imaging, not B-Mode.***

15.2.4 Sound Velocity

The sound velocity setting is adjustable from 1300 m/s to 1780 m/s. It allows matching of the biological tissue sound speed to the assumed sound speed used by the Imagio Breast Imaging System in calculating placement of returning echoes. The result is better overall resolution.

For example: When imaging breast tissue, adjust the sound velocity to 1450-1480 m/s.

The Imagio Breast Imaging System defaults to 1480 m/s for the breast imaging preset.

15.2.5 B-Mode Zoom Imaging Button / Zoom Percentage Parameter Button

To Activate the Zoom Feature

(1) On a live image, press the Touch Screen HD Zoom button. Press the System Console Update button to activate.

(2) Press the System Console Select button to alternate between reposition field of view and resize field of view. Use the trackball to reposition or resize the magnified field of view.

(3) On a live image, press the Zoom imaging parameter button and turn the associated dial to increase or decrease the zoom percentage.

IMPORTANT: ***Repositioning of the Zoom field of view is only possible after the image has been magnified to a size that is larger than the image field.***

(4) To exit the HD Zoom feature, press the Touch Screen B-Mode Button.

15.2.6 Dual Imaging Format

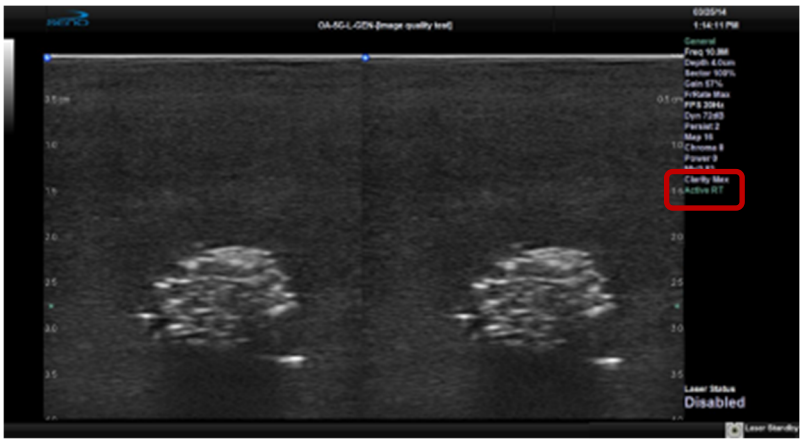


Figure 76: Dual Imaging

Table 18. Dual Imaging

Active Image	Indicates Active image: Active LT: left Active RT: right

To Activate Dual Imaging

(1) With an active B-Mode image, press the touch Screen Display Mode button once.

(2) When a live image appears on the left side of the Display Monitor (Active LT), press the System Console Update button to freeze the Active LT image and unfreeze (i.e., make active) the Active RT image in one step.

IMPORTANT: ***As an alternative, press the System Console Freeze button. Pressing System Console Update button will then toggle between the frozen images. Press the System Console Freeze button again at any time to activate the current image.***

(3) Press the System Console Update button to toggle back and forth between the dual images, freezing the inactive image and unfreezing the newly active image.

(4) Press the System Console Display Mode Twice or Touch Screen B-Mode button to exit Dual imaging.

IMPORTANT: ***Color Doppler is available during Dual but not Quad imaging.***

15.2.7 Quad Imaging Format

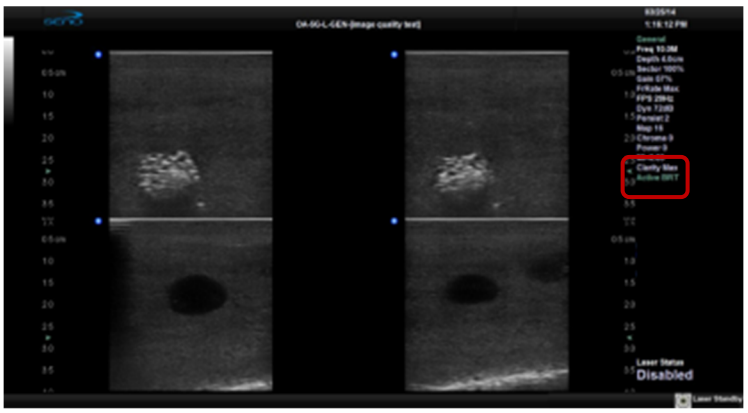


Figure 77: Quad Image

Table 19. Quad Imaging

Active Image	Indicates ***Active*** quadrant: ***Active ULT***: upper left ***Active URT***: upper right ***Active BLT***: bottom left ***Active BRT***: bottom right.

15.2.7.1 To Activate the Quad Imaging Format

(1) With an active B-Mode image, press the Touch Screen Display Mode button twice.

(2) When a live image appears on the upper left side of the Display Monitor (Active ULT), press the System Console Update button to freeze the Active ULT image and unfreeze (i.e., make active) the upper right (URT) quadrant in one step.

(3) Press the System Console Update button again to freeze the current image and move to the next quadrant.

IMPORTANT: ***System Console Update button toggles through the images sequentially: ULT, URT, BLT, BRT.***

(4) Continue pressing the System Console Update button to move through the four (4) images as required. Depending on the method selected above - Update only or System Console Freeze button and -the images will be active or frozen, respectively.

(5) Press the Touch Screen Display Mode once or Touch Screen B-Mode button to exit Dual imaging.

IMPORTANT: ***Color Doppler is available during Dual but not Quad imaging.***

15.3 Color/Power Doppler Imaging Mode

Color Doppler is used to detect blood flow and determine flow direction. Color Doppler displays a red/blue color map providing directional flow information. Power Doppler is more sensitive to low flow rate in small vessels but offers no directional information and uses a yellow color intensity map.

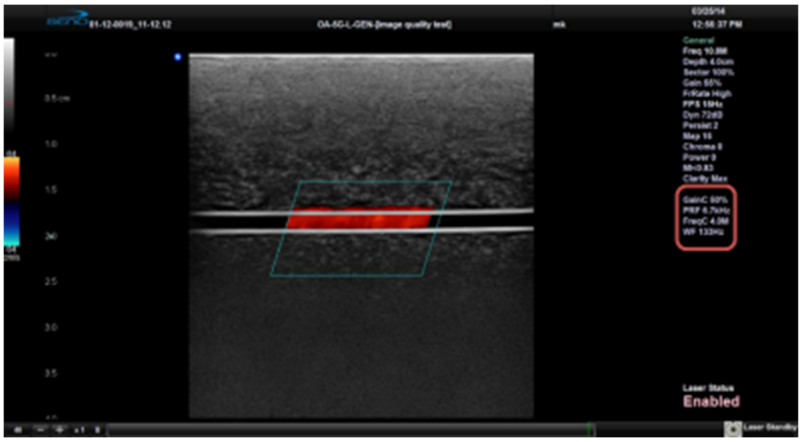


Figure 78: Color Doppler Image

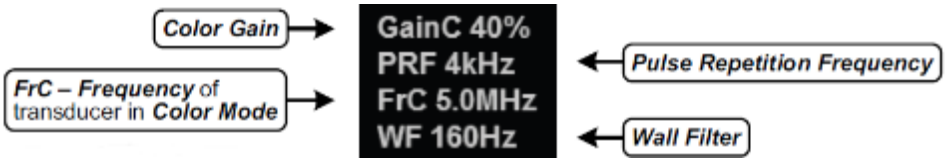


Figure 79: Color Doppler Imaging Parameters

The main Color/Power Doppler imaging controls are located on the Touch Screen.

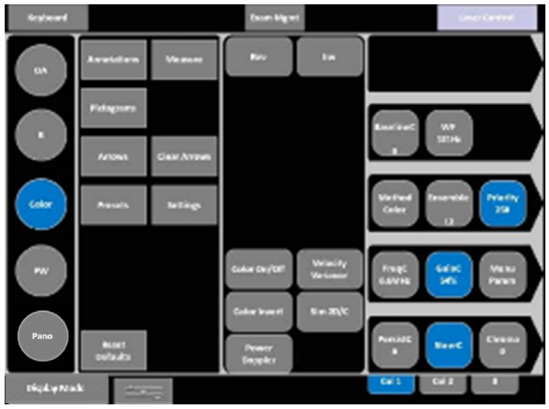


Figure 80: Color Doppler Console Controls

Table 20. Color Doppler Console Controls

	Enters Color Mode
	Activates Power Doppler imaging.
	Adjust the Color Wall Filter higher or lower.
	Adjust the Color Doppler Pulse Repetition Frequency up or down.
	Inverts the direction of the Color Map.
	Steers the Color ROI box right or left.

Additional Color/Power Doppler image optimization controls are available on the touch screen Color Mode tab when the Color imaging mode is active.

15.3.1 To Activate Color Doppler Imaging Mode

(1) Press the Touch Screen Color Doppler button.

(2) Use the trackball to position the Color ROI box to the area of interest.

(3) Press the System Console Select button to toggle control of the trackball to resize the Color ROI box.

(4) Use the trackball to resize the Color ROI box.

IMPORTANT: ***During multiple mode imaging (e.g., B-Mode/Color/PW Doppler) use the System Console Update button to toggle control of the trackball for Color ROI box positioning, Color ROI box resizing and PW cursor/Gate positioning. The Color ROI box moves with the PW cursor.***

15.3.2 To Select/Adjust Touch Screen Color Imaging Parameters

(1) While in Color imaging, select one of the Touch Screen Color Mode Tabs.

(2) On the touch screen, press the desired imaging parameter button to make any required adjustments.

(3) Turn the associated touch screen dial to adjust the imaging parameter.

15.3.3 Power Doppler Imaging Mode

To Activate Power Doppler Imaging Mode

(1) Press the Touch Screen Color Doppler button.

(2) Press the Touch Screen Power Doppler button and use the trackball to position the Color Power ROI box to the area of interest.

(3) Press the System Console Select button to toggle control of the trackball to resize the Color Power ROI box. Move the trackball to resize.

(4) Press the System Console Select button to set the new size and reposition with the track ball.

(5) Press the Touch Screen Color Doppler button to exit Power Doppler imaging.

15.3.4 Pulse Wave (PW) and Triplex

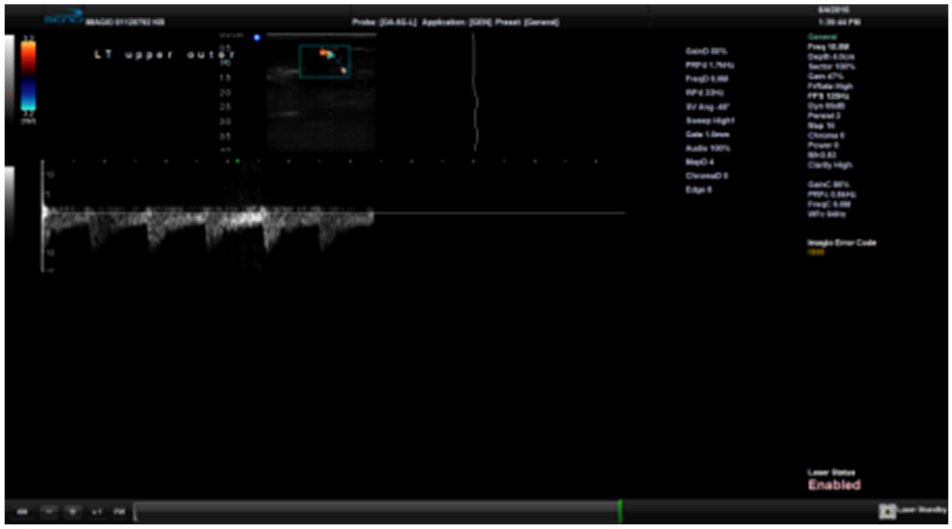


Figure 81: PW Doppler Imaging (Combined with Triplex)

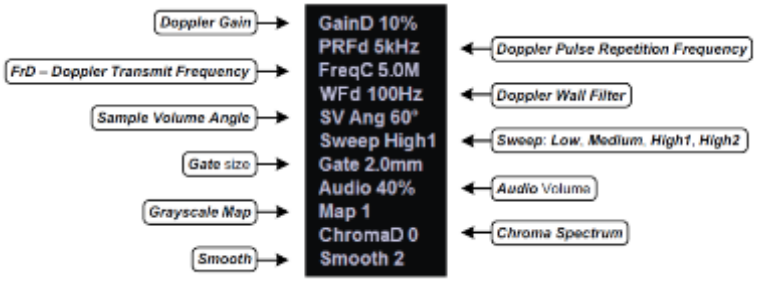


Figure 82: PW Imaging Parameters

The key PW imaging controls are located on the Touch Screen.

Table 21. PW Touch Screen Controls

	Press to activate PW mode.
	Press and turn the adjacent dial to adjust the trace baseline up or down.
	Press and turn the adjacent dial to adjust the PRF up or down.
	Press to Invert the direction of the trace.
	Press to toggle between +60, -60 and 0 degree angle correct selections. Turn the adjacent dial to make angle corrections in 2-degree increments.
	Press and turn the adjacent dial to steer the cursor angle right or left. Also used to steer Color ROI box and B-Mode linear image field.
	Press and adjust the adjacent dial to increase or decrease the audio volume.

Additional PW imaging parameters are available on the touch screen to optimize the Live Trace. Refer to Appendix A: Touch Screen Mode Action and Imaging Parameters.

15.3.5 PW Imaging Mode

15.3.5.1 To Activate PW Doppler Imaging Mode:

(1) Press the Touch Screen Pulsed Wave Doppler button.

IMPORTANT: ***To adjust the Sample Volume Gate size in full screen B-Mode/PW cursor, press the Touch Screen Gate button and turn the associated dial.***

(2) Use the trackball to position the cursor/Gate in the area of interest.

(3) Press the System Console Update buttons to display a live Trace.

(4) Press the System Console Update buttons to toggle back and forth between PW Trace and B-Mode/cursor.

(5) Press the Touch Screen Pulsed Wave Doppler or B-Mode button to exit PW imaging mode.

15.3.5.2 To Select/Adjust Touch Screen PW Imaging Parameters:

(1) While in PW, select one of the Touch Screen PW Mode tabs.

(2) Press the desired selection (e.g., Chroma).

(3) Turn the associated touch screen dial to adjust the imaging parameter.

15.3.6 Triplex Imaging Mode

Triplex imaging mode combines live B-Mode/Color with live PW imaging, allowing the User to image with B-Mode/Color and PW modes simultaneously.

IMPORTANT: ***Triplex imaging may diminish the quality of the B-Mode/Color image and may cause artifacts.***

15.3.6.1 To Activate Triplex Imaging Mode:

15.4 Auto-Gain/B

Auto-Gain/B automatically optimizes image brightness for the following modes:

- B
- Dual/Quad
- Compound (Spatial Compounding)
- Color
- PW Doppler
- Triplex

15.4.1 To Initiate Auto-B Functionality:

(1) With an active image in any of the supported modes, press the Touch Screen Gain button.

(2) Press the corresponding dial to active the Auto-Gain feature.

15.5 PANORAMIC MODE

Panoramic imaging enables the user to generate a panoramic view of the B-Mode ultrasound image field, which is much wider than the typical probe field of view.

Panoramic images are composed of several standard ultrasound images acquired as the probe is moved along the anatomical area of interest in a direction parallel to the probe array. The resulting compound or composite image displays a large cross section of the area of interest which can then be viewed, measured, labeled and archived.

IMPORTANT: ***The Pano ROI box can only be vertically resized and/or repositioned.***

IMPORTANT: ***Measurements performed on the acquired Panoramic image may be inaccurate as the accuracy of the geometric re-composition is very user-dependent. Measurements performed on the acquired Panoramic image should be used for informational purposes only.***

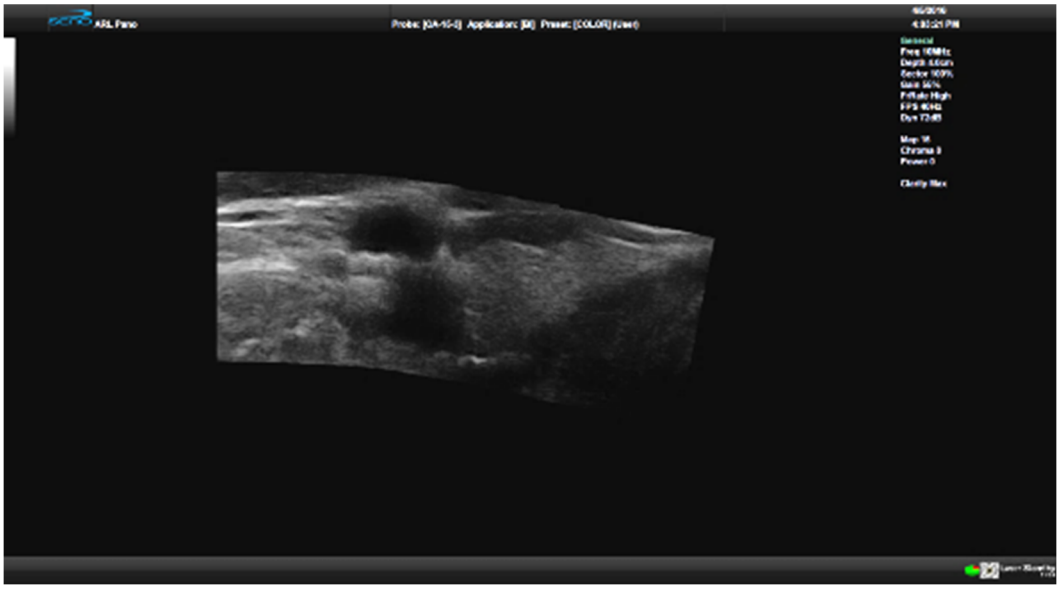


Figure 83: Panoramic Image

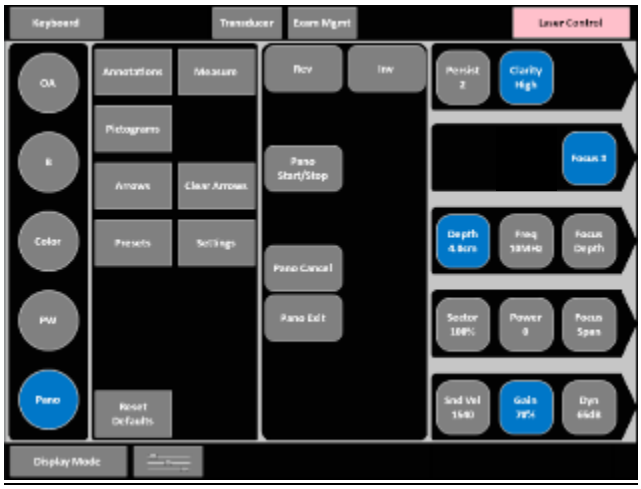


Figure 84: Panoramic Mode Button

15.5.1 To Activate the Panoramic (Pano) Imaging Mode:

(1) Press the Touch Screen Pano mode button during live B-Mode imaging. A progress bar with the message **Loading Panoramic Tables…** will be presented onscreen.

(2) Use the trackball to vertically position the Pano ROI box. The edge of the Pano ROI box will be marked with a solid line.

(3) Press the System Console Select button to set it. The edge of the Pano ROI box will change to dotted line.

(4) Use the trackball to vertically resize the Pano ROI box. To switch back and forth between positioning (solid line) and resizing (dotted line) the Pano ROI box, press the System Console Select button.

(5) To begin acquiring a panoramic image, position the left side of the anatomical area of interest within the Pano ROI box.

(6) Press the System Console Update button or tap Pano Start/Stop on the touch screen to begin the panoramic acquisition.

(7) Move the probe along a path parallel to the probe array in the area of interest. For best results move the probe at a slow and steady pace.

(8) When a suitable Pano image is acquired, press the System Console Freeze or Update button or press the touch screen Pano Start/Stop. The generated panoramic image appears in the image field.

(9) Press the touch screen Pano Exit button to exit panoramic mode and return to B-Mode imaging.

Chapter 16: Managing Patient Data

Entering patient-specific data through the Exam Management Page automatically creates a unique folder in which the patient data is stored.

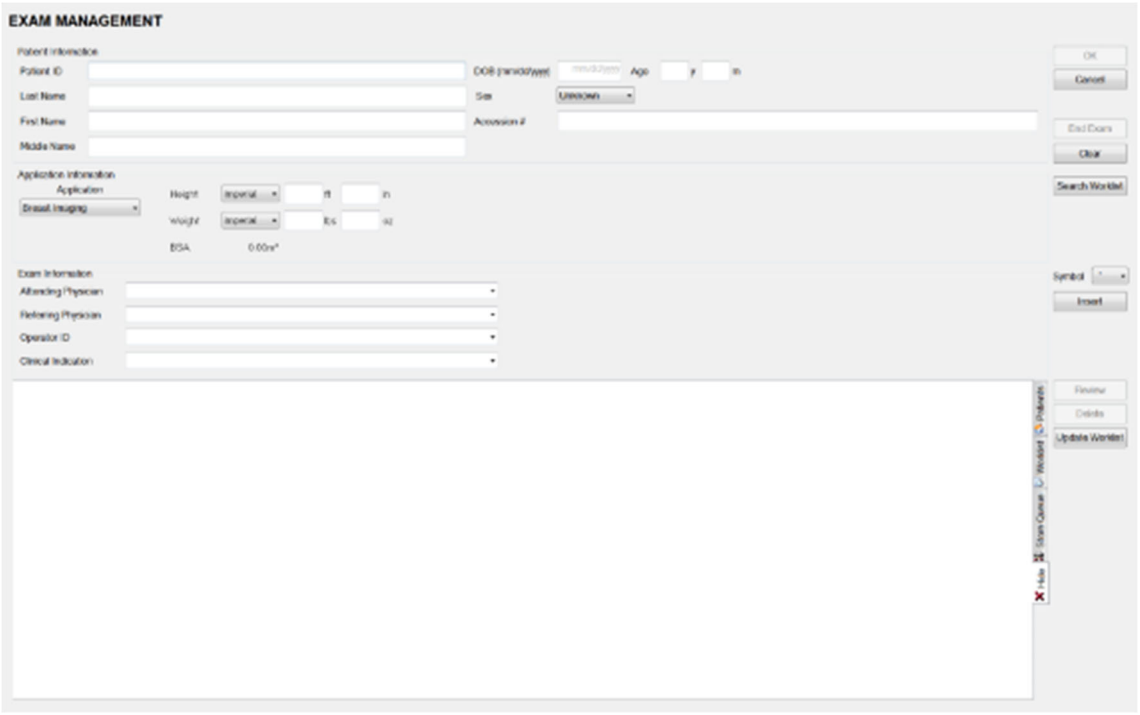


Figure 85: Exam Management Screen

When in imaging mode, the user can navigate to the Exam Management Page using the top buttons, Exam Management or End Exam. Use the End Exam Button when a patient exam is complete. This automatically disables the laser and enters the Exam Management Page.

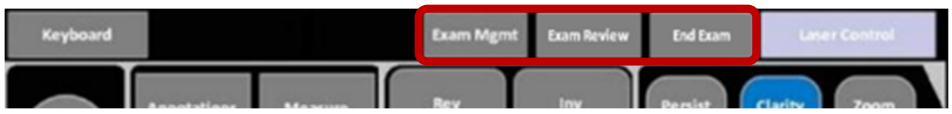


Figure 86: Touch Screen Exam Management Buttons

Table 22. Exam Management Page Options

OK	Saves the changes made to the Exam Management Page and returns to imaging. Note: If a unique Patient ID is not entered manually the system will create one automatically (e.g., {C9B3F82B-BE52-4C79-8C45-28375D69F8C9}).
Cancel	Cancels any changes made to the Exam Management Page and returns to live imaging. Cancel will not undo the End Exam function.
End Exam	Ends the current exam session, clears the Patient, Application and Exam data fields and prints/clears the printer queue (e.g., if printer image sheet is set for 2x2 and only two (2) images were saved, ending the exam signals the system that no more images are coming to fill up the sheet and sends the image sheet to the printer). All measurements visible on the LCD display are cleared. Note: Before ending an exam, ensure the active image has been saved/printed using the console 1 or 2 button to be able to recall it via the Review button on the Exam Management Page or the Exam Review button on the touch screen.
Clear	Clears the Patient and Exam data fields. Clear will also end current exam if one is open, however, it does not delete the file.
Search Worklist	Enables a DICOM or ERM Worklist search.
Insert (Symbol)	Enables the insertion of text symbol(s) not available on the keyboard (e.g., punctuation, symbols and letters from other languages).
Review	Opens the Exam Review Page for the current patient or patient(s) selected from Patient file storage.
Delete	Removes the currently selected patient(s) from Patient file storage.
Update Worklist	Updates a DICOM or ERM Worklist search. Note: This button will only be available if the system is configured for DICOM. To update Worklist data, the system must also have an active connection to a DICOM server.

Tabs	• Patients: list of Patients/Exams currently available on the system
	• DICOM
	  • Worklist: if enabled in DICOM
	  • Store Queue: if enabled in DICOM
	  • Print Queue: if enabled in DICOM
	  • Hide: hides data to preserve privacy.

MANAGING PATIENT DATA

16.1 To Enter Patient Data

16.2 Patients, Hide, and Store Queue Tabs

16.3 Reviewing / Deleting Recorded Patient Scan Files Before Uploading to PACS

16.4 End Exam Command

16.5 Completing the Scan Session

16.6 After Scan Tasks

16.7 Uploading Image and Video Data

Uploading image and video data is configurable by the local service provider during the Imagio Breast Imaging System install.

16.7.1 Transferring Image and Video Data

(1) Press the Touch Screen Exam Management button.

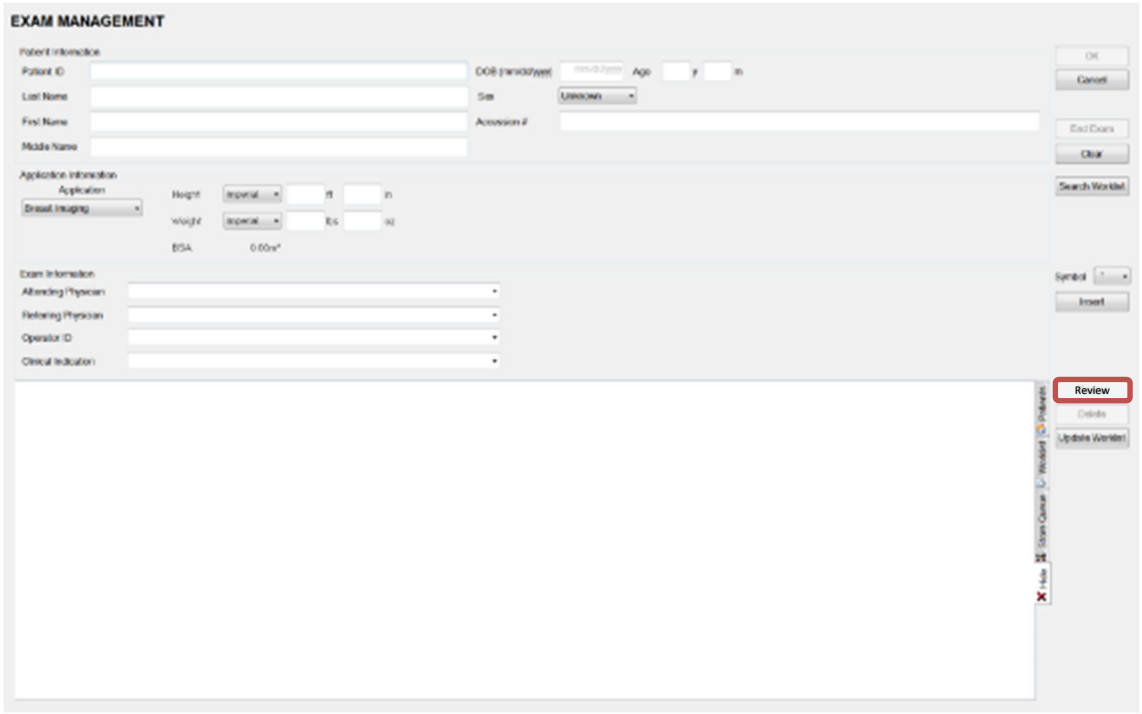


Figure 90: Display of the Exam Management Page

(2) In the Patient ID column, select the patient file.

(3) Press the Exam Management Page Review button.

(4) Select the desired Patient(s), Exam Date and/or images in the Image Review Page.

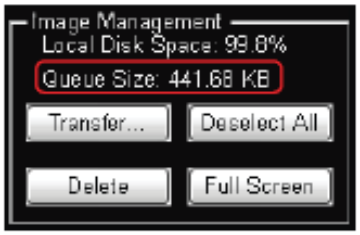


Figure 91: Patient(s), Exam Data Entry

IMPORTANT: ***The amount of space required is listed under Image Management as Queue Size. Select Deselect All to reset the screen and deselect the patient(s), exam(s) and image(s).***

(5) Select Transfer

(6) Select the desired Storage Destination.

IMPORTANT: ***If a DICOM Storage Server is connected, it will also be available for selection.***

IMPORTANT: ***This field is only available if the selected Storage Destination will create a digital copy of the file (e.g., a removable USB device).***

(7) Select the desired Image Format (Default (PNG), JPEG, Bitmap (BMP), or DICOMDIR).

(8) If desired, select Save Settings to save the current transfer settings as the default.

(9) Select Send to transfer the files and/or images or Close to exit without transferring.

IMPORTANT: ***The original files will remain unchanged on the local hard drive.***
The Update Progress bar displays the transfer progress for USB. PACS transfers are listed in the exam management Storage Queue tab until they are complete.

The image management system enables Users to transfer stored images and Cine clips to a storage medium: DICOM archive or USB medium, etc.

IMPORTANT: ***To select an entire exam, select the checkbox for the desired exam.***
To select all exams for a patient, select the checkbox for the desired patient.
To select only the desired image(s) open each exam and select the individual checkbox(es).

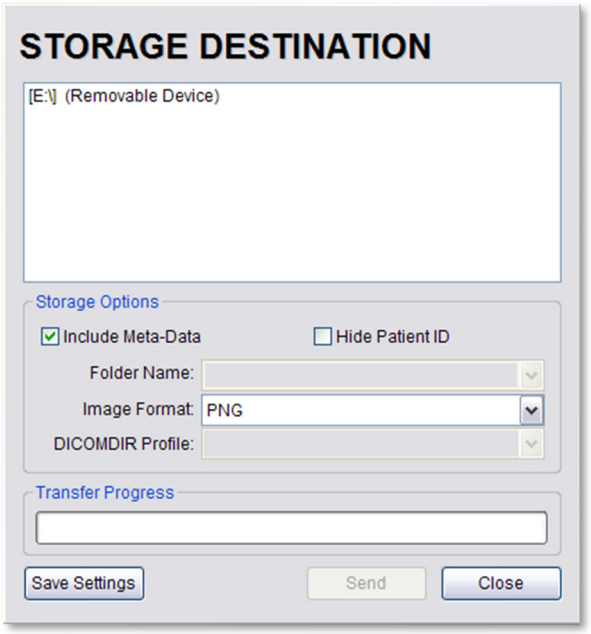


Figure 92: Storage Destination Dialogue

Table 23. Storage Destination Options

Storage Destination			All available storage options will be listed here, either locally or via the network: DICOM archive or USB medium. IMPORTANT: ***A removable USB device must be connected to the system in order to have it appear in the list of Storage Destinations.***
	Image Format		Enables the selection of four (4) different image formats. IMPORTANT: ***Selecting anything other than the default (PNG) will extend the image transfer time as PNG images will have to be converted to the new format. Bitmap and DICOM images in particular will take significantly more time to transfer.***
		PNG	Portable Network Graphics image format. This is the default selection. The average PNG image size is 100Kb.
		JPEG	Joint Photographic Experts Group image format.
		Bitmap (BMP)	Converting the image to a Bitmap (BMP) increases the image size as follows: • 800 x 600 Bitmap image = approximately 2Mb • 1024 x 768 Bitmap image = approximately 3Mb.
		DICOMDIR	DICOMDIR image format. DICOMDIR enables Users to copy images to an alternate media if—for whatever reason—it is not possible to transfer the images directly to the DICOM server. They can then be copied to the DICOM server later.

DICOMDIR Profile	Select the appropriate DICOMDIR Profile (DICOMDIR Profiles are defined in the DICOM Standard.)
Transfer Progress	Displays the file transfer progress. If multiple DICOM Storage Servers have been configured, after selecting Send, the User will be able to select the specific Server (or set of Servers) to which the data will be transferred.
Save Settings	Select to save the transfer settings as the default for future use.
Send	Select to complete the image transfer.
Close	Select to clear the dialog and exit without transferring the images.

Chapter 17: User Activities

Usage of the Imagio Breast Imaging System and laser emission may be documented to satisfy Regulatory requirements. Typically, System usage is recorded in an Imagio Breast Imaging System Usage Log and laser emissions are recorded in a Laser Usage log. One or more agencies may review this information. For example, your region Laser Certification authority may audit your facility and request proof of laser usage documentation.

17.1 The Imagio Breast Imaging System Daily Log

17.2 Daily Inspection of Probe, Cables and Connections

17.3 Adding Distilled Water to the Imagio Breast Imaging System's 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 System usage. It is required that the User add distilled water to the laser coolant reservoir as needed. Typical refill frequency is 1 -4 weeks. Additionally, the Add Coolant message appears on the bottom right of the display to alert the User of the need to add distilled water to the laser coolant reservoir.

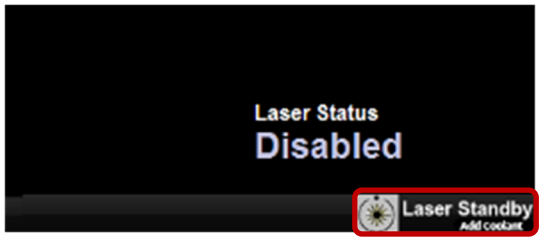


Figure 93: Adding Distilled water to Laser Coolant Reservoir

⚠***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.

- Fill the refill bottle away from the Imagio Breast Imaging System.
- 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 microbiology contamination of the cooling system. Use only distilled water when filling the laser coolant reservoir.

17.3.1 To Add Distilled Water to the Imagio Breast Imaging System's Laser Coolant Reservoir

(1) In an area away from the Imagio Breast Imaging System, add distilled water to the Seno approved refill bottle with distilled water with only enough distilled water to reach the fill line.

17.3.2 To Refill the Distilled Water Bottle

(1) Turn the distilled water bottle cap in the counterclockwise direction to remove.

(2) Pour only approved Purified Water – Distilled into the bottle until full. Specifications for Distilled Water is found in Appendix B: .

(3) Replace the distilled water bottle cap, turn distilled water bottle cap clockwise until snug.

(4) On the back of the Imagio Breast Imaging System cart, 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.

Figure 94: Refill Bottle

Figure 95: Overflow Bottle

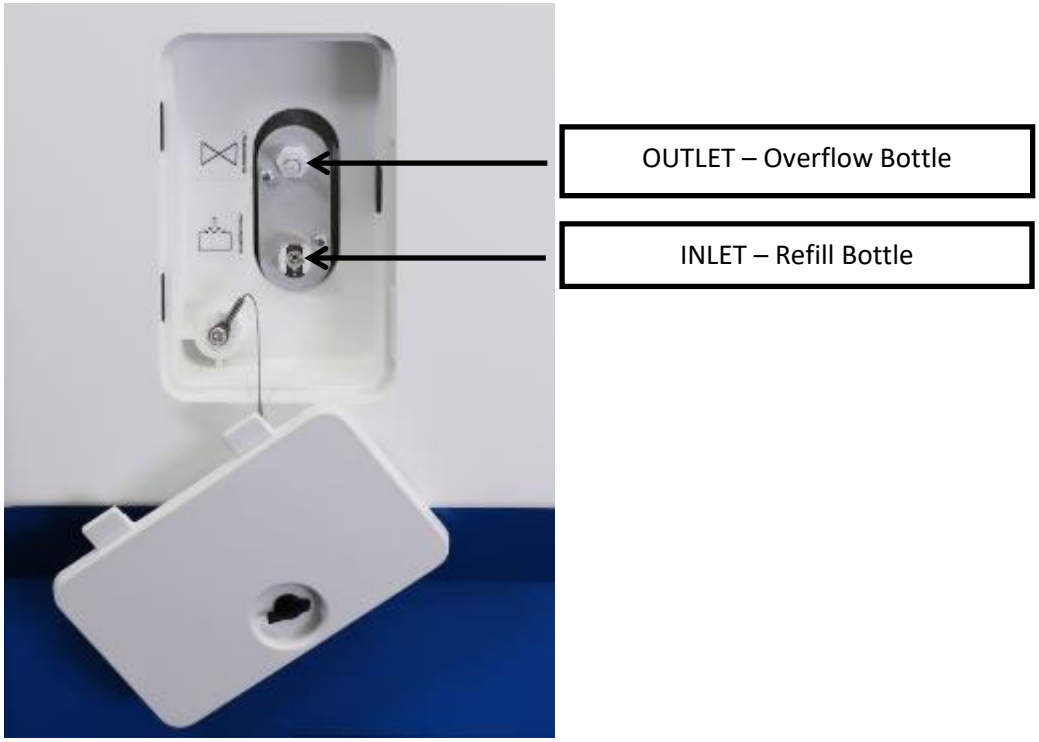


Figure 96: Outlet and Inlet Coolant Reservoir Ports

(5) Ensure that the refill bottle cap is securely tightened, connect the refill bottle spout to the distilled water supply **inlet**. Push the connector onto the inlet until an audible click is heard which indicates the connector is locked to the inlet.

(6) Hold the distilled water bottle in the upright position. Squeeze the bottle to feed distilled water into the reservoir until distilled water is visually seen flowing into the overflow bottle.

(7) 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.

(8) 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 you are 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.***

17.4 Correct Laser Power Calibration

Calibrating the Imagio Breast Imaging System lasers maximizes image quality. Laser power calibration is to be performed whenever the Imagio Breast Imaging System displays a message to the User that a laser power calibration is due. (The Imagio Breast Imaging System may require additional calibration checks based on the Imagio Breast Imaging System usage.)

The Imagio® Breast Imaging System Calibration Wizard is a software application that steps the User through the laser power calibration procedure used to check the OA/US Probe energy output. The OA/US Probe will be placed in the Calibration Port, a hardware tool that measures the laser output power from the OA/US Probe to enable the Imagio Breast Imaging System software to make laser power adjustments. Upon completion of the Imagio® Breast Imaging System Calibration Wizard, the Imagio Breast Imaging System software uses the data collected during the procedure to calibrate the laser output power for optimum image quality and performance. Results are automatically documented in the Imagio Breast Imaging System log.

After 1 days and 23 hours (or as defined), the system will recommend that calibration be performed communicated through messages in the bottom left of screen. After 2 days, the system will require calibration. The laser status code Cal. Required will appear on the bottom right.

Figure 97: Calibration Required Example

If calibration is needed, the User is informed why in a pop-up message.

IMPORTANT: ***If calibration is determined to be required, the User is allowed 60 minutes of use to finish the current scan.***

17.4.1 General Instructions

Please allow 5 minutes to complete the calibration procedure.

The Laser Enable password must be entered to perform the calibration.

IMPORTANT: ***If the incorrect password is entered, a pop-up message appears indicating "Invalid Laser Password"***

IMPORTANT: ***Perform the Imagio® Breast Imaging System Calibration Wizard and the Machine Check if an OA/US Probe is replaced with a new OA/US Probe to ensure proper power output and image quality.***

IMPORTANT: ***If a calibration error is detected at any time during the procedure that requires the Imagio® Breast Imaging System Calibration Wizard to be terminated, a termination message will appear on the Display. Call the local service provider. Minor error messages may appear on the Display Monitor that will not terminate the calibration wizard. If these messages appear, continue the wizard through to completion. Do NOT dismiss these errors until the calibration is complete and the wizard closed.***

IMPORTANT: ***Document the date and time of each laser calibration in the Imagio Breast Imaging System Daily Log if you are required to record the Imagio Breast Imaging System usage by your local laser authority.***

17.4.2 Performing Laser Power Calibration

It is necessary to reach the end of the Imagio® Breast Imaging System Calibration Wizard (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 Wizard to shut down early, the OA/US Probe calibration has failed. Please call the local service provider.

IMPORTANT: ***Selecting the Cancel button to prematurely end the Imagio® Breast Imaging System Calibration Wizard at any point after the wizard has started will log this action as "Calibration terminated by User."***

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 Probe face or Calibration Port Shield during calibration may cause erroneous calibration errors.***

17.4.2.1 To Perform the Laser Power Calibration Procedure

(1) Wear Seno approved laser protective eyewear and instruct everyone in the room to wear the Seno approved eyewear.

⚠ ***WARNING:*** Invisible laser light is emitted from the OA/US Probe. Reflected and/or misdirected laser light may damage eyes.

- Never use any controls or adjustments or performance settings other than those specified herein.
- The Patient, the Imagio Breast Imaging System User, 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 OA/US Probe is out of its holder. Refer to Chapter 2.4.12 Laser Protective Eyewear. 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 Probe, and calibrating laser energies or any other time the Imagio Breast Imaging System is powered on and the OA/US Probe is removed from the probe holder.
- Never look directly at the laser beam even when laser protective eyewear is being worn.
- Never 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 Probe away from everyone's eyes at all times.
- Only use your foot to press the foot switch.
- Always release the foot switch before removing the OA/US Probe from the skin or holder/sheath.
- Always follow the laser safety precautions prior to laser emitting to protect the Patient, User, and Observers.
- Always place the OA/US Probe in the OA/US Probe holder when not in use. This OA/US Probe holder is designed to minimize the release of laser light due to an unintentional activation of the foot switch.

---

(2) Inspect:

a) the OA/US Probe cables and connections for damage.

b) the external labels on the Imagio Breast Imaging System.

Report any damage or label degradation by calling the local service provider.

(3) Inspect and clean the face of the OA/US Probe with the Seno approved wipes ensuring all gel (wet and dry) and other debris are completely removed. Refer to Chapter 5.1 Inspect, Clean, and Disinfect, the OA and Ultrasound Probes

(4) The OA/US Probe Calibration Adapter is a device used to guide and properly seat the OA/US Probe in the Calibration Port. The OA/US Probe Calibration Adapter is stored in the Calibration port. The Power Sensor Shield is a clear window barrier that protects the light sensor.

a) Open the front panel door and remove the OA/US Probe Calibration Adapter and set aside.

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

Figure 98: OA/US Probe Calibration Adapter and Calibration Port Inspection

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

Figure 99: OA/US Probe Calibration Adapter and Calibration Port Inspection

(6) Enter OA mode and Enable laser emission by entering the password into the password dialog box.

(7) Place the OA/US Probe Calibration Adapter over the OA/US Probe.

Figure 100: Installing the OA/US Probe Calibration Adapter onto the OA/US Probe

Figure 101: OA/US Probe with Properly equipped OA/US Probe Calibration Adapter

(8) Verify the Calibration Port is dry before inserting the OA/US Probe and equipped Calibration Adapter. Insert the OA/US Probe with the equipped Calibration Adapter into the Calibration Port until it is seated firmly against the Power Sensor Shield. The Imagio® Breast Imaging System Calibration Wizard appears automatically once the OA/US Probe with the Calibration adapter is seated properly in the Calibration Port.

Figure 102: Inserting the OA/US Probe with Properly equipped OA/US Probe Calibration Adapter into the Calibration Port

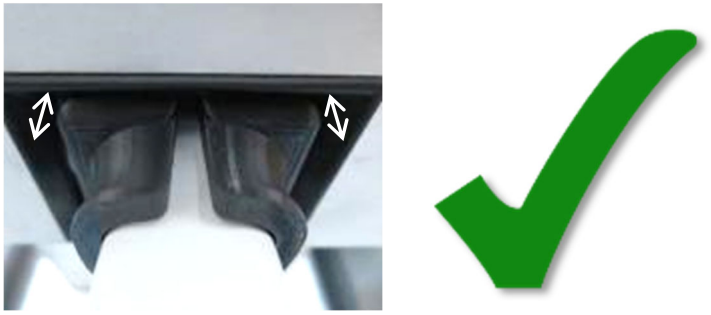


Figure 103: Properly Seated: OA/US Probe with equipped OA/US Probe Calibration Adapter flush with the Power Sensor Shield

Figure 104: Improperly Seated: OA/US Probe with equipped OA/US Probe Calibration Adapter face is angled and not flush with the Power Sensor Shield

IMPORTANT: ***Ensure that the OA/US Probe is securely seated firmly against the Power Sensor Shield in the Calibration Port. If the OA/US Probe becomes slightly dislodged from the port, the procedure will automatically stop.***

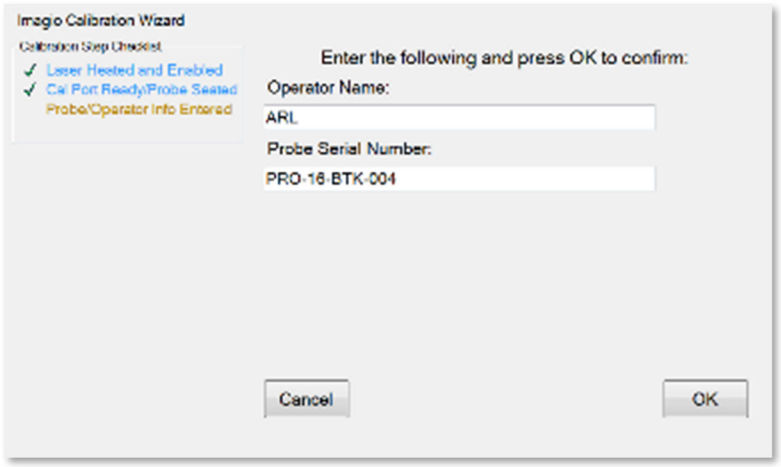


Figure 105: The Imagio® Breast Imaging System Calibration Wizard Starts

(9) In the Operator Name field, enter name of user performing calibration.

(10) In the Probe Serial Number field, enter the OA/US Probe serial number exactly as it appears on OA/US Probe label.

(11) Select the OK button.

Figure 106: Warning: Laser Protective Eyewear Required Screen

(12) Select the OK button on the Laser Protective Eyewear Required screen.

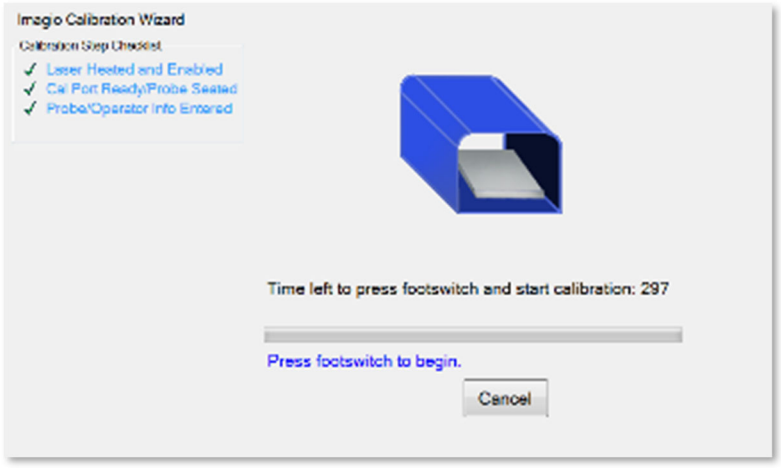


Figure 107: Foot Switch Dialog Box

IMPORTANT: ***The calibration procedure is about to begin. From this point forward, you will need to press the foot switch down completely and fully to the floor for approximately 3 minutes.***

IMPORTANT: ***If necessary, the foot switch can be momentarily released during the calibration. If the foot switch release exceeds 300 seconds, the wizard will automatically terminate and a "Terminated by User" message will be logged.***

(13)Press the foot switch down completely to begin. The calibration screens will update as the calibration proceeds.

⚠ ***WARNING:*** Invisible laser light is emitted from the OA/US Probe. Reflected and/or misdirected laser light may damage eyes.

- Only use your foot to press the foot switch.
- Always release the foot switch before removing the OA/US Probe from the skin or holder/sheath.

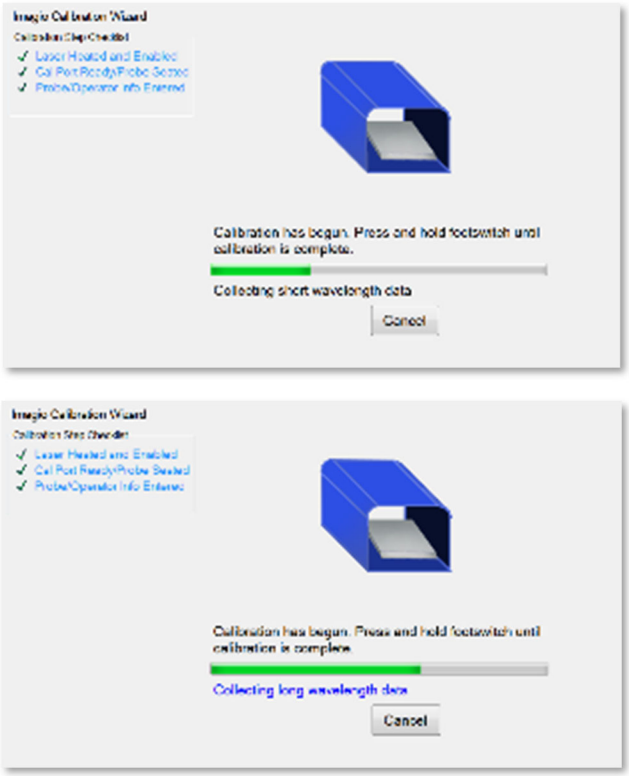


Figure 108: Calibration Status Screen Examples

(14)Upon completion of the Imagio® Breast Imaging System Calibration Wizard, the Calibration Complete message will appear on the Display Monitor with either a success or failure message.

(15)On the Calibration Completed dialog, follow the action bullet list and select the Exit button.

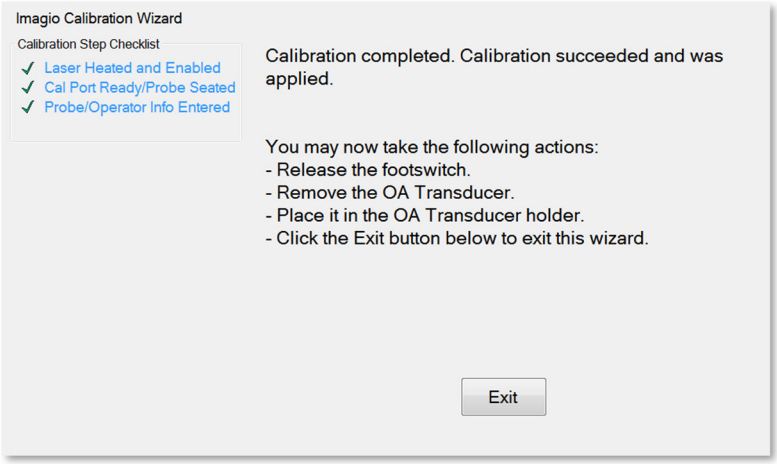


Figure 109: Successful Calibration Message

(16)Remove the OA/US Probe from the Calibration Port.

(17)Remove the Calibration adapter from the probe and place the Calibration adapter in the Calibration port. Place the OA/US Probe in the OA/US Probe Holder.

Unsuccessful Calibration Message

IMPORTANT: ***If the calibration was unsuccessful, a message will be displayed that reads: "Calibration Completed. Calibration Data was invalid and calibration was not applied." along with a failure code. Please make note of this Failure Code and call the local service provider.***

If the Imagio Breast Imaging System computer communication is slow, calibration error messages such as "Error obtaining calibration success/failure result" or "Calibration complete. Status of calibration application could not be determined" may be displayed instead of the standard successful/unsuccessful messages.

The Imagio Breast Imaging System will request an additional calibration if the calibration results are not satisfactory.

If time permits, completely shut down the Imagio Breast Imaging System as described in Chapter 6.2 6.2 Powering , then power on Imagio® Breast Imaging System refer to Ch 6.1 6.1 Powering On the , and attempt to run the Imagio® Breast Imaging System Calibration Wizard. If the calibration fails again, please call the local service provider.

Laser Adjustment Period

The system may begin a Laser Adjustment Period after laser power calibration. The adjustment period generally requires 3-10 seconds and a maximum of 60 seconds. Laser Adjustment Period 0

- No laser energy will emit from the OA/US Probe during the Laser Adjustment Period
- The laser emit light will illuminate during the Laser Adjustment Period
- No OA images will be displayed on the monitor until adjustment is complete
- The word "Preparing" is shown below the laser "Ready" icon on the bottom right of the display

Figure 110: Laser Adjustment Period - Preparing

17.5 Machine Check

Machine Check is a procedure which a Service representative performs after service or maintenance.

A user may perform a machine check to confirm the Imagio Breast Imaging System operation.

Always call Seno Service with any Imagio Breast Imaging System image or performance concerns. Seno Service will determine whether suboptimal performance is related to phantom degradation or suboptimal machine performance.

With the Imagio Breast Imaging System, using the OA Flat Breast Phantom, an image is taken, saved, and assessed to confirm the Imagio Breast Imaging System operation on a regular basis.

A user may be asked to perform the machine check procedure by Seno Service if there are any changes in image quality between service intervals.

IMPORTANT: ***Perform the Imagio Breast Imaging System Machine Check if the OA/US Probe is replaced with a new OA/US Probe.***

17.5.1 To Initiate the Imagio Breast Imaging System Machine Check Procedure

Ensure everyone in the scan room is wearing laser protective eyewear; wear the Seno approved laser protective eyewear and instruct everyone in the room to also wear the Seno approved eyewear. This is a laser safety requirement.

⚠ ***WARNING:*** Invisible laser light is emitted from the OA/US Probe. Reflected and/or misdirected laser light may damage eyes.

- Never use any controls or adjustments or performance settings other than those specified herein.
- The Patient, the Imagio Breast Imaging System User, 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 OA/US Probe is out of its holder. Refer to Chapter 2.4.12 Laser Protective Eyewear. 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 Probe, and calibrating laser energies or any other time the Imagio Breast Imaging System is powered on and the OA/US Probe is removed from the probe holder.
- Never look directly at the laser beam even when laser protective eyewear is being worn.
- Never 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 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 Probe from the skin or holder/sheath.
- Always follow the laser safety precautions prior to laser emitting to protect the Patient, User, and Observers.
- Always place the OA/US Probe in the OA/US Probe holder when not in use. This OA/US Probe holder is designed to minimize the release of laser light due to an unintentional activation of the foot switch.

---

(1) If necessary, turn the Imagio Breast Imaging System on.

(2) Refer to System Power ON/OFF Chapter 6.

IMPORTANT: ***If the laser times out and goes into laser standby as indicated by the Laser Standby icon appearing on the Display Monitor, press the System Console ❄ Freeze button twice (Freeze/Unfreeze) to take the laser out of standby and display the Laser Ready icon.***

---

(3) Ensure the face of the OA/US Probe is completely free of dried gel and other debris. If necessary, clean the shield of the OA/US Probe with the Seno approved wipes.

IMPORTANT: ***A dirty OA/US Probe face or calibration port shield during the Machine Check may cause imaging artifacts.***

---

(4) Place the OA Flat Breast Phantom within 62 cm (2 feet) of the Imagio Breast Imaging System cart.

(5) Open the OA Flat Breast Phantom lid and apply the Seno approved gel to the Flat Breast Phantom.

(6) On the console press the Exam Management button to display the Exam Management Page.

(7) In the Patient ID field, enter “Machine Check 000” where 000 represents the sequential numbering of the daily images.

(8) In the Operator ID field enter your full name.

(9) Select the OK button to move to the live imaging Display Monitor screen.

(10) Verify that Laser Enabled is displayed on the right side of the Display Monitor. If necessary, press the touch screen Laser Control button and enable the laser by entering the laser password.

(11) Observing the Display Monitor, press the foot switch completely and fully to the floor, and ensure that you have a clear, complete image.

(12) Move/rotate the OA/US Probe on the Breast Flat Phantom with varying pressure and attempt to duplicate the image in Figure 111. Call the local service provider if this image cannot be duplicated or artifacts appear that prohibit a diagnostic quality image.

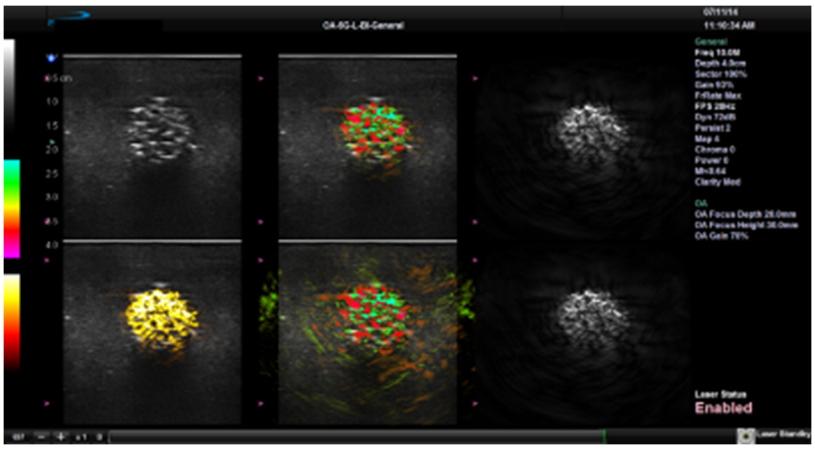


Figure 111: Machine Check Image Recording

(13) When you are ready to record the image, press the Console image Record 1 button.

(14) Release the foot switch.

(15) On the touchscreen, select the End Exam button to save and close out the Machine Check exam.

(16) Thoroughly clean the OA/US Probe with the Seno approved wipes, and then securely store the OA/US Probe in the OA/US Probe.

(17) Machine Check is now complete and the laser protective eyewear can be removed.

(18) Clean the gel from the Flat Breast Phantom using the Seno approved wipes.

(19) Cover the OA Flat Breast Phantom and return it to the designated storage location.

Chapter 18: Emergency Laser Stop Button

The Imagio Breast Imaging System is equipped with an Emergency Laser Stop Button. Only press this button when there is a need to immediately stop laser emission in the event of a device or environmental emergency. When the red emergency laser stop (also referred to as Emergency Stop or E-Stop) button is pressed, the laser components of the Imagio Breast Imaging System will shut down immediately. The Imagio Breast Imaging System cart is still powered and the software continues to run to enable the laser to be brought back online when the emergency is resolved.

Figure 112: Location of Emergency Laser Stop Button

18.1 To Immediately Shut Down the Laser

18.2 To Restart the Laser after Emergency Shut Down

Chapter 19: Laser Emitting Alerts, Laser State Messages, Status Codes, and System Messages

19.1 Laser Protective Eyewear Message Reminder

19.2 Laser Emitting Alerts

19.2.1 Laser Emitting LED

The laser emitting LED located at the top of the display monitor will illuminate a blue light to alert everyone in the scan room that laser light energy is being emitted from the Imagio Breast Imaging System.

Figure 113: Laser Emitting LED. Foot switch is pressed and the OA/US Probe is emitting laser energy.

19.2.2 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 Probe is emitting laser energy.

19.2.3 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.

Figure 114: Laser State Message Shows Laser Emitting. Foot switch is pressed and the OA/US Probe is emitting laser energy.

19.3 Laser Icons

19.4 Status Codes

19.5 Information and System Codes

Messages to indicate System status to the User are displayed on the Display Monitor top center, bottom left and bottom right.

Types of System Codes

19.5.1 Information Message

- Convey information of interest to the user.
- Appear on the display monitor bottom left.
    - Example Laser Heating Percentage or Reminder Everyone Wear Laser Protective Eyewear

19.5.2 F Codes and Notifications

- F Codes are 4 character codes beginning with F that Seno uses to identify issues.
- Notifications are text descriptions communicating system issues to the user.
- F Codes and Notifications appear on the display monitor bottom right.
- F Codes and Notifications convey information about errors that prevent the Imagio Breast Imaging System from acquiring data and do not pose a potential harm to the user or patient.
- Record the code and call the local service provider.

19.5.3 Alert Messages

- Alert Messages appear on the display monitor top center.
- Alert Messages indicate an automatic system response to address a potential condition.
- Record the code and call the local service provider for all of these messages except normal, user initiated, Imagio Breast Imaging System power off.

Message	Type	Will the Imagio Breast Imaging System Continue to Operate Correctly?	Actions to Take to Attempt to Resolve the Message
System is shutting down	Alert	Yes	Message will appear when the system is shutting down. If normal shut down has been attempted, no further action is necessary and the system will resume normal operation when powered on. If the system is shutting down but the user did NOT attempt to power down the system call the local service provider.
HIGH LASER POWER – (x) WAVELENGTH	Alert	No	Call the local service provider.
UNABLE TO COMMUNICATE WITH LASER	Alert	No	Call the local service provider.
LASER SHUT DOWN DUE TO HIGH OUTPUT POWER	Alert	No	Call the local service provider.
UNABLE TO START LASER DUE TO HIGH TEMPERATURE	Alert	No	Call the local service provider.
LASER HIGH TEMPERATURE SHUTDOWN	Alert	No	Call the local service provider.
LOW LASER POWER – (x) Wavelength; Image Quality Degraded	Alert	No	Call the local service provider.
LASER SHUT DOWN DUE TO LOW OUTPUT POWER	Alert	No	Call the local service provider.

Chapter 20: Removing/Connecting OA/US Probe, Ultrasound Probe and Foot Switch

The Imagio Breast Imaging System Laser power output at the face of the probe is dependent on and limited by the condition of the optics along the entire laser path from the lasers to the probe face. Always perform the Imagio Breast Imaging System Calibration if the OA/US Probe is replaced with a new OA/US Probe.

IMPORTANT: ***Perform the OA/US Probe Calibration Wizard and the Machine Check if an OA/US Probe is replaced with a new OA/US Probe to ensure proper power output and image quality.***

20.1 Maintenance that can be Performed by System Users

20.1.1 Removing/Connecting the OA/US Probe

Typically, the OA/US Probe will not be removed from the Imagio Breast Imaging System. Examples of when the OA/US Probe may need to be removed include situations when the Imagio Breast Imaging System will be moved to a new location or if Seno has provided a new OA/US Probe.

⚠***WARNING:*** The Imagio Breast Imaging System contains dangerous voltages that are capable of serious injury or death.

- If any defects are observed or malfunctions occur, stop operating the Imagio Breast Imaging System. Call the local service provider. There are no user serviceable components inside the Imagio Breast Imaging System cart. Refer all servicing to Service personnel only.
- Always connect the Imagio Breast Imaging System to supply mains with protective earth.
- Never touch the Patient and any exposed connector simultaneously.
- Never touch any exposed connector when the OA/US Probe is in contact with the Patient.
- Never attempt to operate the Imagio Breast Imaging System if panels are removed or not properly attached.
- Never clean the power cord while it is plugged in to the mains power outlet or the Imagio Breast Imaging System.

⚠***CAUTION:*** The Imagio Breast Imaging System is designed for use with the Imagio Breast Imaging System OA-16-1S Opto-acoustic (OA/US) and US/L-14-5 Linear Probes only. Other Probes will not be recognized or usable and may damage the system.

- Never attempt to attach any other probe to the Imagio Breast Imaging System.

20.1.1.1 To Remove the OA/US Probe

(1) Remove the ZIF Connector:

a) Turn connector lock counterclockwise ¼ turn to release ZIF connector.

b) Carefully pull ZIF connector from connector socket.

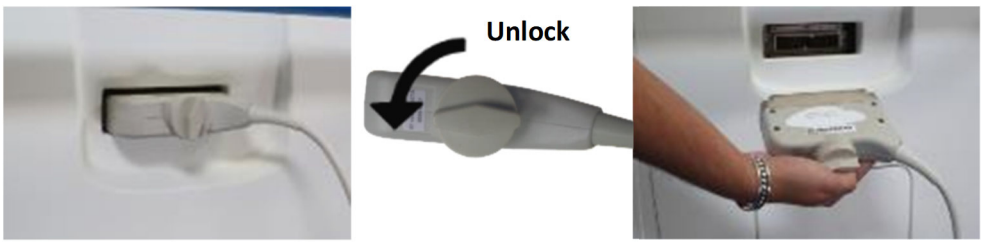


Figure 116: OA/US Probe ZIF Connector

(2) Remove fiber optic laser cable from aperture:

a) Turn outer connector counterclockwise to unscrew.

b) Carefully pull connector from connector socket.

c) Place OA/US Probe in a secure location.

Figure 117: OA/US Probe Connection

20.1.1.2 To Connect the OA/US Probe

(1) Insert fiber optic laser cable internal connector to the laser aperture: Carefully push connector into the laser aperture connector socket.

(2) Turn outer connector clockwise to screw in until unable to turn. Do not tighten with force.

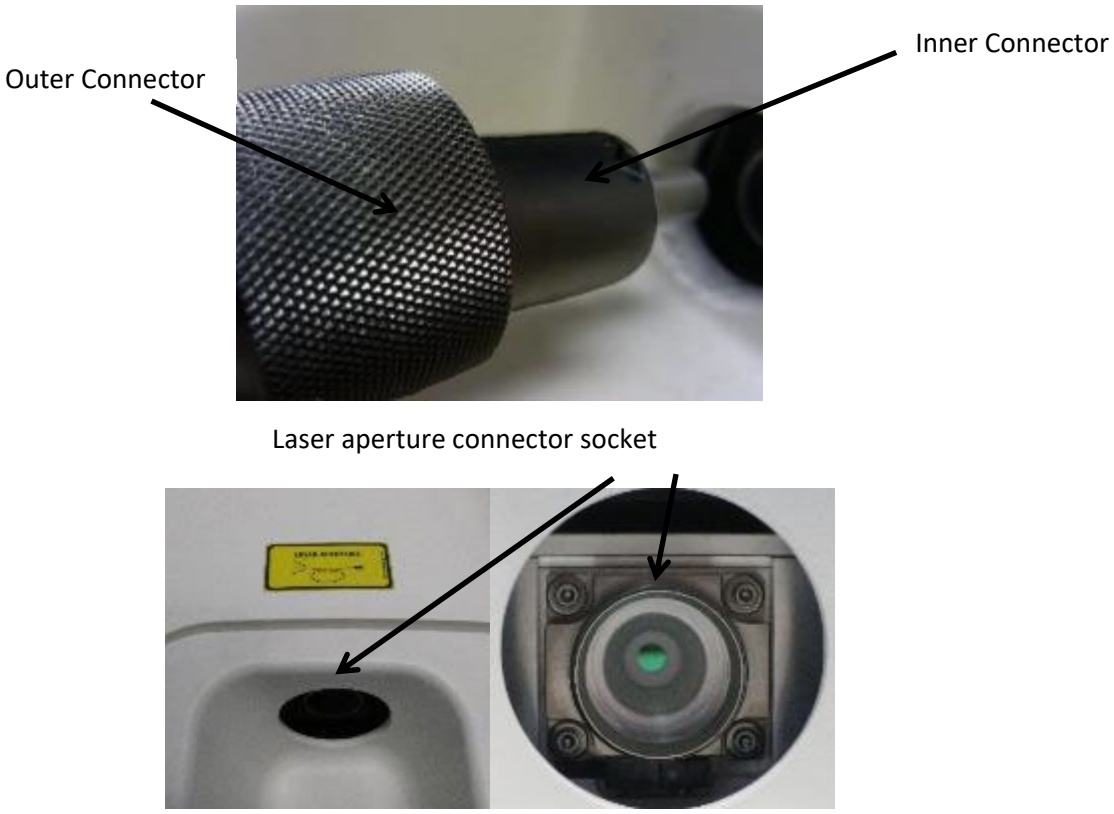


Figure 118: OA/US Probe Connection

(3) Insert the ZIF Connector:

a) Carefully push ZIF connector into connector socket.

b) Turn connector lock ¼ turn clockwise to secure ZIF connector.

Figure 119: OA/US Probe ZIF Connector

20.1.2 Removing and connecting the Ultrasound Probe

To remove the Ultrasound Probe

(1) Remove the ZIF Connector:

a) Open the access panel by pulling the doorknob and turn ZIF connector lock counterclockwise ¼ turn to release ZIF connector.

b) Carefully pull ZIF connector from connector socket and strain relief.

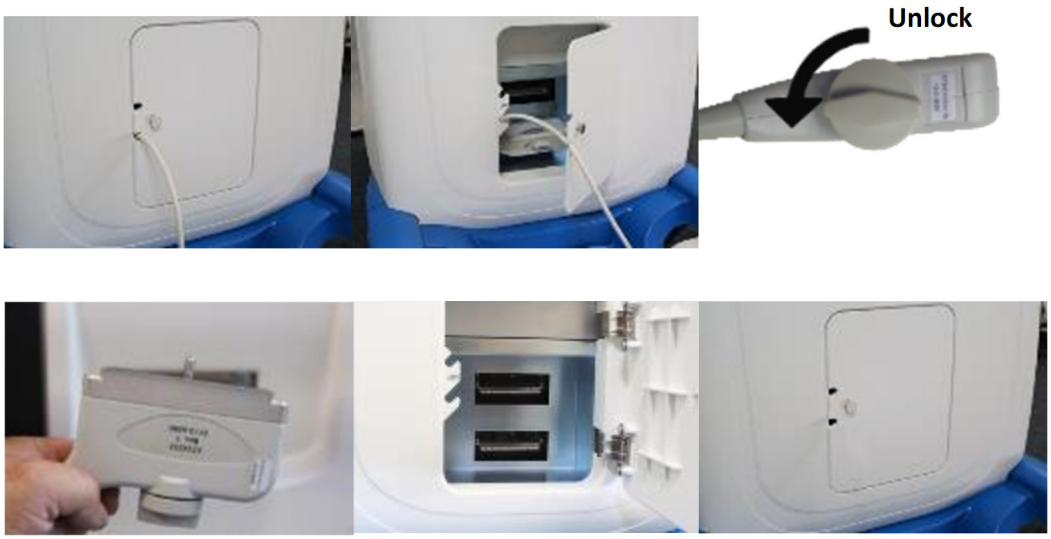


Figure 120: Removing Probe ZIF Connector

c) Place Probe in a secure location then close the panel door.

20.1.3 To connect the Ultrasound Probe

(1) Insert the ZIF Connector:

a) Open the access panel by pulling the doorknob and carefully push ZIF connector into connector socket.

b) Turn connector lock ¼ turn clockwise to secure ZIF connector. Route the cable through the strain relief. Close probe connector access panel door.

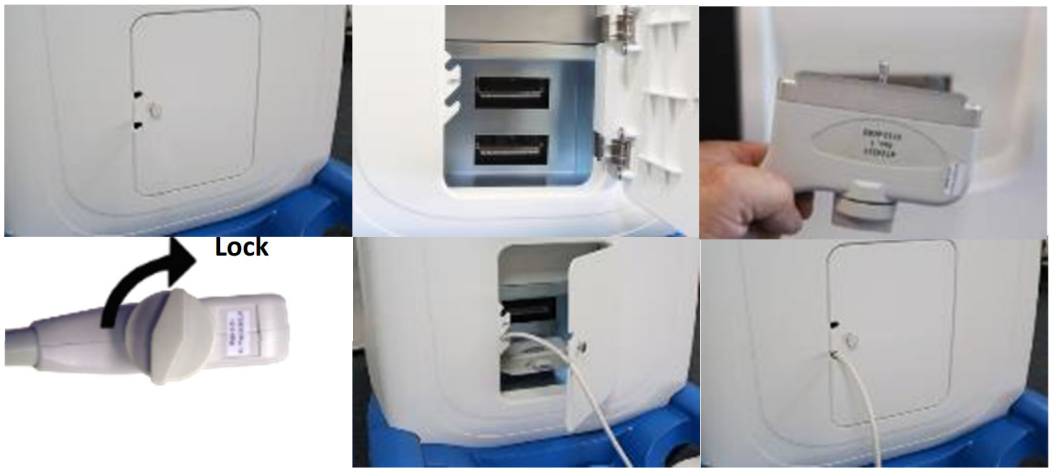


Figure 121: Connecting US Probe ZIF Connector

20.1.4 Removing/Connecting OA Foot Switch

Typically, the foot switch will not be removed from the Imagio Breast Imaging System.

Examples of when the foot switch may need to be removed include situations when the Imagio Breast Imaging System will be moved to a new location or if Seno has provided a new foot switch.

20.1.4.1 To Remove the Foot Switch

(1) Perform an orderly shutdown of the Imagio Breast Imaging System as described in the section System Power ON/OFF Chapter 6. Set the Circuit breaker to the OFF position.

(2) Disconnect the Foot Switch connector by pulling the outer ring.

20.1.4.2 To Connect the Foot Switch

(1) Perform an orderly shutdown of the Imagio Breast Imaging System as described in the section System Power ON/OFF Chapter 6.

(2) Set the Circuit breaker to the OFF position.

(3) 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.

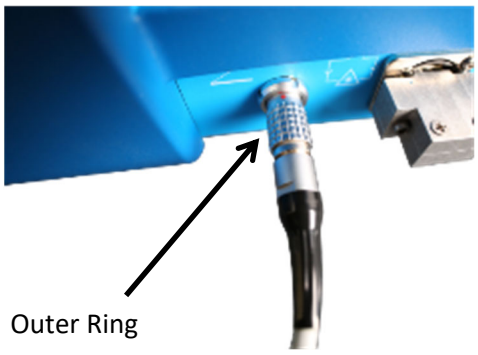


Figure 122: Footswitch Connector

Chapter 21: User Settings

21.1 User Setting Menu

In the User Systems Settings Menu, the various features and settings of the system can be customized via one of the two (2) System Setup menus: Setup and Support.

To access any of the following functions, press the Touch Screen Settings button.

The following table provides a quick overview of the system setup menus.

Table 26. User Settings Menu

Setup	System Settings	Access the System Settings menu. Note: A unique Systems Password is required.
Support	Remote Support	Access the Remote Support option.
	Documentation	View an electronic version of the User Manual on the Display Monitor. This option requires internet access.

IMPORTANT: ***The software version number is displayed across the bottom of this menu.***

21.1.1 To Access the User Settings Menu:

(1) Press the Touch Screen Settings button and the User Settings menu will be presented.

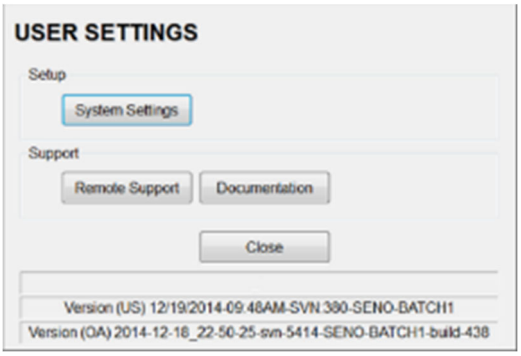


Figure 123: User Settings

Table 27. System Settings Menu

Application Setup	***Presets***	View and manage Presets with their associated Annotations, Pictograms, Measurements and Imaging Presets.
	Annotations	Toggle on/off the five (5) global Annotation settings. Customization of Preset-specific Annotations is handled through Presets.
	Measurements	Configure measurement Graphics and Measurement settings.
	System	Configure/customize basic System Settings: Institution Name, Regional options, Auto-Freeze, User Data, Master Volume and Settings and Laser Passwords. Reset system to Factory Defaults.
	Network	Configure settings for: Network LAN (Local Area Network), TCP/IP Support. (Transmission Control Protocol/Internet Protocol), E-mail and Remote Support ⚠***CAUTION:*** When connected to a network, the Imagio Breast Imaging System is susceptible to cybersecurity issues and may be vulnerable to unauthorized access. Application parameters should only be configured by a qualified individual. Never operate the Imagio Breast Imaging System without a firewall or anti-virus software. Organizations that elect to configure/use the networking functionality provided by Seno are assuming all liabilities and risks associated with that decision. Never install unapproved software or hardware on the Imagio Breast Imaging System. Always call the local service provider. for cybersecurity issues with the Imagio Breast Imaging System. Always maintain configuration and data backups for your Imagio Breast Imaging System. Always employ strong password policies.
	DICOM	Enable and configure DICOM Storage, Print and Worklist.
System Setup	***Custom Keys***	Set custom actions for the system console Custom Key buttons (1 and 2 buttons).
	Peripherals	Configure Peripherals: Touch Screen settings.
	Display Monitor	Change display to show or hide thumbnails.
	Patient	Customize entry of Patient information using a variety of options, including show/hide fields, create new fields, allow/disallow editing of specific fields, and selection of gender and application defaults.
	Status Bar	Configure which Status Bar icons are visible on the Display Monitor.
	Imaging Modes	Configure a variety of Imaging Mode options including Split Imaging and Initial Active Display.
System Maintenance	***Service***	Access the Service Mode dialog.

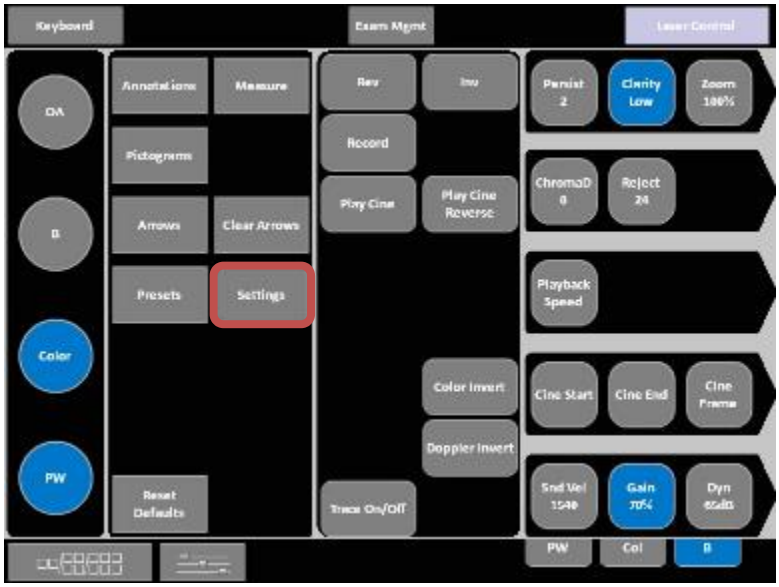
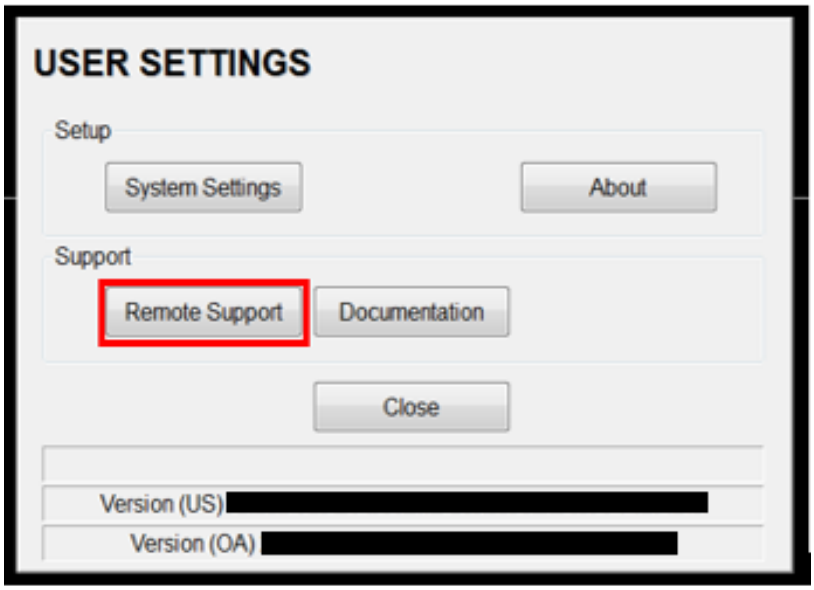
21.2 Remote Support Menu

Call the local service provider prior to using this feature.

Remote Support is a licensed User subscription fee option that allows the local service provider to view and control the system remotely for equipment diagnostic purposes.

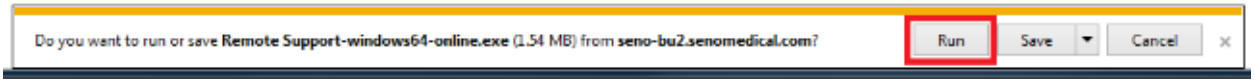
If Remote Support does not appear to be available, contact your IT Department and have them check to make sure the network connection is active and the Remote Support option has been configured for use.

21.2.1 To Access Remote Support:

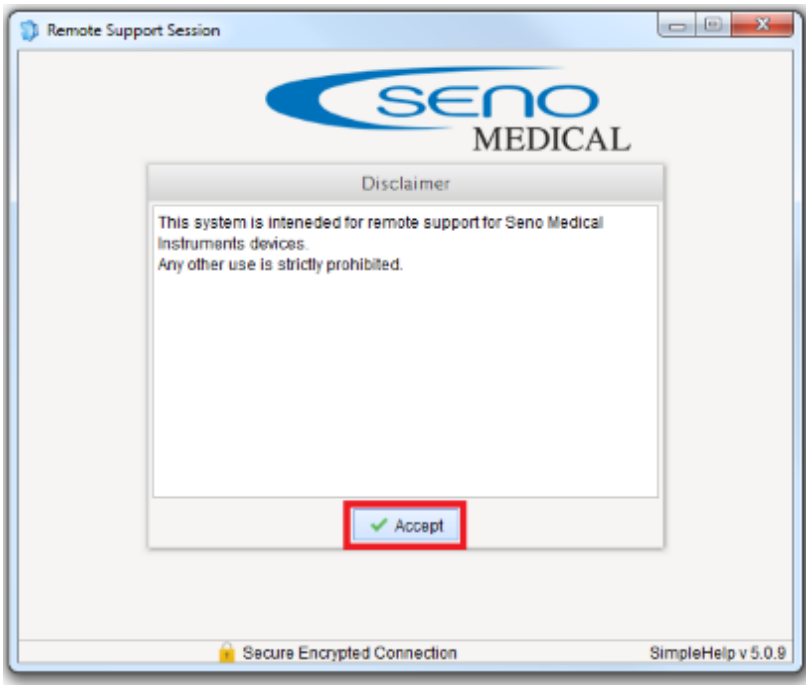
Step 1 *On the System Console Touch Screen press the Settings button.*	
Step 2 *Select the Remote Support button.*	

Step 3 *The Seno Medical Remote Support dialog box will display – Select the Download Remote Support button.*

Step 4 *Windows Remote Support box to Run or Save will be displayed – Select the Run button.*

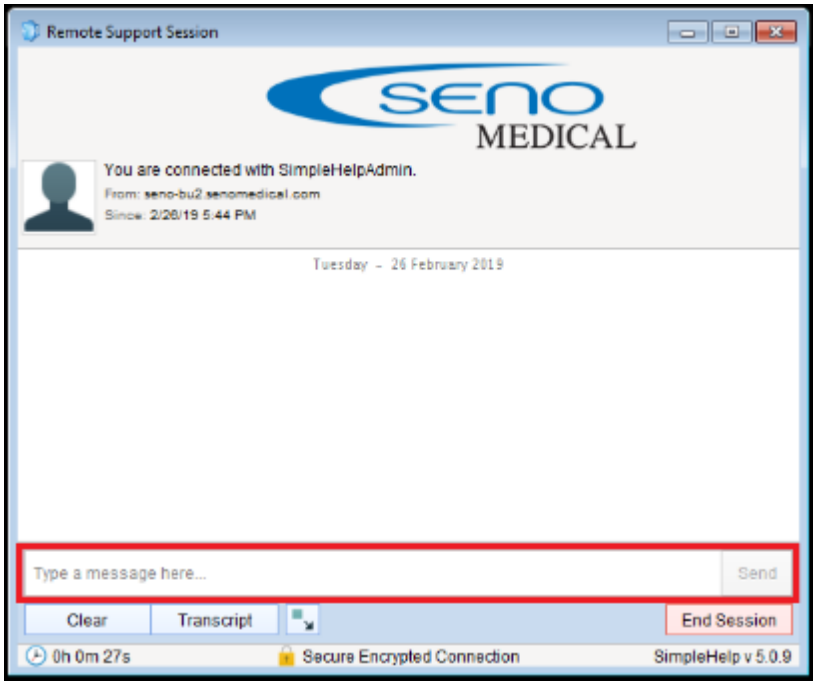
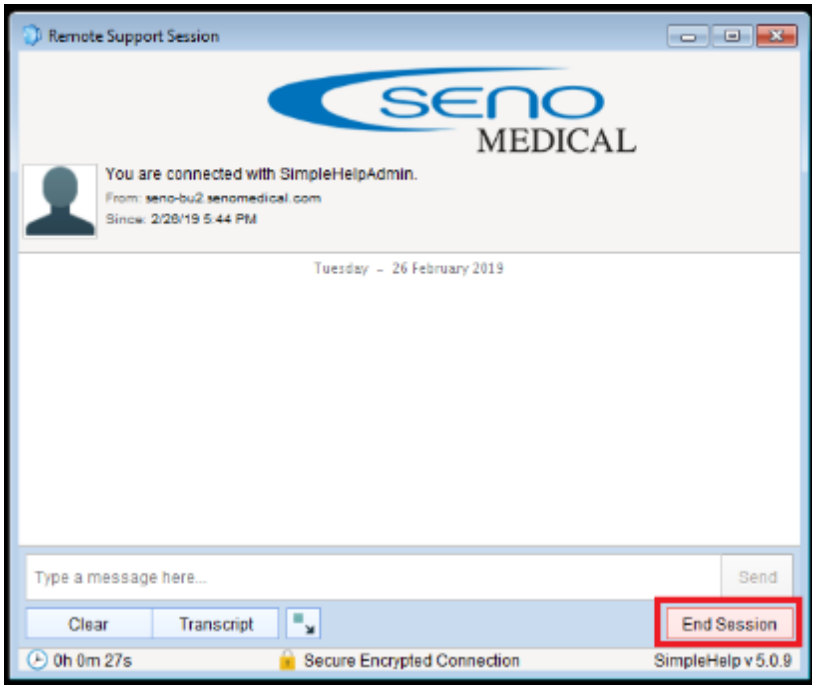


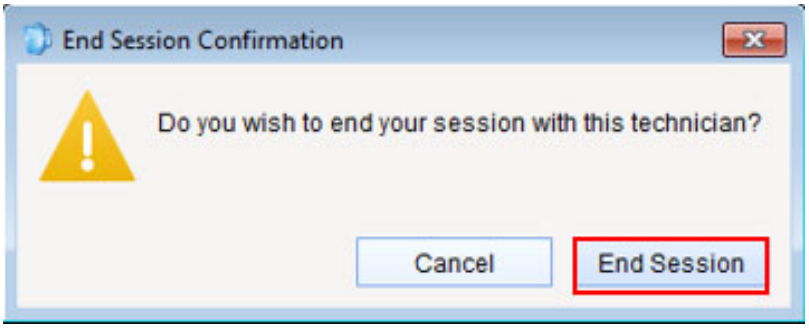
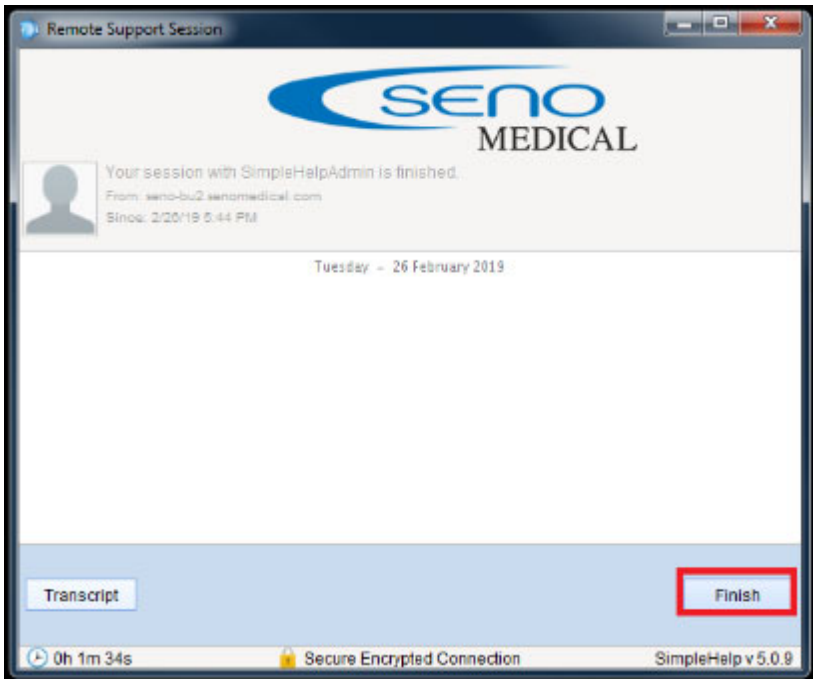
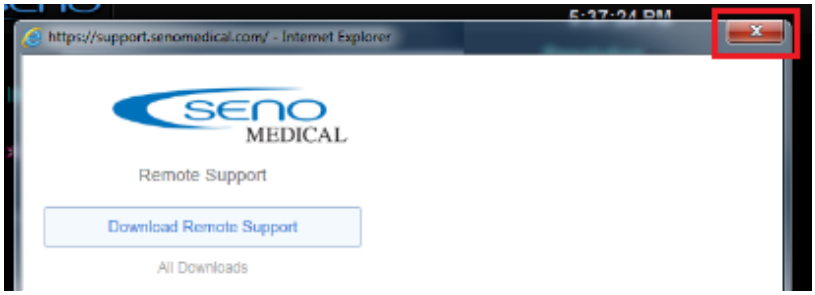
Step 5 *Remote Support Session box with Disclaimer for Seno Medical Instruments remote support box will be displayed – Select the Accept button.*



USER SETTINGS

Step 6 *User details box will be displayed – enter Users Name and Facility's Name and select the Submit (Secure) button.*	
Step 7 *After initial progress bars update, message a message stating "You are connected and in a queue, please wait" will be displayed until the request is accepted by Seno Medical Remote Support Technician.* *If support is no longer needed, to exit from Waiting in Queue screen, user will need to select the X in top right hand corner. – Skip to Step 10.*	

Step 8 *Once connected user will see Remote Support chat box. Enter questions/message in the "Type a message here…" box and select Send.*	
Step 9 *When ready to end, select the End Session button.*	

Step 10 *"Do you wish to end your session with this technician?" message will be displayed – Select the End Session button.*	
Step 11 *Remote Support ended. Select the Finish button to close the Remote Support box.*	
Step 12 *Select the X in the top right hand corner to close the Remote Support.*	

21.3 Documentation Menu (The Imagio Breast Imaging System User Manual)

To Access the Imagio Breast Imaging System User Manual (Internet Connection Required):

(1) Press the System Console Touch Screen Settings button.

(2) Select the Documentation button.

(3) The Imagio Breast Imaging System User Manual will be displayed.

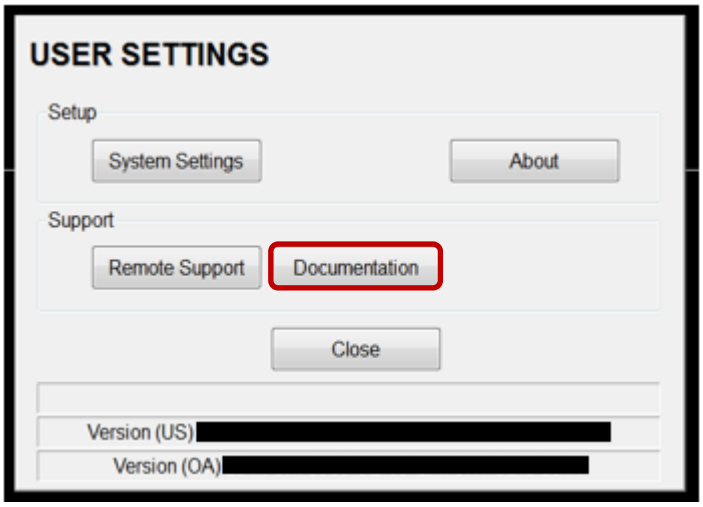


Figure 124: Documentation

21.4 System Settings

System Settings allow the User to configure high level Application and System settings as well as perform certain System Maintenance functions.

Typically, the System parameters are set during initial installation and only require limited access and adjustment. By default, the Imagio Breast Imaging System is delivered with an active System Settings Password.

⚠***CAUTION:*** When connected to a network, the Imagio Breast Imaging System is susceptible to cybersecurity compromise and unauthorized access to data, extraction of data, loss of data and corruption of data.

- Application parameters can only be configured by a qualified individual.
- Never operate the Imagio Breast Imaging System without a firewall or anti-virus software. Organizations that elect to configure/use the networking functionality provided by Seno are assuming all liabilities and risks associated with that decision.
- Never install software or hardware on the Imagio Breast Imaging System.
- Always call the local service provider for cybersecurity compromise on the Imagio Breast Imaging System.
- Always maintain configuration and data backups for the Imagio Breast Imaging System.

To Access System Settings:

(1) Press the Touch Screen Settings button.

(2) Select System Settings to access the System Settings menu.

(3) Enter password and select OK.

Figure 125: System Settings Menu and Password Dialogue

21.5 Presets Setup

Presets Setup enables Users to manage factory default and User-defined Imaging Presets.

21.5.1 Presets – Probe Tree

Each Preset can be selected/deselected via the Presets Setup options.

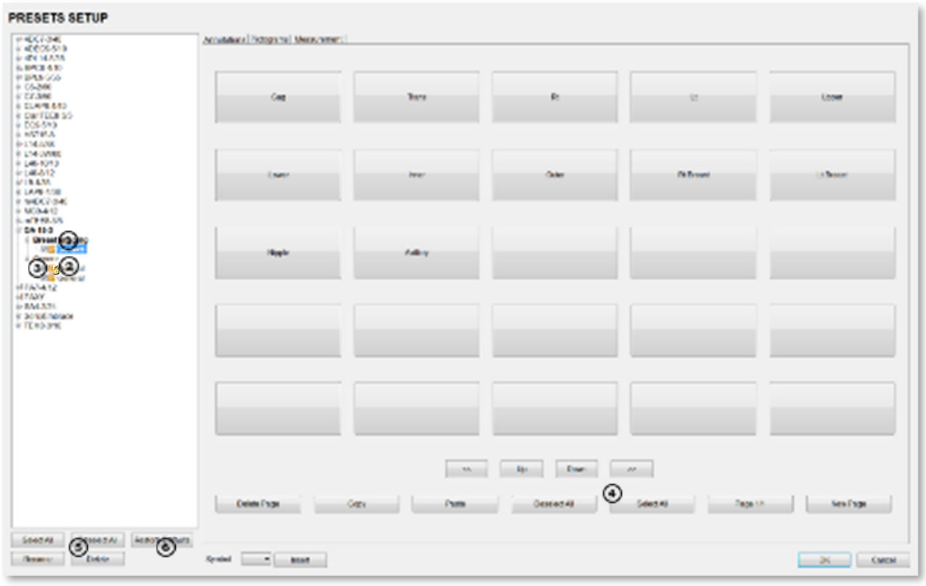


Figure 126: Presets Setup

Table 28. Presets Setup

1	Key Icon	
2	Lock Icon	
3	Preset Checkbox	
4	Select/Deselect All	
5	Rename and Delete	Rename and Delete are only available if a User-defined Preset has been selected.
6	Restore Defaults	IMPORTANT: ***Restore Defaults restores all Presets Setup changes to their factory settings.***

Default settings are locked (as indicated by the lock icon adjacent to the Preset name). Additional User-definable aspects of the default settings are available through the three (3) tabs on the Presets Setup Page: Annotations, Pictograms and Measurements.

User-defined Presets are marked with a key icon. These cannot be locked.

The left-hand menu displays all currently available Presets, both default and User-defined. Each Application is delivered with at least one default Preset.

21.5.1.1 To Access the Presets Setup Page:

(1) Press the Touch Screen Settings button.

(2) Select System Settings

(3) Enter password and select OK.

(4) Select Presets.

21.5.1.2 To Rename a Previously Created User-Defined Preset

(1) Press the Touch Screen Settings button.

(2) Select System Settings> Presets.

(3) Select the User-defined Preset to be renamed.

(4) Select the Rename button.

(5) Type a new, unique name in the Rename Preset message box.

Figure 127: Rename Preset

(6) Select OK to accept the changes and exit or select Cancel to exit without saving.

21.5.1.3 To Delete a User-Defined Imaging Preset

(1) Press the Touch Screen Settings button.

(2) Select System Settings > Presets.

(3) Select the User-defined Preset to be deleted.

(4) Select the Delete button.

(5) Select Yes to confirm the deletion or select No to cancel the operation.

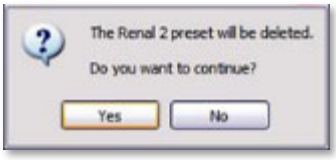


Figure 128: Preset Choice Confirmation Dialogue

The message will specify the name of the User-defined Preset selected for deletion.

21.5.1.4 Show/Hide Imaging Presets

Preset availability can be controlled using its associated checkbox. When selected, as indicated by the presence of the green checkmark, the Preset will be available from both the touch screen.

To hide Presets on the touch screen, all versions of that Preset must be deselected (i.e., deselect every Preset of the same name under every Application for every probe).

IMPORTANT: ***The show/hide function applies to both default and User-defined Presets.***

To Show/Hide Imaging Presets:

(1) Press the Touch Screen Settings button.

(2) Select System Settings > Presets.

(3) Select/deselect the relevant checkbox under Preset OA-16-1S.

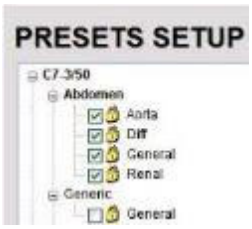


Figure 129: Preset Setup

IMPORTANT: ***Deselecting General under Breast Imaging will not hide the General Preset when Abdomen is selected for the Breast Imaging probe. Deselecting General under Abdomen for all applicable probes will hide that Preset from view on the touch screen.***

(4) Select OK to accept the changes or Cancel to exit without saving.

21.5.2 Presets – Annotations

The ability to manipulate the text of a specific Annotation attached to either a User-defined or default Preset is handled through the Annotations tab on the Presets Setup Page. Annotation text appears by Application on the console touch screen.

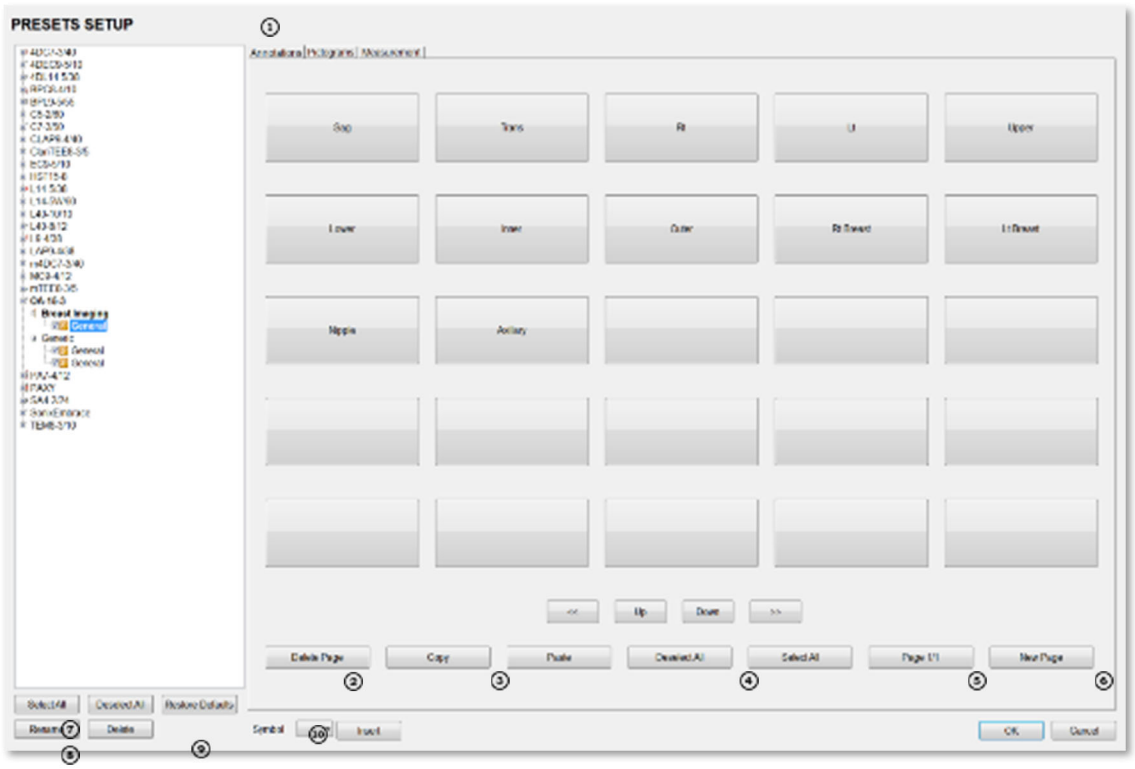


Figure 130: Presets Setup – Annotations

Table 29. Presets Setup – Annotations

1	Annotations Tab	
2	Delete Page	
3	Copy/Paste	
4	Deselect/Select All	
5	Page Selector	
6	New Page	
7	Select/Deselect All	
8	Rename and Delete	Rename and Delete are only available if a User-defined Preset has been selected
9	Restore Defaults	IMPORTANT: ***Restore Defaults restores <u>all</u> Presets Setup changes to their factory settings***
10	Insert (Symbol)	

IMPORTANT: ***The order in which Annotations are presented is matched on the touch screen during Text entry.***

<u>Modify Annotations</u>

Changes can only be made to the Annotations of one Exam Type/Application at a time. Within the annotation application, the system allows Users to define/change the Home Position for the Annotation cursor. Once set, whenever the Home Position touch screen button is pressed, the Text cursor will move directly to that spot.

21.5.2.1 To Modify a Preset Annotations

(1) Press the Touch Screen Settings button.

(2) Select System Settings > Presets.

(3) Select the + to open the branch levels to highlight the relevant Preset from the left hand menu.

(4) Select the relevant Annotation space on the right hand side of the Display Monitor.

(5) Use the keyboard to type in the new Annotation.

IMPORTANT: ***If multiple pages of Annotations are required, select the New Page button as often as necessary to create the desired number of Annotation spaces. Alternatively, if multiple pages already exist, move through them using the onscreen page selection button, making changes as required.***

(6) Press ENTER on the keyboard to accept the changes or ESC to delete the entry.

21.5.3 Presets – Pictograms

The ability to attach/detach specific Pictograms to both User- defined and default Presets is handled via the Pictograms tab in Presets Setup. Re-ordering the sequence in which they will appear on the touch screen during a scanning session is managed here as well.

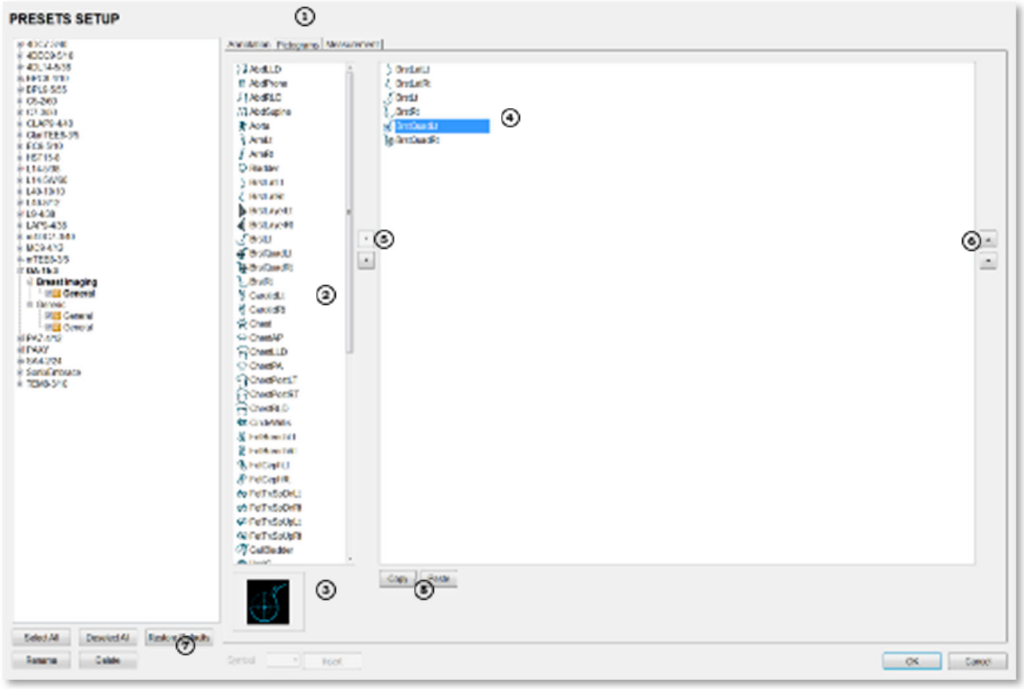


Figure 131: Presets Setup – Pictograms

Table 30. Presets Setup – Pictograms

1	Pictograms Tab	
2	List of available Pictograms	
3	List of Pictograms attached to the selected Preset	
4	Selected Pictogram	
5	Pictogram Selectors	
6	Pictogram Order Selectors	
7	Restore Defaults	IMPORTANT: ***Restore Defaults restores all Presets Setup changes to their factory settings.***
8	Copy/Paste	

21.5.3.1 Modify the Pictograms Attached to Presets

To Add Pictograms to an Imaging Preset

(1) Press the Touch Screen Settings button.
(2) Select System Settings> Presets.
(3) Highlight the relevant Preset in the left hand column.
(4) On the Presets Setups Page, select the Pictograms tab.
(5) From the list of available Pictograms, highlight the relevant Pictogram.
(6) Use the right facing selector button to move the item to the list of selected Pictograms.
(7) Repeat step 5 and step 6 as many times as required.
(8) Select OK to accept the changes and exit or Cancel to exit without saving.

To Delete Pictograms from an Imaging Preset

(1) Press the Touch Screen Settings button.
(2) Select System Settings > Presets.
(3) Highlight the relevant Preset in the left hand column.
(4) On the Presets Setups Page, select the Pictograms tab.
(5) Highlight the relevant Pictogram in the list of selected Pictograms.
(6) Use the left facing selector button to delete the item from the list of selected Pictograms.
(7) Repeat step 5 and step 6 as many times as required.
(8) Select OK to accept the changes and exit or Cancel to exit without saving.

To Reorder Selected Pictograms Attached to an Imaging Preset

(1) Press the Touch Screen Settings button.
(2) Select System Settings > Presets.
(3) Highlight the relevant Preset in the left hand column.
(4) On the Presets Setups Page, select the Pictograms tab.
(5) Highlight the relevant Pictogram in the list of selected Pictograms.
(6) Use the order (up/down) selector buttons to move the item to another place in the list of selected Pictograms.
(7) Repeat step 5 and step 6 as many times as required.
(8) Select OK to accept the changes and exit or Cancel to exit without saving.

21.5.4 Presets – Measurements

Based on Exam Type, Presets – Measurements allows Users to select/deselect the available touch screen Measurement Package options. It also enables Users to edit the default imaging Measurement Package for a specific Exam Type.

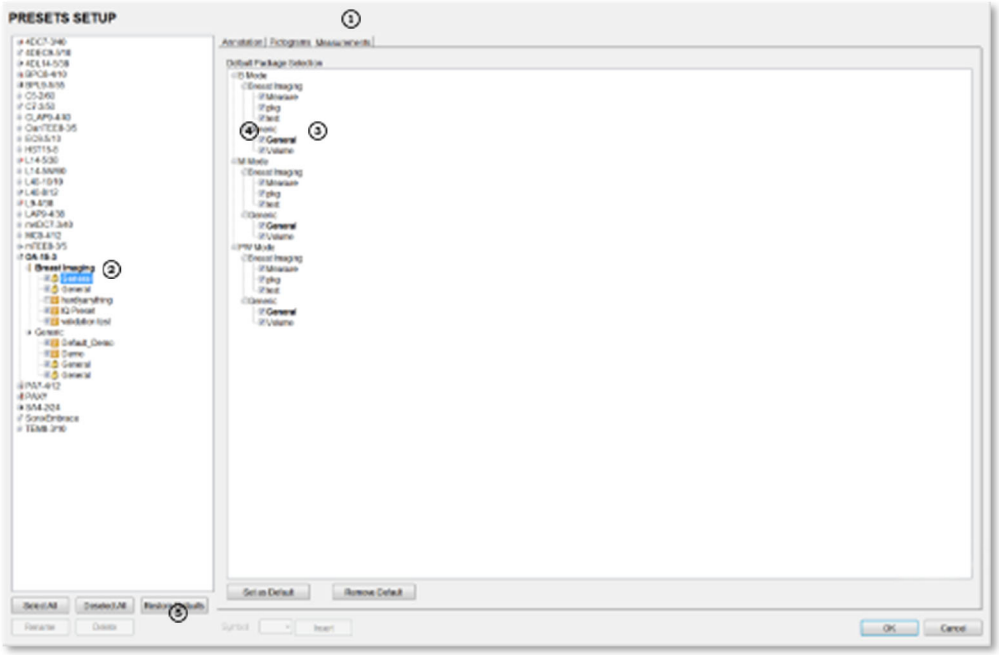


Figure 132: Presets – Measurements

Table 31. Presets – Measurements

1	***Measurements Tab***	
2	***Preset***	
3	Default Imaging ***Measurements Package*** (labelled in bold face type)	
4	***Measurements*** checkbox	
5	***Restore Defaults***	IMPORTANT: ***Restore Defaults restores all Presets Setup changes to their factory settings.***

21.5.4.1 To Edit the List of Measurements Packages Available on the Touch Screen

(1) Press the Touch Screen Settings button.
(2) Select System Settings> Presets.
(3) Highlight the relevant Preset in the left hand column.
(4) On the Presets Setups Page, select the Measurements tab.
(5) From the available Default Package Selection list, select/deselect the checkbox for the relevant Measurements Package.
(6) Repeat step 4 and step 5 as many times as required.
(7) Select OK to accept the changes and exit or Cancel to exit without saving.

21.5.4.2 To Edit the Default Touch Screen Measurements Package

(1) Press the Touch Screen Settings button.
(2) Select System Settings> Presets.
(3) Highlight the relevant Preset in the left hand column.
(4) On the Presets Setups Page, select the Measurements tab.
(5) From the available Default Package Selection list, highlight the desired Measurements Package.
(6) Select Set as Default button.
(7) Repeat step 5 and step 6 as many times as required.
(8) Select OK to accept the changes and exit or Cancel to exit without saving.

IMPORTANT: ***There can be only one (1) default Measurements Package for each Exam Type.***

21.6 Annotations

There are five (5) global Annotation settings available.

Figure 133: (Global) Annotations Settings

Table 32. (Global) Annotation Settings

Auto-Complete	Select to automatically fill in a word when the first letter(s) is entered on the Display Monitor. If more than one Preset begins with the same letter use the Tab key to move through the list or continue typing the Preset name. When enough of the name has been completed, to jump to the correct entry, the desired Preset name will appear onscreen and can be selected.
Capitalize All Annotations	Select to automatically force the first letter of each word in the Annotation to be typed as an upper-case character.
Clear on Unfreeze	Select to automatically clear the Annotations from the image field with unfreeze. If this option is not selected, the text will remain on the image field until the User deletes it.
Use Text Arrow with Length (mm)	Select to override the standard system Text Arrow. This enables the User to define the Text Arrow length in mm. The range is 5–30 mm with a default setting of 15 mm.
Use Fixed Vertical Arrow	Select to immobilize arrow to the vertical position.

To Access the Global Annotation Settings Dialog

(1) Press the Touch Screen Settings button.

(2) Select System Settings > Annotations.

21.6.1 Text Arrow Customization

To Customize the Text Arrow

(1) Press the Touch Screen Settings button.

(2) Select System Settings > Annotations.

(3) Select Use Text Arrow with Length (mm).

Figure 134: Annotations Settings

(4) Enter the appropriate Length in millimeters.

(5) Select OK to accept the setting and exit or Cancel to exit without saving.

21.7 Measurements

The Measurements dialog enables Users to customize the onscreen appearance of calipers, caliper labels and certain display details of the measurement/calculation packages. When the touch screen Measure button is pressed, Measurements are available on the touch screen based on clinical Application.

IMPORTANT: ***It is not possible to edit factory-installed Measurement Packages.***

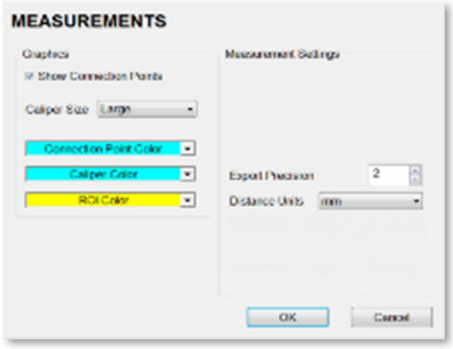


Figure 135: Measurements Settings

Table 33. Measurement Options

Graphics	***Show Connection Points***	Select to display the connection points (dotted line) between the linear calipers.
	Caliper Size	Allows the selection of one (1) of three (3) caliper size options: Small, Medium and Large.
	Connection Point Color	Allows the selection of the color of the caliper connection points (dots) between the linear calipers. The default is turquoise.
	Caliper Color	Allows the selection of the color of the caliper end points. The default is turquoise.
	ROI Color	Allows the selection of the color of the ROI trace.
	Note: To ensure the caliper modifications have been activated, switch imaging modes after exiting the Setup menus.	
Measurement Settings	***Export Precision***	Sets the decimal placement for some types of third party reporting packages. Range: 0–6. The default is 2 decimal places.
	Distance Units	Unit used to display Distance calculation: Use default, µm, cm, in, m or mm. Changing Distance Units during an exam will result in anomalous measurement labeling. Use default will use the default set on a per measurement

21.7.1 To Access Measurement Settings

(1) Press the Touch Screen Settings button.

(2) Select System Settings > Measurements.

21.7.2 To Configure Measurement Graphics

(1) Press the Touch Screen Settings button.

(2) Select System Settings > Measurements.

(3) Configure the Graphics settings as required: Show Connection Points, Caliper Size, Connection Point Color, Caliper Color, and ROI Color.

(4) Select OK to accept the settings and exit or Cancel to exit without saving.

21.7.3 To Configure Basic Measurement Settings

(1) Press the Touch Screen Settings button.

(2) Select System Settings > Measurements.

(3) Configure Export Precision and Distance Units as required.

(4) Select OK to accept the settings and exit or Cancel to exit without saving.

21.8 System Settings

System Settings are used to configure the Institution Name, Regional parameters, Auto-Freeze, User Data settings and Passwords.

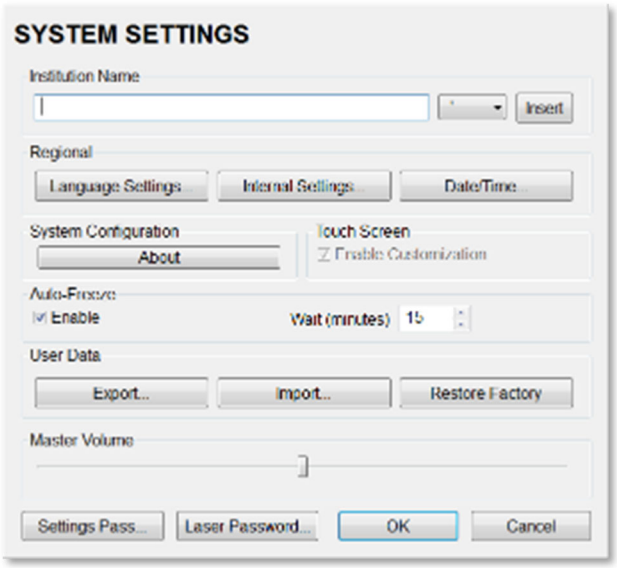


Figure 136: System Settings

Table 34. System Settings Configuration Options

Institution Name			Enter the Institution Name using the keyboard. The text entered here appears at the top of the image field.
Insert (Symbol)			Enables the insertion of text symbol(s) not available on the keyboard (e.g., punctuation, symbols and letters from other languages).
Regional	***Language Settings***	Interface Language	Select the desired language for the User interface
		Keyboard Layout	Select the desired keyboard language. During imaging, press Shift+Del to toggle access between English and the non-English Keyboard Layout language There is no correlation between Interface Languages and Keyboard Layout. For example, when English is used as the Interface Language, it is possible to select Turkish or Korean as the language for Keyboard Layout. Additionally, because Keyboard Layout selections are controlled by Windows rather than Seno l, there are many more Keyboard Layouts to choose from than there are Interface Languages
	Internal Settings…		Select country-specific parameters including Date and Time formats and Number display modes
	Date/Time…		Configure the actual Date and Time (based on the Date Time format selected in Internal Settings…).
System Configuration	***About***		Contains (non-editable) system information, for example, Software Version.
Auto-Freeze	***Enable***		Enables Auto-Freeze, which deactivates any probe that is connected but not currently in use.

Table 35. System Settings Configuration Options (Continued)

	Wait (minutes)			Once Auto-Freeze is enabled, Wait controls the number of minutes a stationary probe will remain active before Auto-Freeze is triggered. Deactivating/freezing probe usage will help to prolong its life span. Select a setting of 5 to 15 minutes. The default is Auto Freeze Enabled, with a 15-minute Wait time. To reactivate (or unfreeze) the probe/imaging session, simply press the console ❄ button.
User Data	***Export***	Exports User-configured System Settings to an external storage device (e.g., USB medium).		
		Imaging Presets		Exports all User-defined Imaging Preset data.
		DICOM Server Configuration		Exports DICOM configuration data.
		Settings		Exports all User-defined Settings that are not explicitly specified in any other Export option (e.g., DICOM Network, Peripherals, Patient, etc.).
		Exam Management Field Lists		Exports all User-defined Exam Management Page data (e.g., Attending Physician, Operator ID, etc.
		Protocols		Exports Protocol Data.
		General	***Preset Assignments***	Exports all Preset data as configured under Menu > System Settings > Presets (e.g., Annotations and Pictograms).
			Measurement Customization	Exports settings defined under Customize Measurements… on the Measurements dialog Measurement Customization is Protocol specific
			Touch Screen Customization	Exports customized Touch Screen Settings (e.g., Favorites).
		System Logs		Exports copies of all current System Logs. These cannot be imported.

Table 36. System Settings Configuration Options (Continued)

Import	Imports User-configured System Settings from an external storage device (e.g., USB medium). Settings must have been previously exported from an equivalent Seno system. Seno does not recommend importing User-defined Presets created with a previous software version as they may not be compatible for use with a more recent software update.	
	Imaging Presets	Imports all User-defined Imaging Preset data.
	DICOM Server Configuration	Imports DICOM configuration data.
	Settings	Imports all User-defined Settings that are not explicitly specified in any other Import option (e.g., DICOM, Network, Peripherals, Patient, etc.).
	Exam Management Field Lists	Imports all User-defined Exam Management Page data (e.g., Attending Physician, Operator ID, etc.).
Preset Assignments	Imports all Preset data as configured under Menu > System Settings > Presets (e.g., Annotations and Pictograms). Presets are Protocol specific.	
Restore Factory	Resets the system to the default settings installed during manufacturing.	
Settings Pass	Add a Settings/Super User password to allow modification of Settings.	
Laser Password	Add a Laser Password to allow enabling of the laser.	

To Access System Settings

(1) Press the Touch Screen Settings button.

(2) Select System Settings > System.

21.8.1 Export/Import User Data

21.8.1.1 To Export User Data

(1) Connect the external USB storage device on which the Export will be saved.

(2) Press the Touch Screen Settings button.

(3) Select System Settings > System > Export.

(4) Select the item(s) to be exported.

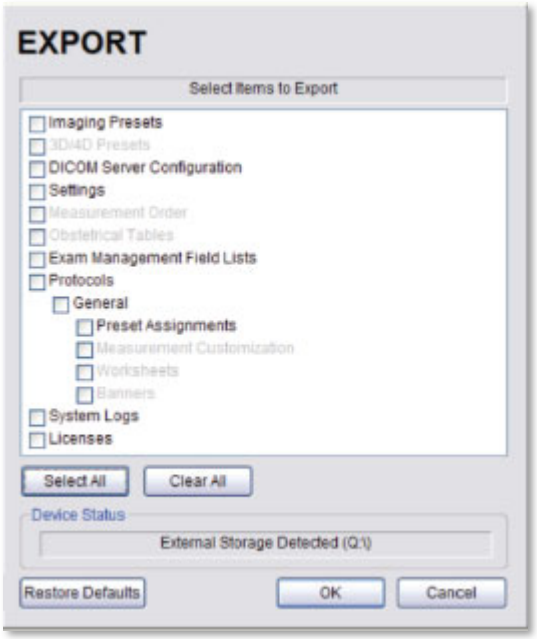


Figure 137: Export User Data

IMPORTANT: ***Use Select All to select all items at one time and Clear All to clear all checkboxes. Only configurations modified by the user will be available for Export.***

(5) Select OK to begin the export process or Cancel to exit without exporting.

(6) If OK is selected in the previous step, a completion dialog will be presented when the export process has finished (this will take approximately 15–45 seconds).

21.8.1.2 To Import User Data

(1) Plug the previously-created removable USB key into one of the USB ports at the front of the console.

(2) Press the Touch Screen Settings button.

(3) Select System Settings > System > Import.

(4) Select the item(s) to be imported.

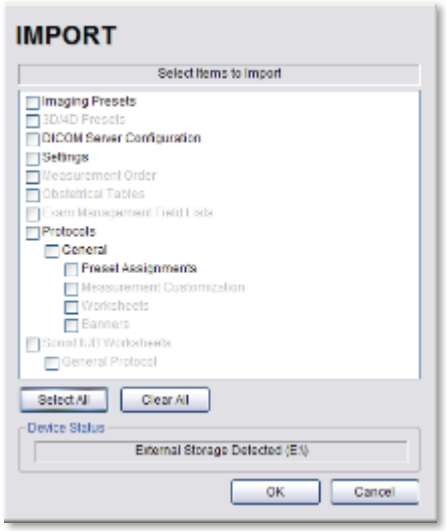


Figure 138: Import User Data

IMPORTANT: ***Use Select All to select all items at one time and Clear All to clear all checkboxes. Only active Protocols with changes to default Presets, and Measurement settings will be available for Import.***

(5) Select OK to begin the import process or Cancel to exit without importing.

21.8.2 Passwords

21.8.2.1 To Add a Settings Password

(1) Select “Settings Pass” to change the Settings/Super User Password.

(2) If prompted, enter the “Current Password” as the current settings password.

(3) At the “New Password” prompt, enter the new settings password.

21.8.2.2 To Add a Laser Password

(1) Select “Laser Password” to change the laser enable password.

(2) If prompted, enter the “Current Password” as the current laser password.

(3) At the “New Password” prompt, enter the new laser password.

21.9 Network

The Network setup dialog allows Users to configure the Imagio Breast Imaging System network through a hard-wired LAN. Remote Support is a licensed option that allows the local service provider to view and control the system for diagnostic purposes.

⚠***CAUTION:*** When connected to a network, the Imagio Breast Imaging System is susceptible to cybersecurity compromise and 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 user.
- Never operate the Imagio Breast Imaging System without a firewall or anti-virus software. Organizations that elect to configure/use the networking functionality provided by Seno are assuming all liabilities and risks associated with that decision.
- Never install software or hardware on the Imagio Breast Imaging System.
- Always call the local service provider for cybersecurity compromise on the Imagio Breast Imaging System.
- Always maintain configuration and data backups for the Imagio Breast Imaging System.

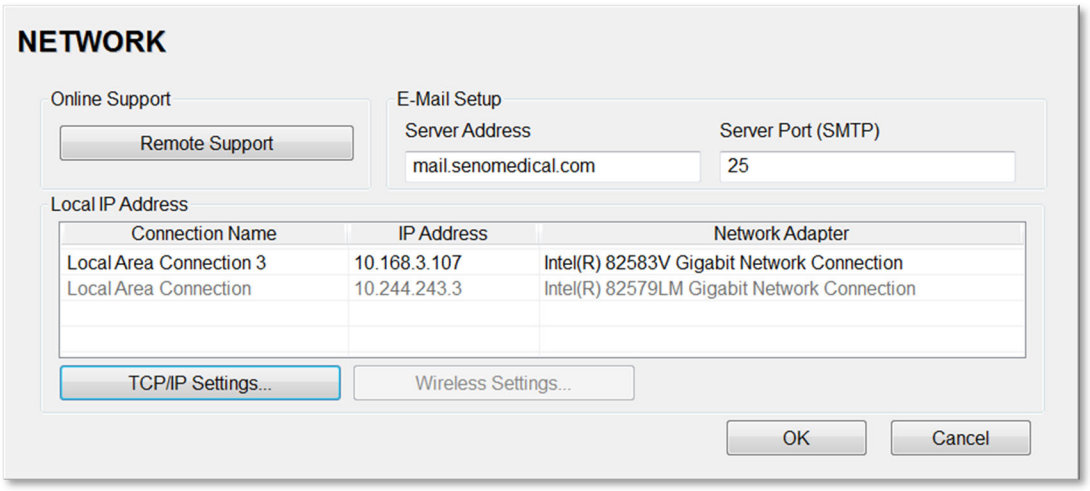


Figure 139: Network Dialog

IMPORTANT: ***A network connection is required to use any of the following: DICOM, electronic User Manual (Documentation) and Remote Support.***

Table 37. Network Settings

Remote Support		After receiving a PIN (Personal Identification Number) from Seno, use this option to connect to the Internet. This will allow a Seno Support technician to remotely access the system to resolve any issues that may have arisen.
Local IP Address		If the system is not connected to a network, instead of a Local IP Address, the field will read No Network Available.
TCP/IP Settings		Select to configure TCP/IP Settings. Refer to Ethernet (LAN) Network Configuration for details.
Email Setup	***Server Address***	Enter the Outgoing (SMTP) Server Address here for delivery of system error reports.
	Server Port	Enter the Outgoing Server Port number here for delivery of system error reports.

IMPORTANT: ***Seno recommends that Network connections be configured using the settings provided by your IT Department.***

21.9.1 Ethernet (LAN) Network Configuration

To Configure an Ethernet (LAN) Connection (If Available)

(1) Connect an RJ45 cable to the Imagio Breast Imaging System Cart.

(2) Press the Touch Screen Settings button.

(3) Select System Settings > Network.

(4) Select TCP/IP Settings.

(5) Under General, select obtain an IP address automatically or Use the following IP address and enter the assigned static IP address, Subnet mask, and Default gateway. Under General, select obtain DNS address automatically or Use the following DNS address and enter the preferred and alternate DNS address.

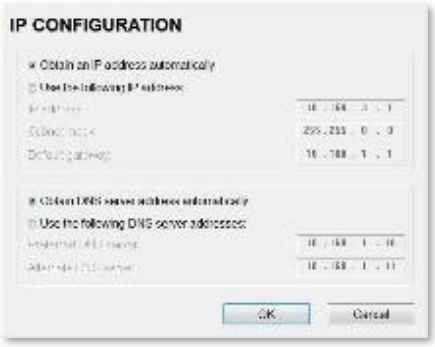


Figure 140: Internet Protocol

(6) Select OK and exit the Menu system.

IMPORTANT: ***It may be necessary to restart in order for the changes to take affect.***

21.10 DICOM Configuration

The system uses the Digital Imaging and Communications in Medicine (DICOM) standard to share medical information with other digital imaging systems. The system, by means of the DICOM protocol, communicates with Storage, and Modality Worklist Service Class Providers.

IMPORTANT: ***DICOM Structured Reporting is supported.***

IMPORTANT: ***When using a hard-wired network connection, ensure the network is connected via a CAT5 cable at the back of the system. (Check with the local IT Department to ensure that the jack from the wall is live.)***

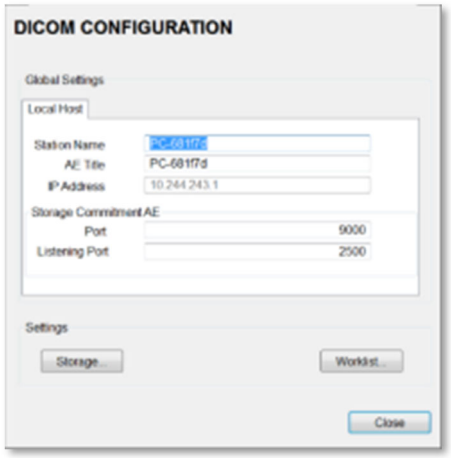


Figure 141: DICOM Configuration

IMPORTANT: ***Global Settings for the Local Host apply to DICOM Storage and Worklist.***

Table 38. DICOM Configuration – Global Settings

Local Host	***Station Name***		General DICOM Station Name.
	AE Title		AE (Application Entity) Title of the Imagio Breast Imaging System.
	IP Address		Unique identifier of the Imagio Breast Imaging System (informational only).
	Storage Commitment AE	***Port***	Port issues Storage Commitment requests (N-Action).
		Listening Port	Listening Port receives incoming Storage Commitment responses (N-Event).
Settings	***Storage…*** ***Worklist…***		Use to access specific DICOM Storage and Worklist settings.

To Configure the Global DICOM Settings

(1) Press the Touch Screen Settings button.

(2) Select System Settings > DICOM.

(3) Configure the global settings as required.

21.10.1 DICOM Storage Settings

The DICOM Storage Settings dialog offers basic and advanced settings for configuring the system for DICOM image storage.

To Configure the DICOM Storage Setting

(1) Press the Touch Screen Settings button.

(2) Select System Settings > DICOM > Storage.

(3) An onscreen dialog with three (3) tabs will be presented: AE Configuration, Global Storage Settings, and Brightness/Contrast.

(4) Create/select a Device Name. Edit the Application Entity (AE) settings for the selected Device.

(5) Repeat step 4 as many times as required.

(6) Configure settings as required.

The DICOM Storage AE Configuration dialog enables configuration of AE properties.

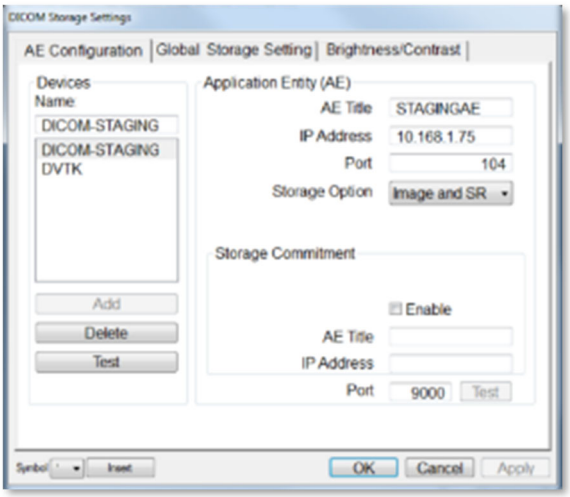


Figure 142: DICOM Storage Settings – AE Configuration

Table 39. DICOM Storage Settings – AE Configuration

Devices	Use the ***Devices*** option to add as many ***DICOM Storage Servers*** as required. If more than one **DICOM Storage Server** is configured, during data transfer the **User** has the option of selecting which **Storage Server(s)** will receive the data.		
	Name		Enter/select the Name of an AE Storage Device and populate the four (4) AE fields: AE Title, IP Address and Port, and Structured Report Storage Options.
	Add		Select to ***Add*** the new ***AE Storage Device***.
	Delete		Select to ***Delete*** the selected ***AE Storage Device***.
	Test		Select ***Test*** to send verification request to ***DICOM Storage Device*** (ping to verify connection).
Application Entity (AE)	The data entered/edited in the following fields is specific to the selected Device Name.		
	AE Title		AE Title of the Storage SCP
	IP Address		Unique identifier of Storage SCP
	Port		Listening Port of the Storage SCP
	Storage Options		Select the ***Storage Option*** to be used during data. • ***Image*** and ***SR***: transfers both ***Images*** and ***Structured Report*** • ***Image***: transfers only ***Images*** • SR (***Structured Report***): transfers only the ***Structured Report.***
	Storage Commitment	Enable	Select to enable ***Storage Commitment*** functionality
		AE Title	***AE Title*** of the ***Storage Commitment SCP***.
		IP Address	Unique identifier of ***Storage Commitment SCP***
		Port	Listening Port of the Storage Commitment SCP
		Test	Select to send verification request to ***DICOM Storage Commitment Device*** (ping to verify connection).
Insert (Symbol)			Enables the insertion of text symbol(s) not available on the keyboard (e.g., punctuation, symbols and letters from other languages).

The DICOM Global Storage Settings dialog specifies global image storage parameters.

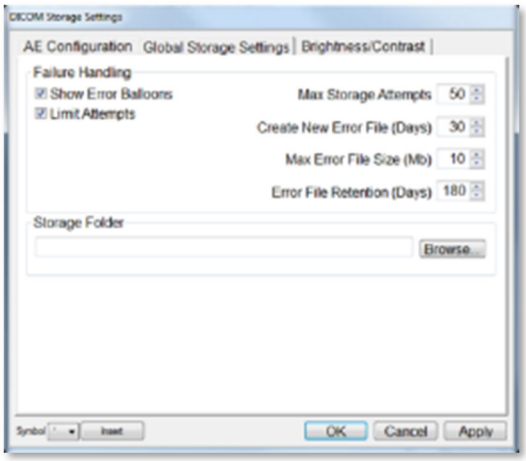


Figure 143: DICOM Storage Settings – Global Storage Settings

Table 40. DICOM Storage Settings – Global Storage Settings

Failure Handling	***Show Error Balloons***	Select to enable the display of DICOM Storage error messages (e.g., Failed to connect to DICOM).
	Limit Attempts	Whether max storage attempts are applied.
	Max Storage Attempts	The number of times storage is attempted.
	Create New Error File	The number of day's errors is shown the storage failures tab in the Exam Management screen. After this time period, the error list will be copied to a backup file.
	Max Error File Size	The file size of the errors is shown in the storage failures tab in the Exam Management screen. After this time period, the error list will be copied to a backup file.
	Error File Retention	This deletes the current and backup files after the specified number of days.
Storage Folder		Select the location (local or remote) where the images will be stored. If a value is specified, the AE Configuration and Storage Commitment dialogs are disabled—images will be saved in the specified folder and will be stored to an SCP.
Insert (Symbol)		Enables the insertion of text symbol(s) not available on the keyboard (e.g., punctuation, symbols and letters from other languages).

The DICOM Storage Brightness/Contrast dialog changes the Brightness and Contrast settings. These settings are applied to the images that are sent to the SCP, not the images stored locally.

The effects of these settings can be seen in the Before and After images.

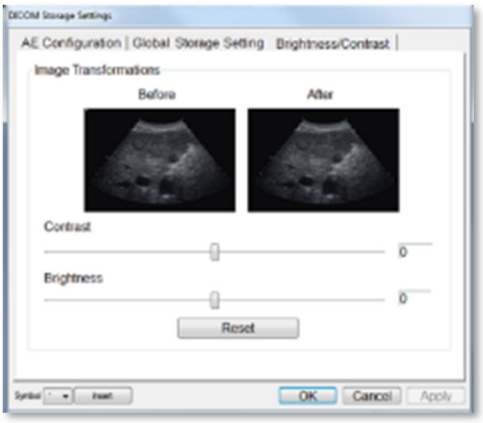


Figure 144: DICOM Storage Settings – Brightness/Contrast

Table 41. DICOM Storage Settings – Brightness/Contrast

Contrast	Adjusts the level of Contrast applied to the images.
Brightness	Adjusts the level of Brightness applied to the images.
Reset	Resets the values of DICOM Storage Brightness and Contrast back to zero. IMPORTANT: ***To adjust the Brightness/Contrast settings, position the trackball arrow over the Brightness or Contrast slider. Press and hold the button while moving the trackball left or right to the desired position.***

21.10.2 DICOM Worklist Settings

DICOM Worklist Settings offer advanced settings for configuring the DICOM Worklist SCU.

To Configure DICOM Worklist Settings

(1) Press the Touch Screen Settings button.

(2) Select System Settings > DICOM > Worklist.

(3) Create/select a Device Name. Edit the Application Entity (AE) settings for the selected Device.

(4) Repeat step 3 as many times as required.

(5) Configure the dialog as required.

The DICOM Worklist AE Configuration dialog enables configuration of AE properties.

Figure 145: DICOM Worklist Settings – AE Configuration

Table 42. DICOM Worklist Settings – AE Configuration

Devices	Use the Devices option to add as many DICOM Worklist Servers as required.	
	Name	Enter/select the Name of an AE Worklist Device and populate the three (3) AE fields: AE Title, IP Address and Port.
	Add	Select to Add the new AE Worklist Device.
	Delete	Select to Delete the selected AE Worklist Device.
	Test	Select to send verification request to DICOM Worklist Device (ping to verify connection).
Application Entity (AE)	The data entered/edited for the next three (3) fields is specific to the selected Device Name.	
	AE Title	AE Title of the Worklist SCP.
	IP Address	Unique identifier of Worklist SCP.
	Port	Listening Port of the Worklist SCP.
Insert (Symbol)		Enables the insertion of text symbol(s) not available on the keyboard (e.g., punctuation, symbols and letters from other languages).

21.11 Custom Keys

Custom Keys allow Users to configure two (2) console buttons: 1, and 2.

The Custom Key setup dialog has a tab that corresponds to each of the Custom Key console buttons. Once configured, pressing one of these buttons will produce the defined action.

Figure 146: Custom Keys

Table 43. Custom Key Settings

Custom Key 1, Custom Key 2	***Store Locally***		This setting is always selected by default and can only be deselected (or reselected) if all options are deselected. When selected, regardless of other settings, images will always be saved to the system local storage. IMPORTANT: ***Access locally stored images through the Exam Management Page or the touch screen Exam Review button.***
	Record Cine	***Enables the system to be configured to record a Cine loop.***	
		DICOM Store Cine	Enables the User to send animated DICOM to a DICOM archive.
	The Imagio Breast Imaging System DVR Recording		Enables DVR Recording (i.e., a physical recording device is not required).
	Programmable Action		Specifies the action taken by the programmed key.

To Configure Custom Keys

(1) Press the Touch Screen Settings button.

(2) Select System Settings > Custom Keys.

(3) Select the desired Custom Key tab.

(4) Configure the individual Custom Keys.

(5) Select OK to accept the changes and exit or Cancel to exit without saving.

21.12 Peripherals

The Peripherals dialog enables Users to adjust touchscreen brightness and calibrate the button touch sensing accuracy on the System Console Touch Screen. The touch screen should be calibrated if a button press does not result in the expected button action.

(1) Press the Settings button on the System Console Touch Screen.

(2) Select the System Settings button.

(3) Enter the password when prompted and select OK.

(4) Select the Peripherals button.

(5) Select Calibrate Touch Screen. The on-screen instructions will direct the user to press the touchscreen at three locations where the plus (+) sign appears.

(6) Once calibration is completed select OK and exit all menus.

21.13 Patient Settings

Patient Settings allows Users to configure options for the Exam Management Page.

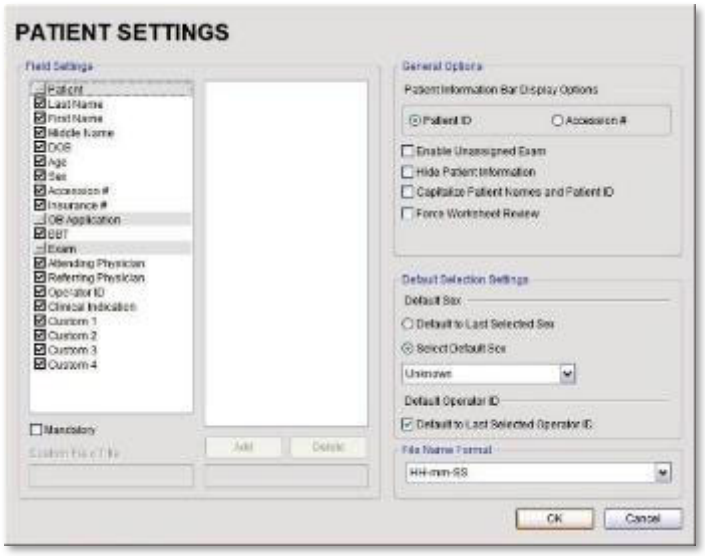


Figure 147: Patient Settings

Table 44. Patient Settings

Field Settings	Select/deselect the Field Setting data entry fields as required. Selected fields will appear on the Exam Management Page and, where applicable, in the relevant databases.	
	Last Name ***First Name*** ***Middle Name*** ***DOB*** ***Age*** ***Sex*** ***Accession #*** ***Insurance #***	When selected, these fields will be available under Patient Information.
	Note: Users can add/edit/delete data in the following fields. Deleting data does not affect existing patients. *Once deleted, the data can be added again later either here or on the Exam Management Page.*	
	Attending Physician ***Referring Physician*** ***Operator ID*** ***Clinical Indication***	When selected, these fields will be available under Exam Information.
	Custom 1, 2, 3, 4	Use these four (4) User-defined data entry fields to create the desired label in the Field Title text entry box (e.g., Nationality). The customized label appears as one of the data entry fields under Exam Information.
	Mandatory	Forces Users to complete specific Patient data fields. If a User tries to begin an exam using either the Exam Management Page before all Mandatory fields have been completed, an Input Required message will be presented.

Table 45. Patient Settings (Cont.)

(General Options	General Options control the ability to include/exclude or display/hide certain fields in the Patient Bar on the imaging screen.		
	Patient Information Bar Display Options	***Patient ID*** ***OR*** ***Accession #***	The selected option (Patient ID or Accession #) will be displayed in the Patient Information Bar along the top of the Display Monitor during an exam.
	Enable Unassigned Exam		Select/deselect to enable/disable the ability to begin an exam without selecting a patient. ⚠ ***WARNING:*** You may elect to configure/use the Enable Unassigned Exam functionality and this feature may be used at your own risk. Exams that are assigned to a Patient after images have been saved do not include identifying Patient data (such as Patient ID or Name). • Individuals or organizations that enable the Enable Unassigned Exam feature are assuming all liabilities and risks associated with that decision.
	Hide Patient Information		Select/deselect to display/hide the Patient Information during an exam.
	Capitalize Patient Names and Patient ID		Select to capitalize all letters in a patient'' name or identification number.
Default Selection Settings	*Default Sex*	***Default to last selected sex*** ***OR*** ***Select default sex***	When Default to last selected sex is chosen, opening a fresh Exam Management Page will result in the Sex field being populated with the same gender that was selected in the last Exam Management Page. When Select default sex is chosen, the User must select a specific Sex from the drop-down menu. The Sex selected will then become the default and be automatically entered in the Sex field of every new patient record that is created. There are four (4) choices available: Female, Male, Other and Unknown.
	Default Operator ID	***Default to last selected Operator ID***	When Default to last selected Operator ID is chosen, opening a fresh Exam Management Page will result in the Operator ID field being populated with the same User that was selected in the last Exam Management Page. *Note: This option is especially useful if the same User will be using the system for an extended period.*

21.13.1 To Access the Patient Settings Dialog

(1) Press the Touch Screen Settings button.

(2) Select System Settings > Patient.

21.13.2 To Configure Patient Settings

(1) Press the Touch Screen Settings button.

(2) Select System Settings > Patient.

(3) Configure Patient Settings as required.

(4) Select OK to accept the changes and exit or Cancel to exit without saving.

21.13.3 To Create Mandatory Settings

(1) Press the Touch Screen Settings button.

(2) Select System Settings > Patient.

(3) Select the desired Field Setting (e.g., Last Name).

(4) Select the Mandatory checkbox.

(5) Repeat step 3 and step 4 as required.

(6) Select OK to accept the changes and exit or Cancel to exit without saving.

21.14 Status Bar

When Status indicators are enabled, the system will present the relevant icons at the bottom right of the Display Monitor. Read the definitions carefully as not all icons will always be visible— even if the relevant option has been activated.

By default, all Status Bar options are unselected.

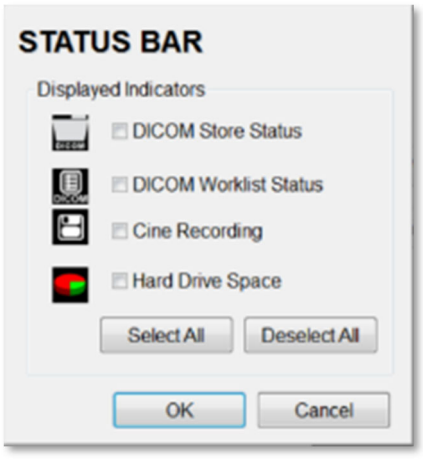


Figure 148: Status Bar

Table 46. Status Bar – Displayed Indicators

DICOM Store status  	Indicates the system is connected to a DICOM Storage server. This icon will be visible for only a short period of time. When a User accesses the DICOM Storage server, the icon will be presented while the operation is underway. A Network connection must exist to have access to a DICOM network.
DICOM Worklist status  	Indicates the system is connected to a DICOM Worklist server. This icon will be visible only when the DICOM Worklist server is being accessed. A Network connection must exist to have access to a DICOM network.
Cine Recording 	When Cine Recording is underway, this icon will be visible during the recording process.
Hard Drive Space 	Indicates the space used (green) and the space remaining (red) on the patient data hard drive.
Select All	Enables the selection of all options in one step.
Deselect All	Enables the deselection of all options in one step.

21.14.1 To Access Status Bar Indicators:

(1) Press the Touch Screen Settings button.

(2) Select System Settings > Status Bar.

21.14.2 To Configure Status Bar Indicators:

(1) Press the Touch Screen Settings button.

(2) Select System Settings > Status Bar.

(3) Select/deselect Displayed Indicators as required.

(4) Select OK to accept the changes and exit or Cancel to exit without saving.

21.15 Imaging Modes

The Imaging Modes dialog allows the configuration of a variety of Imaging Mode options.

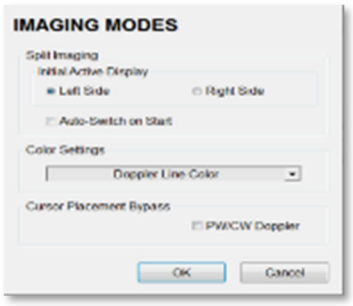


Figure 149: Imaging Modes and Color Settings

Table 47. Imaging Modes

Split Imaging	***Initial Active Display***	***Left Side***	When scanning in B-Mode, selecting Left Side will ensure the left image is the active image when the console Dual/Quad button is pressed. Left Side is the default setting.
		Right Side	When scanning in B-Mode, selecting Right Side will ensure the right image is the active image when the console Dual/Quad button is pressed.
	Auto-Switch on Start		Selecting this option will ensure that the selected side is active after the console Dual/Quad button is pressed, but then that image will immediately freeze and the active image will move to the opposite side. For example, if Left Side is set as Initial Active Display and Auto-Switch on Start is selected, after pressing the console Dual/Quad button, the Left Side image will be presented as active, then immediately freeze and active imaging will move to the Right Side.
	PW Doppler		PW Doppler automatically displays the split-screen B-Mode/Doppler Trace immediately after Doppler is activated. Deselecting PW Doppler displays a full screen B-Mode image with the Doppler SV (Sample Volume) cursor immediately after Doppler is activated. Activates the Doppler Trace.
	Color Settings		Changes the color of the Doppler Line.
	Cursor Placement Bypass		Disables the ability to position the gate cursor prior to live PW imaging.

To Configure Imaging Modes

(1) Press the Touch Screen Settings button.

(2) Select System Settings > Imaging Modes.

(3) Configure settings as required.

(4) Select OK to accept the changes and exit or Cancel to exit without saving.

Appendix A: Touch Screen Mode Action and Imaging Parameters

Touch Screen Mode Action Buttons (by Imaging Mode)						
		Imaging Mode				
Mode Action	Description	OA-Mode	B-Mode	Color	PW	Panoramic
End Exam	Press to end the current exam.	•	•	•	•	•
B-Mode Zoom	IMPORTANT: ***Press to activate B-Mode Zoom. Use the trackball to position the ROI. Enables ROI resizing with the trackball. Press again to accept the resized. ROI and return to ROI repositioning or to move directly to imaging. Both HD Zoom and Zoom mode action buttons can be applied to an image.***		•			
Invert	Press to Invert the image orientation by 180°.		•			•
Pano	Press to activate Panoramic imaging mode.	•	•	•	•	•
Pano Cancel	Press to cancel the current Panoramic acquisition. Note: This is not a toggle button.					•
Pano Exit	Press to exit Panoramic imaging. Note: This is not a toggle button.					•
Pano Start/Stop	Press to start or stop the Panoramic acquisition.					•
Reverse	Press to Reverse the image orientation right/left.		•			•
Simultaneous B-Mode/Color-Color Mode	Press to activate/deactivate Simultaneous B-Mode/Color (side-by-side split screen): Left side: live B-Mode/Color Right side: live B-Mode			•		
Trace On/Off	Press to activate/deactivate live spectral Doppler Trace display with measurement values.				•	
Triplex	Press to activate/deactivate Triplex imaging mode. Note: Triplex is only available if both PW and Color have been activated. Once Triplex is active, press the console button to toggle through Active PW, Active B/C and Triplex imaging modes.				•	
Baseline	Adjusts the Color Doppler Baseline: 0.2–6.7kHz.			•		
BaselineC	Adjusts the Color Doppler Baseline.			•		
BaselineD	Adjusts the Doppler Trace Baseline up or down.				•	
Box Height	Adjusts the size of the Color ROI box vertically.			•		

APPENDIX A

Touch Screen Mode Action Buttons (by Imaging Mode)							
		Imaging Mode					
Mode Action	Description	**OA-Mode**	**B-Mode**	**Color**	**PW**	**Panoramic**
Box Width	Adjusts the size of the Color ROI box horizontally.			•		
Chroma	Adjusts the color Maps overlaying the B-Mode image: 0–7.		•	•		•
ChromaD	Adjusts the color Map of the Doppler Trace: 0–7.				•	
Clarity	Adjusts the level of speckle reduction: Off, Low, Med, High, Max.		•	•	•	•
Dyn (Dynamic Range)	Adjusts the overall image contrast resolution in 1 dB increments. Displayed Dynamic Range varies from 15dB to 145dB. Complete system Dynamic Range is 302dB. ***IMPORTANT: An increase in dB increases the level of grays displayed.***		•	•	•	•
Ensemble	Adjusts Color Doppler sensitivity: range 6–16.			•		
Focus #	Adjusts the number of transmit focal zones on the screen. The maximum number of focal zones varies depending on which probe is selected. IMPORTANT: ***Increasing the number of focal zones will reduce the Frame Rate.*** If desired, enable Auto-Focus by setting the Focus # to 0 (zero).		•			•
Focus Span	Adjusts the distance between focal zones.		•			•
FreqC	Adjusts the Frequency of the Color Doppler: 4–6.6MHz.			•		
FreqD	Adjusts PW Doppler Frequency: 4.0–6.6MHz.				•	
FrRate	Adjusts the Frame Rate: Med, High and Max.		•	•	•	•
GainD	Adjusts the PW Doppler Gain: 0–100% in 2% increments.				•	
Gate	Adjusts the PW Sample Volume Gate size from 1.0mm–40.0mm in 0.5mm increments.		•	•	•	
Map	Adjusts the grayscale Map: 1–17.	•	•	•	•	•
MapC	Adjusts the Color Doppler Map: 1–9.			•		
MapD	Adjusts the grayscale Map of the Doppler Trace: 1–3.				•	
(Imaging) Method Color/Power/TDI	Toggles between the (Imaging) Method options: Color, Power and TDI (Tissue Doppler Imaging).			•		
Persist	Adjusts the level of visual smoothing of the B-Mode image: 0– 6.		•		•	•
PersistC	Adjusts the Color Doppler Persistence: 0 – 6.			•		

APPENDIX A

Touch Screen Mode Action Buttons (by Imaging Mode)							
		Imaging Mode					
Mode Action	Description	**OA-Mode**	**B-Mode**	**Color**	**PW**	**Panoramic**
Priority	Adjusts the Color Doppler B-Mode Priority.			•		
Reject	Eliminates or Rejects noise from the image: 25–60.		•	•	•	•
Smooth	Adjusts spectrum smoothing: 1–5.				•	
Sweep	Adjusts the Sweep speed of Doppler Trace (Low, Med, High1 and High2).				•	
WF	Adjusts the Wall Filter: 67–3333Hz.			•	•	
WFc	Adjusts the Color WF: 20–1000Hz in 20Hz increments.			•		
WFd	Adjusts the Doppler WF: 40–2000Hz in 40Hz increments.				•	

Appendix B: Distilled Water

Seno initially provides the distilled water to be used to fill the laser coolant reservoir.

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

- Fill the refill bottle away from the Imagio Breast Imaging System.
- Do NOT place the refill bottle or overflow bottle on any surface of the Imagio Breast Imaging System.
- Use only distilled water when filling the laser coolant reservoir.

Distilled Water Specifications

Purified Water – Distilled

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

Appendix C: Supplies and Accessories

⚠ ***WARNING:*** Unapproved supplies and accessories are NOT permitted and may cause tissue or Imagio Breast Imaging System damage.

- ***There are many supplies and accessories available that may appear similar to Seno approved supplies and accessories. Use only Seno approved supplies and accessories.***

The following supplies and accessories are the only approved and compatible items for use with the Imagio® Breast Imaging System. To order call the local service provider or an authorized Seno Medical representative.

Item	Cable Length	Part Number
OA-16-1S Opto-acoustic Probe	2.1 m (7 ft.)	SID-4220170020
US/L-14-5 Linear Probe	2.1 m (7 ft.)	SID-0000000929
Foot Switch	1.5 m (5 ft.)	SID-0000001038
Power Cord – USA	2.5 m (8 ft.)	SID-4120010339
Power Cord – Netherlands	2.5 m (8 ft.)	SID-4120010336
Ethernet Cable	4.5 m (15 ft.)	SID-4120010147
Laser Protective Eyewear User (180-400nm + 730-767nm + 990-1040nm OD 5+ 720-770nm + 960-1067nm OD 4+) 51%VLT SMI – Wrap-Around-Large	-	SID-0000002203
Laser Protective Eyewear User (180-400nm + 730-767nm + 990-1040nm OD 5+ 720-770nm + 960-1067nm OD 4+) 51%VLT SMI – Fit-Over-Large	-	SID-0000002206
Laser Protective Eyewear User (747-850nm DIR LB6 + M LB7Y LV CE OD7+)(>850-950nm DIRM LB4 LV CE OD5+) (>950-<980nm DIRM LB5 LV CE OD5+) (980-<1030nm D LB6 + IRM LB7 LV CE OD7+) (1030-1400nm D LB6 + IRM LB8 LV CE OD 8+) (>1400-3000nm DIRM LB4 LV CE OD4+) (>3000-11000 DI LB4 +R LB2 LV CE OD4+) 55%VLT F14.T5K17Goggle Over the Eyewear	-	SPEC-0000000021
Laser Protective Eyewear Patient or User (180-400nm + 730-767nm + 990-1040nm OD 5+ 720-770nm + 960-1067nm OD 4+ 747-767 DIR LB5 1061-1067 DIR LB4 NOIR CE) 51%VLT – SMI#50Goggle	-	SID-0000003622
Flat Breast Phantom	-	SID-4420010006
Examination Gel, Aquasonic Clear® Case of 12 - .25 L bottles	-	SID-0190000047
Refill Bottle	-	SID-4320010368
Overflow Bottle	-	SID-4320010370
Sani Cloth® AF3 Germicidal Disposable Wipe (U.S.A. use only)	-	SID-0190000039
CaviWipes™, Surface Disinfectant US (U.S.A. use only)	-	SID-0190000198
CaviWipes™, Surface Disinfectant EU (E.U. use only)	-	SID-0000003158
Pyramex LCT100 Lens Cleaning Towelette	-	SID-0190000607

Appendix D: Guidance and Manufacturer's Declaration

This guidance and manufacturer's declaration information pertains to the Imagio Breast Imaging System. Refer to 1.3.9 Electromagnetic Compatibility Compliance, 1.3.9.1 Electromagnetic Interference Testing, 1.3.9.2 Special EMC Precautions, and 1.3.9.3 Interference from Other Devices.

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.

***Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.**

Electromagnetic Emissions		
The ® is intended for use in the electromagnetic environment specified below. The customer or the User of the Imagio Breast Imaging System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF Emissions CISPR 11	Group 1, Class A (30 MHz – 1 GHz)	The 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.
Conducted Emissions CISPR 11	Group 1, Class A (150 kHz – 30 MHz)	The Imagio Breast Imaging System must emit Electromagnetic energy to perform its intended function. Nearby electronic equipment may be affected.
Harmonics IEC 61000-3-2	Class A,B,C,D or N/A	Class A
Flicker IEC 61000-3-3	Complies or N/A	Complies
RF Emission CISPR 14-1	Complies	The Imagio Breast Imaging System is not suitable for interconnection with other equipment.
RF Emission CISPR 15	Complies	The Imagio Breast Imaging System is not suitable for interconnection with other equipment.

APPENDIX D

Electromagnetic Immunity			
The Imagio Breast Imaging System is intended for use in the electromagnetic environment specified or user of the Imagio Breast Imaging System should ensure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2: 2014 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 15 kV Air	± 8 kV Contact ± 15 kV Air	Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the Relative Humidity should be at least 30%
Electric fast transient/burst (EFT) IEC 61000-4-4	± 2 kV AC Mains 100 kHz rep. rate	± 2 kV AC Mains 100 kHz rep. rate	Main power quality should be that of a typical commercial or hospital environment.
Surge Immunity IEC 61000-4-5	± 1 kV Differential ± 2 kV Common	± 1 kV Differential ± 2 kV Common	Main power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropouts IEC 61000-4-11	>95 % dip in 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 100% dip for 1 cycle at 0° 30 % dip for 25 cycles at 0° >95% dip for 250 cycles	>95 % dip in 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 100% dip for 1 cycle at 0° 30 % dip for 25 cycles at 0° >95% dip for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user 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 or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	30 A/m at 50 Hz 30 A/m at 60 Hz	30 A/m at 50 Hz 30 A/m at 60 Hz	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

APPENDIX D

Electromagnetic Immunity			
The Imagio Breast Imaging System is intended for use in the electromagnetic environment specified below. The customer or the User of the Imagio Breast Imaging System should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601-1-2:2014 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz, 80% 1kHz AM	3 Vrms 150 kHz to 80 MHz 80% 1kHz AM	The Imagio Breast Imaging System by no less than the distances calculated/listed below: D=(3.5/V1)(Sqrt P) 150kHz to 80MHz D=(3.5/E1)(Sqrt P) 80 to 800 MHz D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site. D be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz, 80% 1kHz AM 27 V/m 380-390 MHz, 18 Hz Pulse Mod. 28 V/m 430-470 MHz, 1kHz FM 9 V/m 704-787 MHz, 217 Hz Pulse Mod. 28 V/m 800-960 MHz, 217 Hz Pulse Mod. 28 V/m 1700-1990 MHz, 217 Hz Pulse Mod. 28 V/m 2400-2570 MHz, 217 Hz Pulse Mod. 9 V/m 5100-5800 MHz, 217 Hz Pulse Mod.	3 V/m 80 MHz to 2.7 GHz, 80% 1kHz AM 27 V/m 380-390 MHz, 18 Hz Pulse Mod. 28 V/m 430-470 MHz, 1kHz FM 9 V/m 704-787 MHz, 217 Hz Pulse Mod. 28 V/m 800-960 MHz, 217 Hz Pulse Mod. 28 V/m 1700-1990 MHz, 217 Pulse Mod. 28 V/m 2400-2570 MHz, 217 Hz Pulse Mod. 9 V/m 5100-5800 MHz, 217 Hz Pulse Mod.	

APPENDIX D

Recommended Separation Distances for the Imagio Breast Imaging System			
The Imagio Breast Imaging System is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user 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

Appendix E: Product Specifications

Testing performed with a laser emission duty cycle of 10 minutes on and 10 minutes off.

System Cart	
Size (not including monitors)	76 cm x 122 cm x 147 - 160 cm (30” x 48” x 58 - 63”)
Maximum Weight	575 pounds (261 kg)
Power Requirements	208/220/230 VAC, 50-60 Hz, 12 A
Warm-up Time	Up to 14 minutes
Environmental Requirements: Operational Temperature and Humidity	Ambient temperature 10 °C to 30 °C (50 °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	<3000 W
Mode of Operation	OA duty cycle: 10 minutes ON / 10 minutes OFF
Ingress	IP20 cart IPX6 foot switch
Monitor	61 cm (24.1”) diagonal; 1920 x 1200 resolution
User Interface	Touchscreen, keyboard, trackball, multi-button console, foot switch
Mobility	Wheels and locking casters

Laser System	
Laser Types	Alexandrite, Nd:YAG
Wavelength	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	75 ns nominal +/-25 ns (Alexandrite);15 ns nominal +/-10 ns (Nd:YAG)

APPENDIX E

Laser System	
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.
Activation	Password, Interlock, Foot Switch
Cooling System	1.0 L of Distilled water required
Heating Element Rating	230 W, 220 VAC/230 VAC

OA-16-1S Probe	
Number of Elements	128
Type	Linear array
Biocompatibility	Parts intended for patient contact made of biocompatible materials; Latex free
Cable Length	5 ft. or 1.52 m minimum, 7 ft. or 2 m maximum
Minimum Cable Bend Radius	5.08 cm (2”)
Maximum Patient Contact Surface Size	54 +/- 1 mm x 41 +/- 1 mm
Center Frequency Response	9.4MHz +/- 0.9
Percent Bandwidth	>80%
Pulse Width (Acoustic)	<130 ns measured at the -20 dB point level
Mechanical Focal Length	20 ± 6 mm
Ultrasound Connector Type	Zero Insertion Force (ZIF) ITT Cannon LLC DLM1-156P
Laser Connector Type	Seno custom
Probe Fluence	Skin Exposure <20 mJ / cm^2

US/L-14-5 Probe	
Number of Elements	128
Type	L14-5 (38 mm Linear Array)
Ultrasound Connector Type	Cannon DLM1-156 with ZIF mate

Imaging/Data Acquisition	
Imaging Modes	Color Doppler overlaid on B-Mode, Power Doppler overlaid on B-Mode, OA co-registered with B-Mode, B-Mode
Cine Videos	Yes
Image Type	DICOM 3.0 compatible

APPENDIX E

Imaging/Data Acquisition	
Display	2 and 6 images concurrently in near Real Time
Imaging Depth	2 – 40 mm
Gain	70 dB +/- 2dB, programmable downwards by 40db
Signal to Noise Ratio	70 dBFS
Analog to Digital Conversion Resolution	14 bits
Low Frequency Cut-off	<100 KHz
Acquisition/Processing Speed	31.25 Million Samples Per Second (MSPS)

Appendix F: Ranges, Accuracies and Precision

OA-16-1S Probe Imagio Breast Imaging System Combination						
Variable	**Range**	**Accuracy**	**Precision**	**Units**	**Description**	**Default for OA-Mode**
Freq	6-14	N/A	.01	MHz	The displayed frequency. Is changed through the B Mode Optimization.	14 MHz
Depth	2.0 - 4.0	N/A	0.5	cm	The depth to acquire data. Applies to B mode and OA mode. Can be modified by User.	4.0 cm
Sector	50-100+	N/A	5	%	The percentage of the vectors being acquired, as a maximum of the line density. There is one Ext. setting that goes just past 100% size.	100%
Gain	0-100	N/A	1	%	B mode gain. Can be changed by User.	55%
FrRate	Med,High,Max	N/A	64	N/A	The frame-rate optimization. Automatically adjusts the line density. The values listed here are the numerical values in the xml file, but the User will see the settings FrRate Med, FrRate High, and FrRate Max. Can be changed by User.	FrRate High
FPS	15-47	N/A	1	Hz	The acquisition rate in frames per second. Not directly changed by User and is calculated from other values, such as Persist, Depth, and FrRate variables.	26Hz
Dyn	15-145	N/A	1	dB	Adjusts B Mode dynamic range by altering the log compression table after envelope detection. Can be changed by User.	72dB
Persist	0-6	N/A	1	N/A	The frame averaging level. Filter type (0-6) can be changed by User.	2
Map	1-17	N/A	1	N/A	The greyscale map index that adjusts brightness, contrast and gamma. Map selection (1-17) can be changed by User.	Map 4
Chroma	0-16	N/A	1	N/A	The Chroma index to colorize the B Mode image. Index (0-16) can be changed by User.	0

APPENDIX F

OA-16-1S Probe Imagio Breast Imaging System Combination						
Variable	**Range**	**Accuracy**	**Precision**	**Units**	**Description**	**Default for OA-Mode**
OA Focus Depth	3.0-37.0	N/A	0.5	mm	The OA focus depth. This is the depth of the halfway mark between the two focus lines. (E.g. If focus lines are at 5 and 30 mm, the depth is 17.5 mm). This can be changed by the User with the OA Focus Depth knob. It will change automatically if the field depth is changed.	20 mm
OA Focus Height	0.5-30	N/A	0.5	mm	The OA focus height. The distance between the focus lines. This can be changed by the User with the OA Focus Height knob. It will change automatically when the field depth is changed, or when an OA Focus Depth change is too extreme (too far to the top or bottom of the image) for the focus height to be maintained.	30 mm
Laser Enabled	0 to 15 minutes	+/- 1.0 Seconds	+/- 0.5 Seconds	min/sec	This shows the authorization state of the laser. When the laser is authorized and not emitting, Laser Enabled will be displayed; Ready. When the laser is not authorized, this will say Laser Disabled. When the laser is authorized and emitting, Laser Enabled will be displayed and the idle timeout will restart at the beginning of emission. Laser Status Disabled indicates that the laser authorization has not been manually attempted yet and that the laser is not authorized. The idle timeout will reset when the ready state is entered.	Laser Status

Measurement Accuracies			
Variable	**Relative Error**	**Range**	
		Minimum	**Maximum**
Axial Distance	+/-0.3%	0.1 mm	90.0 mm
Lateral Distance	+/-0.3%	0.1 mm	37.6 mm
Area	+/-04.29%	0.01 cm^2	27.00 cm^2

APPENDIX F

US/L-14-5 Probe Imagio Breast Imaging System Combination						
Variable	**Range**	**Accuracy**	**Precision**	**Units**	**Description**	**Default for B-Mode**
Freq	6-14	N/A	.01	MHz	The displayed frequency. Is changed through the B Mode Optimization.	14 MHz
Depth	2 - 9 B-Mode 2 - 4 OA-Mode	N/A	0.5	cm	The depth to acquire data. Applies to B mode and OA mode. Can be modified by User.	9.0 cm (OA-Mode 4.0 cm)
Sector	50-100+	N/A	5	%	The percentage of the vectors being acquired, as a maximum of the line density. There is one Ext. setting that goes just past 100% size.	100%
Gain	0-100	N/A	1	%	B mode gain. Can be changed by User.	55%
FrRate	Med,High,Max	N/A	64	N/A	The frame-rate optimization. Automatically adjusts the line density. The values listed here are the numerical values in the xml file, but the User will see the settings FrRate Med, FrRate High, and FrRate Max. Can be changed by User.	FrRate High
FPS	15-47	N/A	1	Hz	The acquisition rate in frames per second. Not directly changed by User and is calculated from other values, such as Persist, Depth, and FrRate variables.	26Hz
Dyn	15-145	N/A	1	dB	Adjusts B Mode dynamic range by altering the log compression table after envelope detection. Can be changed by User.	72 dB
Persist	0-6	N/A	1	N/A	The frame averaging level. Filter type (0-6) can be changed by User.	2
Map	1-17	N/A	1	N/A	The greyscale map index that adjusts brightness, contrast and gamma. Map selection (1-17) can be changed by User.	Map 4
Chroma	0-16	N/A	1	N/A	The Chroma index to colorize the B Mode image. Index (0-16) can be changed by User.	0

Measurement Accuracies			
Variable	**Relative Error**	**Range**	
		Minimum	**Maximum**
Axial Distance	+/-1.0%	9.9 mm	10.1 mm
Lateral Distance	+/-1.0%	19.8 mm	20.2 mm
Area	+/-5.0%	11.97 cm^2	13.23 cm^2

Appendix G: Acoustic Output Tables

The following tables indicate the acoustic output energy for the system and OA/US Probe combination. These tables show the worst-case indices for the OA/US Probe type and operating condition that must be reported. Note that all thermal and mechanical indices are below 1.0 for the OA-16-1S Probe and below 1.06 for the US/L-14-5 for all device settings.

The OA-16-1S Probe; B-mode + Color and Triplex (B-mode + Color + PW-mode) were evaluated, but neither produced higher $I_{spta.3}$, MI, or TI than the B-mode + PW-mode summarized below. The highest MI was produced in B-mode only, as this B-mode setting was not available in the combined mode that produced the highest TI.

Track 3 Reporting Tables are included to summarize the acquired acoustic data for each sample tested. The statistics analysis of worst-case measurements tables below show the worst-case indices for each probe type and operating condition that must be reported. The values in the table are the average of the three samples measured.

Statistical analyses of worst-case measurements		
Mode:	B-Mode (6.7 MHz)	
Probe:	OA-16-1S	
	MI [Dimensionless]	$I_{SPTA.3}$ [mW/cm^2]
Sample Size	3	3
K	4.258	4.258
Mean	0.905	10.1
StdDev	0.0431	0.474
Limit	**1.09**	**12.1**

Statistical analyses of worst-case measurements		
Mode:	B-Mode + PW Mode	
Probe:	OA-16-1S	
	MI [Dimensionless]	**$I_{SPTA.3}$** [mW/cm^2]
Sample Size	3	3
K	4.258	4.258
Mean	0.724	276.8
StdDev	0.029	13.2
Limit	**0.846**	**333.1**

Neither the MI nor the TI exceeded 1.0 for any sonication conditions. As such, per the FDA guidance, the following Track 3 summary table is provided as more detailed tables are not required. However, detailed, mode-specific tables are provided for informational purposes.

Track 3 Summary					
Probe	$I_{SPTA.3}$	TI Type	TI Value	MI	$I_{PA.3}$@MI_{max}
OA-16-1S	276.8	TIB	0.872	0.905	260

APPENDIX G

Acoustic Output Reporting Table for Track 3

Probe Model: OA-16-1S **Operating Mode**: B-Mode

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt≤1 cm²	Aaprt>1 cm²		
Maximum index value			0.905	0.0458	-	-	-	(a)
Associated Acoustic Parameter	Pr.3	(MPa)	2.29					
	W0	(mW)		5.67	-		-	(a)
	min of [W.3(z1) : ITA.3(z1)]	[mW]				-		
	Z1	[cm]				-		
	Zbp	[cm]				-		
	Zsp	[cm]	1.10				-	
	deq(zsp)	[cm]					-	
	Fc	[MHz]	6.43	6.43	-	-	-	(a)
	Dim of Aaprt	X [cm]		0.480	-	-	-	(a)
		Y [cm]		0.400	-	-	-	(a)
Other Information	PD	[µsec]	0.276					
	PRF	[Hz]	5120					
	pr@PIImax	[MPa]	2.93					
	deq@PIImax	[cm]					-	
	Focal Length	FLX [cm]		0.0757	-	-		
		FLY [cm]		0.201	-	-		
	IPA.3@MImax	[W/cm²]	260					
Operating Control Conditions	10 mm focus, 6.7 Mhz	✓	✓					

Note 1: Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.

Note 2: Information need not be provided regarding TIC for any PROBE ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed

No data reported.

APPENDIX G

Probe Model: OA-16-1S **Operating Mode**: B-Mode + PW-Mode

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt≤1 cm²	Aaprt>1 cm²		
Maximum index value			0.724	0.0281	0.507	-	0.872	(a)
Associated Acoustic Parameter	Pr.3	(MPa)	1.92					
	W0	(mW)		3.04	16.0		16.0	(a)
	min of [W.3(z1) : ITA.3(z1)]	(mW)				-		
	Z1	(cm)				-		
	Zbp	(cm)				-		
	Zsp	(cm)	1.77				1.87	
	deq(zsp)	(cm)					0.181	
	Fc	(MHz)	7.03	7.03	6.66	-	6.66	(a)
	Dim of Aaprt	X (cm)		0.960	0.800	-	0.800	(a)
		Y (cm)		0.400	0.400	-	0.400	(a)
Other Information	PD	(µsec)	0.129					
	PRF	(Hz)	5120					
	pr@PIImax	(Mpa)	2.95					
	deq@PIImax	(cm)					0.181	
	Focal Length	FLX (cm)		0.0962	0.330	-		
		FLY (cm)		0.128	0.141	-		
	IPA.3@MImax	(W/cm²)	260					
Operating Control Conditions	B-mode, 20 mm focus, 10 MHz	✓	✓					
	PW-mode, 40 mm gate, 6.7 MHz, 12.5 kHz PRF				✓		✓	

Note 1: Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.

Note 2: Information need not be provided regarding TIC for any PROBE ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed

No data reported.

APPENDIX G

Acoustic Output Reporting Table for Track 3

Probe Model: US/L-14-5 **Operating Mode**: B-Mode

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					A_{aprt}≤1 cm^2	A_{aprt}>1 cm^2		
Maximum index value			0.59	(a)	(a)	(a)	(a)	(a)
Associated Acoustic Parameter	$P_{r.3}$	(MPa)	1.49					
	W_0	(mW)		(a)	(a)		(a)	(a)
	min of [$W_{.3}(z_1)$: $I_{TA.3}(z_1)$]	[mW]				(a)		
	z_1	[cm]				(a)		
	z_{bp}	[cm]				(a)		
	z_{sp}	[cm]	2.09				(a)	
	$d_{eq}(z_{sp})$	[cm]					(a)	
	f_c	[MHz]	6.29	(a)	(a)	(a)	(a)	(a)
	Dim of A_{aprt}	X [cm]		(a)	(a)	(a)	(a)	(a)
		Y [cm]		(a)	(a)	(a)	(a)	(a)
Other Information	PD	[µsec]	0.37					
	PRF	[Hz]	260					
	$p_r@PII_{max}$	[MPa]	2.35					
	$d_{eq}@PII_{max}$	[cm]					(a)	
	Focal Length	FL_X [cm]		(a)	(a)	(a)		(a)
		FL_Y [cm]		(a)	(a)	(a)		(a)
	$I_{PA.3}@MI_{max}$	[W/cm^2]	114.78					

Operating Control Conditions

System Settings:
Depth 25 mm
Focus 25 mm
Gate 0 mm
Preset GEN-General-PEN

Note 1: Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.

Note 2: Information need not be provided regarding TIC for any PROBE ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed

No data reported.

APPENDIX G

Acoustic Output Reporting Table for Track 3

Probe Model: US/L-14-5 **Operating Mode**: PW + CFD

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt≤1 cm^2	Aaprt>1 cm^2		
Maximum index value			0.59	0.13	(a)	(a)	(a)	0.08
Associated Acoustic Parameter	$P_r.3$	(MPa)	1.49					
	W_0	(mW)		4.21	(a)		(a)	4.21
	min of $[W_{.3}(z_1), I_{TA}.3(z_1)]$	[mW]				(c)		
	z_1	[cm]				(c)		
	z_{bp}	[cm]				(a)		
	z_{sp}	[cm]	2.09				(a)	
	$deq(z_{sp})$	[cm]					(a)	
	f_c	[MHz]	6.29	6.29	(a)	(a)	(a)	6.29
	Dim of A_{aprt}	X [cm]		(a)	(a)	(a)	(a)	(a)
		Y [cm]		(a)	(a)	(a)	(a)	(a)
Other Information	PD	[µsec]	0.37					
	PRF	[Hz]	31					
	$p_r@PII_{max}$	[MPa]	2.35					
	$d_{eq}@PII_{max}$	[cm]					(a)	
	Focal Length	FL_X [cm]		2.50	(a)	(a)		2.50
		FL_Y [cm]		2.50	(a)	(a)		2.50
	$I_{PA.3}@MI_{max}$	[W/cm^2]	114.78					

Operating Control Conditions	System Settings:
	Depth 40 mm
	Focus 25 mm
	Gate 0 mm
	Preset GEN-General-PEN

Note 1: Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.

Note 2: Information need not be provided regarding TIC for any PROBE ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed

No data reported.

APPENDIX G

Acoustic Output Reporting Table for Track 3

Probe Model: US/L-14-5 **Operating Mode**: PW

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					A_{aprt}≤1 cm^2	A_{aprt}>1 cm^2		
Maximum index value			0.53	(a)	0.48	0.3027	1.38	0.69
Associated Acoustic Parameter	$P_{r.3}$	(MPa)	1.36					
	W_0	(mW)		(a)	15.17		15.17	15.17
	min of [$W_{.3}(z_1)$: $I_{TA.3}(z_1)$]	[mW]				9.61		
	z_1	[cm]				1.56		
	z_{bp}	[cm]				0.83		
	z_{sp}	[cm]	1.56				1.56	
	$d_{eq}(z_{sp})$	[cm]					0.10	
	f_c	[MHz]	6.65	6.65	6.65	6.65	6.65	6.65
	Dim of A_{aprt}	X [cm]		(a)	0.60	0.60	0.60	0.60
		Y [cm]		(a)	0.40	0.40	0.40	0.40
Other Information	PD	[µsec]	1.09					
	PRF	[Hz]	5000					
	p_r@PII_{max}	[MPa]	1.95					
	d_{eq}@PII_{max}	[cm]					0.03	
	Focal Length	FL_X [cm]		(a)	2.00	2.00		2.00
		FL_Y [cm]		(a)	2.00	2.00		2.00
	$I_{PA.3}$@MI_{max}	[W/cm^2]	93.23					

Operating Control Conditions

System Settings:
Depth 40 mm
Focus 20 mm
Gate 40 mm
Preset GEN-General-PEN

Note 1: Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.

Note 2: Information need not be provided regarding TIC for any PROBE ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed

No data reported.

APPENDIX G

Acoustic Output Reporting Table for Track 3

Probe Model: US/L-14-5 **Operating Mode**: PW + B-Mode

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					A_{aprt}≤1 cm^2	A_{aprt}>1 cm^2		
Maximum index value			0.59	0.94	0.94	0.3027	1.38	0.56
Associated Acoustic Parameter	$P_{r.3}$	(MPa)	1.49					
	W_0	(mW)		31.22	31.22		31.22	31.22
	min of [$W_{.3}(z_1)$: $I_{TA.3}(z_1)$]	[mW]				12.59		
	z_1	[cm]				2.09		
	z_{bp}	[cm]				2.09		
	z_{sp}	[cm]	2.09				2.09	
	$d_{eq}(z_{sp})$	[cm]					0.10	
	f_c	[MHz]	6.29	6.29	6.29	6.29	6.29	6.29
	Dim of A_{aprt}	X [cm]		3.80	3.80	3.80	3.80	3.80
		Y [cm]		0.40	0.40	0.40	0.40	0.40
Other Information	PD	[µsec]	0.37					
	PRF	[Hz]	33					
	p_r@PII_{max}	[MPa]	2.35					
	d_{eq}@PII_{max}	[cm]					0.03	
	Focal Length	FL_X [cm]		2.00	2.00	2.00		2.00
		FL_Y [cm]		2.00	2.00	2.00		2.00
	$I_{PA.3}$@MI_{max}	[W/cm^2]	114.78					

Operating Control Conditions

System Settings:
Depth 40 mm
Focus 20 mm
Gate 40 mm
Preset GEN-General-PEN

Note 1: Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.

Note 2: Information need not be provided regarding TIC for any PROBE ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed

No data reported.

APPENDIX G

Acoustic Output Reporting Table for Track 3

Probe Model: US/L-14-5 **Operating Mode**: B-Mode + CFD + PD

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					A_{aprt}≤1 cm^2	A_{aprt}>1 cm^2		
Maximum index value			0.53	1.05	0.95	0.30	1.38	0.57
Associated Acoustic Parameter	$P_{r.3}$	(MPa)	1.34					
	W_0	(mW)		34.99	31.66		31.66	31.66
	min of [$W_{.3}(z_1)$: $I_{TA.3}(z_1)$]	[mW]				2.35		
	z_1	[cm]				2.09		
	z_{bp}	[cm]				2.09		
	z_{sp}	[cm]	2.09				2.09	
	$d_{eq}(z_{sp})$	[cm]					4.12	
	f_c	[MHz]	6.29	6.29	6.29	6.29	6.29	6.29
	Dim of A_{aprt}	X [cm]		3.80	3.80	3.80	3.80	3.80
		Y [cm]		0.40	0.40	0.40	0.40	0.40
Other Information	PD	[µsec]	0.37					
	FPS	[Hz]	9					
	PRFd	[Hz]	6400					
	$p_r@PII_{max}$	[MPa]	2.11					
	$d_{eq}@PII_{max}$	[cm]					2.63	
	Focal Length	FL_X [cm]		2.00	2.00	2.00		2.00
		FL_Y [cm]		2.00	2.00	2.00		2.00
	$I_{PA.3}@MI_{max}$	[W/cm^2]	114.78					

Operating Control Conditions

System Settings:
Depth 40 mm
Focus 20 mm
Gate 40 mm
Preset GEN-General-PEN

Note 1: Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.

Note 2: Information need not be provided regarding TIC for any PROBE ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed

No data reported.

Marketing Clearance of Diagnostic Ultrasound Systems and Transducers *Guidance for Industry and Food and Drug Administration Staff* JUNE 2019

Appendix H: 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 User Manual as outlined in ISO 14971:2012 Medical devices – Application of risk management to medical devices.

Appendix I: General Guidelines for OA/US Scanning

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 user should minimally perform the OA/US captures listed for each application.

OA provides information consistent with conventional diagnostic ultrasound and interleaves the US frames with OA frames containing functional data from the mass of interest. The images and videos that need to be captured for OA evaluation should not supersede or replace examination procedures and policies of the individual study sites.

Our scan procedures are created in accordance with The American College of Radiology and the European Society of Breast Imaging Practice Guidelines.

Optimizing technical factors and scanning techniques for OA/US

- Adjusting the Frequency to the highest available and optionally interrogating with harmonics optimizes the detail and contrast resolution of the OA/US image
- Adjust the Frequency to its lowest setting to better laterally resolve superficial < 1cm depth tissue
- Adjusting the TGC so there is uniform gray scale from superficial to deep optimizes spatial brightness uniformity of OA/US image
- 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)
- Adjusting the gray scale Focus to 3 zones that are centered on the target structure optimizes lateral resolution
- Adjusting the OA Focus to maximum height for the depth of field optimizes the OA signal when no dominant source is present
- Adjusting the Clarity to Max optimizes the lines per frame
- Applying just enough gel to wet the skin surface while avoiding too much gel optimizes OA/US transmission and reception
- Applying normal to light probe pressure optimizes OA/US Probe face skin contact

See 0 Chapter 4: OA-16-1S Probe and US/L-14-5 Probe **for care and handling.**

APPENDIX I

OA/US Breast Imaging Interrogation

Some critical Opto-acoustic findings occur within the tissues that surround the primary breast mass. Therefore, it is important for the user to interrogate the tissues and structures around the main portion of the lesion and to capture images and videos 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.

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 video frame in which to draw a region of interest(ROI) to segment between the nidus, boundary zone, peripheral zone.

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

It is important to make a mental note of the number, location and orientation of single or paired vessels along the mass wall or capsule while interrogating the mass. This will assist in choosing a representative video frame in which to draw regions of interest(ROI) to segment between the nidus, boundary zone, and peripheral zone.

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 deoxygenated 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 central nidus, the boundary zone, and the peritumoral 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 mass's vascularity may not always be colorized red and benign vessels may not always be colorized green

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 video frame in which to draw regions of interest(ROI) to segment between the nidus, boundary zone, and peripheral zone.

Example: Highly Suspicious Breast Mass OA Features

(Refer to OA feature training resources for the complete range of reassuring to highly suspicious 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

Breast OA/US Imaging and Recording

- To capture critical OA/US features such as radiating vessels occurring in peri-tumoral tissue on larger than 1 cm masses, take multiple bilateral and offset to the nidus parallel video sweeps to record up to 2 cm of the surrounding peri-tumoral tissue
- 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.
- To video capture the highest detailed OA/US signal, move the probe slowly and methodically approximating a maximum of 5 mm / second of probe movement
- 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.

Transverse and longitudinal scan planes may be used in place of radial and anti-radial scan planes

APPENDIX I

Recommended Captures

Imagio® US (Minimum) Recommended Video Recordings:

- 1 video in the radial scan plane: (5-10 second single direction video volumetric sweep)
- Move the probe parallel to the short axis of probe or “Short Axis Video Sweep (SAX)”
- 1 video in the anti-radial scan plane: (5-10 second single direction video volumetric sweep)
- Move the probe parallel to the short axis of probe or “Short Axis Video Sweep (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 performing a long axis LAX video:

- 1 video in a scan plane centered on the mass: (5-10 second single direction video)
- Move the probe parallel to the long axis of probe or “Long Axis Video Sweep (LAX)”

Imagio® OA (Minimum) Recommended Video Recordings:

- 1 video in the radial scan plane: (5-10 second single direction video volumetric sweep)
- Move the probe parallel to the short axis of probe or “Short Axis Video Sweep (SAX)”
- 1 video in the anti-radial scan plane: (5-10 second single direction video volumetric sweep)
- Move the probe parallel to the short axis of probe or “Short Axis Video Sweep (SAX)”

APPENDIX I

Axillary Lymph Node OA/US Scanning

- The most frequent site of breast cancer metastasis are lymph nodes; therefore, it is important for the user to explore internal mammary lymph nodes and axillary lymph nodes when a suspicious breast mass is identified.

Example: Highly Suspicious Lymph Node OA Features
(Refer to OA feature training resources for the complete range of reassuring to highly suspicious OA features)

Internal

- Red(deoxygenated) blush
- Multiple tortuous vessels

External

- Non-hilar trans capsular vessels – red or green

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).

Recommended Captures

Imagio® OA (Minimum) Recommended Video Recordings for Lymph Nodes:

- 2 videos in the transverse or long scan plane position: (5-10 second single direction video)
- Move the probe parallel to the short axis of probe or "Short Axis Video Sweep (SAX)"
- Move the probe parallel to the long axis of probe or "Long Axis Video Sweep (LAX)"

Appendix J: Tissue Phantom Study

Testing was conducted using various tissue-mimicking phantoms to assess device image quality and blood oxygenation measurement performance. Phantom testing was also used to demonstrate equivalent performance of the final device version against the previous device version used to collect original clinical study image data in the PIONEER study. Specific phantom tests were performed to evaluate spatial resolution (axial, lateral, and elevational); geometric accuracy and precision; OA/US co-registration accuracy; image uniformity; depth of visualization; OA signal sensitivity, linearity, and dynamic range; vessel size measurement accuracy; oxygen saturation resolution and precision; out-of-plane absorber artifacts; and effects of laser energy variation on image quality and OA image colorization. Results showed that the device can detect blood vessel-mimicking targets in a breast-like background medium and map relative differences in blood oxygen saturation.

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 deoxygenated 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 dynamic range of the Imagio system	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.

Appendix K: 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 (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 (IUS+OA) at the same sensitivity.

Secondary endpoints: Evaluate the following for IUS alone versus Imagio (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 (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). 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. <u>Clinical Inclusion and Exclusion Criteria</u>

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 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.
g. Has all mass(es) characterized as BI-RADS 1 and/or 2 as determined using a CDU.
h. Currently has mastitis.
i. Has focal pain without thickening or mass.
j. Is pregnant or lactating.
k. Has open sores including insect bites, rash, poison ivy, and chafing on the skin of the ipsilateral breast.
l. Has an acute or a chronic hematoma and/or acute ecchymosis of the ipsilateral breast.
m. 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.
n. Has a history of any photosensitive disease (e.g., porphyria, lupus erythematosus) or undergoing treatment for a photosensitive disease and was experiencing photosensitivity.
o. Concurrent neoadjuvant therapy prior to the Imagio evaluation or the biopsy.
p. Has previously had image guided core biopsy, image guided DVAB, or surgical biopsy of the mass of interest.
q. Has nipple rings that cannot be removed or are not removed during Imagio 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™ 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.

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 procedure after the decision whether to biopsy was made, but prior to any biopsy. The subjects must have had the Imagio 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 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.

Appendix K

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 thus consisted 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.

The number of masses was 480 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.)

A total of 480 complete read sets (4 blocks of 120 read sets each) from the original PIONEER ITD analysis population were randomly selected with stratification in accordance with the Reader-02 Pivotal Study Sampling Plan from within the previous PIONEER Pivotal Study. 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. 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.

Appendix K

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 (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.

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

Appendix K

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 (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 (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 paraesthesia (10 events) and post procedural hematoma (all post-biopsy; 5 events). Twenty-five events, including 10 events of paraesthesia, 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.

Appendix K

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.

Appendix L: Certificate of Completion

Certificate of Completion

Seno Medical Instruments, Inc.

Imagio® Breast Imaging System User Training

This certificate acknowledges that

_____ _____

Name *License #*

has successfully completed the Imagio Training Program

SENO MEDICAL®

_____ _____

Seno Clinical Applications Specialist *Date*