PERIMETER

claire™

USER MANUAL

Contact Information:
Phone (Toll-Free): 1-888-988-7465 (PINK)
Email: support@perimetermed.com
Web: perimetermed.com

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WARNING: It is unsafe to operate the device before reading this entire manual.

Claire OCT System
User Manual

Manufacturer:
Perimeter Medical Imaging AI, Inc.
555 Richmond St W, Suite 511
Toronto, Ontario,
Canada M5V 3B1

Contact Information:
Phone (toll-free): 1-888-988-7465
Email:support@perimetermed.com
Web: www.perimetermed.com

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LEGAL DISCLAIMER

Perimeter Medical Imaging's Claire OCT System is an adjunctive, three-dimensional imaging tool which provides clinicians with the ability to review breast tissue microstructure. The device provides volumetric cross-sectional, real-time depth visualization, coupled with an artificial intelligence computer aided detection algorithm which identifies and marks focal areas suspicious for breast cancer and is used concurrently with physician interpretation of the images. The Claire OCT System is intended for use in conjunction with other standard methods for evaluation of the margins of an excised lumpectomy specimen during surgical procedures in patients with a biopsy-confirmed diagnosis of breast cancer.

The Claire OCT System is not responsible for any false negatives, false positives, or any errors arising from the maintenance, use or other application of the device and disclaims any responsibility for the same. Responsibility for the medical care of the patient and any user of the device lies with the user and supervising medical practitioner.

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Preface

To Customers

This user manual will outline the operation and maintenance of the Claire OCT System device. Before using the device, be sure to read this manual thoroughly in order to use the device more effectively.

The Claire OCT System device integrates into standard lumpectomy workflows, providing surgeons with an adjunctive, three-dimensional imaging tool, with real-time depth visualization of tissue microstructures to assess margin status of lumpectomy and shave specimens. The Claire OCT System couples intraoperative imaging capability with ImgAssist, a computer-aided detection software, leveraging artificial intelligence to analyze OCT images. ImgAssist highlights suspicious regions for surgeons' prioritized review.

The graphics, figures and clinical images used in this user manual are examples only. The actual display and design of these may be slightly different on the Claire OCT System.
It is the user's responsibility to ensure that the security of the specimen data, which may relate to a patient, is guarded in accordance with HIPAA regulations.

Definition of Terms

Claire OCT System: Perimeter's Claire OCT System device, including all the components necessary for acquiring images and reviewing them, such as the Claire imaging cart with Claire software that includes ImgAssist, an AI-based feature to identify regions suspicious for breast cancer, and the Specimen Immobilizer.

Case: A collection of WF-OCT Images that also includes Specimen Photograph(s), user-specified specimen side(s), and user annotations, if applicable, typically for a single patient. A Case can therefore contain multiple scans of an excised tissue specimen from the same patient.

> **Scan:** Data collected for one side/margin or orientation of a specimen.

Specimen Immobilizer: A clean, packaged set of single-use accessories, which contains:

> **Specimen Tray:** A single-use component which contains one Imaging Window, on which the specimen is placed for imaging. The Specimen Tray is secured to the Claire OCT System device in preparation for specimen imaging.
>
> **Specimen Lid:** A single-use component which is placed on top of the specimen during imaging and connects to the Specimen Tray.

Eligible Specimen Diameter: Up to a maximum of 10 cm.

Imaging Gate: The protective cover in the center of the Specimen Tray Dock which opens once the Specimen Tray has been properly secured to allow scanning to begin.

ImgAssist: A concurrent reading aid for physicians interpreting WF-OCT images of breast tissue, acquired on the Claire OCT System device, to identify regions suspicious for breast cancer. The ImgAssist feature includes a trained artificial intelligence algorithm.

Imaging Lens: An internal optical component which illuminates the specimen with non-ionizing, low-power optical radiation and collects the resulting OCT signal.

Live Specimen View: A real-time view of the surface image of the specimen which is in contact with the Imaging Window.

Optical Coherence Tomography (OCT): An optical imaging modality which is similar to ultrasound, but uses non-ionizing, low-power optical radiation to produce high-resolution, sub-surface images of a specimen.

Patient Identifier: Information about a patient that discloses or can help disclose the identity of the patient; also known as individually identifiable information including demographic data, which relates to:

- the individual's past, present or future physical or mental health or condition,
- the provision of health care to the individual, or
- the past, present, or future payment for the provision of health care to the individual,

and that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual. Individually identifiable health information includes many common identifiers (e.g., name, address, birth date, Social Security Number).

Protected Health Information (PHI): Under the U.S. law, PHI is any information about health status, provision of health care, or payment for health care that is created or collected by a Covered Entity (or a Business Associate of a Covered Entity) and can be linked to a specific individual.

Review Tools: Tools on the Claire OCT System that facilitate the Review of each Case by the user. For example- Scroll, Pan, Zoom and Image annotation tools such as Measure and Comment.

Scan Area: The area of the specimen, which is selected by the user for imaging, as displayed in the Live Specimen View.

Scan Density: Scan density is related to the spacing between consecutive B-scans in a WF-OCT volume. A high scan density corresponds to a smaller distance between B-scans. Therefore, high density scans provide more information about the tissue (i.e. more WF-OCT Images make up the WF-OCT Volume), however high-density scans take a longer time to acquire. Conversely, low scan density means there is a larger distance between B-scans, and therefore less information is gathered, resulting in a shorter scan time.

Scan Time: The estimated time required to acquire the WF-OCT Volume for the selected Scan Area at the selected Scan Density.

Single-Use: A single-use device, or device component, is intended for use on one patient during a single procedure. It is not intended to be reprocessed (cleaned, disinfected/sterilized) and used on another patient.

Software User Interface (Software UI): The Claire OCT System login and workflow screens.

Spatial Indicator: A line on WF-OCT Images that coarsely indicates the spatial relationship between the different OCT Image views.

Spatial Locator: A line on the Specimen Photograph that corresponds coarsely to the position of the WF-OCT Image visible on the screen.

Specimen Photograph: An image of the specimen surface that is in contact with the Imaging Window.

Specimen Tray Dock: The portion of the Claire OCT System device into which the Specimen Tray is secured prior to specimen imaging.

Wide-Field OCT (WF-OCT) Image: An image composed of combined OCT Images displayed side-by-side to provide a wider field of view.

WF-OCT B-scan Image: A 2-dimensional, cross-sectional OCT image into the depth of the specimen.

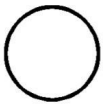
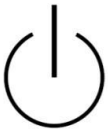
WF-OCT Enface Image: A 2-dimensional, transverse OCT image of the specimen.

WF-OCT Volume: A collection of adjacent WF-OCT Images which create a 3-dimensional volumetric image.

Definition of Symbols and Safety Notices

The following symbols are used in this manual or on the Claire OCT System device labelling:

Symbol	Meaning
 WARNING	A warning symbol is used to identify conditions or actions for which a specific hazard is known to exist. These conditions or actions may cause **SEVERE** personal injury or substantial property or device damage if the instructions are not followed.
	Warning: Hand crushing hazard
 CAUTION	A caution symbol is used to identify conditions or actions for which a potential hazard may exist. These conditions or actions may cause **MINOR** personal injury or property damage if the instructions are not followed.
	Do not remove display when mount is not at highest position
	Do not touch
	Do not re-use
	Consult user manual

Symbol	Meaning
	Refer to instruction manual
	Note icon. Notes highlight considerations and/or unusual points. An information note is not intended as an instruction.
	Display may only be removed when mount is at highest position
	Power on
	Power off
	Stand-by
	Protective earth (ground)
	Serial number
	Model/catalog number

Symbol	Meaning
	Lot or batch number
	Weight of labeled item
	Manufacturer
	Manufacturing date
	Federal law restricts this device to sale by or on the order of a physician.
	Equipment generates a laser beam
	RF Transmitting Device
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation

Symbol	Meaning
	Protect device from moisture
	Device is fragile and should be handled with care
	This way up
	For indoor use only
	Fuse rating (in example shown, 2x=2 units, T=Time Delay, 10A breaking current, L=low breaking capacity or glass fuse, 250V voltage rating)

Summary of Warnings and Precautions

This manual summarizes the basic steps for the safe operation of the device. Please review this manual thoroughly before using the device. The user is advised to follow all product safety guidelines as instructed in this manual.

WARNING: It is unsafe to operate the device before reading this entire manual.

WARNING: System is for use with Perimeter's single-use Specimen Immobilizer only. Specimen Immobilizers are single use only. Do not re-use or attempt to sterilize the Specimen Immobilizer.

WARNING: This Equipment is intended for use by healthcare professionals only.

WARNING: This Equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the Equipment or shielding the location.

WARNING: This device should not be used adjacent to or stacked with other equipment. If the device must be operated adjacent to or stacked with other equipment, the device should be observed to verify normal operation in that configuration.

WARNING: This device contains no user-serviceable parts. Do not disassemble, modify, or attempt to repair the device. User injury and equipment damage may result.


WARNING

WARNING: No modification of this equipment is allowed.


WARNING

WARNING: Do not place specimen directly on the Imaging Gate. Placing the specimen directly on the Imaging Gate could lead to the specimen becoming trapped within the device, personal injury, or damage to the device. Placing the specimen directly on the Imaging Gate could require immediate assistance from Perimeter's Service and Maintenance Team.


WARNING

WARNING: The moving monitor arm introduces potential hand-crushing hazards. Keep hands clear of pinch-points at all times.


WARNING

WARNING: The Claire OCT System is not a sterile device. The Claire OCT System should be positioned outside the immediate patient environment, no closer than 1.5 meters (4.9 feet) from the patient table. Take necessary precautions per the facility's infection prevention and control polices if the Claire OCT System will be used in a sterile area.


WARNING

WARNING: To avoid risk of shock, the Claire OCT System must only be connected to a supply main (power outlet) with protective earth (ground).


CAUTION

CAUTION: Only a dedicated USB drive should be used when exporting data from the Claire OCT System. The use of a compromised USB drive may affect the security of the device. It is highly recommended to monitor and control use of USB drives with the Claire OCT System and ensure that USB drives are safe to use prior to using it with the Claire OCT System.


CAUTION

CAUTION: Planned Operating System, Software and Firmware updates shall be communicated by Perimeter to the Department Manager. Updates not authorized by Perimeter, should not be installed on the Claire OCT System as these may affect performance and may compromise or corrupt data acquired by the device.


CAUTION

CAUTION: If a data security breach or a malware attack is suspected, please contact the Perimeter Service.


CAUTION

CAUTION: Contact Perimeter immediately to report an incident and/or injury to a specimen or operator that occurred as a result of the Claire OCT System operation.

CAUTION: If an incident occurs as a result of the Claire OCT System operation, do not operate the equipment until a Perimeter authorized investigation has been conducted.

CAUTION: Contact Perimeter immediately to report an incident or event in which a security alert was received during device use.

CAUTION: Do not attempt to use the device until a Perimeter-authorized investigation of the related log files has been conducted and the device has been cleared for use

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CAUTION

CAUTION: It is highly recommended for the Claire OCT to be installed in a secure location for both use and storage.

CAUTION: The Claire OCT System shall be installed only by Perimeter-authorized personnel. Only qualified personnel, trained by Perimeter, shall perform troubleshooting and service procedures on the software and internal device components

CAUTION: It is recommended for users to select strong passwords for the Claire OCT System and to keep passwords confidential.

CAUTION: Unrelated software applications cannot be installed or used on the Claire OCT System as this may affect performance and may compromise or corrupt data acquired by the device

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CAUTION

CAUTION: Only personnel trained by Perimeter shall be authorized to have administrator access. Each clinical user will be provided login credentials and will be trained on how to delete data on the Claire OCT System.

CAUTION: Do not move the Claire OCT System while imaging.

CAUTION: Do NOT move or bump the system during initialization

CAUTION: The Claire OCT System is intended for indoor use only.


CAUTION

CAUTION: Handle the Specimen Immobilizer carefully. The Imaging window of the Specimen Tray is made of glass.

CAUTION: Do not power down or unplug the Claire OCT System unless the system is completely powered off.

CAUTION: Select a vacuum level that is appropriate for the specimen being imaged.


CAUTION

CAUTION: The Claire OCT System's ImgAssist feature is intended to be used concurrently with physician interpretation of the images. Use of ImgAssist alone without review of the OCT images may result in false negative or false positive clinical decisions. ImgAssist detections should always be confirmed by the user by review of the corresponding morphological features in the OCT image, in accordance with their OCT modality training and expertise.


CAUTION

CAUTION: ImgAssist identifies regions suspicious for breast cancer and highlights these, when they are observed across multiple B-scans. In low density scans, tissue microstructures indicative of breast cancer may not be visible across multiple consecutive B-scans and may therefore not be identified by ImgAssist. Thus, low density scans are not ideal for optimal ImgAssist output.


CAUTION

CAUTION: Low vacuum levels can lead to poor surface contact between the specimen and the Imaging Window. This may negatively impact the ImgAssist output.


CAUTION

CAUTION: The Claire OCT System was not studied for diagnostic performance to include breast density stratified analysis.

Indications for Use

The Claire OCT System is an adjunctive three-dimensional imaging tool which provides volumetric cross-sectional, real-time depth visualization, coupled with an artificial intelligence computer-aided detection algorithm which identifies and marks focal areas suspicious for breast cancer and is used concurrently with physician interpretation of the images. Claire is intended for use in conjunction with other standard methods for evaluation of the margins of excised lumpectomy tissue during surgical procedures in patients with a biopsy-confirmed diagnosis of breast cancer.

Limitations of Use

The device is not intended for use in individuals who:

- Are under the age of 18
- Are male
- Have metastatic cancer (Stage IV)
- Have lobular carcinoma as their primary diagnosis
- Have had previous ipsilateral breast surgery for benign or malignant disease within 2 years (including implants and breast augmentation)
- Have multi-centric disease (histologically diagnosed cancer in 2 different quadrants of the breast), unless resected in a single specimen
- Have bilateral disease (diagnosed cancer in both breasts)
- Are currently lactating
- Are currently pregnant

The device is not intended for concurrent use in surgeries with cryo-assisted localization

Use clinical expertise and judgement for device use with specimen margins that have been destroyed, damaged, or are otherwise not intact prior to imaging.

The Claire OCT System device offers an additional source of information to the user by providing rapid, automated visualization of near surface microstructure. This information is an adjunct to visual observation of the surface of an excised tissue sample and other intraoperative margin assessment techniques.

Contraindications

The Claire OCT System should not be used to replace standard tissue histopathology assessment. The Claire OCT System should not be used for diagnosis.

Federal law restricts this device to sale by or on the order of a physician.

Device Classification and Compliance

This device is intended to meet the following requirements:

- IEC 60601-1:2005, IEC 60601-1L2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 Medical Electrical Equipment – Part 1 – General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014+A1:2020 Medical Electrical Equipment Part 1-2: General Requirements for the Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- IEC 60825-1:2014, Safety of Laser Products – Part 1: Equipment Classification and Requirements
- AAMI ANSI IEC 62304:2006/A1:2016 Medical Device Software – Software Life Cycle Management
- AAMI ANSI ISO 15223-1:2021 Medical Devices – Symbols to be used with Medical Devices Labels, Labeling and Information to be Supplied – Part 1: General Requirements
- AAMI ANSI ISO 10993-1:2018 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
- IEC 62366-1 (Edition 1.0 2015-02) Medical Devices - Part 1: Application of Usability Engineering to Medical Devices.
- AAMI TIR57: 2016- Principles for medical device security—Risk management

Table 1: Device classification

Classification	Description
Class I Equipment	Per IEC 60601-1. Protectively earthed electrical equipment.
Class III Medical Device	Per FDA risk classification framework
Class B Device - Software	Per IEC 62304
Class 1 Laser Equipment 	Super Luminescent Diode Nominal Center Wavelength: 1325 nm Nominal Power Output: <20 mW  Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 56, dated February 21, 2023.
Water Ingress	The device is designed for an IPX0 rating per IEC 60601-1.
General cleaning	Surfaces of the device enclosure can be disinfected by using Dimethyl (ethyl) Benzyl Ammonium Chloride (quaternary ammonium) cleaners and/or wipes. See **Cleaning and Disinfection** for more information.
Continuous operation	This unit is suitable to run continuously.
Degree of protection against electric shock	Class I, connect to earthed supply circuitry only.
Applied Part	NO applied part.

Device Specifications

Table 2: Device Specifications	
Device Performance	
Maximum Specimen Diameter	3.9 in (10 cm)
Maximum Scan Acquisition Diameter	3.4 in (8.7 cm)
Scan Depth	>= 2.2 mm, up to 7 mm (in air)
Tissue Type	Excised tissue
Device Warm-up Time	< 2 minutes
Typical Scan Time	1 minute*
Operating Environmental Requirements	
Room Temperature	59°F to 78°F (+15°C to +26°C)
Humidity	20-60% humidity non-condensing
Atmospheric Pressure	10.15 psi to 15.37 psi (700hPa to 1060hPa)
Effect of shock and vibration	Possible damage to sensitive internal optical components
Effect of ultra-violet radiation	None. For indoor use only
Physical Specifications	
Device Footprint (whole system)	25.6 in x 29.1 in (65 cm x 74 cm)
Device weight	275 lb (125 kg)
Noise Emission	65 dB(a)
Electrical Specifications (Isolation Transformer)	
Input Voltage	115 VAC / 230 VAC
Frequency	50 Hz – 60 Hz
Current (Rated / Actual)	4 A / 2 A
Power Rating	1000 VA
Electrical Specifications (OCT Engine)	
Input Voltage	120 VAC / 230 VAC
Frequency	50 Hz – 60 Hz
Maximum Power Consumption	150 W
Other Specifications	
OCT center wavelength (nominal)	1325 nm
Estimated product life (if serviced and maintained by Perimeter)	7 years
Maximum vacuum pressure	Approx. 13 inHg (330 mmHg)

Table 2: Device Specifications	
* Typical scan time is based on one-sided scanning of an average scan area (4 cm x 4 cm).	
OCT Imaging Specifications	
Axial resolution	Less than or equal to 15 µm in tissue (21 µm in air)
Vertical (axial) image scale	Vertical image scale will be displayed for an index of refraction (n) which mimics human tissue (n=1.4)
Lateral resolution	Less than or equal to 50 µm
Storage Environmental Requirements	
Room Temperature	14°F to 140°F (-10°C to +60°C)
Humidity	10-90% humidity non-condensing
Atmospheric Pressure	7.25 psi to 15.37 psi (500hPa to 1060hPa)
Transportation Environmental Requirements	
Room Temperature	14°F to 140°F (-10°C to +60°C)
Humidity	10-90% humidity non-condensing
Atmospheric Pressure	7.25 psi to 15.37 psi (500hPa to 1060hPa)

WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply with protective earth.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

CAUTION: The Claire OCT System is intended for indoor use only.

Remarks for Electromagnetic Emissions and Immunity

This device was tested for a standard hospital environment as indicated in the device specification section above. The device user should ensure that it is used in such an environment.

Table 3: Electromagnetic emissions

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration- Electromagnetic emissions</th></tr>
<tr><td colspan="3">The Claire OCT System device is intended for use in the electromagnetic environment specified below. The customer or the Claire OCT System user should ensure that it is used in such an environment.

All necessary instructions for maintaining safe and effective use of the device during its expected service life are included in this user manual.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment- guidance</th></tr>
<tr><td>Radiofrequency (RF) emissions
CISPR 11</td><td>Group 1</td><td>The Claire OCT 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The Claire OCT System device is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:

 
WARNING

This Equipment is intended for use by healthcare professionals only. This Equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the Equipment or shielding the location.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Table 4: Electromagnetic immunity			
Guidance and manufacturer's declaration- Electromagnetic emissions			
The Claire OCT System device is intended for use in the electromagnetic environment specified below. The customer or the user of the Claire OCT System device should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**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 covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV line to line & ± 0.5 kV, ± 1 kV, ± 2 kV line to ground	± 0.5 kV, ± 1 kV line to line & ± 0.5 kV, ± 1 kV, ± 2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T (100% dip in U_T) for 5 sec	0% U_T (100% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T (100% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Claire OCT System device requires continued operation during power mains interruptions, it is recommended that the Claire OCT System device be powered from an uninterruptible power supply or a battery.

Table 4: Electromagnetic immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Guidance**
Power frequency magnetic field (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM bands inside 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz RF communication equipment inside 80 MHz to 6 GHz	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM bands inside 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz RF communication equipment inside 80 MHz to 6 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Claire OCT System device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $\boldsymbol{d} = \mathbf{1}.\mathbf{2}\sqrt{\boldsymbol{P}}$ $\boldsymbol{d} = \mathbf{1}.\mathbf{2}\sqrt{\boldsymbol{P}}$ 80 MHz to 800 MHz $\boldsymbol{d} = \mathbf{2}.\mathbf{3}\sqrt{\boldsymbol{P}}$ 800 MHz to 2.7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b] Interference may occur in the vicinity of known RF transmitting devices and System marked with the following symbol: 
NOTE 1: U_T is the a.c. mains voltage prior to application of the test level.			
NOTE 2: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Table 4: Electromagnetic immunity
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Claire OCT System device is used exceeds the applicable RF compliance level above, the Claire OCT System device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Claire OCT System device. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 5: Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications system and the ME Equipment.

The Claire OCT System device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Claire OCT System device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications system (transmitters) and the Claire OCT System device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

NOTE 1: For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Reporting of Incidents

Contact Perimeter immediately to report an incident and/or injury to a specimen or operator that occurred as a result of the Claire OCT System operation.

If an incident occurs as a result of the Claire OCT System operation, do not operate the equipment until a Perimeter authorized investigation has been conducted.

Contact Perimeter immediately to report an incident or event in which a security alert was received during device use.

Contacting Perimeter

Use the following information to contact Perimeter to report an incident or for technical support:

Calling from the U.S.A (including Technical Support): +1-888-988-7465
Calling from Canada: 1-888-988-7465
Calling from outside U.S.A/Canada: +1-214-845-5154

Email: support@perimetermed.com

Troubleshooting, applications support, and service support hours are 9AM – 5PM Eastern Standard Time (EST).

Correspondence can be sent to:

Perimeter Support
555 Richmond St W, Suite 511
Toronto, Ontario M5V 3B1
Canada

Chapter 1: Introduction

Principles of OCT Imaging

Optical Coherence Tomography (OCT) is a non-invasive method of evaluating tissue that provides imaging of internal structures using light, in much the same way that sound is used to produce an image with ultrasound. OCT is a non-destructive imaging technique utilizing non-ionizing optical illumination, which maintains the integrity of the surgical specimen for later pathological assessment. The device speed and near-cellular resolution capabilities are amenable to visually evaluating the entire surface of a surgical specimen.

About the Claire OCT System and WF-OCT

The Claire OCT System is an AI-enabled imaging tool for use on excised biological tissue. It is based on Optical Coherence Tomography (OCT) coupled with photographic surface images, with image review manipulation software. OCT uses light to produce high-resolution, sub-surface images of excised tissue specimens which a clinician user can review in real-time.

The specimen is positioned against the flat, OCT-transparent Imaging Window of the Specimen Tray. This facilitates scanning and collection of an in-focus array of Wide-Field OCT (WF-OCT) images that are viewed together to create volumes of WF-OCT images for the user to review. The features in a WF-OCT image are created by changes in the optical properties (namely scattering, absorption, and index of refraction) of the specimen.

Each Claire OCT System case contains two dimensional, cross-sectional WF-OCT B-scan images, two dimensional, transverse WF-OCT Enface images and photographic surface images of a specimen. This Case data enables a trained user to correlate microstructure features seen in the Claire OCT System WF-OCT images to a location on the tissue specimen. The Claire OCT System includes image review manipulation software for manually interacting with the WF-OCT images and annotating Regions of Interest (ROI) (focal areas) suspicious for breast cancer.

The Claire OCT System offers an additional source of information to the user by providing rapid, automated visualization of sub-surface tissue microstructure. This information is supplemental to standard of care techniques such as visual observation and palpation of the surface of an excised tissue specimen.

Principles of Artificial Intelligence

The Claire OCT System's ImgAssist feature includes an artificial intelligence based deep learning algorithm. The algorithm is based on a multi-layered convolutional neural network (CNN) and it performs binary classification of regions of interest suspicious for breast cancer in a WF-OCT B-scan acquired on the Claire OCT System, into a "suspicious" and "non-suspicious" class. Perimeter has trained, validated, and tested the model using WF-OCT B-scans of excised human female breast tissue acquired on Perimeter's OCT devices and optimized the device's sensitivity and specificity to identify regions suspicious for breast cancer. The user can turn the ImgAssist display ON/ON (Show Less)/OFF at their discretion. ImgAssist highlights regions suspicious for breast cancer, thereby drawing the clinician's

attention for further review.

The Claire system is designed as a human-AI team, where the AI acts as a high-sensitivity screening tool and the surgeon provides clinical judgment and specificity. The system is not designed for the AI to make a final diagnostic decision, but rather to serve as an efficiency and screening tool to guide the surgeon's attention during a time-sensitive procedure.

- The AI's Role (High Sensitivity): The standalone AI algorithm is evaluated at the patch level. A single tissue margin is composed of thousands of these small image patches. The AI is intentionally calibrated for high sensitivity to reduce false negatives. Its purpose is to flag every potential area of concern across the entire margin, even if this means flagging benign but ambiguous features (higher false positives).
- The Surgeon's Role (High Specificity): The surgeon acts as the "specificity engine." Their role is to review the AI-flagged regions and apply their clinical expertise, anatomical knowledge, and a holistic view of the entire margin to determine if further action (excision) is needed. They synthesize information from the AI with their intraoperative assessment and other critical patient information in their decision making.

Predetermined Change Control Plan (PCCP)

The Claire OCT device incorporates machine learning (ML) to assist in the identification of suspicious regions of interest. The device was approved with a PCCP, which allows specific, bounded modifications to the artificial intelligence/machine learning (AI/ML) functions. The PCCP ensures that all modifications are predetermined and confined within authorized parameters to maintain a consistent standard of safety and effectiveness. Users should thus be aware of the following:

- Perimeter may issue periodic software updates pursuant to this authorized plan. These updates may modify the device’s performance, inputs, or use.
- Modifications will be accompanied by version identification and, as appropriate, updated labeling to account for any changes to performance results and instructions for use.
- Users are informed of these modifications through advisory notices, and may also include updates to labeling and user training.


CAUTION

CAUTION: The Claire OCT System’s ImgAssist feature is intended to be used concurrently with physician interpretation of the images. Use of ImgAssist alone without review of the OCT images may result in false negative or false positive clinical decisions. ImgAssist detections should always be confirmed by the user by review of the corresponding morphological features in the OCT image, in accordance with their OCT modality training and expertise.

Device Overview

Claire OCT System Basic Features

- Scanning on the Claire OCT System is non-invasive and non-destructive to the specimen.
- WF-OCT images on the Claire OCT System allows visualization of structures up to 50 µm resolution.
- The Claire OCT System supports specimens with a footprint of up to 10 cm (3.9 in) in diameter.
- Maximum Scan Acquisition Diameter is 8.7 cm (3.4 in)
- The Claire OCT System's user interface provides a live specimen photograph to visualize the area of WF-OCT image acquisition.
- The Claire OCT System facilitates scanning of all sides of the specimen, in any position.
- The Claire OCT System allows for review, annotation, and manipulation of WF-OCT images for the purpose of aiding in the detection of regions of interest suspicious for breast cancer.

Primary Hardware Components

The Claire OCT System consists of the primary hardware components shown in Table 6 below.

Table 6: Claire OCT System's Primary Hardware Components

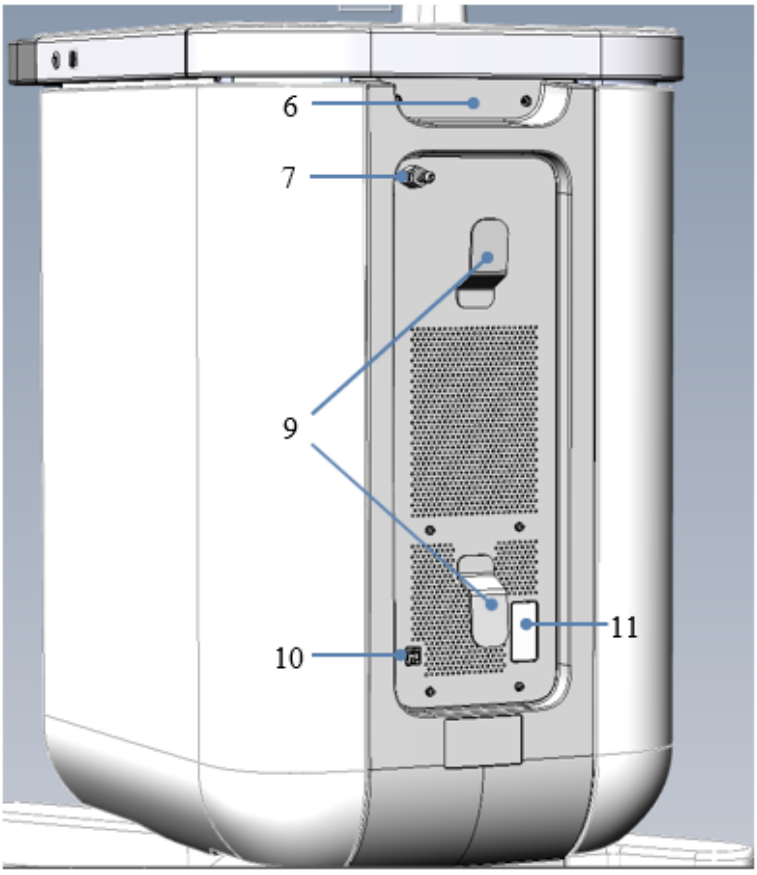
Claire OCT System front and back views:

1. Touchscreen Monitor
2. Articulating monitor arm
3. ON/OFF button
4. Portable media port (USB)
5. Specimen Tray manifold
6. Rear handle
7. Vacuum port
8. Front handle
9. Power cable storage hooks
10. Ethernet port
11. Power port and power switch
12. Foot brake
13. Device power cable, 8 ft length

Table 6: Claire OCT System's Primary Hardware Components

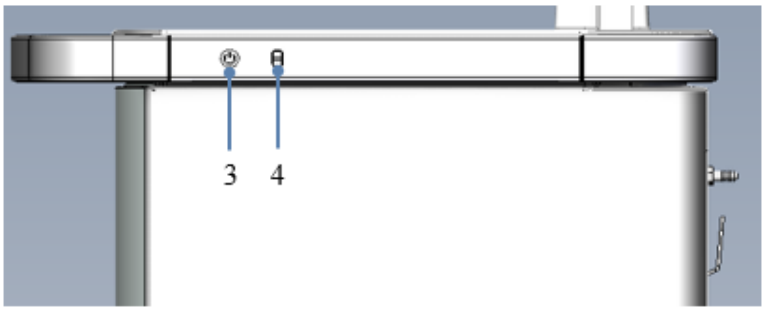
Claire OCT System back view:

6. Rear handle
7. Vacuum port
9. Power cable storage hooks
10. Ethernet port
11. Power port and power switch



Claire OCT System side view:

3. ON/OFF button
4. Portable media port (USB)



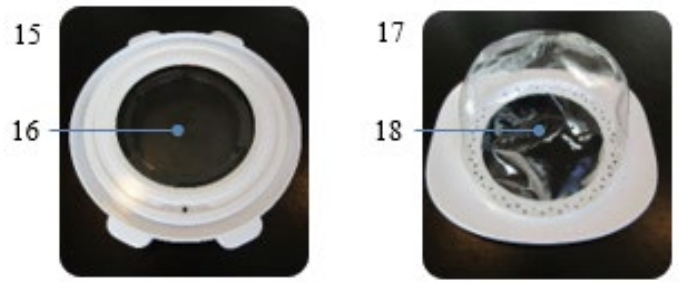
Claire OCT System top view:

5. Specimen Tray Manifold
14. Imaging Gate

Table 6: Claire OCT System's Primary Hardware Components

Single-use Specimen Immobilizer

15. Specimen Tray
16. Imaging Window
17. Specimen Lid
18. Transparent bag



Claire OCT System Touchscreen Monitor

The Claire OCT System includes a touchscreen monitor for displaying and reviewing data. See Chapter 2: Claire OCT System Software User Interface for more information on using the touchscreen monitor.

Single-Use Specimen Immobilizer

The Claire OCT System is intended to be used solely with Perimeter-supplied Specimen Immobilizers. These Specimen Immobilizers, when used correctly, help to ensure proper positioning of the specimen for scanning. Each Specimen Immobilizer consists of a clean, packaged set of single-use accessories, including:

- 1x Specimen Tray: a single-use component which contains one Imaging Window (see Figure 1). The specimen is placed on the Imaging Window for scanning.

Figure 1: Specimen Tray of Specimen Immobilizer

CAUTION

CAUTION: Handle the Specimen Tray carefully. The Imaging Window of the Specimen Tray is made of glass.

The Imaging Window in the Specimen Tray should be kept clean for imaging. For optimal imaging, always keep fingers off the glass.

- 1x Specimen Lid: a single-use component which is placed over the specimen during imaging (see Figure 2).

Figure 2: Specimen Lid of Specimen Immobilizer

CAUTION

CAUTION: The Claire OCT System is for use with accessories contained in the Single-Use Specimen Immobilizer only.

CAUTION

CAUTION: Specimen Immobilizers are for single-use only. Do not re-use or attempt to sterilize the Specimen Immobilizer.

Image quality may degrade if specimen residue dries on the glass Imaging Window between scans, or if the user attempts to clean the Imaging Window.

Specimen Tray Manifold

The Specimen Tray Manifold is located on the top surface of the device enclosure, as shown in Table 6. An Imaging Gate is located in the center of the Specimen Tray Manifold and has a warning symbol on the label (see Figure 3 below).

Figure 3: Specimen Tray Dock and Imaging Gate

The Specimen Immobilizer is installed into the Claire OCT System by rotating the Specimen Tray onto the Specimen Tray Manifold until locked. Ensure that the manifold is clear of any debris prior to seating a Specimen Tray.

Device set up

WARNING

WARNING: The Claire OCT System is not a sterile device. The Claire OCT System should be positioned outside the immediate patient environment, no closer than 1.5 meters (4.9 feet) from the patient table.

WARNING: To avoid risk of shock, the Claire OCT System must only be connected to a supply main (power outlet) with protective earth (ground).

WARNING: The moving monitor arm introduces potential hand-crushing hazards. Keep hands clear of pinch-points at all times.

The Claire OCT System has been set up by a Perimeter Technician. The device should not require any additional setup steps prior to use.

See Chapter 3: Operator Workflow for more information about device set up.

Chapter 2: Claire OCT System Software User Interface

Basic Functionality

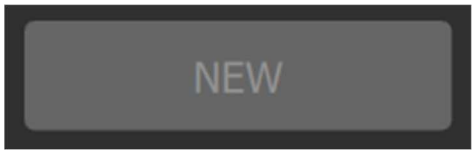
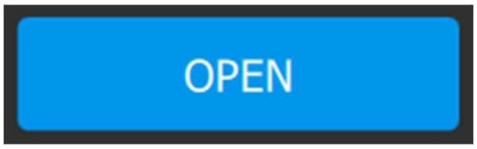
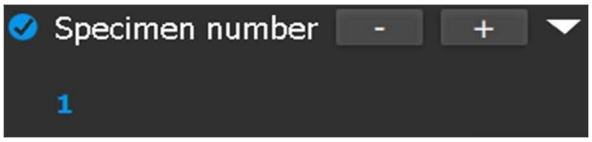
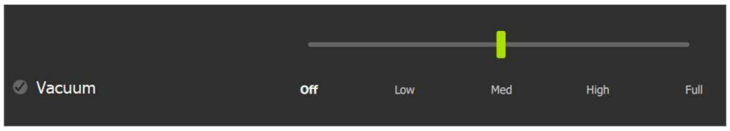
Table 7: Common Functions		
Feature	**Feature Picture**	**Action**
New		Start the scan acquisition workflow for a new case.
Open		Access the Case List Screen to see a list of previously acquired cases.
Select Body Side		Select Right, Left or Other
Select Specimen Number		Press the "-" or "+" buttons to change the number of the specimen
Vacuum Control Select the desired vacuum level to secure the specimen for scanning.		Position the specimen on the Specimen Tray with the scan side down on the Imaging Window. Hold the specimen in the desired orientation through the transparent bag of the Specimen Lid. Select the vacuum level to apply for securing the specimen.

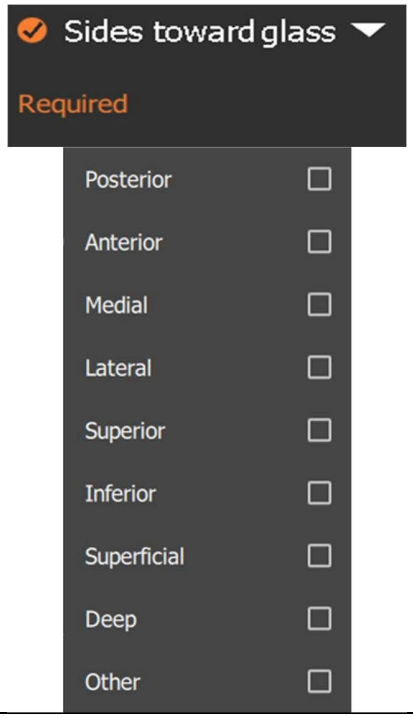
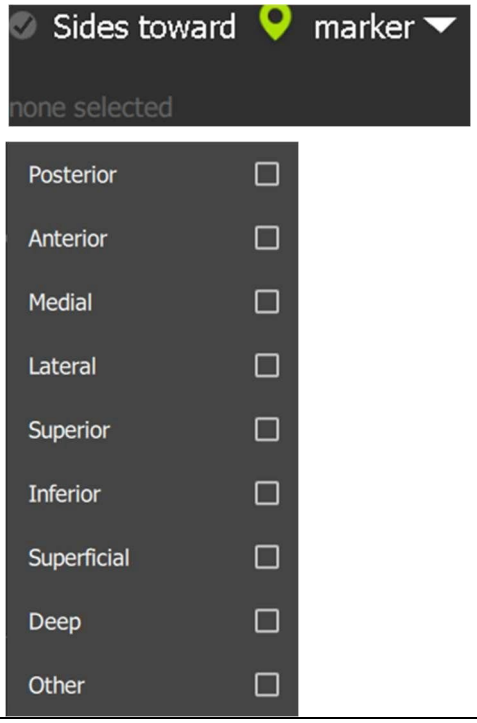
Table 7: Common Functions		
Feature	**Feature Picture**	**Action**
Select Orientation - Sides Toward Glass		Select the surface of the specimen to scan
Select Sides Toward Marker (optional)		Select the side of the specimen that is pointing to the marker found in the scanning window

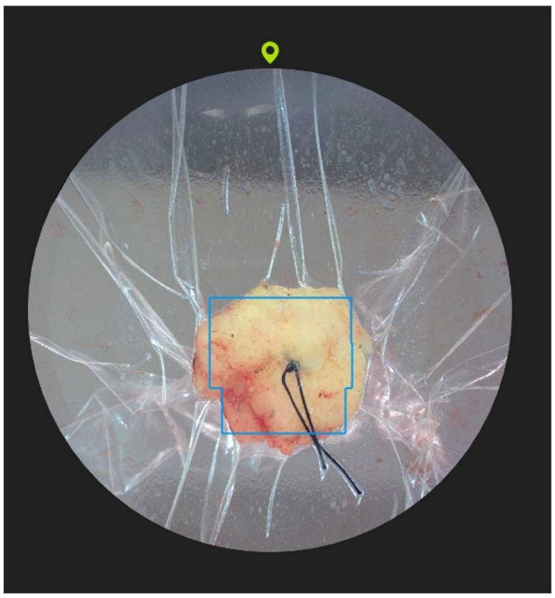
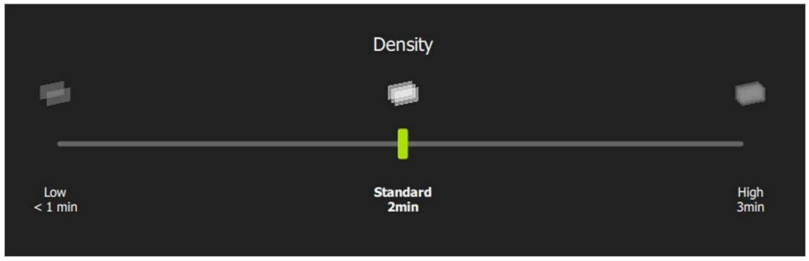
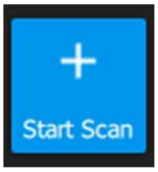
Table 7: Common Functions		
Feature	**Feature Picture**	**Action**
Select Scan Area Select the area of the Specimen to scan.		Drag a finger around the area of the specimen to image in the live view image to select the scan area.
Select Scan Density Select the scan density (i.e. how many WF-OCT Images will make up the WF-OCT Volume for the selected Scan Area).		Move the slider to the desired scan density. High density scans will take longer to complete than standard density scans.
Start Scan Select **Start Scan** to initiate scanning.		Do not move the Claire OCT System until scan is fully acquired.

Table 7: Common Functions		
Feature	**Feature Picture**	**Action**
During Scan		
Cancel Scan Select Cancel Scan to cancel a Scan before it is fully acquired.		Use this function if a specimen must be retrieved or repositioned before the scan is complete. A prompt will be displayed to confirm that the scan should be stopped. Any partially collected data will be saved and displayed after the scan is stopped.
Review Scan		
Fine Scroll Tap the up & down arrows to scroll through individual WF-OCT Images belonging to the same Volume.		Scroll through the WF-OCT Volume, slice by slice.
Play WF-OCT Volume Select the play symbol to watch the WF-OCT image volume in a loop. Select the pause symbol to stop at a region of interest.	 	This plays the WF-OCT volume in a loop until paused.

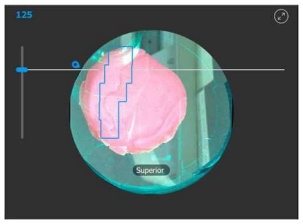
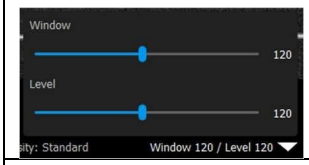
Table 8: Image Review Tools		
Tool	**Description**	**How to Apply Tool(s)**
Scroll through WF-OCT Volume  C. Slider Bar to scroll through the image.	Scroll through the volume of WF-OCT Images.	A. Place a finger anywhere on the WF-OCT Image and drag it on the screen to scroll through the WF-OCT Volume. B. Tap the Specimen Photograph within the demarcated scan area (i.e., the blue box) to jump to the WF-OCT Image from the approximate corresponding location. Tap above the demarcated scan area to jump to the first WF-OCT Image in the Volume. Tap below the demarcated scan area to jump to the last WF-OCT Image in the Volume. C. Click and drag the slider bar to the left of the Specimen Photograph to scroll through the WF-OCT Volume. D. Use Fine Scroll as defined in Table 7. E. Play through the WF-OCT Volume as described in Table 7.
Zoom WF-OCT Image 	Zoom in/out of the WF-OCT Image.	Place two fingers anywhere on the WF-OCT Image. Use a pinching motion to zoom out of the WF-OCT Image. Use a stretching motion to zoom into the WF-OCT Image. The zoom percentage will be shown at the base of the image.
Expand image 	Enlarge the Specimen Photograph & Enface Image	Tap on the icon in the top right-hand corner of the specimen photo or enface view. This will open a pop-up window with an enlarged image for review. Press the "X" on the top right corner to close the expanded view.
Reset Image 	Reset Pan, Zoom, and Window/Level Settings	Activate the Reset function by tapping on the Reset icon on the left side of the screen, in the WF-OCT Image.
Window Level (W/L) 	Change the Window Level of the WF-OCT Image.	Activate the Window Level function by tapping on the triangle next to the Window/Level display. Use the slider bars to adjust the image Window and Level
ImgAssist On/Off 	Allows the ImgAssist feature to be toggled on and off	Toggles the ImgAssist feature on or off based on user preference

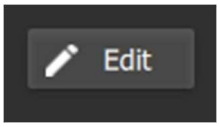
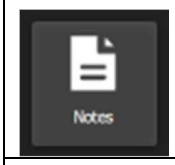
Table 8: Image Review Tools		
Tool	**Description**	**How to Apply Tool(s)**
Edit Scan Information 	Edit specimen information for the scan	Tap the Edit button to change previously entered specimen information for the scan currently being viewed.
Specimen Note 	Type notes related to the case in this text box.	From the Edit Scan Information screen, tap the Notes button. Enter information of interest and then save the note.
ImgAssist Thumbnail 	Access ImgAssist Thumbnail view	Tap to enter the ImgAssist thumbnail view to review ImgAssist detections

Table 9: Annotation Tools		
Tool	**Description**	**How to Apply Tool(s)**
Comment Tool 	Place an indicator with an associated comment on a WF-OCT Image.	Activate the Comment tool by tapping on the Comment icon. Place a finger on the region of the WF-OCT Image where the comment should be placed. Enter the desired text in the box that appears. The WF-OCT Image number of the comment and the text entered will appear on the reverse of the scan card in the Review Screen. Tap the entry in the scan card to go to the WF-OCT image with the comment. Tap the comment indicator on the WF-OCT image to edit the comment.
Measure Tool 	Measure a distance on a WF-OCT Image.	Activate the Measure tool by tapping on the Measure icon. Place a finger at the start of the feature to measure and drag it to the end of the feature. As the finger moves, a box at the top of the screen will display the measurement value. The measurement can be edited by tapping and dragging either end of the measurement. The WF-OCT Image number and measurement value (in mm) will appear on the reverse of the scan card. Tap the entry in the scan card to go to WF-OCT image of interest. The measurement annotation will also appear on the screen. Tap the measurement to add/edit a note for the measurement.
Region of Interest (ROI) Tool 	Outline an area of interest on a WF-OCT Image.	Activate the Region of Interest tool by tapping on the ROI icon. Place a finger near the area of interest, drag it diagonally across the area of interest and then release it. The area of interest will now be enclosed in a rectangle. The WF-OCT Image number of the ROI and any additional user entered comments will appear on the reverse of the scan card in the Review Screen. Tap the ROI on the WF-OCT Image to add/edit the comment associated with the annotation.

The axial measurement scale of the Claire OCT System assumes an index of refraction of n=1.4.

Claire OCT System Screen Overview

There are seven main Screens as part of the Claire OCT System Software User Interface:

1. Home Screen (see Figure 4)
2. Patient Information Screen (see Figure 5)
3. Scan Setup Screen (see Figure 6)
    a. Body Side Selection
    b. Tissue Type Selection
    c. Specimen Number (Optional)
    d. Vacuum Pressure Selection Step
    e. Specimen Orientation
    f. Scan Area Selection Step
    g. Scan Density Selection Step
4. Scan in Progress Screen (see Figure 7)
5. Review Screen (see Figure 8)
6. Case List Screen (see Figure 10)
7. Export Screen (see Figure 11)
    a. Export to USB
    b. Export Screenshot

Home Screen

The Home Screen will appear after logging in. From the Home Screen, start a **New** case, or **Open** a previously acquired case (Figure 4).

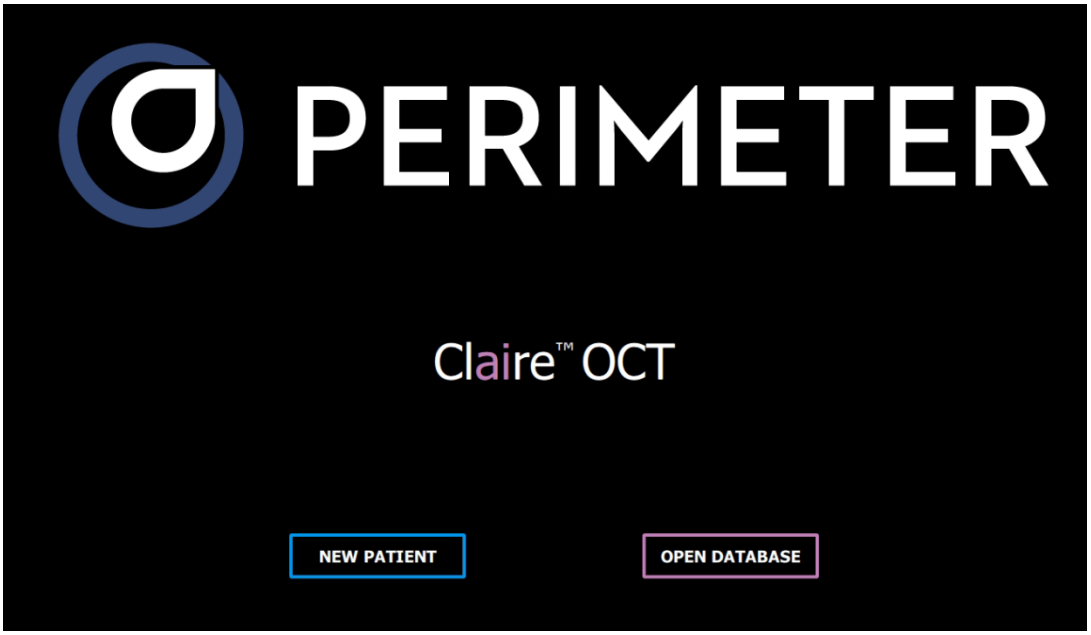


Figure 4: Home Screen

Patient Information Screen

Patient-specific information can be entered on the Patient Information Screen (see Figure 5). Completed patient information is displayed at the top of the screen throughout the scanning and review workflow. Patient information can be corrected after a case is completed. Any changes should only be made by authorized healthcare facility personnel.

It is only mandatory to input the fields marked **Mandatory** in the Patient Information Screen.

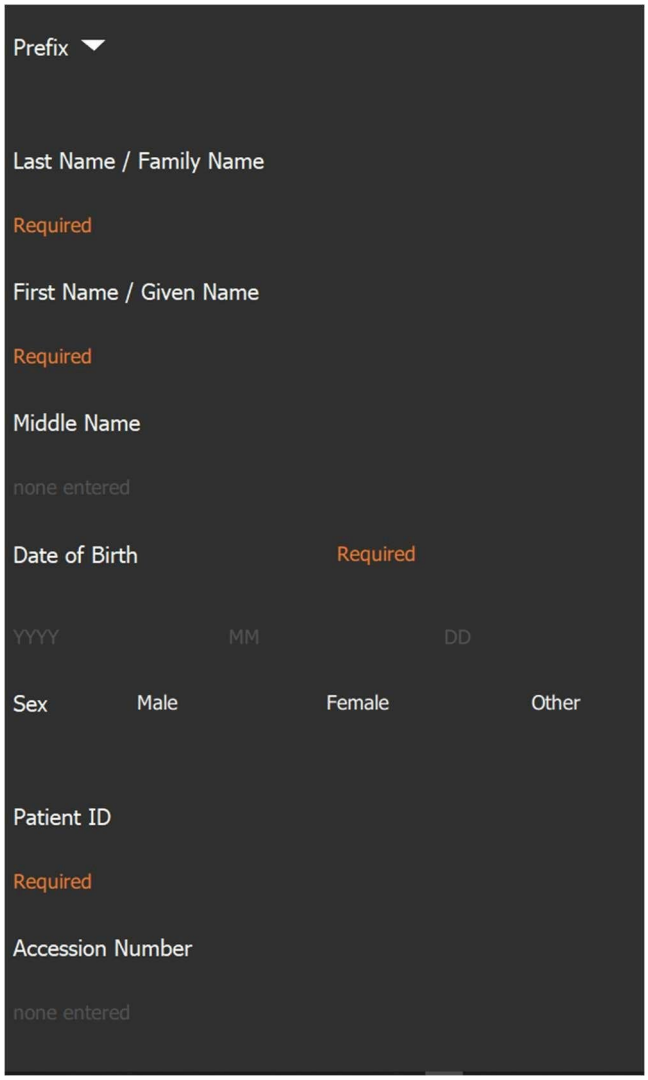


Figure 5: Patient Information Screen

Patient cases exported from the Claire OCT System are anonymized to safeguard Protected Health Information.

It is the responsibility of the user to ensure that data transferred off the Claire OCT System to a portable drive is done in compliance with applicable privacy and security regulations of the country where the Claire OCT System is used.

CAUTION

CAUTION: Only a dedicated USB drive should be used when exporting data from the Claire OCT System. The use of a compromised USB drive may affect the security of the device.

CAUTION

CAUTION: If a data security breach or a malware attack is suspected, please contact the Perimeter Service.

Scan Setup Screen

There are multiple parameters on the Scan Setup Screen, including: Body Side, Specimen Number, Orientation, Vacuum Level, Scan Area, and Scan Density (Figure 6).

All of the required fields must be completed before acquiring a scan.

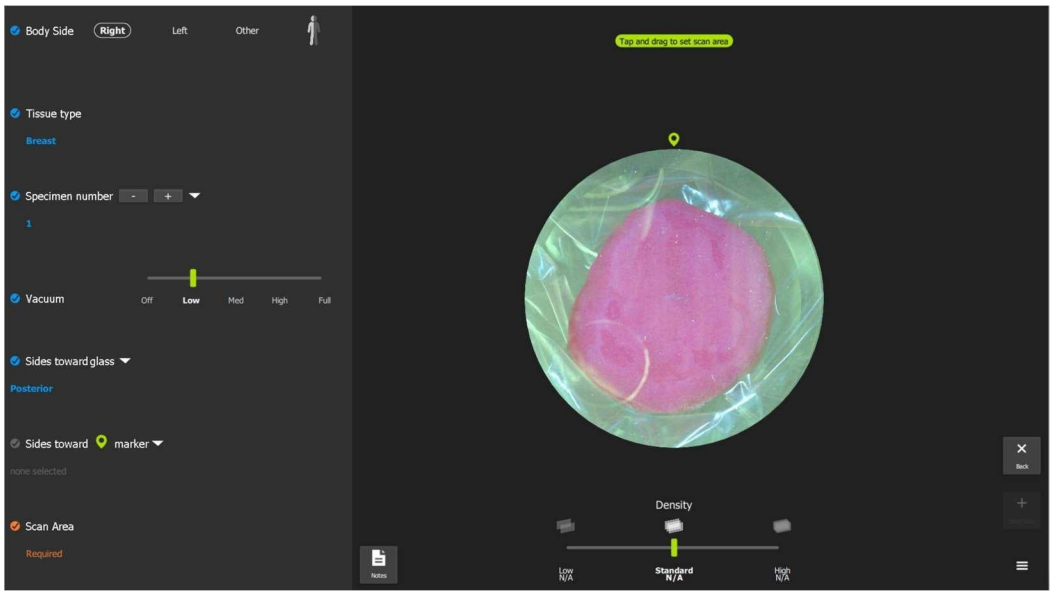


Figure 6: Scan Setup Screen

Use the Specimen Orientation Guide provided during training as an aid for Specimen Orientation.

During scanning, the Review Screen will display the words “Scan in Progress” and a progress indicator appears on the scan card (Figure 7). The progress indicator displays the estimated scan time and the elapsed time.

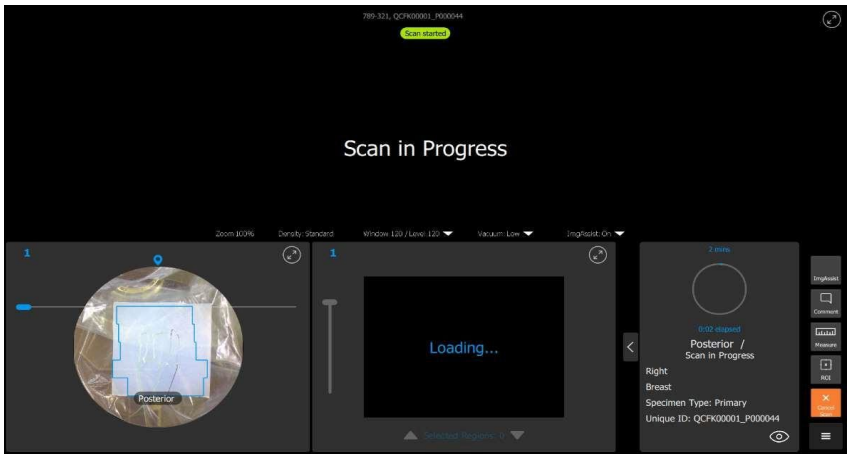


Figure 7: Scan in Progress and Progress Indicator

The Review Screen will begin to display WF-OCT Images as soon as they are acquired.

Review Screen

The Review Screen consists of a WF-OCT Image review window, a specimen image, an enface image, the scan card, and a tool bar. The menu button at the bottom right of the screen allows the user to start new scans, access the case list, export data, access the about screen, and log out of the system.

From the Review Screen, the user can scroll through WF-OCT Images. The user can select different scans from the same Case by tapping the arrow beside the scan card. The spatial locator (white lines) on the Specimen Photograph can be used to reference the approximate corresponding region of the WF-OCT Image on the specimen. Review Tools and Annotation Tools for adding comments, measuring distances, and placing regions of interest (ROI) are available on the Review Screen (Figure 8).

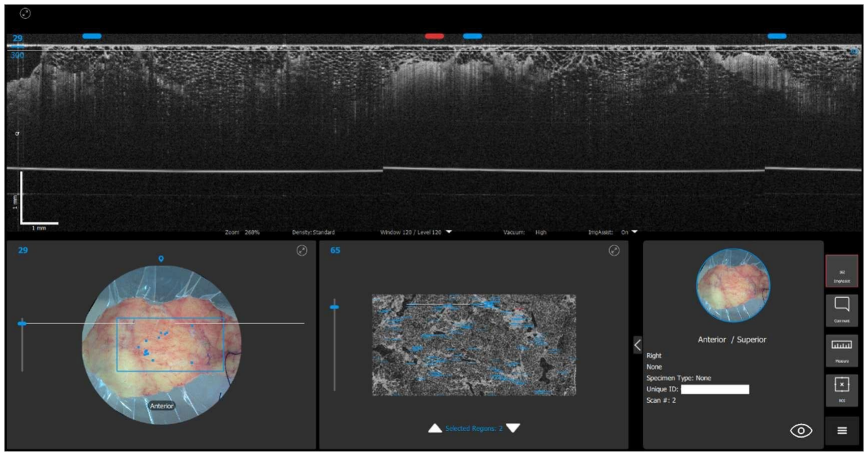


Figure 8: Review Screen

The Case List Screen

From the Review Screen, the user can tap the menu button in the bottom right corner of the screen and then tap on **Case List** (see Figure 9), to access the Case List Screen (see Figure 10). The user can also access the Case List Screen from the Home Screen (see Figure 4).

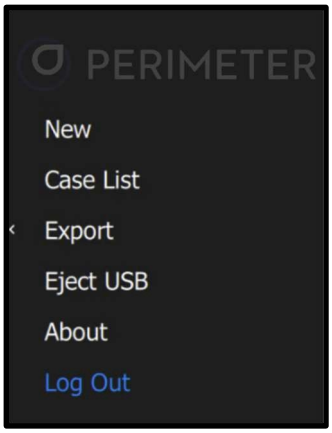


Figure 9: Menu

The user may search for a specific Case in the search bar at the top of the Case List Screen (Figure 10). Double tap a Case to open it in the Review Screen.

The Case List Screen cannot be accessed when the system is initializing, or if there are no previously acquired specimen data sets.

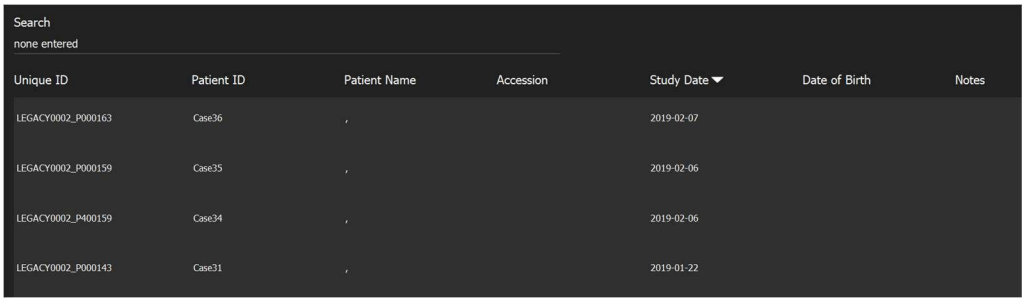


Figure 10: Case List Screen

Export Screens

Data can be exported from the Claire OCT System when the user is on the Review Screen or the Case List Screen.

The Claire OCT System has 4 export options as shown in Figure 11:

1. Export Case
2. Export Screenshot (Only available from the Review Screen)
3. Logs - Saves the event and technician logs
4. Progress Monitor - Displays the status of data transfers

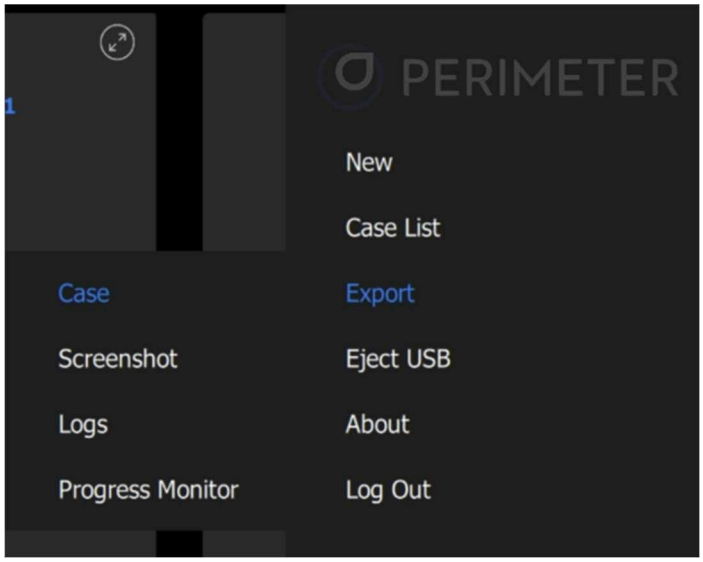


Figure 11: Export Screen

The Patient Identifier information bar at the top of the screen is not captured in a Screenshot.
If the user is unable to transfer data to portable media, Contact Perimeter.

Chapter 3: Operator Workflow

Turning on the Claire OCT System Hardware

Before using the device: Check the device enclosure for obvious damage or defects. The locations of the power plug, power switch and power button are provided in Table 6.

To turn on the device:

1. Ensure the power cable is plugged into the Claire OCT System power plug, and an appropriate supply main.

Figure 12: Plugging in the Claire OCT System Power Cable

2. Ensure the power switch at the back of the Claire OCT System is switched on.

Figure 13: Power Switch On

3. Press the power button on the side of the Claire OCT System to turn it on.

Figure 14: Turning on the Claire OCT System Hardware

WARNING

WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply-mains with protective earth.

Connecting Vacuum Tubing

Connect one end of the vacuum tubing to the Claire OCT System vacuum port at the back of the device (Figure 15). Connect the other end of the vacuum tubing to the OR wall vacuum port. If the vacuum tubing does not fit into the vacuum port at the facility, select tubing of a different inner diameter or use an adapter.

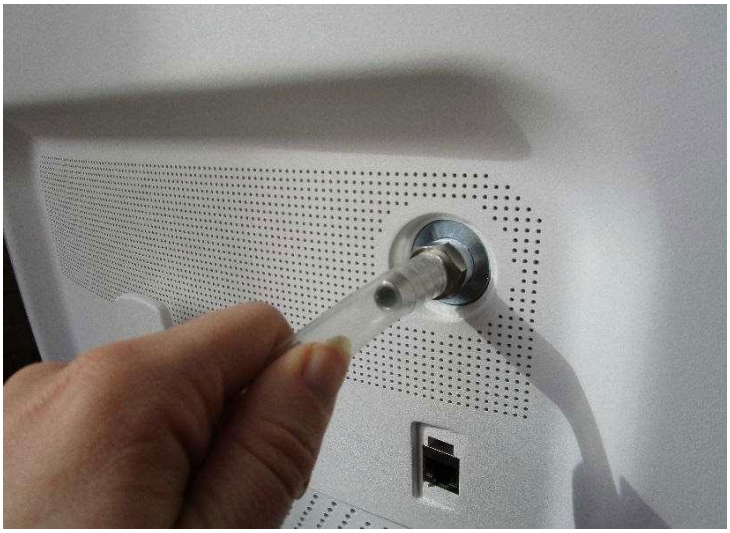


Figure 15: Connect vacuum tubing to the Claire OCT System vacuum port

CAUTION

CAUTION: To ensure effective vacuum use on the device, Perimeter recommends that flexible tubing with a firm hardness rating and an inner diameter of approximately 3/8" be used to connect the device's vacuum port to the vacuum outlet. If alternate tubing is used, ensure that the tubing fits the vacuum port of the device, is sufficiently rigid so that it does not collapse on itself and that the vacuum works effectively once turned on from the device.

Logging In

Once the device has been powered on, the Claire OCT System login prompt will appear. Users can log in with their account information.

The Claire OCT System Home Screen will automatically launch after successful login. The Home Screen will appear as shown in Figure 4.

WARNING

WARNING: The Claire OCT System is not a sterile device. Take necessary precautions per the facility's infection prevention and control polices if the Claire OCT System will be used in a sterile area.

Start a New Case

Select a **New** case from the Home Screen (see Figure 4).

From the Review Screen, select **New** from the menu in the bottom right corner of the screen (see Figure 8).

Enter Patient Information

The Patient Information Screen will appear, allowing the user to enter patient-specific information (see Figure 5). Once the patient information has been entered, tap **SAVE**.

Specimen Immobilizer Preparation

After Patient Information has been entered the Claire OCT System will display a prompt for the user to seat the Specimen Tray.

Remove a new Specimen Immobilizer from its packaging. Secure the Specimen Tray to the Specimen Tray Dock by aligning the arrows and turning the Specimen Tray in a clockwise direction until the Specimen Tray is fully secured, as shown in Figure 16.

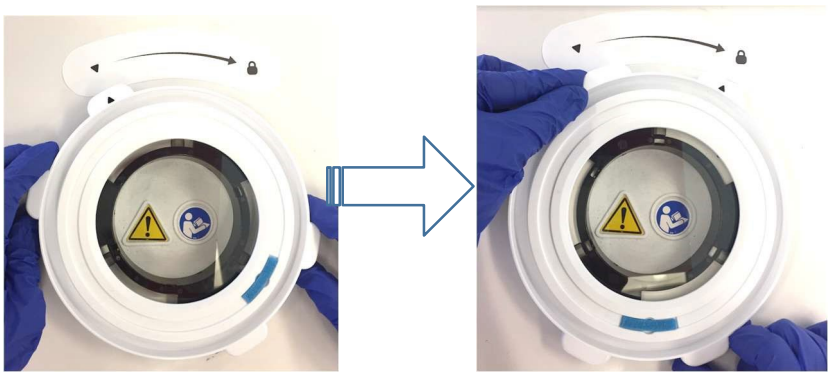


Figure 16: Specimen Tray positioning on the Specimen Tray Dock

The Claire OCT System is for use with accessories contained in the Single-Use Specimen Immobilizer only.

Device Initialization

Once the Specimen Tray has been fully seated, the user will see a message that the system is initializing. Initialization should take less than a minute.

Refer to the Section on Device Prompts if a warning is seen during device initialization. Do NOT remove the Specimen Tray during initialization.

Do NOT move or bump the system during initialization.

Recording Specimen Parameters

Once initialization is complete, the user will see the Scan Setup Screen (see Figure 6). Select the Body Side from which the specimen was excised: **RIGHT**, **LEFT** or **OTHER**. If **OTHER** body side is selected, a text box will appear, prompting the user to enter in the **Body Location** using the onscreen keyboard.

Specimen Loading

Carefully place the specimen (**no larger than 10 cm diameter**) on the Imaging Window of the Specimen Tray. Ensure that the specimen side selected for scanning is face down on the Imaging Window (and therefore visible in the Live Specimen View) with any regions of interest as close as possible to the center of the Imaging Window (Figure 17).

WARNING

WARNING: Do not place specimen directly on the Imaging Gate. Placing the specimen directly on the Imaging Gate could lead to the specimen becoming trapped within the device, personal injury, or damage to the device. Placing the specimen directly on the Imaging Gate could require immediate assistance from Perimeter's Service and Maintenance Team.

WARNING

WARNING: Use clinical expertise and judgement for device use if specimen margins have been destroyed, damaged, or are otherwise not intact prior to imaging. Failure doing so may result in an inappropriate assessment.

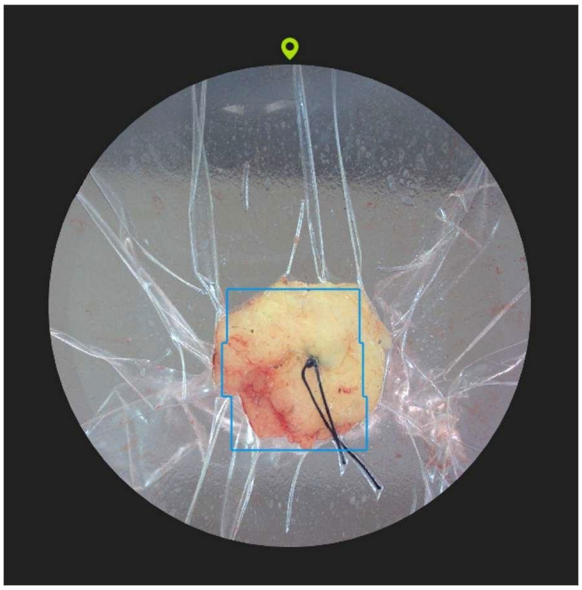


Figure 17: Live Specimen View

Select Specimen Scan Side

To continue, select the side of the specimen to scan (see Figure 6). Multiple scan sides can be selected to fully define the side of the specimen in contact with the imaging window. If **OTHER** scan side is selected, an onscreen keyboard will appear prompting the user to enter the name of the surface being scanned as seen in Figure 18 below.

Figure 18: Scan side OTHER Screen

Select Specimen Side Toward Marker

To assist with specimen orientation, the user can also label the specimen side that is towards the green marker above the specimen image. This is an optional step.

Use the Specimen Orientation Guide provided during training as an aid for Specimen Orientation.

Vacuum-Secure Specimen

Use the Vacuum Control to select the vacuum level (**Off, Low**, **Medium**, **High** or **Full**) to secure the specimen (see Figure 19 below).

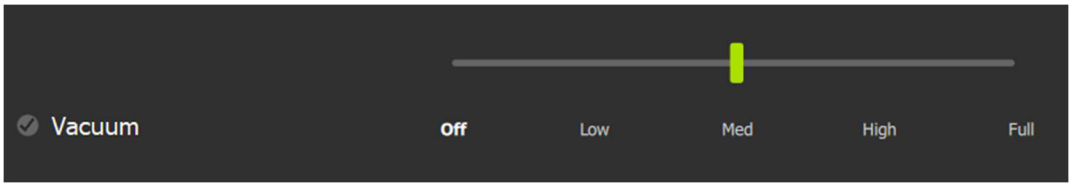


Figure 19: Vacuum Control

CAUTION

CAUTION: Select a vacuum level that is appropriate for the specimen being imaged.

CAUTION: In some cases, the quality of WF-OCT Images may be insufficient for review if the specimen is not vacuum-secured prior to scanning.

CAUTION

CAUTION: Low vacuum levels can lead to poor surface contact between the specimen and the Imaging Window. This may negatively impact the ImgAssist output.

Place the Specimen Lid on the specimen and gently push it down to engage with the Specimen Tray. Maintain the correct positioning of the specimen by supporting it, if needed, through the transparent bag of the Specimen Lid. Press the Specimen Lid down onto the Specimen Tray to initiate suction (see Figure 20 below).

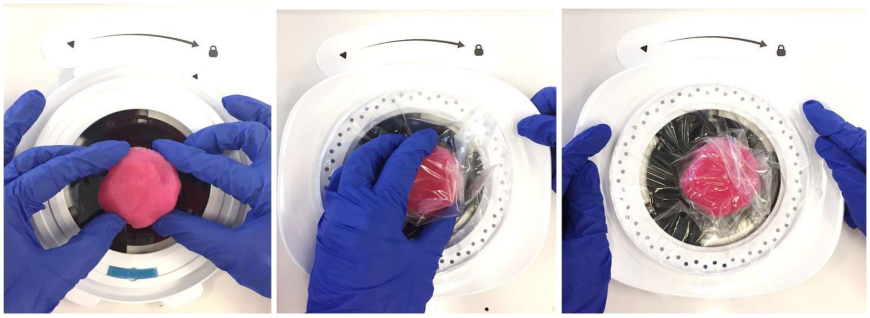


Figure 20: Specimen Immobilizer placement

Review the Live Specimen View to ensure that the specimen is making full contact with the Imaging Window and that there are no large air pockets or portions of the transparent bag trapped between the specimen and the Imaging Window.

Selecting Scan Area

A scan area can be selected using the Live Specimen View. Select the scan area by placing a finger on the Live Specimen View and tracing the area of interest to image. The user may select a scan area as small as 1 cm x 1 cm or as large as 8.7 cm x 8.7 cm. The selection may be cleared by tapping one finger anywhere on the Live Specimen View.

The Claire OCT System supports imaging of a specimen with a footprint of up to 10 cm in diameter, however, only a maximum 8.7 cm diameter circular footprint can be acquired. Place the region of interest as close to the center of the Imaging Window as possible to ensure proper visualization.

Selecting Scan Density

The scan density refers to the spacing between 2 consecutive WF-OCT Images.

A high-density scan involves less spacing between 2 consecutive WF-OCT Images and therefore contains more WF-OCT images in the WF-OCT Volume compared to a low-density scan.

A low-density scan involves more spacing between 2 consecutive WF-OCT Images and therefore contains fewer WF-OCT Images than a high-density scan.

Beneath the scan density options are estimates for the total scan time based on the selected scan area (see Figure 21 below).

Scan time depends on the scan density and the scan area. Typically, high-density scans have longer acquisition scans than low-density scans.

CAUTION

CAUTION: ImgAssist identifies regions suspicious for breast cancer and highlights these when they are observed across multiple B-scans. In low density scans, tissue microstructures indicative of breast cancer may not be visible across multiple consecutive B-scans and may therefore not be identified by ImgAssist. Thus, low density scans are not recommended for optimal ImgAssist output.

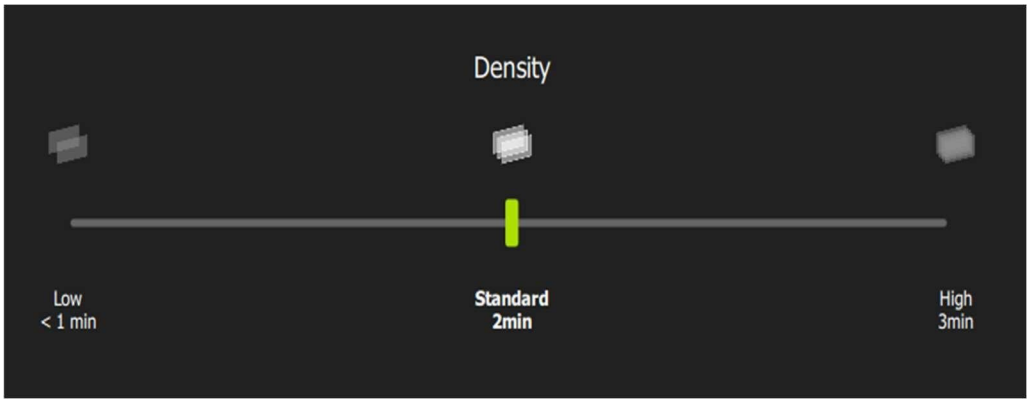


Figure 21: Select Scan Density

After the scan area is selected, the **Start Scan** button will appear. Once tapped, WF-OCT Image acquisition will begin.

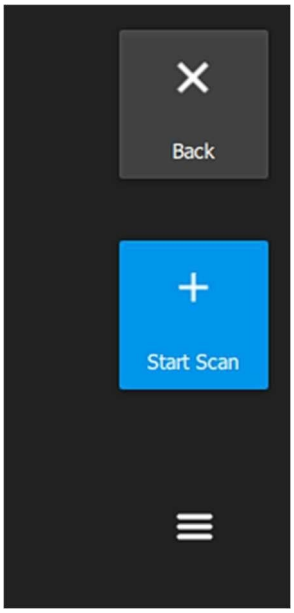


Figure 22: Start Scan

CAUTION

CAUTION: Do not move the Claire OCT System while imaging.

A scan progress indicator will be displayed and WF-OCT Images will be shown as they are acquired. ImgAssist will be enabled once the first WF-OCT Images are available.

Once scanning is complete, the user can choose to review the results of the scan, scan an additional side of the same specimen, end the exam, or exit the program.

See Chapter 4 Reviewing and Storing Images for information on how to review images.

Stopping a Scan

A scan can be stopped anytime after it has begun, select **Cancel Scan** on the Scan in Progress Screen (Figure 23).

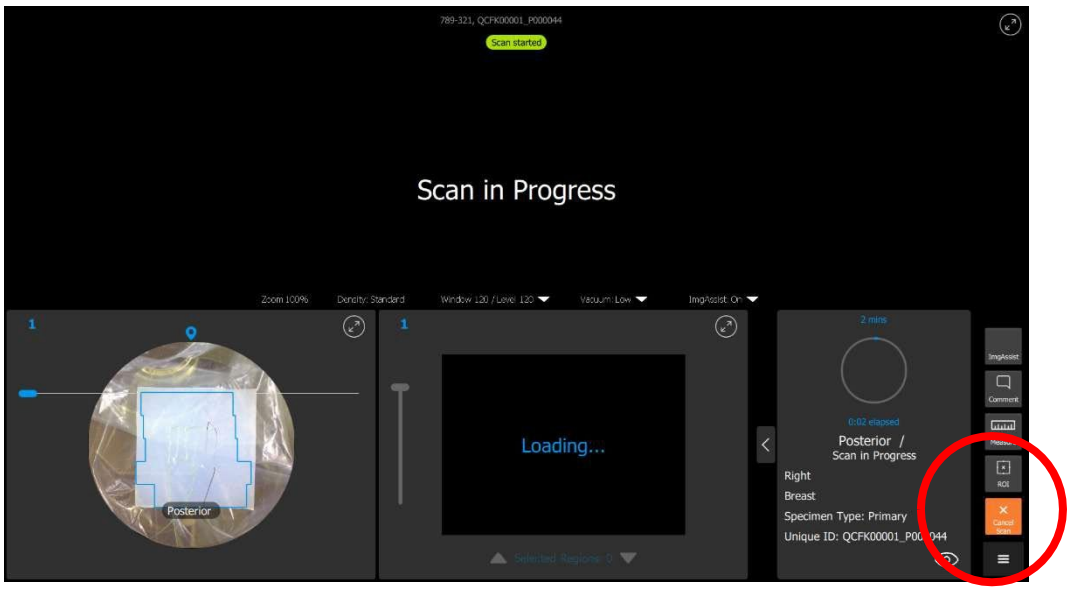


Figure 23: Cancel Scan

The device will prompt the user to confirm stopping the scan. To confirm, tap **Yes**. To continue with the scan, tap **No** (Figure 24 below).

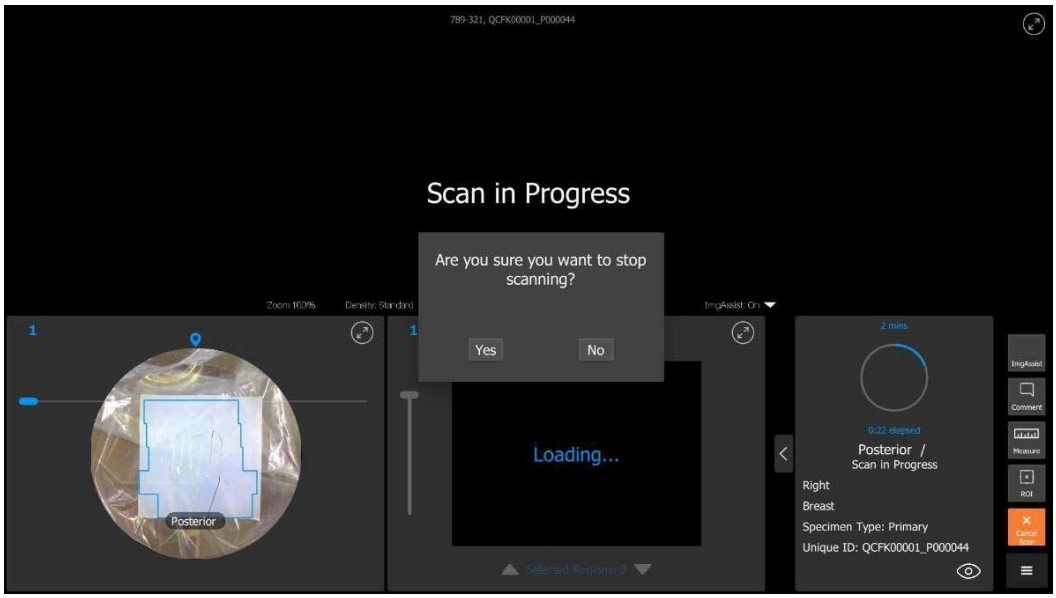


Figure 24: Confirm Stop Scan

Upon confirmation (Figure 24), the device will cease image acquisition. The **Cancel Scan** button will read “Scan Stopping…”. Do not move the device until the scan has fully stopped.

Once the scan has stopped, any data of the partially completed scan which has already been acquired will be displayed on the Review Screen (Figure 25 below).

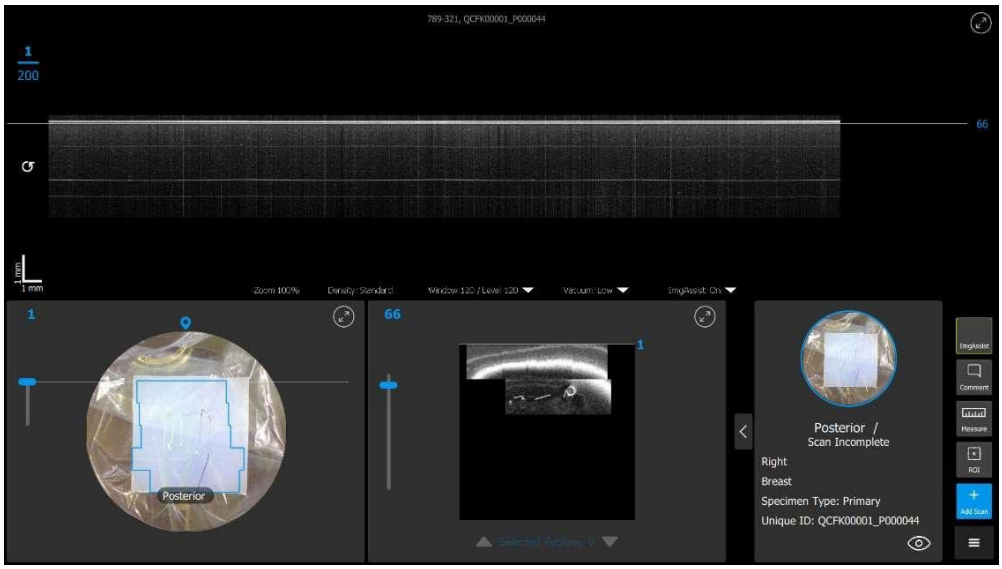


Figure 25: Partially Completed Scan

During scanning, if immediate access to a specimen is needed, select **Vacuum OFF** and remove the Specimen Lid.

All data collected up to that point will be automatically saved and can be opened in the Case List or viewed in the Review Screen.

Specimen Reposition or Unloading

To reposition or unload the specimen, release the suction pressure by tapping the **Vacuum OFF** button on the Screen to turn off the vacuum (Figure 26). Then gently lift up on the tabs of the Specimen Lid. Once the vacuum pressure has been released from the Specimen Immobilizer, the specimen may be repositioned or retrieved.

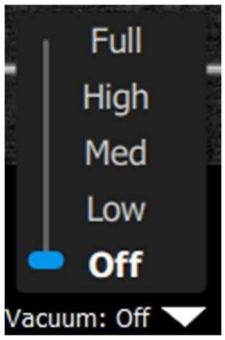


Figure 26: Vacuum OFF

WARNING

WARNING: Do not place specimen directly on the Imaging Gate. Placing the specimen directly on the Imaging Gate could lead to the specimen becoming trapped within the device, personal injury, or damage to the device, requiring immediate assistance from Perimeter service.

Remove the specimen from the Specimen Tray. If a different specimen from the same patient needs to be scanned, return to the instructions in the Specimen Loading section.

When all required specimens and sides from the case have been scanned and removed from the system, dispose of the Specimen Immobilizer(s) per standard facility procedures.

Device Shut Down

When the user is done using the system, ensure that the vacuum has been turned off. Tap the menu button at the bottom right of the Touchscreen Monitor and select Log Out to close the Claire OCT System application and log out of the device.

After the device has logged out press the ON-OFF button on the side panel as shown in Figure 14.

Ensure that the Specimen Immobilizer has been removed from the device and disposed of per standard facility procedures.

After the device has been powered off, turn off the power switch at the back of the device (see Table 6). Remove the vacuum tubing from the device and the wall vacuum port (see Table 6). Unplug the device power plug and store the power cable by wrapping it around the power cable storage hooks (see Table 6).

Cleaning and disinfection may be performed as required, per Chapter 5 Device Cleaning and Maintenance.

CAUTION

CAUTION: Do not power down or unplug the Claire OCT System unless the system is completely powered off.

Readying System for Storage

If the system needs to be moved after the procedure, ensure that the device is shut down using the front power button (Figure 14). Then turn the power switch off on the back of the device (Figure 13), unplug the power cable from the wall and wrap it around the power cable storage hooks. Remove the vacuum tubing from the back of the device and the Claire OCT System is ready for transport or storage.

Chapter 4: Reviewing and Storing Images

View an Existing Case

Previously acquired Cases can be viewed by opening them through the Case List Screen. Access the Case List Screen by tapping the **Open** button from the Home Screen (refer to Figure 4) or by selecting **Case List** in the menu at the bottom right of the screen from any page other than the Home Screen. (refer to Figure 4).

The Case List Screen can not be accessed when the system is initializing, or if there are no previously acquired cases.

Select a Case by double tapping on the entry in the Case List. The WF-OCT Images, Specimen Photograph and any annotations for that case will be shown in the Review Screen (see Figure 8).

Any specimen sides which were scanned will appear in the list of scans which is available by clicking the arrow at the left of the scan card (see Figure 27). The Scan that is currently displayed on the Review Screen will have a color specimen image in the list of scans. For example, in Figure 27, the scan which is currently being viewed is the Superior surface of the specimen.

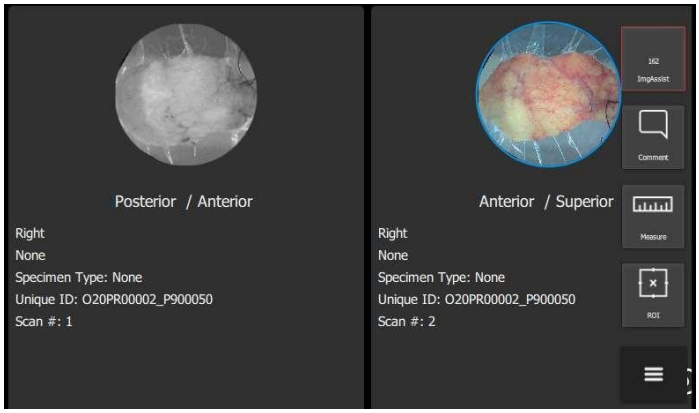


Figure 27: List of Scans

Select the scan card to view the WF-OCT Volume and Specimen Photograph for that particular scan.

Specimen Photograph

The Specimen Photograph allows the user to view the physical specimen and is intended to be used as an aid in image interpretation. The spatial locator (the white line in Figure 28 below) represents an approximate region of the specimen corresponding to the individual WF-OCT Image, as well as zoom extents. The blue box on the Specimen Photograph indicates the scan area selected by the user as explained in the section Selecting Scan Area.

The Specimen Photograph also contains references to the specimen orientation and body side as described in the section Specimen Loading and in the section Recording Specimen Parameters. The scroll to the left of the image can be used to move the Spatial Locator as shown in Table 8 on Image Review Tools.

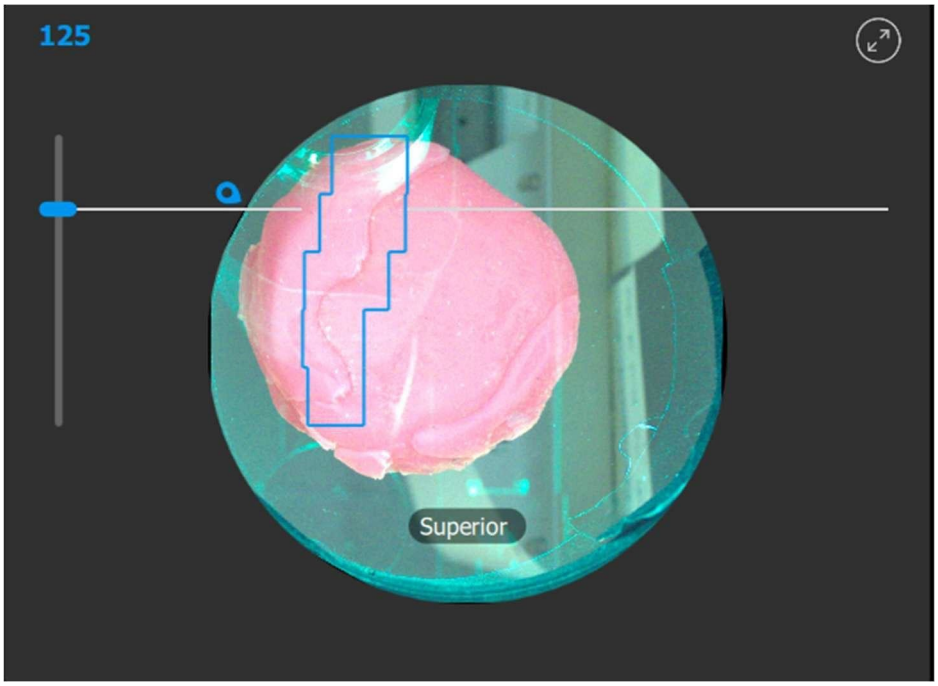


Figure 28: Specimen Photograph

The spatial locator on the Specimen Photograph is provided to assist in general orientation and is intended to provide a coarse WF-OCT image location only.

The Specimen Photograph can be expanded by selecting the double arrow icon in the top right corner as seen in Table 8. To close the expanded Specimen Photograph, tap the white 'X' in the top right corner of the pop-up window, as seen in Figure 29 below.

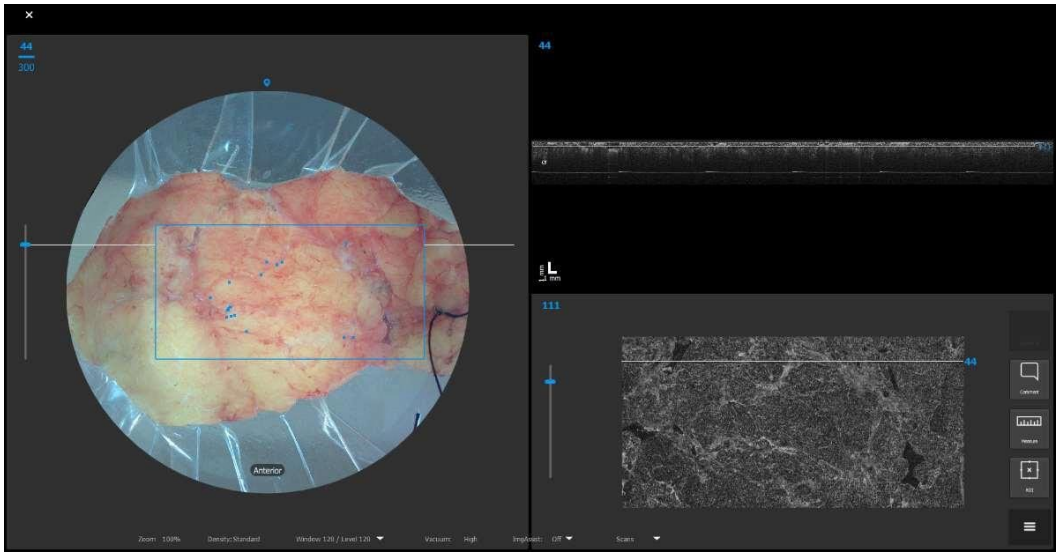


Figure 29: Expanded Specimen Photograph

Enface Image

The enface image is a view created from the volume of WF-OCT B-scans and is intended to be used as an aid in image interpretation. The spatial locator (the white line in Figure 30 below) represents the WF-OCT Image that is currently being displayed. The scroll bar to the left of the image can be used to adjust the depth of the enface image.

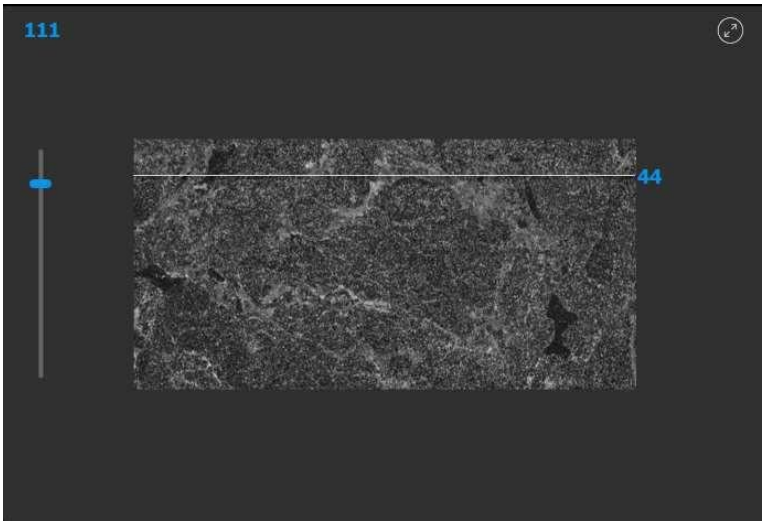


Figure 30: Enface image

The Enface Image can be expanded by selecting the double arrow icon in the top right corner as seen in Table 8. To close the expanded Enface Image, tap the white 'X' in the top right corner of the window, as seen in Figure 31 below.

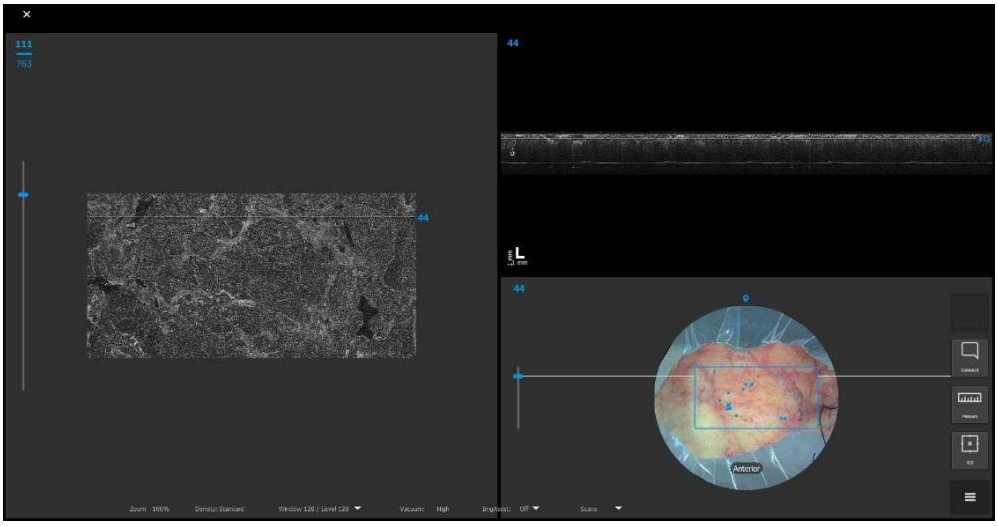


Figure 31: Expanded Enface Image

WF-OCT Image Details

Image details are displayed on the Review Screen and appear beneath the WF-OCT Image.

Zoom percentage (Zoom %): Specifies the zoom level of the WF-OCT Image, as a percentage (seen in a red circle in Figure 32).

Image number: The Claire OCT System displays the WF-OCT Image number currently displayed, and the total number of WF-OCT Images which were collected in the Volume. For example, on the left side of Figure 32 we see blue text in the upper left that shows "44/300", which indicates that WF-OCT Image number 44 is displayed, out of a total of 300 Images which make up the WF-OCT Volume.

Scan density (Density): Scan density is related to the spacing between consecutive B-scans in a WF-OCT volume. A high scan density corresponds to a smaller distance between B-scans. Therefore, high density scans provide more information about the tissue (i.e. more WF-OCT Images make up the WF-OCT Volume), however high-density scans take longer o acquire. Conversely, low scan density means there is a larger distance between B-scans, and therefore less information is gathered, resulting in a shorter scan time. See Selecting Scan Density.

Window Level (W/L): This feature allows the user to adjust the brightness of the WF-OCT Volume and its Contrast. Activate the Window Level function by tapping on the triangle next to the Window/Level information on-screen. Use the sliders to adjust the window & level to the desired settings. Tap the Reset button to return to default Window/Level settings.

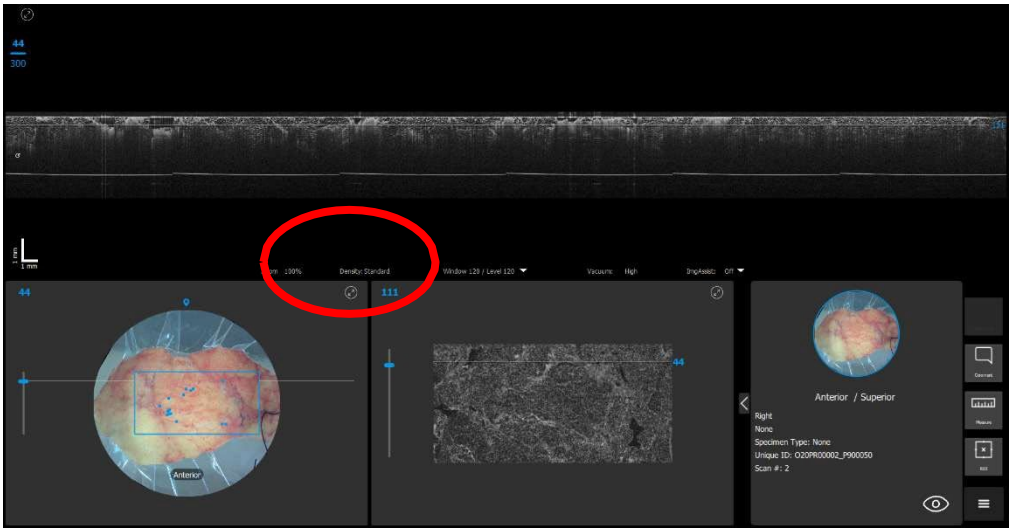


Figure 32: Image Indicators

Image Review Tools

Scroll:

- Place one finger anywhere on the WF-OCT Image and slide a finger on the screen to scroll through the WF-OCT Volume.
- Tap the Specimen Photograph demarcated scan area to jump to the WF-OCT Image from the approximate corresponding location (see Table 7).
- Click and drag the slider bar to the left of the Specimen Photograph to scroll through the WF-OCT Volume.
- Use Fine Scroll as defined in Table 7.
- Play through the WF-OCT Volume as described in Table 7.

Zoom:

- Place two fingers anywhere on the WF-OCT Image.
- Use a pinching motion to zoom out of the WF-OCT Image.
- Use a stretching motion to zoom into the WF-OCT Image.
- Tap the **Reset** button to return to the original zoom setting.
- The zoom percentage is displayed at the base of the image.

Pan:

- Use two fingers to move the image in the desired direction.
- Tap the **Reset** button to return to the original pan setting.

Return to the default image settings (i.e. reset **Zoom, Pan** and **Window Level (W/L)** altogether) at any time by tapping the Reset button on the left side of the screen.

ImgAssist

The Claire OCT System includes a software feature called ImgAssist, a concurrent reading aid for physicians interpreting WF-OCT images, to help identify regions suspicious for breast cancer. The ImgAssist feature includes a trained artificial intelligence algorithm.

Patient management decisions should not be made solely based on analysis of the Claire OCT System or ImgAssist outputs.

To use ImgAssist, the user must first ensure the feature is enabled. This can be done by tapping the drop-down and selecting “ON” or “ON (Show Less)”, see Figure 33.

Figure 33: ImgAssist On/On (Show Less)/Off

If enabled, ImgAssist will automatically process the WF-OCT Images and display several indicators if any Regions of Interest (ROIs) are found. These indicators can be found on the WF-OCT image (Figure 34), the enface image (Figure 35), and the ImgAssist thumbnail button (Figure 36).

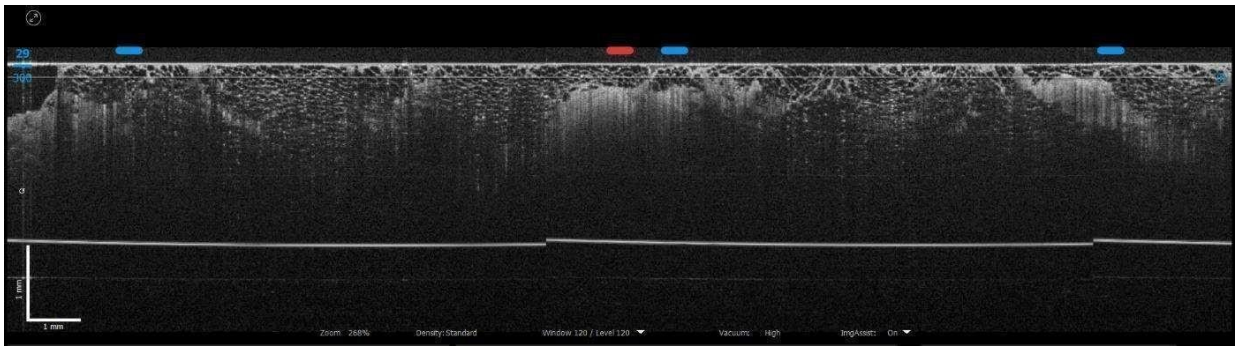


Figure 34: ImgAssist Detection on WF-OCT Image

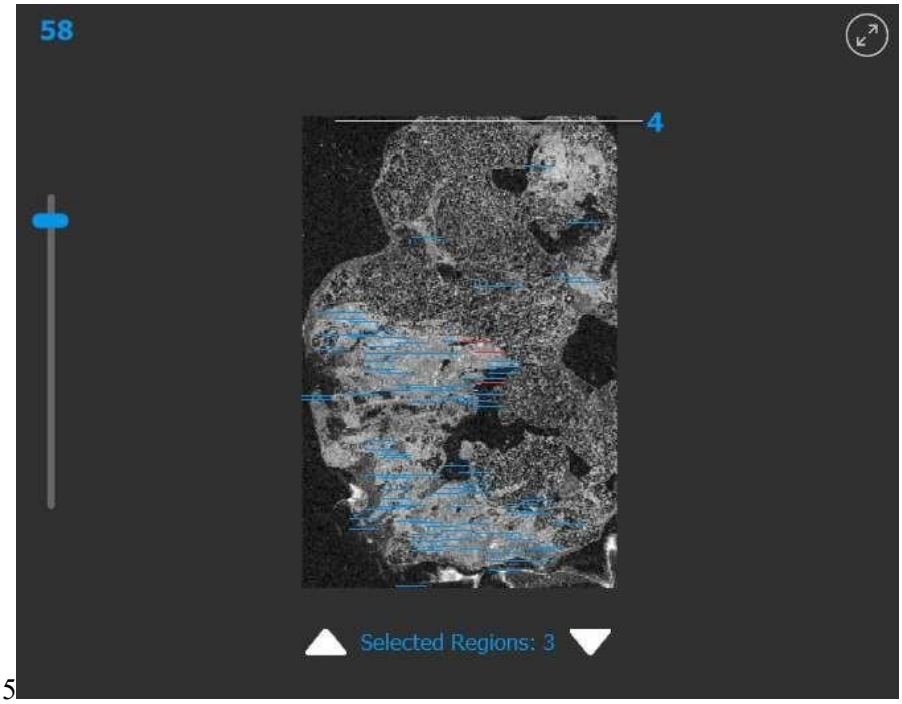


Figure 35: ImgAssist Detections on Enface Image

Figure 36: ImgAssist Review Button

The ImgAssist review button will have a green outline if there are no ImgAssist detections. The ImgAssist review button will be red or orange if the ImgAssist algorithm has detected any ROIs. Red is used to indicate that all detections are currently displayed and orange indicates that only the highest probability findings are displayed. The thumbnail button will also display the number of detections available for review in the thumbnail view based on user selection to show all detections or show less.

To access the thumbnail view, tap the ImgAssist review button and the Thumbnail Review Screen will be displayed (Figure 37).

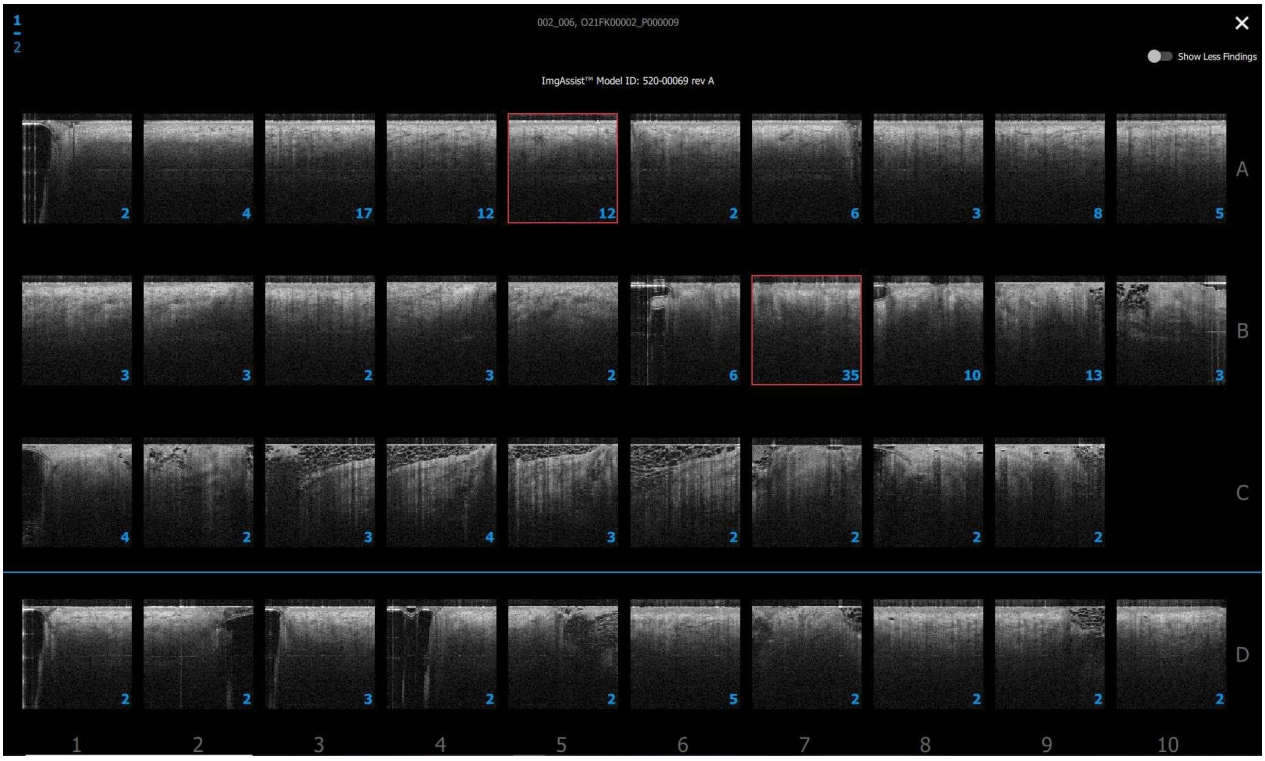


Figure 37: ImgAssist Thumbnail Review Screen

From the thumbnail screen, the user can scroll through the ImgAssist detections and select any areas to highlight for further review on the WF-OCT and enface views. The number in the bottom-right corner of the thumbnail indicates the number of WF-OCT Images contained in the detection. The thumbnail image is the image with the highest likelihood of indicating an interesting feature from the cluster. The blue line between rows delineates the highest probability findings from all other findings.

To select an ROI for review, tap the thumbnail and a red outline will confirm the selection. Selecting an ROI will turn the blue ROI indicator on the corresponding WF-OCT Image and Enface images red. To jump to the location of the ROI on the WF-OCT and Enface images, touch and hold on a thumbnail. From there, scroll up and down on B-scan images to see all the detections relevant to that cluster.

To close the thumbnail view and return to the review screen, tap the “X” in the upper right corner of the screen.

The WF-OCT images will display a blue line above an area with a ROI detection. This line will turn red if the corresponding ROI is selected in the thumbnail view (Figure 38). A long press on an ROI on a WF-OCT Image will navigate back to the thumbnail view.

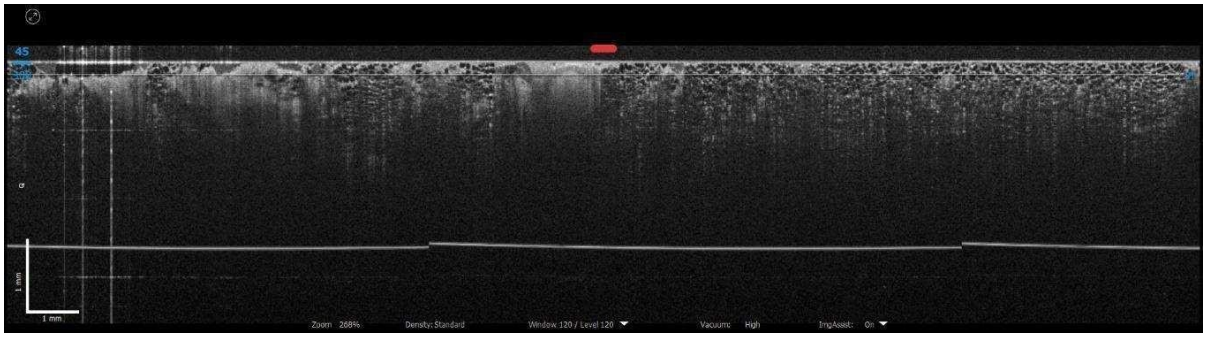


Figure 38: Selected ROI on WF-OCT Image

In the Enface view, ImgAssist detections will be displayed as blue lines which correspond to the blue lines in the WF-OCT images. A blue line will turn red if the corresponding ROI is selected in the thumbnail view (Figure 39).

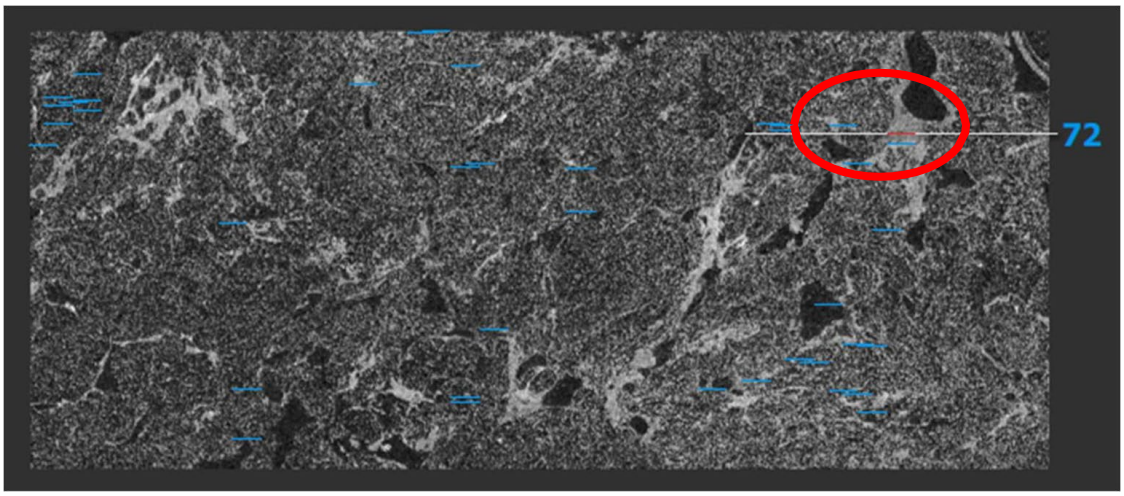


Figure 39: Selected ROI on Enface View

Under the Enface view, the number of selected regions is displayed. The number of detections that are selected, i.e. turned red, in the thumbnail view or via the WF-OCT image are shown here.

If ImgAssist runs successfully but no suspicious regions are identified, a message will be displayed in the thumbnail review screen.

Annotations

The user may **Comment** on a feature, **Measure** a feature, and place a Region of Interest (**ROI**) directly on the WF-OCT Image in the Review Screen.

To use an annotation tool, select the desired tool button (Figure 40) and then select the WF-OCT Image

corresponding to the location to place the annotation, as described below.

A list of annotations will also appear on the reverse side of the scan card on the bottom right of the Review Screen (Figure 41).

Each entry in the annotation box references the WF-OCT Image number on which the annotation appears.

Tapping on the individual entry in the annotation box will display the WF-OCT Image on which the annotation was made (Figure 41).

Tap an annotation to add notes about the specific annotation in a pop-up window. Tap **SAVE** or **CANCEL** to save or delete the changes.

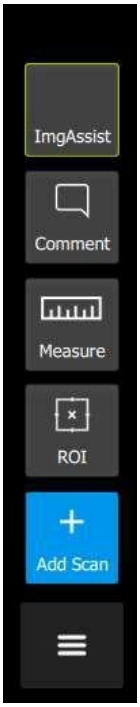


Figure 40: Image Review Tools

The Annotation Notes box is for information pertinent to the Case. It is recommended that Patient Identifiers NOT be included in this box.

Comment tool

- Activate the Comment tool by tapping on the Comment icon.
- Touch the region of the WF-OCT Image where the comment should be placed.
- Enter the desired text in the box that appears.

- The WF-OCT Image number of the comment and the text entered will appear in the comment box on the Review Screen.
- Tap the entry in the comment box to go to the WF-OCT image with the comment.

Measure Tool

- Activate the Measure tool by tapping on the Measure icon.
- Place a finger on the point in the WF-OCT Image to start measuring a feature and drag it to the end of the feature.
- As the finger moves, a yellow box at the top of the screen will display the measurement value.
- The WF-OCT Image number of the measurement will appear in the annotation box on the Screen.
- Tap a measurement to go to the WF-OCT image of interest.

Region of Interest (ROI) Tool

- Activate the Region of Interest tool by tapping on the ROI icon.
- Place a finger near the area of interest, drag it diagonally across the area of interest and then release it.
- The area of interest will now be enclosed in a rectangle.
- The WF-OCT Image number of the ROI and any additional user entered comments will appear in the comment box on the Review Screen.

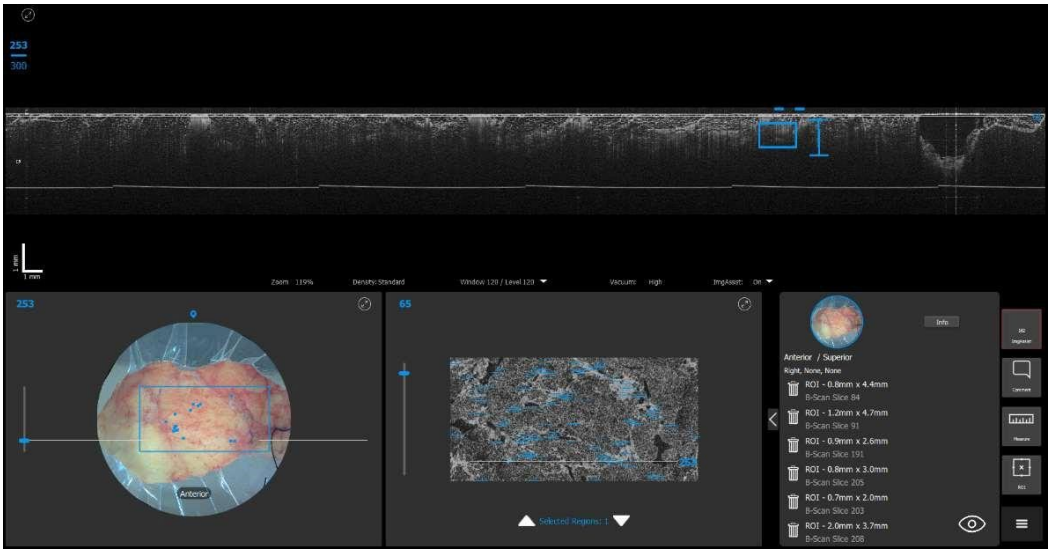


Figure 41: Annotations

Image Storage

The Claire OCT System has an image storage capacity of 1TB.

Once the Claire OCT System's storage is at or above 75% full, the user will be warned each time they log in. It is the user's responsibility to ensure that data is backed-up and deleted on the Claire OCT System.

It is the responsibility of the facility to ensure that data is backed up per any healthcare facility data maintenance policy prior to deleting data.

If the maximum storage capacity of the Claire OCT System is reached, the Claire OCT System will give a warning and disable the ability to scan until the issue is resolved.

Data Export

Data from the Claire OCT System can be transferred to a connected USB drive.

Insert a USB drive into the USB port on the side of the device (refer to Table 6).

Export Screenshot to USB

From the Review Screen**,** follow the steps below to **Export a Screenshot** to USB:

1. Tap on the menu button
2. Tap **Export** and then tap **Screenshot**
3. Select the USB drive in the export destination

CAUTION

CAUTION: Only a dedicated USB drive should be used when exporting data from the Claire OCT System. The use of a compromised USB drive may affect the security of the device.

Export Case to USB

To export an open Case, select **Export** from the menu and then select **Case** to export the current case as shown in Figure 42 below.

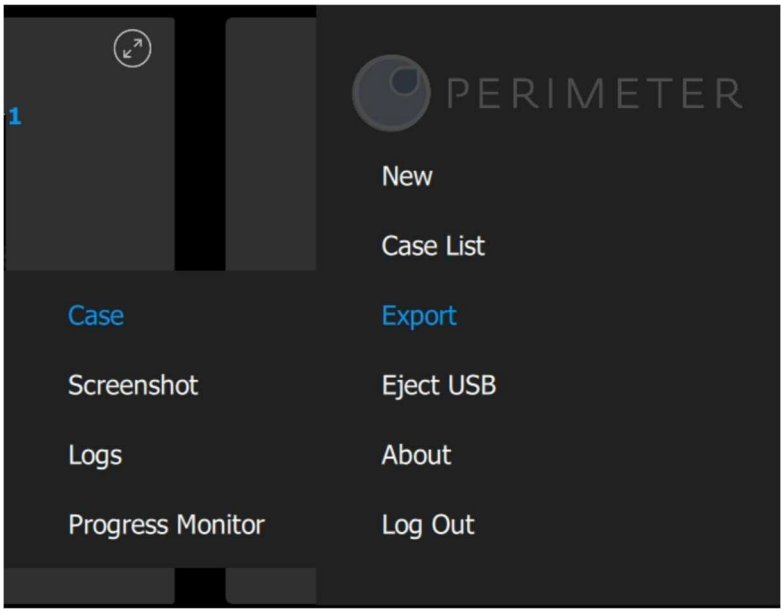


Figure 42: Menu Export options from ongoing case

In the pop-up window select the export destination, as shown in Figure 43 below.

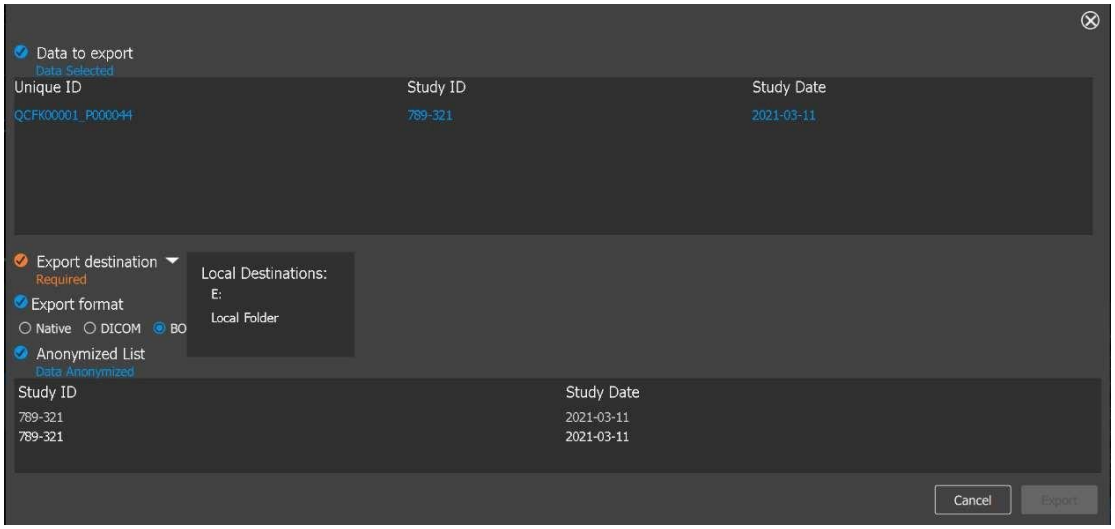


Figure 43: Select Cases for Export Screen

Data exported to USB drive will be anonymized

It is recommended to export data for archival purposes only.

It is the user's responsibility to ensure that the security of the specimen data, which may relate to a patient, is guarded in accordance with local privacy and security policies and regulations.

CAUTION

CAUTION: If a data security breach or a malware attack is suspected, please contact the Perimeter Service.

When a Case is exported, it will be anonymized. A pop-up window will allow users to input patient information as per the fields shown in Figure 44 below. Tap **EXPORT** after including patient information and export location in the fields provided.

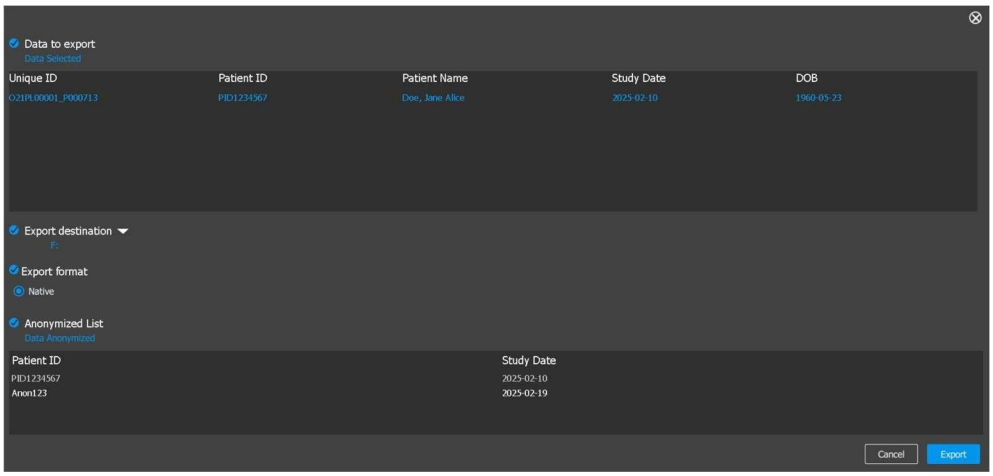


Figure 44: Export Case Information Screen

It is the responsibility of the user to ensure patient privacy and security. It is advised that Protected Health Information (PHI) and Patient Identifiers not be a part of data exported to portable media such as USB.

When an export to USB has started, data transfer progress can be seen by selecting **Progress Monitor** from the **Export** menu.

While **Exporting to USB**, other activities on the Claire OCT System can proceed as data transfer will continue in the background.

Chapter 5: Device Cleaning and Maintenance

Cleaning and Disinfection

The Claire OCT System is designed to operate reliably with minimal user maintenance. The external surfaces of the device that do not come in contact with specimens should be kept clean and free of dust or other debris.

The Single-Use Specimen Immobilizer is the only component of the device that is intended to come in direct contact with the specimen. The Specimen Tray and Specimen Lid of the Specimen Immobilizer must be disposed of according to standard facility procedures, immediately following their use.

Image quality may degrade if specimen residue dries on the glass Imaging Window between scans, or if the user attempts to clean the Imaging Window.

CAUTION

CAUTION: Specimen Immobilizers are for single-use only. Do not re-use or attempt to sterilize the Specimen Immobilizer.

CAUTION: Failure to follow cleaning and maintenance instructions may result in damage to the device.

CAUTION: Do not pour liquid directly onto any part of the device. Pouring liquid directly onto the device may result in equipment damage.

CAUTION

CAUTION: Do not pour or spray liquid directly onto any part of the device. Do not immerse any device part in cleaning fluid. Do not expose device parts to steam or high temperature sterilization.

CAUTION: Do not attempt to remove the device enclosure or clean inside the device enclosure. Doing so may cause permanent damage to the lens, probe and/or stage. Should the inside of the device become soiled, please contact Perimeter for service.

Touch Screen and Monitor Arm Specific Warnings

CAUTION

CAUTION: Do not strike, scratch, or apply excessive pressure to the Touchscreen surface.

CAUTION: Do not use abrasive cleaners, waxes, or solvents to clean the device.

WARNING

WARNING: The moving monitor arm introduces potential hand-crushing hazards. Keep hands clear of pinch-points at all times.

General Cleaning and Disinfection Procedure

This procedure includes cleaning the unit and the surfaces external to the device that the specimens do not contact. Do not use cleaning solutions that are not listed, as they may damage and/or discolor device components.

Depending on desired decontamination per internal infection prevention and control procedures, cleaning can be done alone (steps 1-5 +10), or cleaning can be done followed by disinfection (steps 1-10).

Prior to cleaning and/or disinfection:

1. Ensure that the Touchscreen Monitor is turned off prior to cleaning and/or disinfection.

Cleaning:

2. Get a soft, non-abrasive, non-linting cloth thoroughly wet with a cleaning solution from Table 10.
3. Thoroughly wet the surface of the Touchscreen Monitor, Monitor Arm and the Claire OCT System Body until visible grime is removed.
4. A secondary round of wiping with non-abrasive, non-linting cloths should be used to ensure that wetted surfaces are dried prior to disinfection procedure.
5. Discard used cloths.

Disinfection:

6. Get a soft, non-abrasive, non-linting cloth thoroughly wet with a disinfecting solution from Table 10.
7. Thoroughly wet the surface of the Touchscreen Monitor, Monitor Arm and the Claire

OCT System Body following the disinfection manufacturer label instructions for appropriate wet contact time.

8. Wipe surfaces dry with a clean non-abrasive, non-linting cloth.
9. Discard used cloths.

Check surfaces of the monitor for streaks:

10. If streaks are present repeat cleaning steps with immediate drying with fresh, dry, non-abrasive, non-linting cloth to remove streaks prior to storage or use.

Table 10: Recommended Cleaning and Disinfection Solutions

<table>
<tr><th>Component(s)</th><th>Cleaning Solutions</th><th>Disinfection Solutions</th></tr>
<tr><td rowspan="2">External Surfaces of Device</td><td>Warm water</td><td rowspan="2">Dimethyl (Ethyl)Benzyl Ammonium Chlorides (quaternary ammonium)-based disinfectants (including wipes)</td></tr>
<tr><td rowspan="2">Soap solution, pH neutral/water combination</td></tr>
<tr><td></td><td rowspan="2">Examples:
AseptiWipe™ II (EcoLab
PDI Super Sani-Cloth® (PDI)
CaviWipes (Metrex)</td></tr>
<tr><td>Touchscreen Monitor, Touchscreen Enclosure and Monitor Arm</td><td>70% isopropyl alcohol solution</td></tr>
</table>

Maintenance

The Claire OCT device has been granted an FDA-authorized PCCP, which allows specific, bounded modifications to the artificial intelligence/machine learning (AI/ML) functions, as well as hardware, manufacturing, and non-AI/ML software. The PCCP ensures that all modifications are predetermined and confined within authorized parameters to maintain a consistent standard of safety and effectiveness. Users should thus be aware of the following:

- Perimeter may issue periodic software updates pursuant to this authorized plan. These updates may modify the device's performance, inputs, or use.
- Modifications will be accompanied by version identification and, as appropriate, updated labeling to account for any changes to performance results and instructions for use.
- Users are informed of these modifications through advisory notices, and may also include updates to labeling and user training.


WARNING

WARNING: No modification of this equipment is allowed.

WARNING: This device contains no user-serviceable parts. Do not disassemble, modify, or attempt to repair the device. User injury and equipment damage may result**.**


CAUTION

CAUTION: Planned Operating System, Software and Firmware updates shall be communicated by Perimeter to the Department Manager. Updates not authorized by Perimeter should not be installed on the Claire OCT System as these may affect performance and may compromise or corrupt data acquired by the device.

Preventative Maintenance Schedule

Table 11: User Preventative Maintenance Schedule

Action	Recommended Frequency:	
	Each Use	Yearly (Perimeter Service Only)
Dispose of used Specimen Immobilizer	X	
Clean external surfaces contacted during use	X	
System service and configuration		X


CAUTION

CAUTION: Specimen Immobilizers are for single-use only. Do not re-use or attempt to sterilize the Specimen Immobilizer.

End of Life Disposal

Contact Perimeter to ensure proper disposal of the Claire OCT System at the end of its product life.

Chapter 6: Troubleshooting

Listed below are possible irregularities that may occur with the Claire OCT System, as well as possible causes and solutions. If additional troubleshooting assistance is required, please contact Perimeter. To report a cybersecurity vulnerability, please contact Perimeter customer service or visit https://perimetermed.com/security/ for more information on Coordinated Vulnerability Disclosure.

Table 12: Claire OCT System Troubleshooting

Irregularity Description	Possible Cause	Solution
The Claire OCT System Software User Interface does not launch	Did not login in properly.	Login to the Claire OCT System using a valid username and password.
No specimen visible in Specimen Photographs	No specimen loaded.	Refer to Chapter 3: Operator Workflow for specimen loading details.
	Problem with Specimen Photograph data	Contact Perimeter for support.
Live Specimen View preview blank (or not as expected)	Problem with Specimen Photograph camera	Contact Perimeter for support.
WF-OCT Images blank (or not as expected)	OCT system issue	Contact Perimeter for support.
The computer runs slowly or crashes	Hard drive full	Contact Perimeter for support.
Desired imaging area is outside available scan area	Incorrect scan area selection or specimen positioning.	Reposition specimen and rescan the same specimen side.
Irregular device noise during WF-OCT Image acquisition.	Device maintenance required.	Power down the device immediately. Contact Perimeter for support.

Device Prompts

If additional troubleshooting assistance is required, please contact Perimeter.

Table 13: Device Prompts

Prompt	Seen When	Meaning
Seat Specimen Tray	After selecting **Next** on the Patient Information Screen	The Specimen Tray must be seated on the Specimen Tray Dock before continuing through the workflow.
Device Initializing	After the Specimen Tray has been seated properly	Internal device components are preparing for image acquisition. Do not interact with the device during initialization.
Issue with System Calibration	During application launch i.e., after login	System configuration issue. Cannot continue using the Claire OCT System until the issue is resolved. Contact Perimeter for support.
Disk at 75% (or more) Capacity	When the application is launched. When a **New** case is started. When a Scan is added.	The hard drive is nearing capacity. Delete old cases that are no longer needed. Cases can be deleted by accessing them in the Case List Screen.
Disk at 100% Capacity	When the application is launched. When a **New** case is started. When a Scan is added.	The hard drive is full, please delete data. Contact Perimeter Service for data backup support.
Delete Case	When delete Case is selected	To confirm the deletion of a Case, tap OK. To continue without deleting, tap Cancel.
Confirm Stop	When **Stop Scan** is selected on the software user interface	To confirm, tap OK. To continue with the scan, tap Cancel.
Motion System Error	During launch or login	The internal motion system components are not turned on

Prompt	Seen When	Meaning
		and/or may not be working correctly. Contact Perimeter for support.
External Camera Error	During launch or login	The Specimen Photograph camera is not turned on or may not be working correctly. Contact Perimeter for support.

Summary of the Claire OCT System Workflow

WARNING: This section summarizes the basic safe operation of the equipment. Please review the entire manual thoroughly before using the device. Please refer to the main body of the user manual for additional detail on all steps summarized below. Device use is limited to users trained by Perimeter personnel only.

1	Position and plug in the device. Turn on the power switch. Connect vacuum tubing.
2	Press the power button to turn on the device.
3	When the login screen appears enter the user credentials.
4	On the Home Screen, select **New**.
5	Enter patient information and select **Save.**
6	Open a new Single-Use Specimen Immobilizer. Secure the Specimen Tray on the Specimen Tray Dock and rotate into position. **WARNING: DO NOT place specimen directly on the Imaging Gate.** **CAUTION: DO NOT touch or place any items directly on the Imaging Gate.**
7	Wait for the system to initialize.
8	Carefully place the specimen on the Imaging Window, taking care to position the specimen properly.

9	Adjust the vacuum level using the vacuum control (as desired). Stabilize the specimen by holding through the transparent bag of the Specimen Lid. Press Specimen Lid down onto secured Specimen Tray to initiate vacuum suction.
10	Enter specimen information and select **Start Scan**.
11	Once scanning is complete**,** remove the Specimen Lid.
12	Select **Add Scan** and reposition the specimen to start another scan.
13	Remove the specimen from the device when scanning is complete.
14	Review the acquired WF-OCT Images. Place annotations and/or export data, if desired.
15	Remove the Specimen Tray from the device. Dispose of the Specimen Tray and Specimen Lid according to facility procedures. **CAUTION: Single-Use Specimen Immobilizers are not re-usable.**
16	Export data to portable media, if desired.
17	Select **Log Out** to exit the Claire OCT System application.
18	Press the power button on the side of the device.
19	Turn off the power switch at the back of the device.
20	Clean and disinfect the Claire OCT System.
21	Disconnect the vacuum tubing from the device.
22	Unplug the power cable and wrap it around the power cable storage hooks.

Chapter 7: Clinical Data Summary

This section summarizes the results from the safety and effectiveness assessment for the Claire OCT System.

Summary of Clinical Safety

A pivotal clinical study was conducted to assess the safety and effectiveness of the Claire OCT System in reducing unaddressed positive margins in breast lumpectomy procedures when used with standard intraoperative margin assessment (NCT05113927). The study was performed under approved investigational device exemption (IDE) G210177. A summary of the clinical study is presented below.

Clinical Endpoints

Effectiveness Endpoints

The primary endpoint, the occurrence of at least one unaddressed positive margin for a subject, was evaluated to detect a clinically favorable change following the adjunctive use of the Claire for participants undergoing a standard lumpectomy procedure. The study measured a within-subject comparison, enabling any change in the final margin status between the completion of SOC and the completion of device use to be directly attributed to supplemental device use. This endpoint required complete resection of all residual diseased margins in a given participant after device use.

The secondary endpoints evaluated the number of unaddressed positive margins per participant and the number of false-positive shaves per participant associated with the adjunctive use of the Claire. In addition, margin-level and subject-level effectiveness of clinical decisions aided with Claire were evaluated.

Effectiveness endpoints are a representation of the clinical utility (ie, effectiveness measures of clinical decisions aided by the Claire, rather than a measure of the standalone performance of the device).

Safety Endpoints

Safety was reported on all subjects enrolled, including the roll-in training phase (during which OCT interpretation and device use was practiced under sponsor guidance) and Parts A and B. Adverse events were assessed by recording all adverse events for the duration of the study and then analyzing by seriousness, severity, and device procedure-relatedness. Pre- and post-operative satisfaction with breasts was measured using the Satisfaction with Breasts subscale score of the BCT module of the patient-reported outcomes measurement instrument BREAST-Q.

Additional Reporting

Tissue volume excised during the initial BCS, re-excision rate, and operative time duration were measured.

Safety and Effectiveness Results

The safety analysis was conducted using a comprehensive Safety Set that included 613 participants from the control arm (n =163), device arm (n =317), and training set (n = 133).

Adverse Events

The incidence of adverse events (AEs) was comparable across groups (27.8%, 28.4%, and 30.7% in the training set, device arm, and control arms, respectively). Most reported AEs were minor, transient, and expected (eg, localized discomfort, mild post-operative pain), consistent with AE rates observed in standard BCS procedures. None of these AEs were reported as related to Claire OCT System use.

Serious Adverse Events

Serious adverse events (SAEs) were rare (< 1.2%) across all study arms, with none attributed to the device. Seven SAEs were reported among the 613 participants in the safety population. In the control arm, one participant experienced a sudden, unexpected death unrelated to the device or the BCS procedure, while another experienced neutropenic fever and a COVID-19 infection. In the roll in training portion, one participant developed a breast infection due to a BCS complication, which was unrelated to device use. In the device arm, three SAEs were reported: breast abscess related to BCS, an acute kidney injury unrelated to the study, and a pneumothorax associated with a prior CPAP study.

Unanticipated Device Effects

No unanticipated device effects (UADEs) were reported during the study.

Procedure-Related Adverse Events

Procedure-related AEs associated with BCS were reported in 31 participants (23.3%) in the training group, 75 participants (23.7%) in the device arm, and 40 participants (24.5%) in the control arm. These events highlight the expected incidence of AEs directly related to the lumpectomy surgical procedure.

Satisfaction with Breasts using BREAST-Q (Cosmesis Outcomes)

Patient-reported BREAST-Q was surveyed across all consented participants. While no formal statistical tests were conducted to assess the significance of these cosmesis outcomes differences from the survey, descriptive statistics provide an overview suggesting the device aid did not negatively impact patient satisfaction scores.

Primary Effectiveness Endpoint

In the full analysis set (FAS) (N=206), at least one unaddressed positive margin was identified in 35 participants following SOC procedures and in 28 participants after the completion of SOC and device procedures (Table 14). This result demonstrates that the use of the device facilitated the detection and complete removal of excisable residual diseased margins that would have been missed by SOC alone

in seven participants, representing an absolute reduction of 3.4%, a relative reduction of 20.0%, and an overall positive change in clinical outcome.

Table 14. Participants With At Least One Unaddressed Positive Margin (Full Analysis Set, N=206)

	Device Arm (N = 206)			
	After SOC	**After SOC + Device**	**Absolute Reduction**	**Relative Reduction**
≥ 1 Unaddressed Positive Margin[a]	35 (17%)	28 (13.6%)	7 (3.4%)[b]	7/35 (20%)
0 Unaddressed Positive Margins	171 (83%)	178 (86.5%)		

[a] According to NCCN and SSO/ASTRO guidelines.
[b] P = 0.005 (Exact Binomial Test; alpha 0.025)

The calculated p-value for this test was 0.0050 (Exact Binomial Test, alpha 0.025) and was statistically significant with 95% CI (1.38%, 6.88%). This test evaluated the null hypothesis that the probability of a FAS participant having at least one unaddressed positive margin after SOC treatment but none after SOC combined with the Claire (SOC+DEVICE) was less than or equal to the performance goal of 1% (0.01), against the alternative hypothesis that it was greater than 0.01. Therefore, the difference in unaddressed positive margins was statistically significant using this test and the performance goal was met for the primary endpoint.

Additional clinical benefit was noted that was not captured in the statistical analysis of this endpoint, due to the narrow definition of an unaddressed positive margin by histopathology (defined using NCCN and SSO/ASTRO guidelines) and protocol specifications (Table 15).

Two additional surgical cases had the potential to meet this endpoint criterion and provide additional clinical value; however, extraneous situations prevented this outcome. In both instances, residual disease was undetected during the SOC assessment portion of the BCS, but was correctly detected by the surgeon with device-aid. In one instance, no further tissue could be excised from the diseased orientation, thus classifying the case as "addressed" by protocol definition. The other case was a major protocol violation in which the surgeon misunderstood the parameters surrounding the maximum number of shaves that were permitted to be excised with device-aid, resulting in a subsequent shave to not be excised, despite the surgeon classifying the margin as "positive" with device-aid.

It is noteworthy that at least six patients who were classified in the false positive group had shaves containing disease that did not meet criteria for positive classification. However, in all of these instances, the previous margin was negative for disease. As such, these device-directed shaves resulted in the removal of disease that would have otherwise remained undetected in the body cavity. By protocol classification system, these shaves cannot be classified as True Positive because the previous margin was reported to be negative by pathology. Lumpectomy specimens are representatively sampled in 10–40 small slides, thereby characterizing only 0.007 –0.02% of the entire volume of resected tissue.[1]

Furthermore, four additional surgical cases narrowly missed the primary endpoint. In these four cases, surgeons correctly identified disease with the device aid in close margins, defined as less than 1 mm from the inked surface. This includes one case with residual disease at 0.1 mm. These four participants had no other positive residual margins and would have otherwise met the primary endpoint. These additional cases demonstrate clinical value not captured in the primary endpoint, but indicate a benefit to the patient

[1] Clarke GM, Zubovits JT, Katic M, Peressotti C, Yaffe MJ. Spatial resolution requirements for acquisition of the virtual screening slide for digital whole-specimen breast histopathology. *Hum Pathol.* 2007;38(12):1764-1771.

in that residual disease was appropriately detected with adjuvant use of the Claire.

Table 15. Overall Clinical Benefit[a] of Claire Use (Full Analysis Set, N=206)	
	Number of Participants
Participants with all residual disease[b] addressed with adjunctive use of Claire	7
Participants with all residual disease detected with adjunctive use of Claire, but not excised: ● Additional tissue unable to be excised from 1 participant ● Tissue not excised due to protocol violation from 1 participant	2
Participants with residual cancer removed in the outer shave (excised with use of Claire) and a negative interior margin upon SOC completion.	6
Participants with extremely close final margin(s) (i.e., any DCIS/IDC present ≤ 1mm)	4
Total number of participants who received clinical benefit from adjunctive use of Claire	**19**

[a] Clinical benefit is defined as the detection of residual disease using the Claire that was otherwise undetected by intraoperative SOC modalities and/or final histopathology assessment.
[b] Residual disease is defined as a positive margin after completion of SOC intraoperative margin assessment (prior to Claire use)

Secondary Effectiveness Endpoints

Secondary Endpoint 1: Number of Unaddressed Positive Margins

In the full analysis set (N=206), the numbers of unaddressed positive margins per participant were:

- After SOC only: mean 0.27 ± 0.74 and median 0.0 (0, 5)
- After SOC + DEVICE: mean 0.23 ± 0.71 and median 0.0 (0, 5)

The difference in mean number of unaddressed positive margins per participant, between groups, was 0.044

The difference in mean number of unaddressed positive margins per participant, between groups, was 0.044. **Table 16** presents the number of participants who had between one and six unaddressed positive margins after standard of care (SOC) alone, compared to after SOC + Device.

Table 16. Frequency Distribution of Unaddressed Positive Margins							
	0	**1**	**2**	**3**	**4**	**5**	**6**
After SOC (35 subjects)	171	24	5	4	0	2	0
After SOC + Device (28 subjects)	178	18	5	3	0	2	0

Secondary Endpoint 2: Number of False-Positive Shaves

This result applies only when the device is applied after SOC and number of shaves per orientation restricted to 2 and at most 6 per subject. In the full analysis set (N=206), 173 participants (84%) had one or more false-positive shaves collected within the SOC intraoperative margin assessment portion and 67 (32.5%) participants had one or more false-positive shaves collected as a result of device use.

The numbers of false-positive shaves per participant were:

- After SOC only : mean 2.2 ± 1.7 and median 2.0 (0, 11)
- After SOC + DEVICE: mean 2.7 ± 1.8 and median 3.0 (0, 11)

The difference in mean number of false-positive shaves per participant, between groups, was 0. 5 (indicating that adjunctive use of the device contributed on average 0.5 false positive shaves per participant.

Secondary Endpoint 3: Margin-Level Effectiveness of the Clinical Decisions Aided with Claire per NCCN and SSO/ASTRO Guidelines

While the primary endpoint examined the supporting role of the device in clearing a patient of all residual margins of disease, this endpoint examines each margin independently. Sixteen diseased margins out of 65 residual diseased margin opportunities (25%) were correctly identified with device-aid, while 105 margins (7.9%) were flagged as being suspicious using the device, but did not contain disease per pathology. 49 diseased margins (3.7%) were undetected by the clinician with device-aid and 1160 margins (86.9%) showed concordance between pathology and clinician assessed with device-aid as having no disease.

Six (6) additional margins were deemed suspicious based on OCT imaging. However, subsequent histopathology margin assessments, following protocol criteria aligned with National Comprehensive Cancer Network (NCCN) and Society of Surgical Oncology (SSO)/ American Society for Radiation Oncology (ASTRO) guidelines, did not classify these margins as positive. In these cases, disease was present within 2mm, which correctly correlated with OCT imaging findings, demonstrating concordance between imaging, clinician interpretation, and histopathological findings.

Secondary endpoint analysis of margin-level effectiveness of clinical decisions aided by the Claire, based on NCCN and SSO/ASTRO guidelines includes 1,335 device-assessable margins from the full analysis set, assessing concordance between OCT imaging and histopathology (Table 17).

Table 17. Secondary Endpoint: Margin-Level Effectiveness Based on NCCN and SSO/ASTRO Guidelines (Full Analysis Set, N=206)

Endpoint	Value
True Positives	16 (1.2%)
False-Positives	105 (7.9%)
False Negatives	49 (3.7%)
True Negative	1160 (86.9%)
Missing Positive[a]	0
Missing Negative[a]	5 (0.4%)
Accuracy[b]	88.1% (95% CI: 85.9, 90.2).
Sensitivity[c]	24.62% (95% CI: 14.47, 36.84)
Specificity[c]	91.34% (95% CI: 89.39, 93.20)
Youden's J Statistic	15.95% (95% CI: 5.79, 27.95)
PPV (Positive Predictive Value)	13.22% (95% CI: 7.02, 20.18)
NPV (Negative Predictive Value)	95.95% (95% CI: 94.15, 97.51)

[a] "Missing" indicates that no OCT images were collected for surgeon interpretation

[b] Post-hoc analysis of the accuracy was performed with accuracy as an additional measure of margin-level effectiveness of clinical decisions aided with Claire, with the following definition in the full analysis population (FAS), where T=true, F=false, M=missing, P=positive, and N=negative.

$$\textit{Clinical decision accuracy} = (TP+TN)/(TP+TN+FN+FP+MP+MN)$$

[c] This does not represent true (per margin) sensitivity or specificity of device standalone performance, but instead is a measure of clinical decisions aided with the device after SOC was completed.

Secondary Endpoint 4: Subject -Level Effectiveness on Final SOC Margins with Ground Truth Based on NCCN and SSO/ASTRO Guidelines

The clinical decision aided by Claire for a participant was positive, negative, or missing based on the completeness of the data for the six final SOC margins. This endpoint can be considered a "GO/No GO" assessment of whether the device correctly identified all the diseased margins that had residual disease after completion of SOC. It is important to note that if any diseased margin was missed upon review with the device, that this is considered a false negative (FN), even in instances where some disease was correctly identified using the device.

The subject-level effectiveness of clinical decisions aided with Claire for the final SOC margins in the full analysis set (n=206), assessed according to NCCN and SSO/ASTRO guidelines, demonstrated a sensitivity of 27.03% and a specificity of 64.50%, with a negative predictive value (NPV) of 80.15% and a lower positive predictive value (PPV) at 14.71% (Table 18). This indicates the correct clinical decision was made using the Claire to excise additional tissue in 10 out of 37 participants. Residual disease was detected in an additional four patients, but are not considered true positives (TPs), as only some of the diseased margins were correctly detected using the device. In addition, two of the FN cases had no further action possible, so the device could not provide clinical benefit. Of the 35 patients with actionable residual diseased margins after completion of SOC margin assessments, 14 of these were identified as such by the clinician with aid of the device (40%).

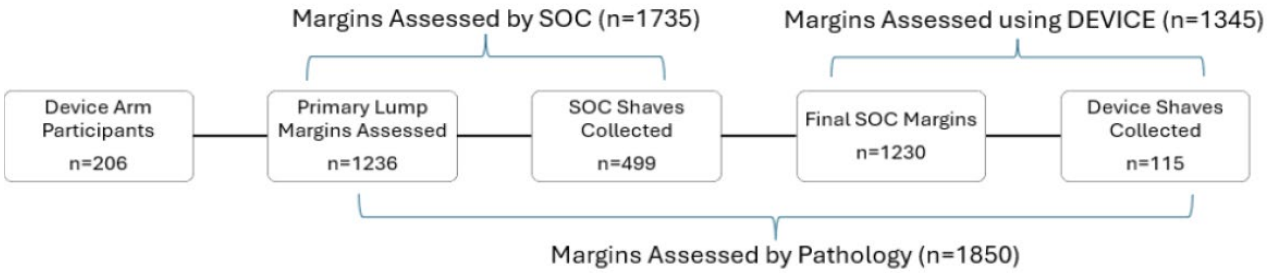
Table 18. Secondary Endpoint: Subject-Level Effectiveness on Final SOC Margins with Ground Truth Based on NCCN and SSO/ASTRO Guidelines (Full Analysis Set, N=206).

Endpoint	Value
True Positives	10 (4.9%)
False-Positives	58 (28.2%)
False Negatives	27 (13.1%)
True Negative	109 (52.9%)
Missing Positive	0
Missing Negative	2 (1.0%)
Sensitivity[a]	27.03% (95% CI: 13.79, 44.12)
Specificity[a]	64.50% (95% CI: 56.78, 71.69)
Youden's J Statistic	-8.48% (95% CI: -24.50, 7.55)
PPV (Positive Predictive Value)	14.71% (95% CI: 7.28, 25.39)
NPV (Negative Predictive Value)	80.15% (95% CI: 72.45, 86.49)

[a] This does not represent true (per subject) sensitivity or specificity of device standalone performance, but instead is a measure of clinical decisions aided with the device after SOC was completed.

Clinical effectiveness of SOC intraoperative assessments are shown with and without adjunctive device use for the subset of margins (N=1,735) that were evaluated by both the device and SOC modalities (**Figure 45**). As Claire serves as an adjunct or additive technology to current SOC margin assessments methods, a combined this analysis shows the impact of this additional tool on intraoperative assessment performance.

Figure 45. Schematic of Margins Assessable by SOC, Device, and Pathology, Full Analysis Set



This schematic outlines the assessment of surgical margins in the Claire Device Arm, Full Analysis Set (N=206). A total of 1,236 primary BCS margins were assessed, with 499 SOC shaves collected. After Final SOC margin assessment (n=1,230), an additional 115 shaves were evaluated using the device, bringing the total margins assessed by pathology to 1,850. Margins were categorized based on evaluation by SOC (n=1,735) and the Claire (n=1,345).
Note: 10 margins were not assessed using the Device due to no further action possible (NFAP), bringing the total number of margins assessed using the Device to 1,335.

The SOC + Device Aid analysis reflects the combined performance of SOC assessment followed by device-assisted evaluation. Margin assessments of the primary specimen and interior shaves were determined using SOC methods, whereas evaluation of the outermost margins incorporated

the Device Aid. This analytical approach mirrors the protocolized serial use of SOC followed by the Device Aid during the pivotal clinical study.

Intraoperative SOC assessment alone had a margin sensitivity and specificity of 48.7% and 72.1% respectively. Intraoperative SOC assessment, followed by device-aided evaluation, accurately detected 72 of 117 diseased margins, resulting in a combined sensitivity of 61.5%, a 12.8% improvement with adjunctive device use (**Table 19**). The modest decrease in specificity observed with supplemental after addition of the device aid following to intraoperative standard-of-care (SOC) assessment is consistent with its use in a serial manner, as adjunctive device assessment can only result in additional tissue excision and cannot reduce the number of margins already excised during the SOC portion of surgery. and the device aid's margin specificity of 91.34%. Because the device was applied after completion of SOC evaluation, only additional tissue excision could occur; thus, refinement of SOC specificity was not possible with device-aid. Additionally, histopathology confirmed that 117 of the 1,735 final SOC margins were diseased (6.7%), resulting in minimal opportunities to detect residual disease with device use.

Table 19. Per-Margin Clinical Effectiveness Performance on Final SOC Margins (N=1,735 Margins)

	Per-Margin Effectiveness Performance							
	Sensitivity(%)	**Specificity(%)**	**PPV(%)**	**NPV(%)**	**TP**	**TN**	**FP**	**FN**
SOC (N=1,735)	48.7 (95% CI: 39.7, 58.2)	72.1 (95% CI: 70.1, 74.2)	11.2 (95% CI: 8.0, 14.7)	95.1 (95% CI: 93.3, 96.7)	57	1167	451	60
SOC + Device Aid[a] (N=1,725)[b]	61.5 (95% CI:53.1, 70.8)	65.89 (95% CI: 64.5, 68.1)	11.6 (95% CI: 8.5, 14.9)	95.9 (95% CI: 94.2, 97. 5)	72	1059	549	45
Difference	+12.8	-6.2	+0.4	+0.8	+15	-108	+98	-15

PPV = Positive Predictive Value ; NPV = Negative Predictive Value; TP = True Positive; TN = True Negative; FP = False Positive; FN = False Negative
[a] Represents a metric of surgeon clinical decision-making aided by the Claire OCT system.
[b] Note: 10 margins were not assessed using the device due to no further action possible due to anatomical constraints such as skin or fascia and were therefore removed from the combined performance metric.

Additional Reporting

Several additional analyses were performed for all participants who completed BCS in the full analysis population.

Tissue Volume Excised

The mean total tissue volume excised during the index BCS was 74.0 ± 74.2 cm^3, with a median of 54.4 cm^3 (range: 5.0-690.60 cm^3) (Table 20).

Table 20. (CSR Table 16-1 REVISED) Tissue Volume Excised Per Participant During the Index Surgery, Full Analysis Set (n=206)

Device Arm (SOC + Device)	Mean ± SD (per participant)	Median (Min, Max) (per participant)
Total Tissue Volume per SOC + Device	74.0 ± 74.2	54.4 (4.9, 690.6)
Primary Lump Tissue Volume	56.5 ± 66.4	37.4 (4.4, 634.2)
SOC Shave Tissue Volume	14.7 ± 16.9	9.0 (0.0, 104.7)
Device-aided Shaves Tissue Volume	2.8 ± 6.7	0.0 (0.0, 56.4)
Total per SOC+Device: participants who underwent additional oncoplastic closures or reductions during surgery*	169.6 ± 166.9*	103.1 (18.6, 690.6)*

All data are presented as cm³
Means are calculated as an average among the 206 subjects.
**Note: This line item was assessed only for participants who underwent additional oncoplastic closures or reductions during surgery (n=15 patients)*

During the index BCS procedure, adjunctive use of the Claire accounted for a mean volume of only 2.8 cm³, representing 4% of the total excised volume, whereas SOC shaves contributed a mean volume of 14.7 cm³, or 20% of the total (Table 21). Furthermore, the mean number of shaves collected with the device was 0.6, compared to 2.4 shaves with SOC alone.

Table 21. Total Tissue Volume Excised During the Index Procedure

	Primary Lump	SOC Shaves	Device Shaves	Total Tissue Volume
Total volume per participant, %	76.3%	20.0%	4.0%	100%
Mean number of shaves collected	N/A	2.4	0.6	N/A

Post-Hoc Tissue Excision Comparison

Examination of the tissue volume of the shaves collected per participant during the initial surgery shows that the shaves excised per SOC intraoperative margin assessment accounted for 82.0% (95% CI: 78.1%, 85.8%) of the total volume of shaved tissue. Additionally, the mean number of shaves excised per SOC intraoperative margin assessment per participant accounted for 80.1% of the total number of shaves excised per participant (95% CI: 76.2%, 83.9%).

Operative Time Duration

The surgical duration, defined as the time from first incision to completion of skin closure, was recorded for all participants. The mean operation time was 87.7 ± 39.68 minutes, with a median of 79.5 minutes (range: 13-330 minutes), reflecting the expected variability in procedure length.

Re-excision Procedures

During the follow-up period (after the index surgery and prior to collection of the post-operative BREAST-Q), 23 participants (11.2%) underwent additional surgical procedures. Of these, 19 participants (9.2%) required a re-excision lumpectomy, and one participant (0.5%) underwent a mastectomy. Other procedures included sentinel lymph node biopsy in three participants (1.5%) and breast reconstruction in one participant (0.5%).

For participants diagnosed with DCIS with margin widths of ≤2 mm or IDC on ink (0 mm) who did not undergo re-excision, alternative management strategies were implemented, including adjuvant therapy.

Additional Post-Hoc Analyses

Standalone ImgAssist Performance

A post-hoc analysis was conducted to evaluate the standalone performance of the ImgAssist 2.0 model based strictly on device output, without clinician interaction. Performance was evaluated against SSO/ASTRO ground truth to define margin status.

For the purpose of this standalone calculation, a margin was classified as positive if it contained one or more AI-detected suspicious clusters. It is important to note that this assumption does not reflect the intended use of the device. The ImgAssist feature is a decision-support tool designed to flag suspicious features to augment the surgeon's judgment, rather than an autonomous diagnostic system.

The standalone analysis evaluated a total of 1,830 margins. This differs from the 1,735 margins evaluated in the clinical study report for the clinical effectiveness of Standard of Care (SOC) intraoperative assessments evaluated by both the device and SOC modalities. The total number of margins assessed by pathology was 1,850. For the standalone analysis, this original total of 1,850 margins was reduced by excluding 20 margins due to protocol deviations, labeling errors, or a lack of actionable tissue, resulting in 1,830 margins available for assessment. The difference arises because the standalone dataset includes cases where the device captured the data and standalone performance could be calculated, even if the surgeon's reads (SOC evaluations) were not available. Refer to **Table 22** for the analysis of all margins.

Table 22. ImgAssist Standalone Margin-Level Performance, All Margins (N=1,850)

	0.75 Threshold	**0.925 Threshold**
True Positives	106 (5.7%)	54 (2.9%)
False Positives	1283 (69%)	518 (28%)
False Negatives	14 (0.8%)	66 (3.6%)
True Negatives	427 (23%)	1192 (64%)
Missing Negative	18 (1.0%)	18 (1.0%)
Missing Positive	2 (0.1%)	2 (0.1%)
Sensitivity	88% (95% CI: 81,93)	45% (95% CI: 36,54)
Specificity	25% (95% CI: 23,27)	70% (95% CI:67,72)

For the analysis of Final SOC margins and Device Shaves (**Table 23**), a total of 1,335 margins were available with five negative margins (0.38%) missing because OCT imaging was not collected in accordance with the study protocol for a total of 1,330 margins.

Table 23. ImgAssist Standalone Margin-Level Performance, Final SOC & Device (N=1,335)		
	0.75 Threshold	**0.925 Threshold**
True Positives	55 (4.1%)	28 (2.1%)
False Positives	915 (69%)	360 (27%)
False Negatives	10 (0.7%)	37 (2.8%)
True Negatives	350 (26%)	905 (68%)
Missing Negative	5 (0.4%)	5 (0.4%)
Sensitivity	86% (95% CI: 79, 92)	44% (95% CI: 35, 53)
Specificity	25% (95% CI: 23, 27)	70% (95% CI: 68, 72)

Breast Density Proxy Analysis

Information regarding patient breast density was not a required data point in the study's data collection protocol and was therefore not collected nor available for a direct subgroup analysis. However, an age-based subgroup analysis as a proxy for breast density, given the strong inverse correlation between age, menopausal status and mammographic density was performed.

The analysis stratified patients into three physiologically distinct age groups: ≤50, 51–64, and ≥65, and assessed performance at both the margin and subject-levels.

The average age of menopause is 51.[20] Epidemiological studies often use the simple binary of cutoff of 50 as a proxy for menopausal status when precise hormonal or menstrual data is unavailable.[21] The ≤50 age group captures the pre-menopausal group. The 51-64 group contains the menopausal group. Lastly, the ≥65 age group contains a distinct non-hormonal postmenopausal group during which lobular involution is largely completed. A large percentage of women over 65 have reached the protective stage of complete involution, which is a major physiological shift from the 51−64 group.[22]

Efficacy outcomes within these subgroups were assessed using descriptive statistics, particularly as this sub analysis contains small sample sizes and/or skewed data sets.

Subject-Level Device-Aided Effectiveness

Subject-level performance of the device-aided clinical assessments are reported in **Table 24**.

Table 24. Subject Level Device-Aided Effectiveness, Final SOC Margins (N=206 subjects)

Age Cohort	TP	TN	FP	FN	Sensitivity	Specificity
≤50 (n=36)	1	21	11	3	0.250 (0.000 – 0.674)	0.656 (0.492 – 0.821)
51-64 (n=74)	2	34	26	11	0.154 (0.000 – 0.350)	0.567 (0.441 – 0.692)
≥65 (n=96)	7	54	21	13	0.350 (0.141 – 0.559)	0.720 (0.618 – 0.822)

Margin-Level Device-Aided Effectiveness

An additional analysis at the margin-level for device-aided clinician assessment using the OCT+AI System is shown in **Table 25**, using these same age cohorts.

Table 25. Summary of Margin-Level ImgAssist Performance Metrics Stratified by Age Cohort (Part B Device Arm, N=206 patients)

Age Cohort	TP	TN	FP	FN	Sensitivity	Specificity
≤ 50 Years (Pre- and peri-menopausal women)	2	206	14	8	0.200 (0.000 – 0.448)	0.936 (0.904 – 0.969)
51–64 Years (Early-to-mid post-menopausal women)	3	415	43	18	0.143 (0.000 – 0.293)	0.906 (0.879 – 0.933)
≥ 65 Years (Older or "late" post-menopausal women)	11	539	48	23	0.324 (0.166 – 0.481)	0.918 (0.896 – 0.940)

The analysis of both the Subject-Level Device-Aided Effectiveness and the ImgAssist standalone performance (**Table 23** and **Table 24**) revealed no clinically meaningful difference in sensitivity or specificity between the age cohorts.

Conclusions Drawn from Preclinical and Clinical Studies

Effectiveness Conclusions

Following primary SoC, the number of participants with residual positive margins leaving 54 participants with positive margins (26.3% of the total). Subsequent SOC intraoperative margin assessment and subsequent shaves collected during the SOC portion of the surgery resulted in a further reduction of 35.2%, leaving 35 participants with residual positive margins (17% of the total) who could potentially benefit from adjunctive use of the device. Per protocol design, the device was used after completion of SOC assessment resulting in a

final decrease in the number of participants with residual disease from 35 to 28 (13.6% of the total). This represents a 3.4% absolute reduction and a 20% relative reduction in the number of participants with unaddressed positive margins who were subsequently converted to having no residual diseased margins after device use.

Use of the Claire OCT System resulted in the detection and removal of residual positive margins that were missed by SOC alone in 7 participants (**Figure 46**).

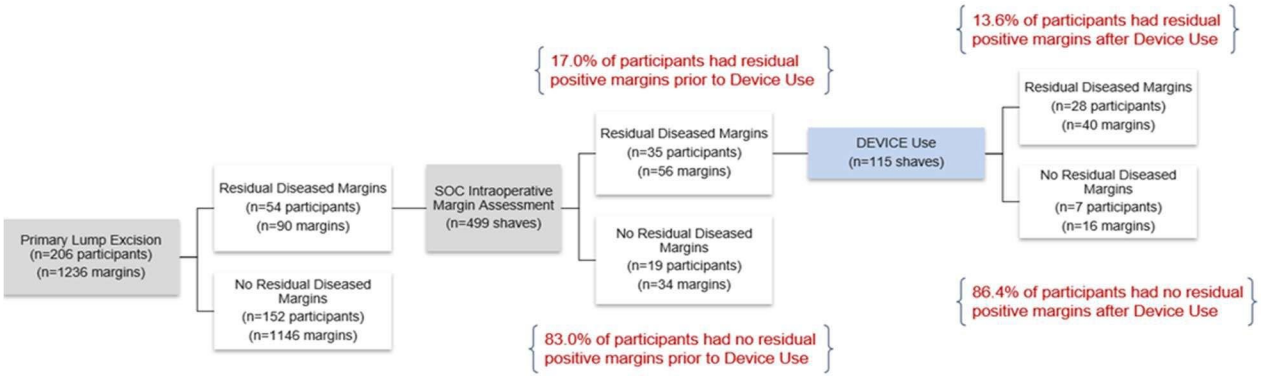


Figure 46. Reduction in Residual Diseased Margins within each Assessment Portion During BCS (FAS, N=206)

The reduction in residual positive margins observed in the study has significant implications for the adjuvant use of the device. By identifying and facilitating the removal of residual disease that would have otherwise remained in the body cavity after completion of the SOC surgery, the device effectively lowers the likelihood of positive margins in the surgical site. This reduction suggests that the device plays a key role in ensuring more thorough margin clearance, which is crucial for minimizing the risk of local recurrence of disease and lessening the residual disease burden for patients.

The performance metrics are a measure of the clinical decisions aided with Claire and are not a measure of standalone device performance. The performance metrics of the device-aided clinical decisions support its use as a complementary tool to SOC, providing a significant reduction in residual disease and potentially lowering re-excision rates in breast-conserving surgeries. For a more robust measure of clinical benefit, device use was isolated in the clinical trial setting so as to be able to attribute all post-randomization shaves excised directly to the device.

Of the 35 patients with residual diseased margins after completion of SOC margin assessments, 14 were identified as such by the clinician with aid of the device (40%). This equated to the correct device-aided detection of 16 diseased margins across 14 participants that were undetected via SOC modalities alone, resulting in 88.1% margin-level accuracy and an increase of 12.8% in sensitivity for the detection of residual disease at the margin with adjuvant device use. The study design required SOC to be completed prior to device use. As such, the device use and subsequent clinical effectiveness was limited to a small number of residual margins that were missed by existing SOC margin assessment modalities.

Moreover, there were six participants who had additional shaves attributed to device use that subsequently contained residual disease. These shaves could not be considered true positive (TP) by definition, as the previous margin was reported to be negative by pathology (primary lump clear from

disease, residual disease reported in the subsequent shave). However, excision of the additional tissue resulted in the removal of cancer that would otherwise have remained unaddressed in the body cavity, including disease identified at the specimen surface by the surgeon with the device aid and pathologic findings in five patients (six margins) with disease present within 2 mm margins, but did not contribute to the primary endpoint or margin effectiveness analysis due to the margin criteria used in the trial protocol (NNCN and SSO/ASTRO Guidelines).

Safety Conclusions

The risks of the device are based on non-clinical laboratory studies as well as data collected in clinical studies as described in this IFU.

The adjunctive device demonstrated a favorable safety profile with no unanticipated device effects (UADEs). Serious adverse events (SAEs) were rare, with none attributed to the device. Procedure-related AEs, typical in breast conserving surgery, occurred in 23.7% of the device arm participants. Overall, the device demonstrated a safety profile comparable to SOC, with no major device-related issues.

Patient-reported satisfaction with the surgery, measured by the BREAST-Q, showed with no significant differences between the device, control, and training groups.

Device use contributed 4% to the total tissue volume excised.

Regarding the number of unnecessary shaves (false positives) that were excised as a result of device use, the average was 0.50 ± 0.23 shaves per patient. These unnecessary shaves had no impact on the distribution of adverse events nor on the patient-reported outcomes for cosmesis when comparing control and device arm participants. Overall, the device demonstrated a safety profile comparable to SOC, with no significant device-related complications or unanticipated adverse events.

Additional Reporting Conclusions

Re-excision Procedures

The use of the Claire device during breast cancer surgery resulted in significantly less tissue excision compared to SOC. The mean excised tissue volume with the device was 2.8 cm^3 (4% of the total), compared to 14.7 cm^3 (20%) with SOC. The mean surgery duration was 87.7 minutes, and 11.2% of participants required additional procedures, including 9.2% who underwent re-excision. SOC assessments led to the excision of 499 shaves across 206 participants. This resulted in the clearance of residual positive margins in 19 participants (34 margins), representing 7.0% (34/499) (Table 27). Conversely, 115 shaves were excised with device-aid, resulting in clearance of residual disease in seven participants (14 margins), yielding a success per shave ratio of 12.2% (14/115). Since device-aided shaves were excised after the completion of SOC assessments, they represent an incremental improvement in reducing residual disease.

Table 27. Comparison of Shave Attribution and Accuracy within the Device Arm (FAS, N=206)			
	Percent of Participants who had any Shaves during BCS	**Number of Shaves Excised**	**Number of TP Shaves Resulting in Cleared Margin**
SOC shaves	180 (87.4%)	499 (81.3%)	34 (7.0%)
Device-aided shaves[a]	76 (36.9%)	115 (18.7%)	14 (12.2%)

Values are presented as n (%); TP=True Positive

[a] Device-aided shaves were excised after the surgeon confirmed completion of SOC assessments during BCS.

There was notable variability in tissue volume excised across both sites and patients, ranging from 4.9 cm^3 to 690.6 cm^3. This variability suggests that surgical outcomes may be influenced by individual patient characteristics, surgical approach, and site-specific practices. Despite this variability, the device contribution consistently represented a small portion to the total excised tissue, with a mean volume of just 2.8 cm^3. Its performance reinforces its role in achieving effective, targeted tissue removal while reducing the need for further interventions.

Quick Start Guide

CLAIRE™ OCT QUICK START GUIDE

PERIMETER

This guide is an overview. Read the user manual for full instructions, symbol glossary, and safety information for full instructions.

1 Touchscreen Monitor
2 Articulating Monitor Arm
3 On/Off Button
4 USB Port
5 Specimen Tray Manifold
6 Rear Handle
7 Vacuum Port
8 Front Handle
9 Power Cable Storage Hooks
10 Ethernet Port
11 Power Port and Power Switch
12 Foot Brake

SET UP

- Position the device and apply the brake.
- Connect the power cable to the power port and a grounded supply main.
- Connect the vacuum tubing to the vacuum port and a central vacuum supply port.
- Turn on the power switch and press the On/Off button to power the system on.
- Log in with user credentials.
- The Claire OCT application will launch automatically.
- Select **New Patient** to begin a new case or select **Open Database** to view a list of previously acquired cases.

Images are for reference only. Actual appearance may vary.

CLAIRE™ OCT QUICK START GUIDE

NEW PATIENT

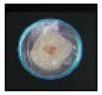
Enter patient information and select Save.

Unpackage a new, Single-use Specimen Immobilizer.

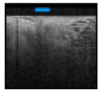
Install the Specimen Tray and wait for initialization to complete.

Center the specimen on the Imaging Window with the surface of interest toward the glass.

Use the Specimen Lid and the vacuum setting to secure the specimen against the Imaging Window.

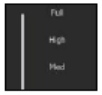


Enter specimen information (Body side, Tissue type, Side toward glass and Scan area are required to proceed) and select **Start Scan**.



Images can be reviewed and annotated as they appear: drag one finger up and down (scroll), pinch with two fingers (zoom) and drag with two fingers (pan).

Enable and use **ImgAssist** to review auto-detected regions of interest



Cancel an ongoing scan and/or turn off the vacuum at any point.

Once the scan is complete, finish review, annotate, edit case information, **Add Scan** to the case and/or export screenshot/case.

OPEN DATABASE

Search for entries in the case list, or sort them by any of the column headings.

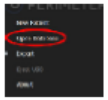
Delete a case by selecting the entry in the case list and selecting the trash can icon.

Select any case in the case list with a single tap, and open it with a double tap.

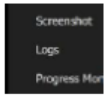
Once a case is open, review, use **ImgAssist**, annotate, edit case information, **Add Scan** to the case and/or export a screenshot.

MENU

The menu icon is found in the lower right corner of each screen (available menu options may vary on different pages).



Start a **New** case or return to the **Case List** at any time (any image information which has been collected is saved automatically).



Export data and/or logs, and check the progress of ongoing exports from the menu (case information is automatically anonymized prior to export)

Log out to close the software and return to the login page (if an export or scan is occurring, a prompt to confirm cancellation will appear).

SHUT DOWN

- Shut down the system, turn off the power switch, disconnect the power cable and the vacuum tubing.
- Remove and dispose of the single-use Specimen Immobilizer as biohazardous waste.
- Clean and disinfect all external surfaces of the system.
- There are no user-serviceable parts.

Manufacturer

Perimeter Medical Imaging AI, Inc.
555 Richmond Street West, Suite 511
Toronto, Ontario M5V 3B1
Canada

For technical support and service

Phone: 214-845-5154 ext. 2
Toll-free: 888-988-7465 ext. 2
Email: support@perimetermed.com

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