Gentuity® High-Frequency OCT Imaging System

User Manual

003907-EN Rev A
February 2023

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Any serious incident that has occurred in relation to the device should be reported to the manufacturer and competent authority of the Member State in which the user and/or patient is established.

The information contained in this document is subject to change without notice. Names and data used in examples are fictitious unless otherwise noted.

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Chapter 12: Glossary of Symbols

Chapter 1
Introduction

This chapter provides an introduction to the Gentuity® High-Frequency OCT Imaging System.

About this document

This document describes the Gentuity High-Frequency OCT Imaging System and includes:

- Descriptions of the system components and user interface
- Procedures for using the Optical Coherence Tomography (OCT) imaging system
- System safety and cleaning information
- System specifications

Indications for Use

The Gentuity® HF-OCT Imaging System with Vis-Rx® Micro-Imaging Catheter is intended for intravascular imaging and is indicated for use in coronary arteries in patients who are candidates for transluminal interventional procedures. The Vis-Rx Micro-Imaging Catheter is intended for use in vessels 1.3 to 6.0 mm in diameter. The Vis-Rx Micro-Imaging Catheter is not intended for use in a target vessel that has undergone a previous bypass procedure.

Contraindications

Contraindications for use of the Gentuity High-Frequency OCT Imaging System include:

- Bacteremia or sepsis
- Major coagulation system abnormalities
- Coronary artery spasm
- Severe hemodynamic instability or shock
- Total occlusion
- Large thrombus
- Acute renal failure
- Any target vessel which has undergone a bypass procedure
- Patients disqualified for CABG surgery
- Patients disqualified for PTCA

Safety Overview

This section lists safety-related information. For detailed safety-related information, see “Safety Information” on page 2-1.

Note — Before creating an OCT recording, review “Performing an HF-OCT Procedure” on page 6-1 for additional cautions and warnings.

Complications

The risks involved in vascular imaging include those associated with all catheterization procedures. The following complications (listed alphabetically) may occur as a consequence of intravascular imaging and may necessitate additional medical treatment including surgical intervention.

- Acute myocardial infarction or unstable angina
- Allergic reaction to the contrast media
- Arterial dissection, injury, or perforation
- Cardiac arrhythmias
- Coronary artery spasm
- Death
- Embolism
- Myocardial ischemia
- Renal insufficiency from contrast usage
- Thrombus formation

Intended Users

The device is intended to be used by physicians and technicians trained in the performance of catheter-based intracoronary interventional procedures. These physicians are interventional cardiologists. The interventional cardiologist will frequently be assisted by an interventional cardiology fellow, catheterization laboratory technician, or nurse.

Conventions Used in this Document

In addition to the traditional mouse and keyboard, the Gentuity High-Frequency OCT Imaging System uses a touchscreen for user interaction with the system.

The following conventions, abbreviations, and shortened expressions are used throughout this manual.

Table 1-1 Document Conventions

Item	Description
Select	If using the touchscreen, indicates touching the item on the screen to select it. If using the mouse, indicates clicking the left mouse button on the item to select it.
Drag	Moving an item on the screen by selecting it and dragging it to another location
Pinch Zoom	Moving two or more fingers together or apart on the touchscreen to zoom in and out on an image. You can also use the scroll wheel on the mouse to zoom in and out.
Pan	When the image is in a zoomed state, use your fingers to pan the image (move it around the screen).
On-screen text and button labels	Displayed in the documentation as bold type. For example, the **Patient List**, **Settings** icon, and so on.
SO **NSO**	In procedures where a sterile operator is required, **SO** and **NSO** preceding the step indicates who performs each step: Sterile Operator (**SO**) or Non-Sterile Operator (**NSO**).

Warning and Caution Conventions

The following conventions are used throughout this manual to highlight safety concerns:

WARNING! A warning indicates conditions, hazards, or unsafe practices that may result in injury or death.

CAUTION! A caution indicates conditions, hazards, or unsafe practices that may result in damage to the device, loss of data, or image misinterpretation.

Chapter 2
Safety Information

This chapter provides important safety information for using the Gentuity High-Frequency OCT Imaging System. For quick reference, this Safety Information chapter lists all of the warnings and cautions that are listed throughout the manual. Be sure to pay attention to the warnings and cautions as listed in the chapters that follow in the context in which they apply.

General Safety

To avoid potential hazards to patients, operators, equipment, and data loss, follow the warnings and cautions listed in this section and throughout the manual.

WARNINGS!

- The Gentuity High-Frequency OCT Imaging System is intended for use only by medical personnel trained in its operation and skilled in the clinical procedures to be used.
- Medical personnel who use the Gentuity High-Frequency OCT Imaging System must be aware of the system's limitations. Only trained operators can determine if the use of the Gentuity High-Frequency OCT Imaging System is appropriate.
- Always use controls, make adjustments, and perform procedures as specified in this User Manual.
- Always read and follow the *Instructions for Use* supplied with the Vis-Rx Micro-Imaging Catheter.

CAUTIONS!

- The system components are integral parts of the Gentuity High-Frequency OCT Imaging System. The Gentuity High-Frequency OCT Imaging System hardware and software must not be modified in any way by the user. Making such modifications may interfere with correct operation and will void system warranties. Contact your Gentuity service representative for more information.
- The Gentuity High-Frequency OCT Imaging System can only be connected to an external monitor that has been set up by Gentuity Support.
- The Gentuity High-Frequency OCT Imaging System can only be connected to angiography systems that have been set up by Gentuity Support.

Patient Safety

To avoid any potential hazard to patients, follow the warnings and cautions outlined in this section, in “Catheter Safety” on page 2-4, and throughout this manual.

WARNINGS!

- Appropriate anticoagulant and vasodilator therapy must be used during the procedure as needed.
- Refer to the contrast media’s instructions for general warnings and precautions relating to contrast media.
- The catheter is sterilized by irradiation and is intended for one time use only. Do not reuse, re-sterilize, or reprocess. Reuse or re-processing could result in a degradation of catheter material or patient infection.
- Non-pyrogenic. Do not use the catheter if the package is opened or damaged.
- Do not use the catheter after the expiration date, or if there is not a date on the package.
- Make sure to use the contrast media and injectors according to injection specifications given by the manufacturers. Excessive flow rate and inflow pressure may damage the blood vessel or devices used with the catheter. Low flush rate may result in a faint image.
- Prior to acquisition, make sure the flush medium identified in the **Pullback Settings** window matches the flush medium you are using. Selecting the wrong flush medium can cause measurement errors which could lead to incorrect treatment.

Note — Prior to use, please review the *Instructions for Use* supplied with the Vis-Rx Micro-Imaging Catheter for more information.

Operator Safety

To avoid any potential hazard to operators and patients, follow the warnings, cautions, and statements outlined in this section and throughout this manual.

Light Emission Hazards

This product has been determined under IEC 60825-1:2014 to be a Class 1 Laser Product.

VISIBLE AND INVISIBLE LASER RADIATION
CLASS 1 LASER PRODUCT
(IEC 60825-1: 2014)

Complies with 21 CFR 1040.10 and 1040.11 except for conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1, as described in Laser Notice No. 56, dated May 8, 2019

Moving the System

To avoid potential hazards to operators and equipment when moving the system, follow the warnings and cautions outlined in this section and throughout this manual.

WARNINGS!

- The system weighs up to 70 kg (154 lb). Use caution when moving the system.
- To avoid a potential tripping hazard and possible equipment damage, before beginning a system move, make sure the system is off, the system's power cord is disconnected from the wall outlet, and the power cord is secured on the cord wrap on the back of the system.
- To avoid a potential tripping hazard and possible equipment damage, position the PIM cable appropriately before moving the system.
- To eliminate the potential danger of the system tipping over, make sure that the system's wheels roll freely before beginning the move. Resolve any wheel problems before you move the system. Be sure the system brakes are in the up position (unlocked).
- To eliminate the potential danger of the system tipping over, avoid ramps that are steeper than 10 degrees. Wheelchair ramps usually have an incline of less than 5 degrees.
- To eliminate the potential danger of the system tipping over, use two people if you must move the system up or down ramps with an incline of more than 10 degrees.

Catheter Safety

To avoid any potential hazards to patients, operators, or equipment when using the Vis-Rx Micro-Imaging Catheter, follow the warnings and cautions outlined in this section, in "Patient Safety" on page 2-2, and throughout this manual.

WARNINGS!

- The catheter is intended for one time use only. Do not reuse, re-sterilize, or reprocess.
- Observe sterile technique when connecting the catheter to the PIM, which is outside of the sterile field.
- Observe all advancement and movement of the Vis-Rx Micro-Imaging Catheter under fluoroscopy. Always advance and withdraw the catheter slowly. Failure to observe device movement fluoroscopically may result in vessel injury or device damage.
- Leave the guidewire engaged with the catheter at all times during use. Do not withdraw or advance the guidewire prior to withdrawing the catheter.
- If resistance is encountered during advancement or withdrawal of the Vis-Rx Micro-Imaging Catheter, stop manipulation and evaluate under fluoroscopy. If the cause of resistance cannot be determined or mitigated, carefully remove the catheter and guidewire together.
- The catheter should never be forced into lumens that are narrower than the catheter body.
- When advancing or withdrawing a catheter with a minirail tip through a stented vessel, the catheter may engage the stent between the junction of the catheter and guidewire, resulting in entrapment of catheter/guidewire, catheter tip separation, and/or stent dislocation.
- To avoid vessel damage or catheter damage, do not push the guide catheter further into the blood vessel when removing the catheter.
- Before injecting flush media, be sure that the hemostasis valve is tightened to reduce the risk of unintended catheter movement or leaking of flush media during injection.
- Excessive flush rate and pressure may damage the blood vessel or devices used with the Vis-Rx Micro-Imaging Catheter. Low flush rate may result in a faint image.
- If the imaging catheter becomes kinked, stop manipulating it to avoid vessel injury or imaging catheter damage.
- To avoid vessel damage, leave the guidewire engaged with the catheter at all times during use.
- To avoid vessel damage, maintain the position of the guidewire when manipulating the imaging catheter in the vessel.
- Do not disconnect the Vis-Rx Micro-Imaging Catheter from the PIM until the procedure is complete to avoid a sterility breach.

CAUTIONS!

- The purge must be performed prior to insertion and imaging. The syringe should be left attached to the side-arm to allow repeated purging throughout the imaging procedure.
- Use a guidewire with a maximum outer diameter of 0.014" (0.36 mm) and a guide catheter with a minimum inner diameter of 0.068" (1.73 mm).
- To avoid catheter damage, make sure the PIM motor is NOT running when inserting the Vis-Rx Micro-Imaging Catheter into the guide catheter.
- To help ensure successful imaging, the guide catheter should be oriented to preferentially direct the flush media flow to the target artery.
- To help ensure successful imaging, do not use a guide catheter with side holes.
- To ensure imaging of selected anatomy, do not move the guidewire after the imaging catheter is in position.
- If the optical imaging core encounters resistance while returning to the distal position within the sheath (due to a kink or breakage), the Advance Force Limiter will buckle to absorb the forward motion. If this occurs, carefully remove the imaging catheter from the guide catheter. Replace with a new catheter if further imaging is required.

Console Safety

The Gentuity High-Frequency OCT Imaging System disables light output and disables all PIM motors in the following situations:

- Catheter breakage is detected
- A critical system error is detected
- Pressing the **STOP** button on the PIM or the stop button on the touchscreen

CAUTIONS!

- When there is no catheter connected to the PIM, be sure the PIM connector cover is securely in place to protect from dirt and damage.
- Make sure the PIM connectors are facing down during storage.
- Do not touch the internal optics of the optical connector on the catheter or on the PIM.
- Protect the PIM connection ports and the catheter connectors from fluids.

Software Safety Features

The computer and software are designed with the following security features. These features do not require any user configuration or action.

- Prevents unauthorized access to the operating system.
- Prevents installation or execution of unauthorized software.

Electrical Safety

To avoid any potential hazards to patients, operators, or equipment when using the Gentuity High-Frequency OCT Imaging System, follow the electrical safety warnings and cautions outlined in this section and throughout this manual.

Avoiding Electrical Hazards

WARNING! Do NOT remove system covers. Only personnel qualified by Gentuity should service the system. Accidentally contacting the electrical circuits inside the housing could cause serious injury or death.

Making Proper Electrical Connections

Ensure the electrical connection for the system is properly rated. Carefully follow the safety guidelines described in this section when connecting the Gentuity High-Frequency OCT Imaging System's power cord to the hospital or lab's AC outlet.

WARNINGS!

Failure to follow the electrical connection warnings below causes the system and its use to be out of compliance with regulations and places the patient and the operator at risk of injury or death and may damage the equipment.

- Connect the system only to properly grounded (three-hole) hospital-grade AC outlets.
- Do not use extension cords.
- The circuit must accommodate an additional load of up to 600 VA.

Note — If the Gentuity High-Frequency OCT Imaging System is used with peripherals that are powered from a separate wall outlet, then the combination is considered to be a Medical System. It is the user's responsibility to comply with IEC 60601-1-1 and test the Medical System according to the requirements.

Electromagnetic Compatibility

The Gentuity High-Frequency OCT Imaging System is designed to meet the following electromagnetic compatibility standard: IEC 60601-1-2 (US and International)

Electromagnetic Interference

The system produces images by using digital signal processing techniques that operate in the radio frequency (RF) energy range. The system is therefore susceptible to interference generated by other RF energy sources such as medical devices, information technology products, or radio/television transmission towers. Tracing the source of radiated interference can be difficult.

In accordance with the standards identified in this user manual, no interference was observed. However, the trained user must determine if an artifact caused by electromagnetic disturbances will negatively impact image quality and the subsequent study results.

To help identify the source of electromagnetic interference, answer the following questions before contacting Gentuity Support. The answers will help Gentuity determine if the problem is in the system or in the imaging environment.

- Is the interference intermittent or constant?
- Does the interference occur with one catheter only, or with every Vis-Rx Micro-Imaging Catheter?
- Is the interference present if the system is moved to a different location in the facility?

Electromagnetic Safety

The Gentuity High-Frequency OCT Imaging System has been tested for compliance with the Safety Requirements of International Electromagnetic standard IEC 60601-1-2 (2014) and EN 60601-1-2 (2015) for use in the Hospital Environment. This means the Essential Performance, listed below, has been verified in the presence of reasonably expected Electromagnetic Disturbances that may occur in a Hospital.

The Essential Performance (safety related performance) of the Gentuity High-Frequency OCT Imaging System is to perform pullback acquisition when and only when initiated by the operator. A pullback acquisition comprises catheter rotation, pullback, and re-advance.

In addition to the requirements of International Electromagnetic Safety standard IEC 60601-1-2, the Gentuity High-Frequency OCT Imaging System has been tested for compatibility with Radio Frequency Identification Devices (RFID).

In order to ensure Electromagnetic Safety, the following warnings must be followed:

WARNINGS

- 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.
- The Gentuity High-Frequency OCT Imaging System was not tested for compatibility with HF Surgical Equipment or Magnetic Resonance Imaging Systems and should not be used near this equipment without first testing for proper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Gentuity High-Frequency OCT Imaging System, including cables specified by Gentuity. Otherwise, degradation of the performance of this equipment could result.

Note — The radiated and conducted EMISSIONS characteristics of the Gentuity High-Frequency OCT Imaging System make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment. (CISPR 11 is an International Standard for Radiated and Conducted Emissions).

Table 2-1 provides information regarding electromagnetic disturbances and the immunity levels of each disturbance for the Gentuity High-Frequency OCT Imaging System. These levels are the reasonably expected level for the Hospital Environment.

Table 2-1 Electromagnetic Disturbances and Immunity Levels

Electromagnetic Disturbance Type	International Standard	Levels Tested	Guidance on the Electromagnetic Environment
Electrostatic discharge (ESD)	IEC 61000-4-2	±8 kV for contact discharge and ±2 kV, ±4 kV, ±8 kV, ±15 kV for air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 50%.
Radio frequency (RF) fields from fixed RF communications equipment	IEC 61000-4-3	3 V/m from 80 MHz to 2.7 GHz	Medical Equipment should be separated at minimum distance ***d*** from fixed RF communications equipment where $d=2.3 \times P^{1/2}$ and ***P*** is the transmitted power in Watts.
Radio frequency (RF) fields from portable and mobile RF communications equipment	IEC 61000-4-3	27 V/m from 380–390 MHz 28 V/m from 430–470 MHz 9 V/m from 704–787 MHz 28 V/m from 800–960 MHz 28 V/m from 1700–1990 MHz 28 V/m from 2400–2570 MHz 9 V/m from 5100–5800 MHz	Medical Equipment should be separated at minimum distance of 30 cm (12") from portable and mobile RF communications equipment.
Electrical transient bursts	IEC 61000-4-4	± 2 kV @ 100kHz (Mains) ± 1 kV @ 100kHz (I/O Lines)	Mains power quality should be that of a typical commercial or hospital environment.
Lightning Surge	IEC 61000-4-5	±0,5 kV, ±1 kV, ±2 kV from Mains lines to Earth and ±0,5 kV, ±1 kV from Mains Line-to-line	Mains power quality should be that of a typical commercial or hospital environment.
Conducted RF	IEC 61000-4-6	3Vrms from 150 kHz to 30 MHz and 6Vrms in ISM bands	Portable and mobile RF communications equipment can induce voltage into cable which may interfere with normal operation of the Gentuity High-Frequency OCT Imaging System.
Power frequency magnetic fields	IEC 61000-4-8	30 A/m @ 50 Hz and 60 Hz	Motors, transformers, and power lines can generate high magnetic fields which may interfere with Medical Equipment. If interference occurs to the Gentuity High-Frequency OCT Imaging System, separate the Gentuity High-Frequency OCT Imaging System and interfering source.

Table 2-1 Electromagnetic Disturbances and Immunity Levels

Electromagnetic Disturbance Type	International Standard	Levels Tested	Guidance on the Electromagnetic Environment
Magnetic fields from RFID	IEC 61000-4-39	65 A/m @ 134.2 kHz 7.5 A/m @ 13.56 MHz	Radio Frequency Identification Devices (RFID) can cause interference with Medical Equipment. If interference occurs to the Gentuity High-Frequency OCT Imaging System, separate the Gentuity High-Frequency OCT Imaging System and RFID.
Voltage dips	IEC 61000-4-11	100 V @ 60 Hz and 230 V @ 50 Hz	Short interruptions in the AC power may cause Medical Equipment to stop functioning. The Gentuity High-Frequency OCT Imaging System is immune to most Voltage dips.
Power interruptions	IEC 61000-4-11	100 V @ 60 Hz and 230 V @ 50 Hz	Interruptions in the AC power will cause the Gentuity High-Frequency OCT Imaging System to stop functioning if not backed up by battery power.

Note — The Gentuity High-Frequency OCT Imaging System transmits and receives radio frequency energy at 13.56 MHz +/- 7 kHz and is used as a Radio Frequency Identification Device (RFID) for identifying the catheter being used. The RFID system utilizes on-off keying modulation which has a bandwidth of approximately 500 kHz. The transmitting field level is approximately 7.5 A/m. The transmitter is only active during the setup procedure to read the RFID tag in the catheter.

Data and Cybersecurity Considerations

To avoid any possible image misinterpretation or potential data loss when using the Gentuity High-Frequency OCT Imaging System, follow the warnings, cautions, and statements outlined in this section and throughout this manual.

CAUTIONS!

- Cardiac motion relative to the catheter can cause lengthening and shortening of longitudinal segments of the Lumen Profile and L-Mode, or can create a jagged appearance of the reconstructed image. Do not rely solely on the Lumen Profile or L-Mode for longitudinal measurements.
- Use caution when interpreting the low confidence slices. If measurements are present, you can manually adjust the lumen trace to more accurately identify the lumen boundary.
- Because image data is displayed centered around the catheter, off-center catheter locations can make the lumen appear significantly smaller than actual diameter in some L-Mode views. When viewing in L-Mode, rotate the cut-plane to avoid image misinterpretation.
- Gentuity makes no representation or warranty that use of the Gentuity High-Frequency OCT Imaging System complies with applicable privacy, security and confidentiality laws, but encourages you to assess your own risk as you use, disclose, control, process or transfer patient health information with the Gentuity High-Frequency OCT Imaging System.
- Passwords are encrypted and cannot be recovered once they are set. If necessary, contact Gentuity Support to help reset the password.
- Do not use personally identifiable information in annotations. Annotations do NOT get anonymized.
- Deleting a patient record deletes all pullback data for that patient, and cannot be recovered.
- Deleting files from the system frees up storage space on the system but the deleted files cannot be imported back into the system.
- Do not use images that have been exported in standard formats (such as MP4, JPEG, and PDF) for clinical decision making. This format uses compression methods that may degrade the image quality.
- If you want to make measurements on files which will be exported in standard formats (such as MP4, JPEG, and PDF), you must make the measurements BEFORE exporting the images.

Cybersecurity Risk Management Approach

Gentuity recognizes that medical device cybersecurity is a shared responsibility among stakeholders including health care facilities, patients, providers, and manufacturers of medical devices. An effective cybersecurity risk management approach is important to reduce the risk of harm to patients, and loss or breach of data. Gentuity recommends that your organization apply an approach comparable to the NIST Framework for Improving Critical Infrastructure Cybersecurity.

For more information, see: http://www.nist.gov/cyberframework/

Threat Modeling

When building a cybersecurity threat model, networking features are disabled in this version of the Gentuity High-Frequency OCT Imaging System. The Gentuity High-Frequency OCT Imaging System only exports and imports image files via a USB drive.

Software Information

To view the full list of commercial and open source off-the-shelf software used in this device, see “Configuring Maintenance Settings” on page 4-15.

Cybersecurity-related Cautions

CAUTIONS!

- If you believe that your system has been compromised by a cybersecurity breach, stop using the system contact Gentuity immediately at support@gentuity.com.
- To minimize the risk of cybersecurity threats, only use USB drives with trusted computers running anti-virus and anti-malware software.
- To prevent unauthorized access, do not use a password that can be easily guessed. Use a combination of letters, numbers, and symbols when creating a password.
- To help protect the system from unauthorized access, Gentuity strongly recommends the use of the lock screen feature.

Chapter 3
System Overview

This chapter provides an overview of the Gentuity High-Frequency OCT Imaging System. It includes information about its features, the components that are included in the system, the input and output connections on the system, the Probe Interface Module (PIM), and the Vis-Rx Micro-Imaging Catheter.

Overview

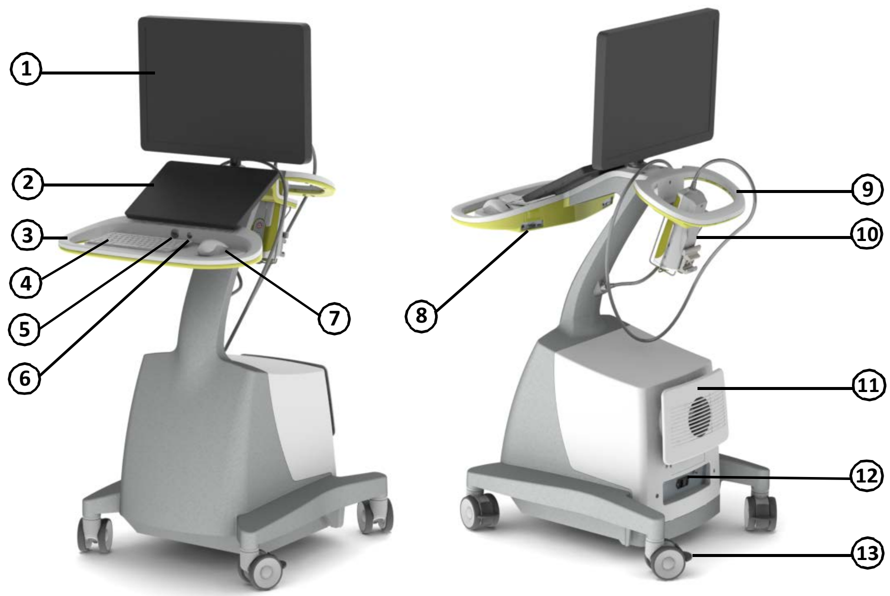
The Gentuity High-Frequency OCT Imaging System is an intravascular Optical Coherence Tomography (OCT) imaging system. It uses near-infrared light to create high-resolution, in vivo images of coronary arteries.

WARNING! Medical personnel who use the Gentuity High-Frequency OCT Imaging System must be aware of the system's limitations. Only trained operators can determine if the use of the Gentuity High-Frequency OCT Imaging System is appropriate.

System Components

The Gentuity High-Frequency OCT Imaging System consists of the following components, as shown in Figure 3-1. Table 3-1 lists and describes the components.

Figure 3-1 Gentuity High-Frequency OCT Imaging System Components



Front view Back view

Table 3-1 Gentuity High-Frequency OCT Imaging System Components

Item	Name	Description
1	Display Monitor (24 in) (Physician Side)	Primary image display for sterile operators (SO). Permits monitor tilt (-3° ± 90°) adjustment, and swivel (± 270°), as well as monitor removal for transport and shipment.
2	Touchscreen (15.6 in) (Operator Side)	Primary image and interface display for the Non-Sterile Operator (NSO).
3	Front handle	Integrated front and rear handles for transporting the system and for table-side positioning.
4	Keyboard	A standard keyboard used for data entry.
5	USB port	Located above the keyboard/mouse tray on the front of the system, used for exporting patient data from the system (archives, images, pullbacks, and so on) and storing the data on a USB drive. For details on supported USB drives, see “USB Connected Media Only” on page 5-8.
6	On/Shut Down button	Located above the keyboard/mouse tray on the front of the system, used to turn the system on or shut down the system. For details, see “Connecting and Powering On the System” on page 4-1.

Item	Name	Description
7	Mouse	Alternative pointing and selecting device.
8	Input/Output connections	Located on each side of the back of the keyboard/mouse tray, provides connection ports. For details, see “Input/Output Connections” on page 3-4.
9	Rear handle	Integrated front and rear handles for transporting the system and for table-side positioning.
10	Probe Interface Module (PIM) and PIM Cradle	Bedside connection to catheter. Contains the bed rail mount, Start/Stop buttons, catheter pullback drive, and catheter rotation drive. Use the PIM cradle to store the PIM when not in use. **CAUTION:** Always store the PIM with the PIM connector cover facing down.
11	Cord wrap	AC power cable storage location for transport.
12	Power switch	Located on the lower back panel of the system, used to turn the main power to the system on and off.
13	Caster with brake	High-quality medical casters for mobile transport, fine positioning, and wheel locks.

CAUTION! The system components are integral parts of the Gentuity High-Frequency OCT Imaging System. The Gentuity High-Frequency OCT Imaging System hardware and software must not be modified in any way by the user. Making such modifications may interfere with correct operation and will void system warranties. Contact Gentuity Support for more information.

Input/Output Connections

The Input/Output (I/O) connections are located on both sides of the back of the keyboard/mouse tray. As you face the touchscreen, the Internet and video input and output connections are on the right side, as shown in Figure 3-2.

Figure 3-2 I/O Connections (Internet and External Video Input/Output)

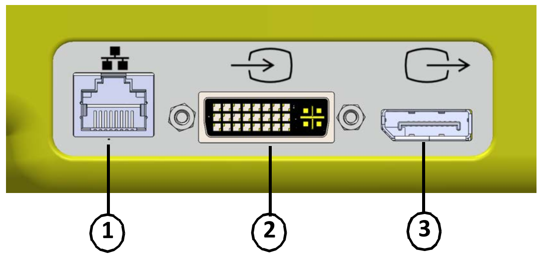


Table 3-2 I/O Connections (Internet and External Video Input/Output)

Item	Name	Description
1	Network connection input	This feature is not available in this release.
2	External video input	Input connector from angiography system to be displayed on the Gentuity High-Frequency OCT Imaging System console.
3	External video output	Output connector for display of the Gentuity High-Frequency OCT Imaging System image on an external monitor.

As you face the touchscreen, the trigger, USB port, and remote connections are on the left side, as shown in Figure 3-3.

Figure 3-3 I/O Connections (Trigger, USB, and Remote)

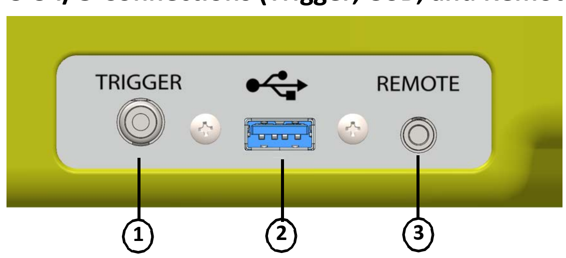


Table 3-3 I/O Connections (Trigger, USB, and Remote)

Item	Name	Description
1	Trigger	This feature is not available in this release.
2	USB port	Input for USB drives.
3	Remote	This feature is not available in this release.

Probe Interface Module (PIM)

The PIM provides both automated rotation and longitudinal pullback of the imaging core within the Vis-Rx Micro-Imaging Catheter. The PIM is rail-mountable and can be placed outside of the sterile field so that a Non-Sterile Operator (NSO) can connect the catheter to the PIM and operate it during the procedure.

The Vis-Rx Micro-Imaging Catheter connects to the Gentuity High-Frequency OCT Imaging System through the PIM. All imaging core rotation and translational pullback is driven by the PIM and occurs inside the catheter sheath.

Rotational speeds of the imaging core in the catheter range from 0 to 250 revolutions per second (rps). 100 rps (Preview mode) is possible and pullback imaging is conducted at 250 rps.

CAUTION! Always store the PIM with the PIM connector cover facing down.

Figure 3-4 PIM

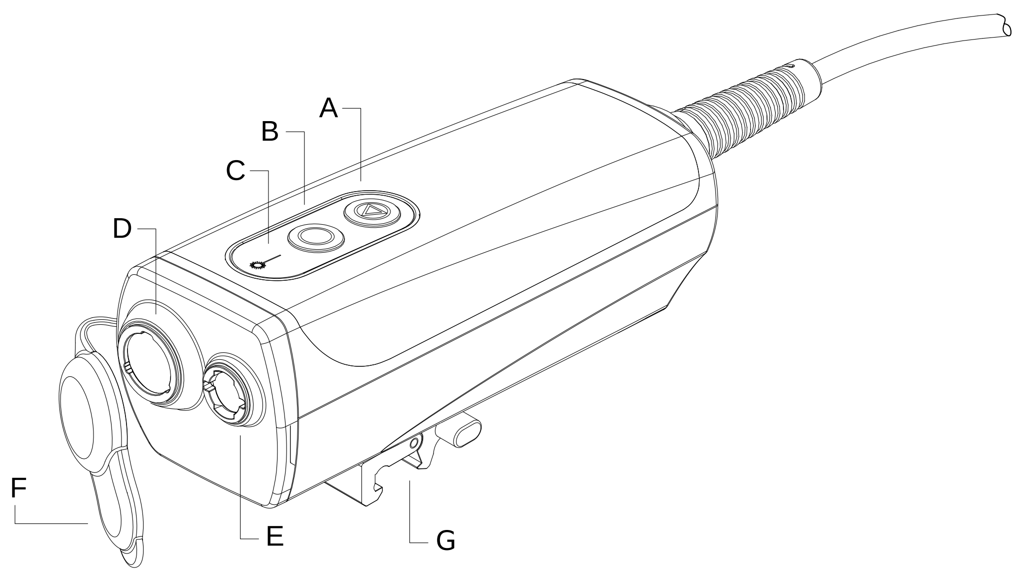


Table 3-4 PIM Components

Item	Name	Description
A	**STOP** button (red)	When pressed, stops the pullback and imaging rotation and turns off the laser output.
B	**GO** button (green)	When illuminated, pressing this button progresses to the next stage of the image acquisition: • If the catheter is connected but the PIM is stopped or in Preview mode, Enables the system. • If the system is Enabled, pressing this button initiates the pullback.

Item	Name	Description
C	Laser Emission Symbol	Illuminated when laser output is on.
D	Optical Connection Port	Optical connection between the catheter and the PIM.
E	Pullback Connection Port	Pullback connection between the catheter and the PIM.
F	Connector Cover	Protects the optical and pullback connection ports from dirt and damage when not in use. **CAUTION!** When there is no catheter connected to the PIM, be sure the PIM connector cover is securely covering the connectors to protect from dirt and damage. Always store the PIM with the PIM connector cover facing down.
G	Rail Clamp	Provides the ability to clamp the PIM to the catheter table rail. • To secure clamp to rail, hook the top of the clamp onto the rail and tilt downward. • To rotate the PIM as needed, push the PIM in and rotate the PIM body. • To disconnect the PIM rail clamp, squeeze the lever at the bottom of the clamp and lift upwards. The rail clamp is compatible with all major catheter table rails.

Catheter

The Vis-Rx Micro-Imaging Catheter is a rapid exchange (RX) catheter with a 17 mm minirail tip designed for compatibility with a 0.014” (0.356 mm) guidewire. The catheter is 1.8 Fr in size, except at the insertion depth markers, where it is 2.0 Fr. The effective length of the catheter is 165 cm. The distal 30 cm has a hydrophilic coating applied to improve lubricity.

The Vis-Rx Micro-Imaging Catheter consists of two assemblies: an external catheter sheath and an imaging core (housing an optical fiber and lens assembly).

Proximal to the minirail tip is the imaging area. During image acquisition, the lens rotates within the imaging core to obtain a 360° image of the surface layer of the artery wall. The imaging core is automatically retracted within the external catheter sheath to obtain a continuous pullback image of the arterial segment.

Markers

There are three radiopaque markers on the catheter:

1. The most distal marker, the **tip marker**, is located 4 mm proximal to the tip of the catheter and is affixed to the catheter sheath.
2. The **lens marker** is located 5 mm distal to the lens on the imaging core. Place the lens marker distal to your target image area. The lens marker and tip marker are 16 mm apart when the imaging core is in its fully advanced, ready-to-image position.
3. There is an additional **pullback marker** placed 50 mm proximal to the lens on the imaging core.

Together, these markers help locate the catheter distal end, lens location, and imaging region. The lens and pullback markers move with the pullback, while the tip marker remains stationary.

The catheter sheath has two insertion depth markers at 90 cm and 100 cm from the distal tip that provide an indication of insertion depth.

Figure 3-5 shows the Vis-Rx Micro-Imaging Catheter and Table 3-5 describes the parts of the catheter.

Figure 3-5 Vis-Rx Micro-Imaging Catheter

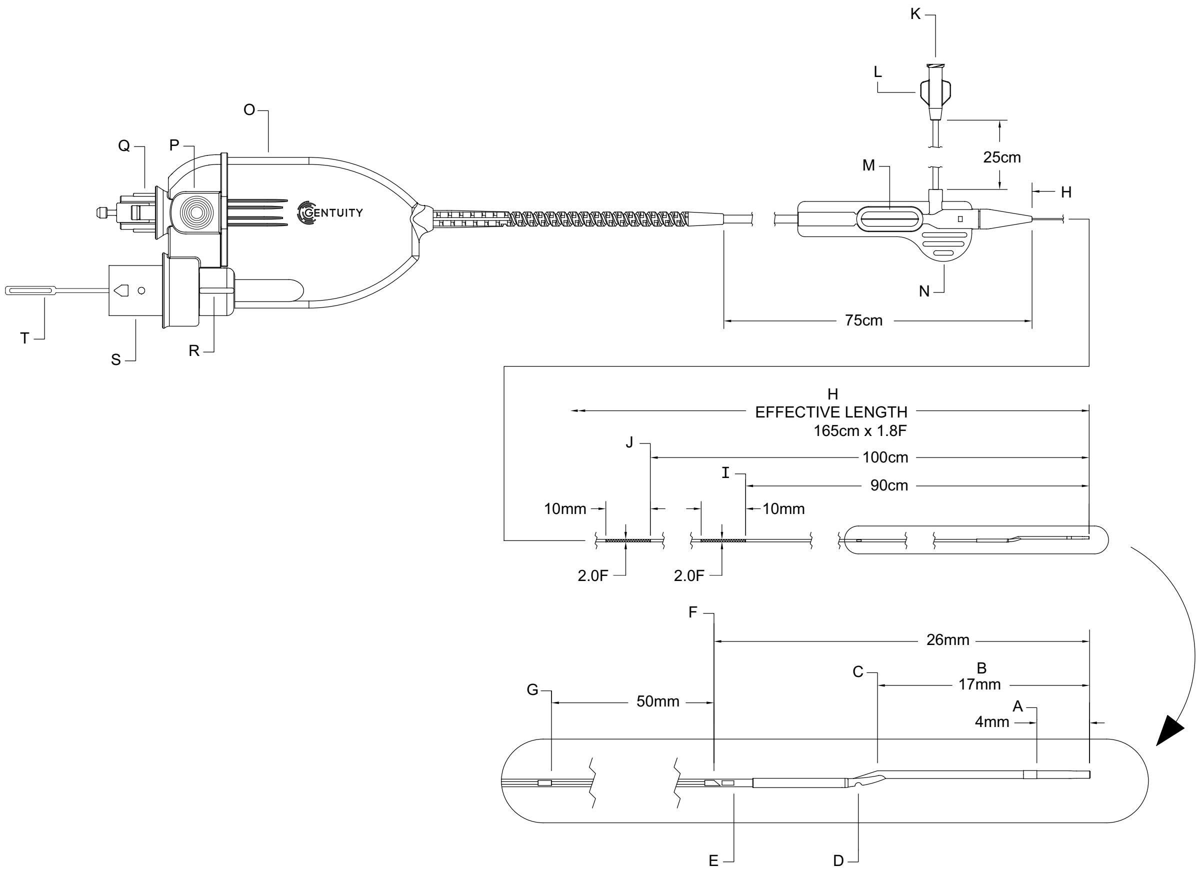


Table 3-5 Vis-Rx Micro-Imaging Catheter

Item	Description	Item	Description
A	Tip Marker	K	Catheter Purge Port
B	Minirail	L	Side Arm Luer
C	Guidewire Exit	M	Advance Force Limiter
D	Purge Exit	N	Purge Handle
E	Lens Marker	O	Catheter Handle
F	Lens	P	Pullback Connector Release
G	Pullback Marker	Q	Pullback Connector Hub
H	Catheter Sheath	R	Optical Connector Lock
I	90 cm Insertion Depth Marker	S	Optical Connector Hub
J	100 cm Insertion Depth Marker	T	Optical Connector Cover (remove before use)

Purging

A luer fitting on the side-arm (L in Table 3-5) at the proximal end of the catheter facilitates purging the central catheter lumen of the Vis-Rx Micro-Imaging Catheter with heparinized saline prior to use. A 3 ml syringe is provided to perform the catheter purge.

CAUTION! The purge must be performed prior to insertion and imaging. The syringe should be left attached to the side-arm to allow repeated purging throughout the imaging procedure.

For details on the catheter and its use, see “Using the Vis-Rx Micro-Imaging Catheter” on page 6-2 and the instructions included with each catheter package.

Chapter 4
System Setup

This chapter provides information and instructions for positioning the Gentuity High-Frequency OCT Imaging System, connecting and powering on the system, shutting down the system, setting up the monitor(s), and configuring system settings.

Positioning the System

Use the following guidelines when positioning the system:

- Position the Gentuity High-Frequency OCT Imaging System at the foot of the patient table with the display monitor facing the sterile operator. The Gentuity High-Frequency OCT Imaging System may be placed at other locations, however care must be taken to ensure the system is clear of any moving equipment, including the angiography system. It is the responsibility of the attending physician to ensure that collisions do not occur.
- Ensure that the physician is able to see and confirm information displayed on the system.
- Ensure the power cord and any other connections to the Gentuity High-Frequency OCT Imaging System are routed to prevent a tripping hazard.
- Ensure that the main power switch and power plug are accessible at all times during the procedure.

Connecting and Powering On the System

Make sure the power cord is connected to the system and is plugged into a grounded electrical outlet. For detailed information on electrical requirements, see “Making Proper Electrical Connections” on page 2-7.

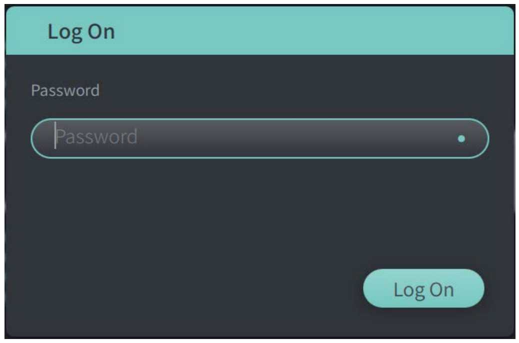
➤ **To connect and power on the system:**

1. Connect the power cord to the power connection on the lower back of the system. The power cord will click into place.
2. Connect the other end to a hospital grade outlet.
3. If necessary, toggle the main power switch at the base of the cart to the ON position to turn on system power.
4. If necessary, press the On/Shut Down button located above the keyboard tray to start the system. The **Patient List** or **Log On** screen is displayed.

Logging Onto the System

If your system is configured to require a password upon login, the **Log On** window is displayed prompting you to enter the password, as shown in Figure 4-1.

Figure 4-1 Log On Window



➤ **To log onto the system:**

1. Enter the password.
2. Select **Log On**. The **Patient List** is displayed. For more information, see “Patient Records” on page 5-1.

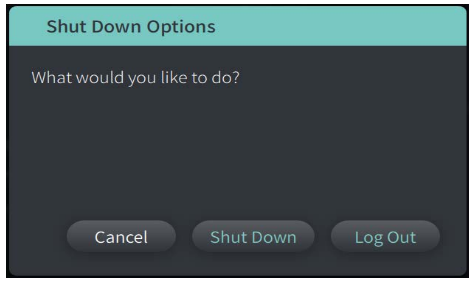
Note — For details on configuring a log on password, see “Configuring General Settings” on page 4-9.

Logging Out of the System

➤ **To log out of the system:**

1. Select the **Shut Down** button located at the top left corner of the screen. The **Shut Down Options** window is displayed, as shown in Figure 4-2.

Figure 4-2 Shut Down Options Window



2. Select **Log Out.**

Note — The **Log Out** button is only displayed if the **User Password** is configured as **Required for Log On**. For more information, see “Configuring General Settings” on page 4-9.

Shutting Down the System

There are two methods to shut down the Gentuity High-Frequency OCT Imaging System:

- By pushing the On/Shut Down button on the front of the system above the keyboard tray.
- By selecting the Shut Down button on the touchscreen:

➤ **To shut down the system using the On/Shut Down button:**

1. Press the On/Shut Down button on the front of the system, above the keyboard tray. The system shuts down immediately.

➤ **To shut down the system using the touchscreen Shut Down button:**

1. Select the Shut Down button located at the top left corner of the screen. The **Shut Down Options** window is displayed, as shown in Figure 4-2 above.
2. Do one of the following:
   - To shut down the system, select **Shut Down.**
   - To log out of the current session, but keep the system powered on, select **Log Out**.
   - To continue using the system, select **Cancel**.

Note — The **Log Out** button is only displayed if the **User Password** is configured as **Required for Log On**. For more information, see “Configuring General Settings” on page 4-9.

Setting Up the Monitor

This section provides instructions for adjusting positions of the Gentuity High-Frequency OCT Imaging System display monitor, connecting an external monitor, and connecting video input from an angiography system.

Setting Display Monitor Positions

You can adjust the angle and tilt of the display monitor (Physician side monitor). You cannot adjust the position of the touchscreen (Operator) monitor.

➤ **To adjust the display monitor position:**

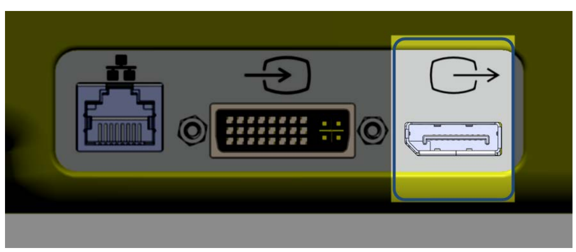
1. Grasp the monitor firmly with one hand on each side of the screen.
2. Rotate the monitor as needed.
3. Adjust the viewing angle by tilting the monitor.

Connecting an External Monitor

CAUTION! The Gentuity High-Frequency OCT Imaging System can only be connected to an external monitor that has been set up by Gentuity Support.

You can connect an external monitor to the Gentuity High-Frequency OCT Imaging System through the video output on the I/O Panel (Figure 4-3) on the right back side of the system's keyboard/mouse tray (as you face the touchscreen). When connected, the monitor duplicates the display of the Physician side monitor.

Figure 4-3 Video Output Connection



➤ **To connect an external monitor:**

1. Connect the external monitor's cable to the port highlighted in Figure 4-3.
2. Make sure the external monitor is plugged in and powered on.

Connecting Video Input from an Angiography System

The Gentuity High-Frequency OCT Imaging System may be connected to an external angiography system using its video input cable.

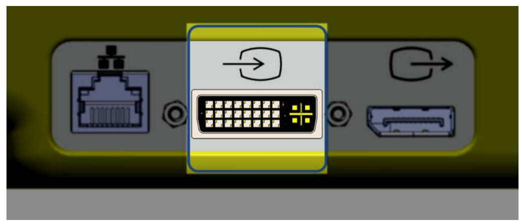
CAUTION! The Gentuity High-Frequency OCT Imaging System can only be connected to angiography systems that have been set up by Gentuity Support.

You can connect the angiography monitor cable to the Gentuity High-Frequency OCT Imaging System through the video input connector on the I/O panel (Figure 4-4) located on the back right side of the system's keyboard/mouse tray. When connected, the current angio image displays during live imaging and is captured during pullback acquisition.

When connecting the cable from the angiography system, note the following:

- Align the connector *before* seating to avoid damaging the connectors.
- Ensure all connectors are properly seated and fully tighten the thumb screws.

Figure 4-4 Angiography Monitor Input Connection

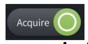


➤ To connect an angio monitor:

1. Connect the angiography monitor's cable to the port highlighted in Figure 4-4.
2. Make sure the angiography monitor is plugged in and powered on.

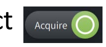
Selecting the Procedure Room

The **Procedure Room** information is configured by Gentuity Support during the system installation.

If more than one room is configured for use for the system, you are prompted to select the room after pressing the 

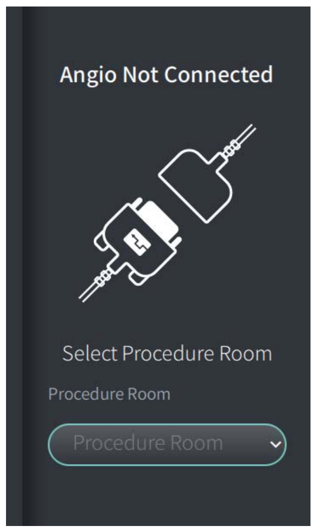
button. If only one room is configured for use, you do not need to select or specify the room information.

➤ To select the Procedure Room:

1. After entering a new patient record, or opening an existing patient record, select 

.
2. In the left lower corner of the screen, tap the **Procedure Room** drop-down and select the room.

Figure 4-5 Selecting the Procedure Room



3. If the angio monitor is not yet connected, follow the instructions in “Connecting Video Input from an Angiography System” on page 4-4.

Once connected, the current angio image displays on the monitor during live imaging, and is captured during pullback acquisition.

Preparing the PIM

➤ To prepare the PIM:

1. Remove the PIM from its cradle on the back of the system.

CAUTION! When there is no catheter connected to the PIM, be sure the PIM connector cover is securely in place to protect from dirt and damage.

---

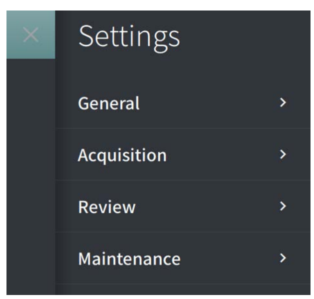
2. Attach the PIM to the surgical bed rail.
   - To secure clamp to rail, hook the top of the clamp onto the rail and tilt downward.
   - To rotate the PIM as needed, push the PIM in and rotate the PIM body.

Configuring System Settings

Use the **Settings** screen, shown in Figure 4-6, to configure the following types of settings in the Gentuity High-Frequency OCT Imaging System:

- **General Settings** to:
  - Set the date, time, and time zone
  - Enter hospital information including name, address, and logo
  - Enter, edit, or delete physician names
  - View the system’s storage capacity
  - Configure User and Administrator passwords, if needed
  - Configure the log off timer
  - Specify what information is required when entering patient record data
- **Acquisition Settings** to:
  - Specify the types of flush media that can be used with the system
  - Set the default flush media
  - Configure an Administrator password, if needed
- **Review Settings** to select the color map
- **Maintenance Settings** to back up data, view system information, view third party attribution information (Open Source Software Notices), and to export the Cybersecurity Bill of Materials (CBOM) to a USB drive

Figure 4-6 Settings Screen



➤ To access the Settings screen:

1. Select the Settings icon to open the **Settings** screen.
2. Use the icon to expand (view) settings. Use the icon to collapse (hide) settings.
3. Configure the following settings as needed:
   - **General**
   - **Acquisition**
   - **Review**
   - **Maintenance**

About the Administrator Password

To prevent unintended changes, some settings can be protected by an Administrator password. When the Administrator password is configured, it must be entered to:

- Change or disable the log off time
- Change or disable the user password
- Change the required patient information in the **General** settings
- Change the available and default flush media settings in the **Acquisition** settings

If the Administrator password is not configured, these settings are available to all users.

CAUTION!

- Passwords are encrypted and cannot be recovered once they are set. If necessary, contact Gentuity Support to help reset the password.
- To prevent unauthorized access, do not use a password that can be easily guessed. Use a combination of letters, numbers, and symbols when creating a password.

Configuring General Settings

Figure 4-7 shows the **General** section of the **Settings** screen and Table 4-1 lists and describes the **General** settings that you can configure.

➤ To access the General settings:

1. Select the Settings icon to open the **Settings** screen.
2. Select **General**.

Figure 4-7 General Settings Screen

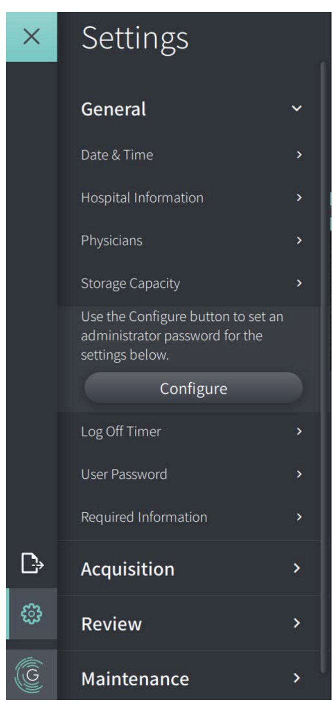


Table 4-1 General Settings

Setting	Description	How to Use
Date & Time	Set the current date and time, and the time zone	1. Select the **Day**, **Month**, and **Year** menus to select the date using this format: DD MMM YYYY (for example, 16 JAN 2022 is January 16, 2022. 2. Select the and icons to set the time in 24-hour format. **Note:** You can also enter the time directly using the keyboard. 3. Select the **Time Zone** for where the system is located.
Hospital Information (for use in Report exports)	Hospital Name	Enter the name of the hospital.
	Hospital Address	Enter the address of the hospital.
	Hospital Logo image (the logo image must be in .png format)	1. Make sure a USB drive is inserted into one of the USB ports on the system and that the USB drive contains the logo image in .png format that you want to use. 2. Select **Upload** and navigate to where the logo image is stored. 3. Select the image.
Physicians	Add and edit physician names in the system.	Enter the name of the physician and select the icon. To edit the physician's name, tap the name and edit the text as needed. To delete a physician's name, tap the icon to the right of the physician's name. The physician's name will no longer appear in the drop-down list of physicians. To enter the physician's name in the patient record, see "Opening a Patient Record" on page 5-5.
Storage Capacity	Displays the percentage of storage capacity used.	**Note:** You can free up storage space by archiving cases and deleting them from the system. For more information, see "Exporting Patient Records" on page 5-8.
Use the Configure button to set an administrator password for the settings below.	This menu item is displayed if you have not set an administrator password.	1. Select **Configure** to open the **Configure Administrator Password** window. 2. Select **Administrator Password Required** to indicate that a password is required to access the settings. 3. Enter the **Administrator Password** and reenter the password in the **Confirm Password** field. 4. Select **Save**.
- OR-		

Setting	Description	How to Use
The controls below require an administrator password	When the administrator password has been set, it allows access to and configuration of the **Log Off Timer**, **User Password**, and the **Required Information** settings.	Enter the Administrator password. For more information, see "About the Administrator Password" on page 4-9.
Log Off Timer	The amount of inactivity time after which the system will log the user off. You can configure the timer from 5 minutes to 2 hours.	1. Select the ⊕ and ⊖ icons to increase and decrease the log off time. **Note:** You can also enter the time directly using the keyboard. The format is hh:mm:ss for hours, minutes, and seconds.
User Password	Use this setting to configure user password requirement and to set the user password.	1. Select **Configure** to open the **Configure User Password** window. 2. Select **Required for Log On** to indicate that a password is required to log on to the system. 3. Enter the **User Password** and reenter the password in the **Confirm Password** field. 4. Select **Save**. **Note:** For details on setting the lock screen, see "Setting the Lock Screen" on page 4-12.
Required Information	Indicates the information that is required to save the patient record. Fields include: **Patient ID Number**, **Last Name**, **First Name**, and **Date of Birth** When selected, an indicator displays next to the field name in the **Add Patient** window to indicate that the user is required to enter that field to save the patient record. If a field is required and the user does not enter that information, they are prompted to enter content in the field before they can save the patient record and proceed to imaging.	Select the check box for each field that is required when a user enters and saves new patient information. You must select at least one of the fields.

Setting the Lock Screen

CAUTION! To help protect the system from unauthorized access, Gentuity strongly recommends the use of the lock screen feature.

For added security, you can configure the Gentuity High-Frequency OCT Imaging System to use a lock screen for when a user may be away from the system for a short period of time.

➤ To configure the lock screen:

1. Select the Settings icon to open the **Settings** screen.
2. Select **General**.
3. Enter the administrator password (if required) and press **Enter** on the keyboard, or tap **Log On**. The **Log Off** and **Configure** buttons are displayed.
4. Select **User Password** and then select **Configure**.
5. Select **Required for Log On** and enter the User password.
6. Enter the password again in the **Confirm New Password** field.
7. Select **Save**.
8. Select in the upper left of the screen to close the **Settings** screen.
9. Select .
10. In the **Shut Down Options** window, select **Log Out**.

Configuring Acquisition Settings

Figure 4-8 shows the **Acquisition** section of the **Settings** screen and Table 4-2 lists and describes the **Acquisition** settings that you can configure.

➤ To access the Acquisition settings:

1. Select the Settings icon to open the **Settings** screen.
2. Select **Acquisition**.

Figure 4-8 Acquisition Settings Screen

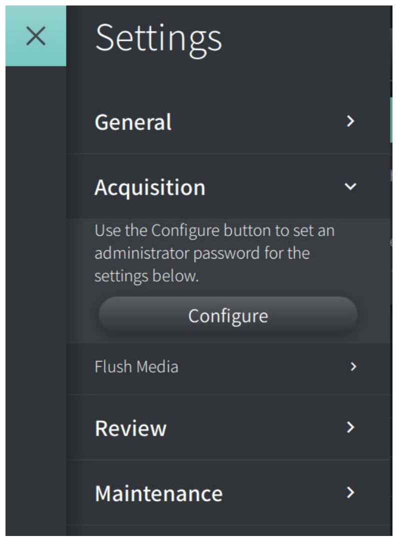
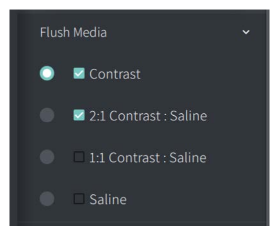


Table 4-2 Acquisition Settings

Setting	Description	How to Use
Use the Configure button to set an administrator password for the settings below.	This menu item is displayed if you have not set an Administrator password.	1. Select **Configure** to open the **Configure Administrator Password** window. 2. Select **Administrator Password Required** to indicate that a password is required to access the settings. 3. Enter the **Administrator Password** and reenter the password in the **Confirm Password** field. 4. Select **Save**.
- OR -		
The controls below require an administrator password	The administrator password allows access to and configuration of the **Flush Media** settings.	Enter the administrator password. For more information, see "About the Administrator Password" on page 4-9.
Flush Media	Lists the flush media and its associated ratio (if applicable) that can be used with the system. Indicates which flush media is the default.	When selected, a check mark indicates that the flush media is available for use on the system during acquisition. Select the default flush media by clicking the button to the left of the media. Only one flush media can be selected as the default.  The default flush media is used for each new patient. However, you can change to any of the other available choices as needed.

WARNING! Selecting the wrong flush media can cause measurement errors which could lead to incorrect treatment. Prior to acquisition, make sure the media identified in the **Pullback Settings** window matches the media you are using.

Configuring Review Settings

Figure 4-9 shows the **Review** section of the **Settings** screen and Table 4-3 lists and describes the **Review** settings that you can configure.

➤ **To access the Review settings:**

1. Select the Settings icon to open the **Settings** screen.
2. Select **Review**.

Figure 4-9 Review Settings Screen

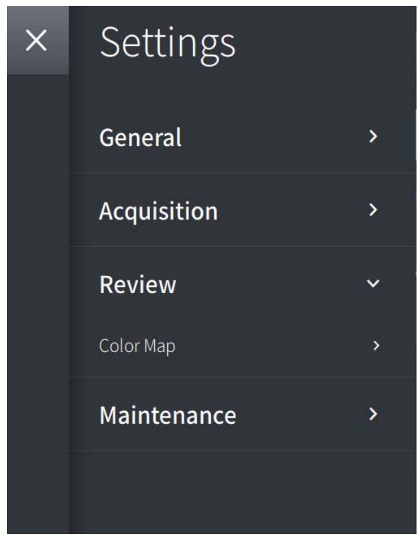


Table 4-3 Review Settings

Setting	Description	How to Use
Color Map	Lets you select the color map that is used to display the OCT image data	Select **Crystal** or **Grayscale** to change the color map. Gentuity HF-OCT images use the Crystal color map by default, but certain applications may require a simple grayscale color map.

Configuring Maintenance Settings

Figure 4-10 shows the **Maintenance** section of the **Settings** screen and Table 4-4 lists and describes the **Maintenance** settings.

➤ To access the Maintenance settings:

1. Select the Settings icon to open the **Settings** screen.
2. Select **Maintenance**.

Figure 4-10 Maintenance Settings Screen

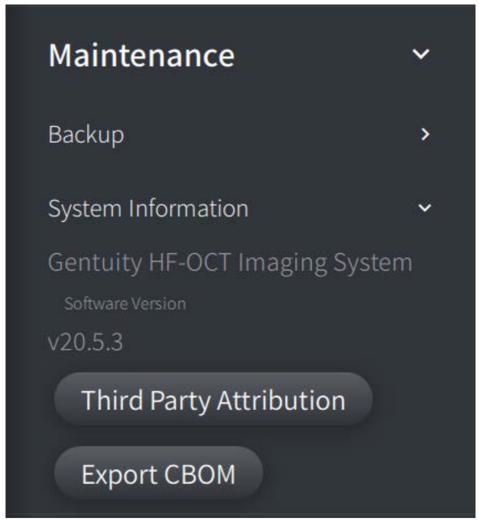


Table 4-4 Maintenance Settings

Setting	Description	How to Use
Backup	**Verify written data** slider control	Slide to **ON** to have the system check that all data was written properly as the final step of creating the backup.
	Shut Down when complete slider control	Slide to **ON** to shut down the system when the backup is complete
	Backup all data button creates a copy of all of the patient data that currently exists on the system onto a USB drive **Note:** Gentuity recommends that you use a high-speed USB drive to reduce the time it takes to back up all data.	1. Make sure a USB drive is inserted in the USB port above the keyboard tray. 2. Select **Backup all data**. 3. In the **Select a Directory** window, select the directory on the USB drive. If necessary, select **New Folder** and enter the name of the new folder. 4. Select **Next**.
System Information	Displays current software version, **Third Party Attribution** button, and **Export CBOM** button.	Refer to this software version when interacting with Gentuity Support. Select **Third Party Attribution** button to view Open Source Software Notices. Select **Export CBOM** button to export the Cybersecurity Bill of Materials to a USB drive.

Note — The **Backup** setting is not used to archive patient records. It is only for use in creating a backup that can be restored by Gentuity Support in the event of an issue. For details on archiving patient records, see “Exporting Patient Records” on page 5-8 and “Exporting Files During Review” on page 7-18.

Chapter 5
Patient Records

This chapter provides information and instructions for accessing the **Patient List**, adding a patient record, and searching for, editing, and pinning patient records.

This chapter also provides details on exporting patient records, the export formats and options, and compatible devices to use for exporting.

Accessing the Patient List

When you first turn on the system, the **Patient List** is displayed, as shown in Figure 5-1. Each patient record contains the patient's HF-OCT images acquired from previous exams, if available, as well as the Patient ID Number. Table 5-1 lists and describes the parts of **Patient List** screen.

Figure 5-1 Patient List Screen

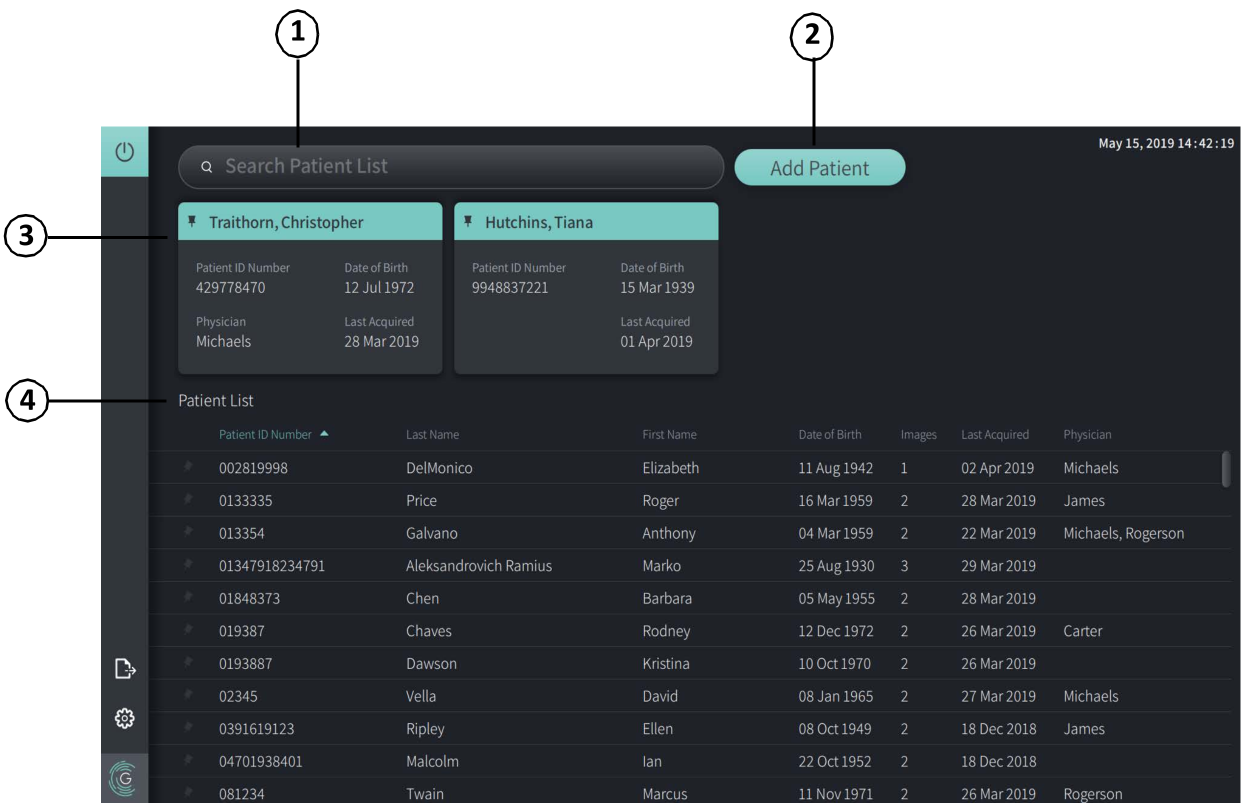


Table 5-1 Patient List Screen

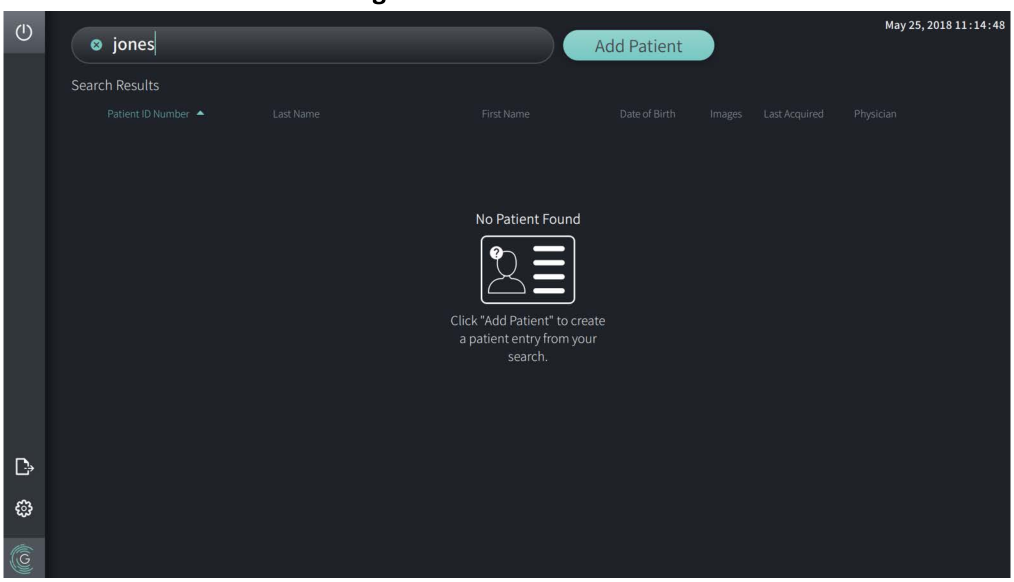
Item	Description
1	**Search Patient List** (Use the search field to begin typing a patient's name or the Patient ID Number)

Item	Description
2	**Add Patient** button
3	**Pinned Patient Records** section
4	**Patient List** section

Adding a Patient Record

You can add a patient by typing the patient's name or number in the search field. If no matching patient record is found, a message is displayed, as shown in Figure 5-2.

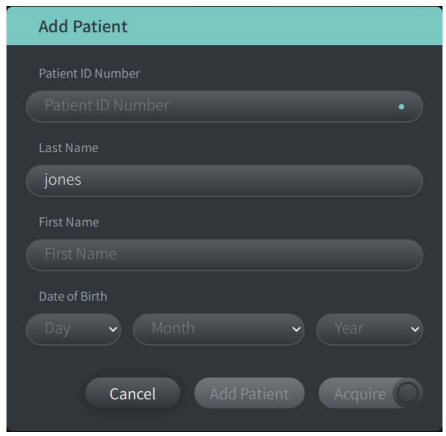
Figure 5-2 Patient Search

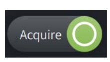


➤ To add a patient record:

1. Select **Add Patient**. The **Add Patient** window is displayed, as shown in Figure 5-3.
2. Enter the following information (fields with * denote required information):
   - **Patient ID Number**
   - **Last Name**
   - **First Name**
   - Patient's **Date of Birth** (DD MMM YYYY). You can enter the date directly, or select the date by clicking or tapping  to display the drop-down options.

Figure 5-3 Add Patient Window



3. Do any of the following:
   - Select **Add Patient** to add the patient information to the database for later imaging. The patient record is automatically pinned in the **Patient List**. For details, see "Pinning a Patient Record" on page 5-7.
   - Select  to immediately start the patient exam.
   - Select **Cancel** to cancel adding the patient information.

Searching for a Patient Record

Search for an existing patient record using either of the following methods:

- Using the search field (**Search Patient List**)
- Sorting the columns in the **Patient List** to easily find a record

Using the search field

Enter any identifying information about the patient record to locate the record in the database. For example, enter the patient's name, part of their name, their Patient ID Number, or other information to narrow the search. As you type, the system displays a list of items that match.

➤ To use the search field:

1. Enter any identifying information about the patient in the search field at the top of the screen.
2. If the patient record is found in the database, you can select the record from the **Patient List**.
3. If the patient record is not found, the system displays a message and prompts you to select the **Add Patient** button. For more information on adding a new patient record, see “Adding a Patient Record” on page 5-2.

Sorting Patient List Columns

You can sort any of the columns in the **Patient List** to help find a patient record. The current sort order is indicated by a blue column heading and a ▲ or ▼ icon, as shown in Figure 5-4.

Figure 5-4 Patient List Sort Order

For example, you can sort the **Patient ID Number** column in ascending or descending order to find the patient, as shown above.

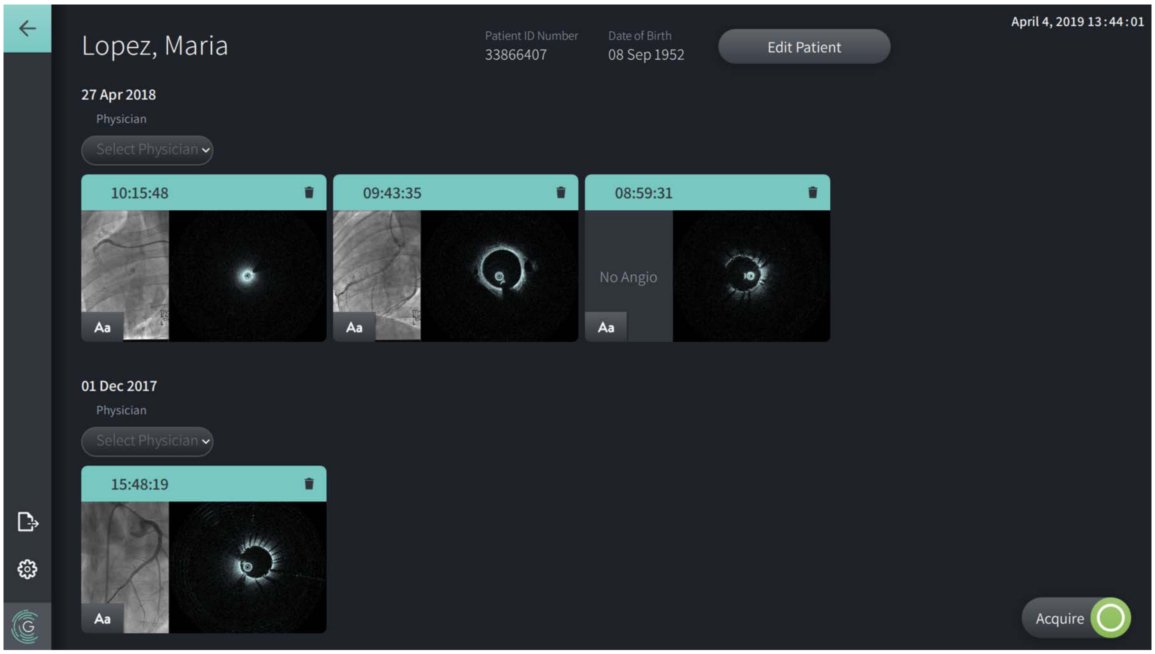
➤ To sort the Patient List columns:

1. Select the column heading to sort the list by the information in the column. A blue heading indicates the current sort order of the list.
2. To switch from ascending or descending order, tap ▲ or ▼ or tap the column heading.

Opening a Patient Record

Each patient record contains the patient's HF-OCT images acquired from previous exams, if available. The pullbacks are organized by date with the most recent exam listed first, as shown in Figure 5-5.

Figure 5-5 Patient Record



➤ To open a patient record:

1. Select the patient record from the **Patient List**. If necessary, use the search field to locate the patient in the list, or sort the list by clicking a column heading to help locate the patient in the **Patient List**.
2. Do any of the following:
   - To review existing images, select the image from the patient records section.
   - To edit the patient's information, select **Edit Patient** in the upper section of the screen. See "Editing Patient Information" on page 5-6 for more information.
   - To edit/add the attending physician for the case, tap the **Enter Physician** button or the **Select Physician** button and type the name or choose the physician's name from the list.

Note — The list of physician's names can also be entered in the **Settings** screen. For more information, see "Configuring General Settings" on page 4-9.

   - To acquire a new image for the current patient, select Acquire.
   - To add a note to an existing image, tap Aa in the bottom panel of the pullback and enter the text for the note.

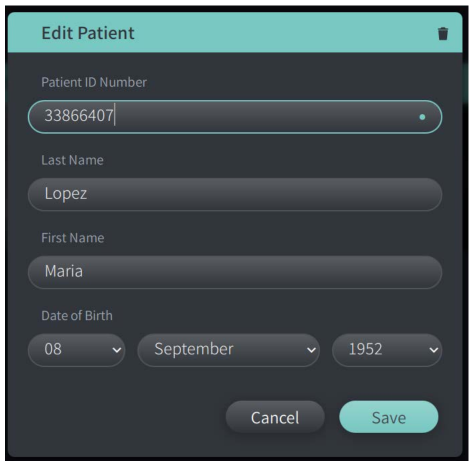
CAUTION! Do not use personally identifiable information in annotations. Annotations do NOT get anonymized.

- To delete a pullback image from the patient record, select the delete icon and confirm the deletion.

Editing Patient Information

Use the **Edit Patient** window to edit the patient's information or to delete a patient record.

Figure 5-6 Edit Patient



➤ To edit a patient record:

1. Select the patient record from the **Patient List** or from the pinned records section, if applicable.
2. Select the **Edit Patient** button.
3. Edit the patient's information as needed.
4. Do either of the following:
   - To save the changes, select **Save**.
   - To discard the changes, select **Cancel**.

➤ To delete a patient record:

CAUTION! Deleting a patient record deletes all pullback data and cannot be recovered.

---

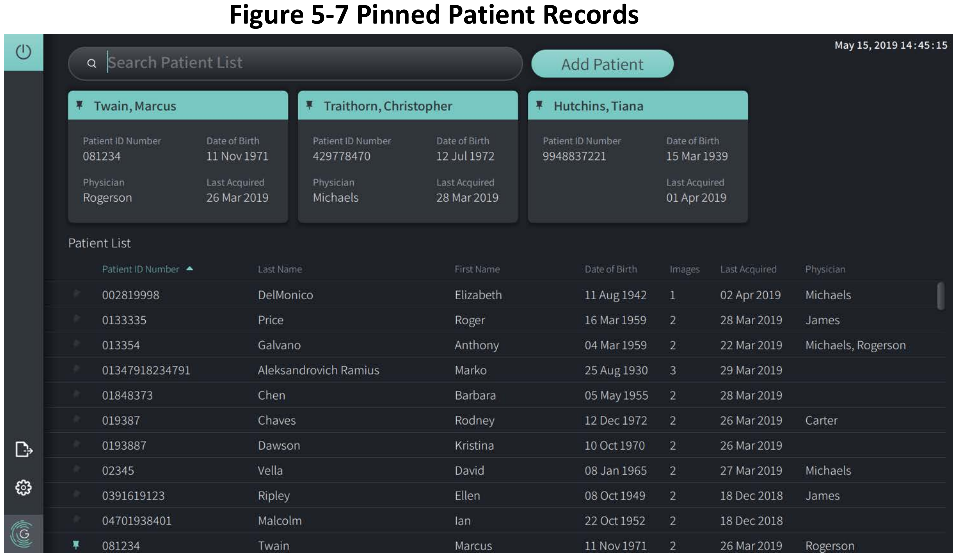
1. Select the patient record from the **Patient List** or from the pinned records section, if applicable.
2. Select the **Edit Patient** button.
3. To delete the patient record, select in the upper right corner of the **Edit Patient** window, and confirm the deletion.
4. Do either of the following:
   - To delete the record, select **Delete**.
   - To discard the changes and keep the record, select **Cancel**.

Pinning a Patient Record

Pinning a patient record lets you add it to the area above the **Patient List**, as shown in Figure 5-7. This is helpful for setting up the list of patients for the day, or keeping the patient record in view for easy reference. The highlighted pin icon indicates that the patient record is pinned.

Note — When you initially add a new patient without acquiring, the patient record is automatically pinned.

Figure 5-7 Pinned Patient Records



➤ **To pin a patient record:**

1. Select the dark pin icon to the left of the patient's ID number. The pin changes to green and the patient's record is displayed in the pinned records section.
2. To scroll through the pinned records, use your finger to swipe right and left, or use the mouse to drag right and left in the pinned records section.
3. To unpin a record, select the highlighted pin or select the pin in the pinned records section. The patient record is removed from the pinned records section, but remains in the **Patient List**.

Exporting Patient Records

This section provides information and instructions for exporting patient records including the compatible devices, file formats, and export settings.

CAUTIONS!

- Gentuity makes no representation or warranty that use of the Gentuity High-Frequency OCT Imaging System complies with applicable privacy, security and confidentiality laws, but encourages you to assess your own risk as you use, disclose, control, process or transfer patient health information with the Gentuity High-Frequency OCT Imaging System.
- To minimize the risk of cybersecurity threats, only use USB drives with trusted computers running anti-virus and anti-malware software.

Notes

- Exporting patient records requires that a USB drive be inserted into the USB port on the Gentuity High-Frequency OCT Imaging System. If the USB drive is not detected, the Export icon is visible but dimmed and not available until a USB drive is detected.
- Do not remove the USB drive during the export function. Verify that the data transfer is complete before removing media.

USB Connected Media Only

To improve export speed of the large Gentuity image files, Gentuity recommends using a USB drive that meets the USB 3.0 Specification.

CAUTION! To minimize the risk of cybersecurity threats, only use USB drives with trusted computers running anti-virus and anti-malware software.

Note — Gentuity recommends that you use a high-speed USB drive to minimize the time it takes to export data.

File Formats

An exported file can contain exactly the same data as the original file, including any measurements and annotation additions, and all patient information associated with each file. For details on what you can include and exclude in exported files, see “Export Settings” on page 5-11.

Different file formats are available depending upon where you initiate the export:

- When viewing the **Patient List** you can export the database and select all or selected patients. The entire pullback is saved in either the Gentuity Format or DICOM SC (Storage Class). For details on exporting the database, see “Exporting Multiple Patient Records” on page 5-12.
- When viewing a specific patient record you can export selected pullbacks. Unless otherwise specified, the entire pullback is exported. If you select Image Collection (JPEG) or Report (PDF), only the annotated slices are exported. For details on exporting selected pullbacks, see and “Exporting a Single Patient Record” on page 5-14.
- When reviewing images, you can export all or selected parts of the currently displayed pullback. For details on exporting all or selected parts of a pullback, see “Exporting Files During Review” on page 7-18.

You can choose whether to delete files after transfer or keep them on the system.

Table 5-2 lists the formats that you can select when exporting patient records to a USB drive.

Table 5-2 Export File Formats

Format	Description
Gentuity Format	Proprietary file format. HF-OCT images can be displayed and analyzed as on the Gentuity High-Frequency OCT Imaging System, including synchronized angio images if captured at the time of acquisition.
DICOM SC	DICOM compatible format for export to image archiving systems. Most Picture Archiving and Communication Systems (PACS) can accept and read DICOM SC files, but images are not calibrated for measurements. The images will show the screen layout that is currently displayed (if exporting from within the image file) or the default image window layout (if exporting multiple pullbacks). **Note —** Gentuity's DICOM Conformance Statement is available on request. Contact support@gentuity.com to request a copy.
Image Collection (JPEG)	Creates a single image for each selected slice of the pullback. The image will show the screen layout that is currently displayed (if exporting from within an image file) or the default image window layout (if exporting multiple pullbacks). Images are compressed and are not suitable for medical archiving or analysis. When you select this export format option, you are prompted to select the export type (**Full Display** or **2D Only**). The **2D Only** option includes only the 2D area of the screen with no graphics.
Video (MP4)	Exports the selected HF-OCT pullback as a series of images displayed as a movie for viewing or embedding in presentations. The movie will show the screen layout that is currently displayed (if exporting from within an image file) or the default image window layout (if exporting multiple pullbacks). Images are compressed and are not suitable for medical archiving or analysis.
Report (PDF)	Creates a report with a single page for each image selected. Each page includes the hospital name and logo (if uploaded) and patient information in the header.
Research (TIFF)	Includes only the 2D area of the screen with no graphics. When selecting this format, you are prompted to select either the Cartesian (8-bit) or Polar (16-bit) coordinate system. When exporting as Research (TIFF), only the HF-OCT image is included.

Export Settings

Table 5-3 lists and describes the export settings in the **Export Review/Configure Export** window when you export single or multiple patient records.

Table 5-3 Export Settings

Option	Option available when selecting this File Type	Description
Select **File Type** Choose from: Gentuity, DICOM SC, Image Collection (JPEG), Video (MP4), Report (PDF), or Research (TIFF)		Specifies the file format. See "File Formats" on page 5-9 for details.
Select **File Size/Quality**	DICOM SC, Image Collection, Report, and Video	Specifies the size and quality of the exported files. Select **Large/High** or **Small/Low**. **Note:** The larger the file size, the more space it consumes on the USB drive.
	Research (TIFF)	Specifies the size and quality of the exported files. Select **768** or **1200**.
Anonymize	Gentuity Format, DICOM SC, Image Collection, Report, and Video **Note:** There is no option to include patient information in a Research export.	Specifies whether Anonymize is on or off when exporting. **On** hides (excludes) patient information in the exported files. **Off** retains (includes) patient information in the exported files.
Select **Format**	Research	Specifies the grid type for the Research export format. Select **Cartesian** to export using a rectilinear grid. Select **Polar** to use a 2D polar grid.
	Video and Image Collection	Select from **Full Display** or **2D Only**.
Select **Slices to Export**	Image Collection and Report	Specifies which slices to include in the export. Select **Annotated Slices** or **Current Slice**.

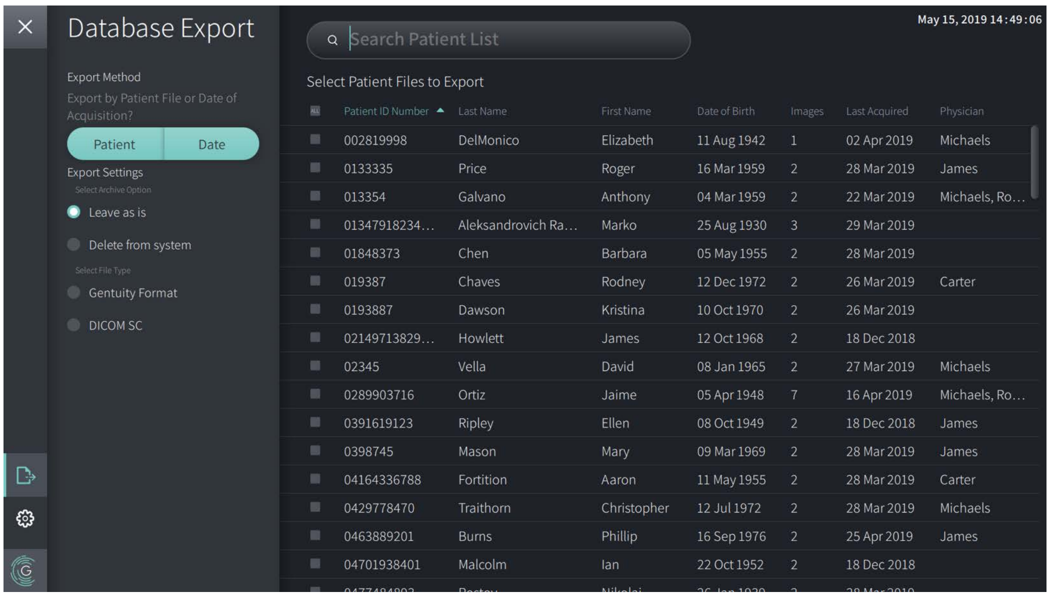
Exporting Multiple Patient Records

When exporting multiple patient records, the system prompts you to include specific export information. You may select specific patient records or all patient records. You also need to specify the format in which to save the exported records, and archiving options.

Figure 5-8 shows the **Database Export** screen where you select whether to export patient records by patient or by date of acquisition.

CAUTION! To minimize the risk of cybersecurity threats, only use USB drives with trusted computers running anti-virus and anti-malware software.

Figure 5-8 Database Export



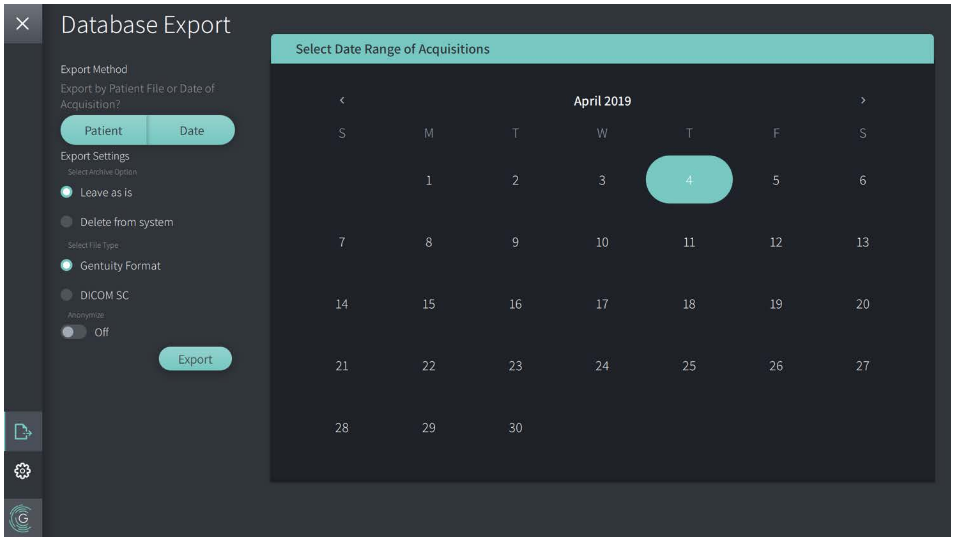
➤ To export multiple patient records

1. Make sure the USB drive is inserted into the USB port on the system.
2. With the **Patient List** displayed, select  to display the **Database Export** menu, as shown in Figure 5-8.
3. Do either of the following:
   - To export specific patient records, select the **Patient** button and then select each patient record to include in the export. A check box is displayed in the **Patient List** for each patient record that you select. You can also select the **ALL** button (located at the top of the first column) to select all patient records:

   - To export patient records by the date of their last acquisition, select the **Date** button and select the date range. A calendar is displayed where you can select the < and > icons to view other months. Select the first date and then select the second date to specify the range. The date range is displayed on the calendar.

Figure 5-9 Export by Date



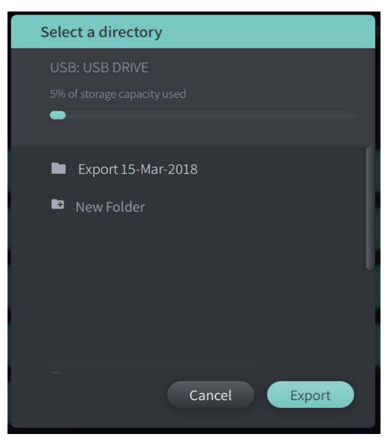
4. Choose one of the following **Archive Options**:
   - To export the patient records without making any changes to the record, select **Leave as is**.
   - To export the patient records and delete the records from the system, select **Delete from system**.

CAUTION! Deleting files from the system frees up storage space on the system but the deleted files cannot be imported back into the system.

---

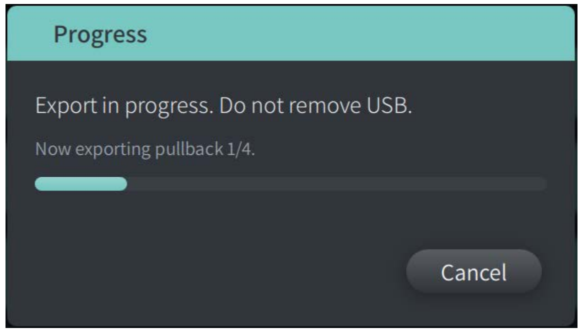
5. In the **Export Settings** section, select the file format and the export options. For details on each, see “File Formats” on page 5-9 and “Export Settings” on page 5-11.
6. Select **Export**. The **Select a Directory** window is displayed (Figure 5-10), prompting you to select a directory or to create a new folder for the archive.

Figure 5-10 Select a Directory



7. Select an existing directory on the USB drive, or select **New Folder** and enter the name of the new folder.
8. Click **Export**. The **Progress** screen is displayed as the records are exported from the system to the USB drive.

Figure 5-11 Export Progress



9. Allow the export to continue or select **Cancel** to cancel the export.

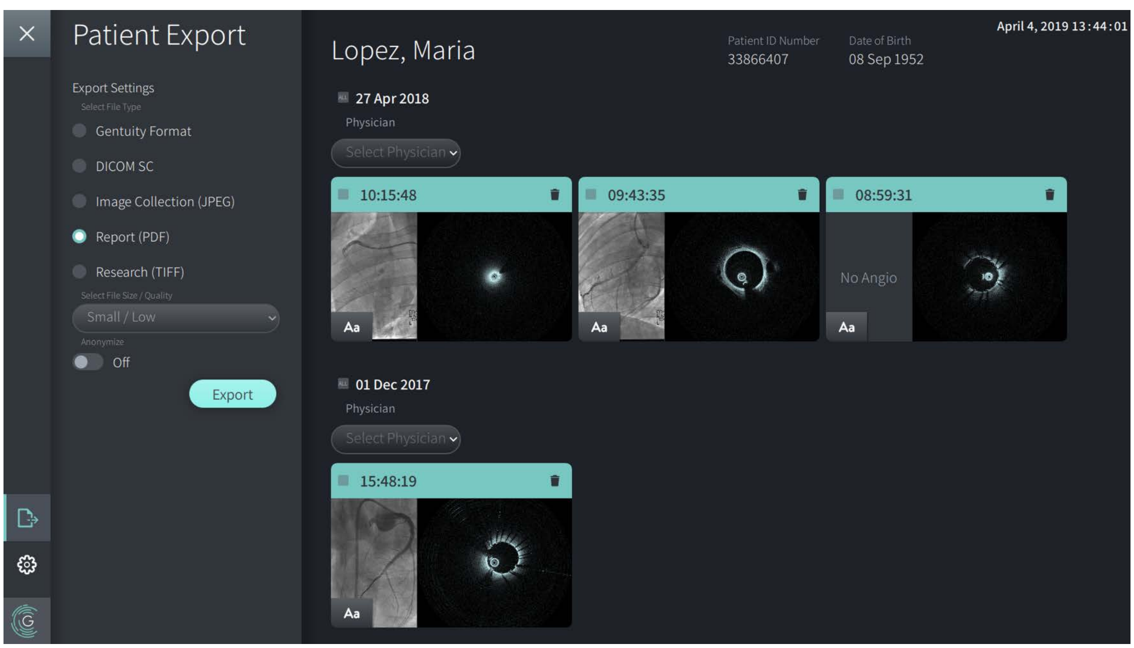
Exporting a Single Patient Record

When exporting a single patient record, the system prompts you to select the specific pullback or pullbacks that are associated with the patient and the format in which to save the exported record.

CAUTION! To minimize the risk of cybersecurity threats, only use USB drives with trusted computers running anti-virus and anti-malware software.

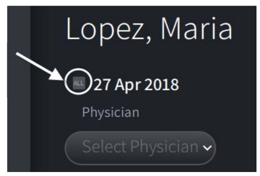
The **Patient Export** menu is displayed when you select a single patient record to export, as shown in Figure 5-12.

Figure 5-12 Patient Export Menu



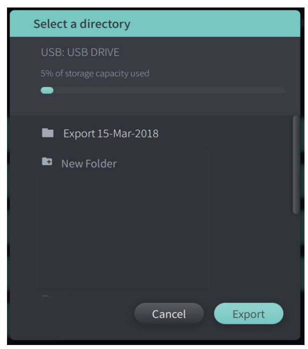
➤ To export a single patient record:

1. Make sure the USB drive is inserted into the USB port on the system.
2. With the record displayed, select  to display the **Patient Export** menu, as shown in Figure 5-12.
3. Do either of the following:
   - To export specific patient pullbacks, select the check box associated with each pullback. A check box is displayed in each pullback that you select.
   - To export all pullbacks, select the **ALL** button (located to the left of the date):



4. In the **Export Settings** section, select the file format and the export options. For details on each, see “File Formats” on page 5-9 and “Export Settings” on page 5-11.
5. Select **Export**. The **Select a Directory** window is displayed (Figure 5-13), prompting you to select a directory or to create a new folder for the archive.

Figure 5-13 Select a Directory



6. Select an existing directory on the USB drive, or select **New Folder** and enter the name of the new folder.
7. Click **Export**. The **Progress** screen is displayed as the records are exported from the system to the USB drive.
8. Allow the export to continue or select **Cancel** in the **Progress** screen to cancel the export.

About File Naming Conventions

When you export files, the system generates the filenames and extensions based on the type of export and file.

For generated reports, the filename includes the date and time that the report was generated. The format is year, month, day, hour, minute, and second. To view actual patient and pullback information in the generated report, you must open the file using any PDF viewer application (not provided by Gentuity). You can rename the generated report file as long as you preserve the .PDF file extension.

Files other than reports can contain patient and pullback information in the filename. The format is: patient ID, last name, and first name, patient year of birth, month, and day, pullback year, month, day, hour, minute, second, and pullback slice number. Not all of this information is present in every filename. For example, the patient's date of birth may not have been entered in the patient record, or the Anonymize option was selected during the export. You can rename these files as long as you preserve the original file extension.

CAUTION! Files exported using the Gentuity format have .g2raw and .patient file extensions. Changing the filename or extension of files exported using the Gentuity format may result in the loss of exported information. Gentuity recommends not changing these filenames or extensions.

Chapter 6
Performing an HF-OCT Procedure

This chapter provides information and instructions for performing an HF-OCT procedure. It includes an overview of the procedure, the materials and equipment required for the procedure, how to set up the system and prepare the PIM and catheter, and how to insert the catheter and acquire images.

Overview

The following summarizes the general steps to image using the Gentuity High-Frequency OCT Imaging System with the Vis-Rx Micro-Imaging Catheter:

1. Set up the system for imaging.
2. Enter or select the patient record.
3. Prepare the PIM and catheter.
4. Prepare flush media.
5. Insert and position the catheter.
6. Begin the acquisition sequence.
7. (Optional) Preview to confirm position of catheter within the vessel.
8. (Optional) Deliver approximately 5 ml of flush media to confirm alignment.
9. Enable the start of high-speed rotation.
10. Inject the flush media.
11. Acquire the pullback.
12. Confirm that the acquired images are acceptable.
13. Remove the catheter.

This chapter provides detailed instructions on each step.

The HF-OCT procedure requires two operators:

- **Sterile Operator (SO):** All steps that require contact with the Vis-Rx Micro-Imaging Catheter must be performed by the sterile operator.
- **Non-Sterile Operator (NSO):** All steps that are performed in direct contact with the Gentuity High-Frequency OCT Imaging System or the PIM are performed by the Non-Sterile Operator.

After the HF-OCT pullback has been recorded, it is immediately available for review. For more information, see“Reviewing HF-OCT Recordings” on page 7-1.

Required Materials and Equipment

The following materials and equipment are required to perform the HF-OCT procedure:

- Gentuity High-Frequency OCT Imaging System
- Vis-Rx Micro-Imaging Catheter
- 3 ml purge syringe (included with the Vis-Rx Micro-Imaging Catheter)
- Contrast media indicated for coronary use, for flush (allow 15 ml for each pullback planned)
- .014" (0.36mm) guidewire (with torque device if desired)
- Guide catheter (6 French, 0.068" (1.73mm) ID or larger, with no side holes)
- Sheath introducer (to match guide catheter)
- Hemostatic Y-Adapter/Connector
- Heparinized saline for hydrophilic catheter preparation and catheter purging
- Power injector pump for coronary angiography or coronary control syringe (minimum 10 ml)

Setting up the System

Setting up the system for performing an HF-OCT procedure includes the following steps:

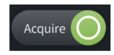
1. Position the system for use as described in “Positioning the System” on page 4-1.
2. Turn the system on, as described in “Connecting and Powering On the System” on page 4-1.
3. Adjust the display monitor as needed, as described in “Setting Up the Monitor” on page 4-4.
4. Prepare the PIM, as described in “Preparing the PIM” on page 4-7.
5. Optionally, connect the angiography input, as described in “Connecting Video Input from an Angiography System” on page 4-4.
6. Optionally, connect to an external display monitor, as described in “Connecting an External Monitor” on page 4-4.

Using the Vis-Rx Micro-Imaging Catheter

Note — The procedures in the following sections indicate who performs each step: Sterile Operator (**SO**) or Non-Sterile Operator (**NSO**).

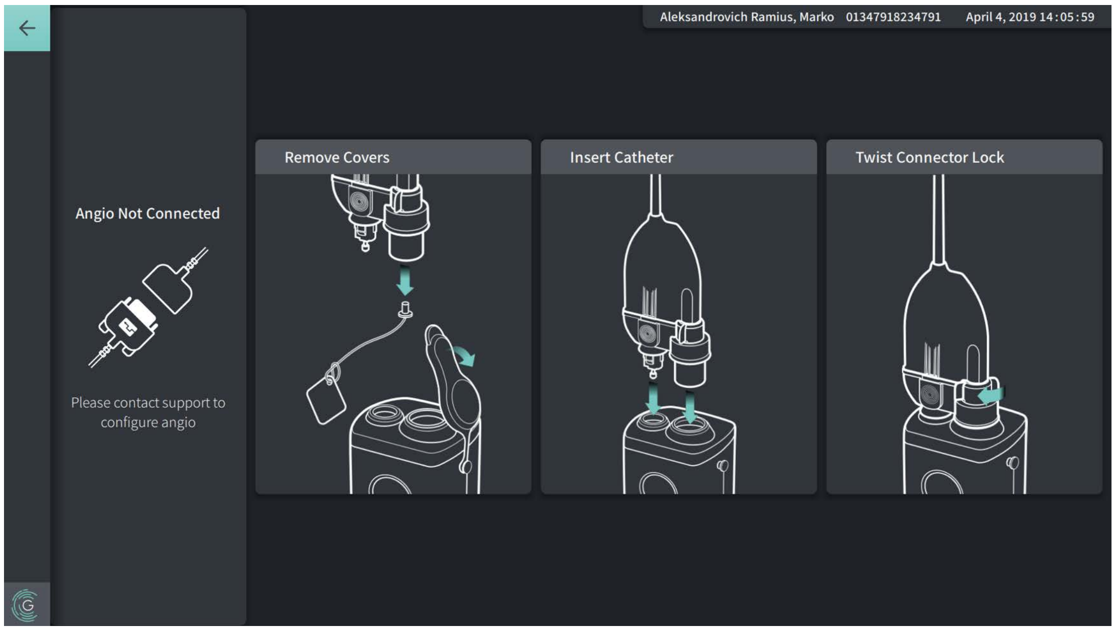
Connecting the Catheter to the PIM

The system provides illustrated instructions for connecting the catheter to the PIM, as shown in Figure 6-1.

The instructions are displayed when you select the 

button if the catheter is not yet connected to the PIM.

Figure 6-1 Connecting Catheter to PIM



➤ To connect the Vis-Rx Micro-Imaging Catheter to the PIM:

1. **NSO:** Attach the PIM to the surgical bed rail.
    - To secure clamp to rail, hook the top of the clamp onto the rail and tilt downward.
    - To rotate the PIM as needed, push the PIM in and rotate the PIM body.
2. **NSO:** Carefully open the catheter and syringe pouches and transfer the contents into the sterile field using sterile techniques.
3. **SO:** Using sterile techniques, pass the catheter connector to the **NSO** near the PIM.
4. **NSO:** Remove the cover from the PIM connector and the cover from the catheter optical connector. (See Figure 6-1 for details)
5. **NSO:** Align the catheter connectors to the connection ports on the PIM and insert the catheter into the PIM until it snaps into place.
6. **NSO:** Rotate the optical connector clockwise to the LOCKED position.

CAUTIONS!

- Protect the PIM connection ports and the catheter connectors from fluids.
- Do not touch the internal optics of the optical connector on the catheter or on the PIM.
- Observe sterile technique when connecting the catheter to the PIM, which is outside of the sterile field.

Once properly connected, the system progresses to the next stage of readiness. The red light on the catheter remains on to indicate that the catheter is connected, the optical pathway is complete, and that the system is active.

Preparing the Catheter

➤ To prepare the catheter:

1. **SO:** When ready to perform imaging, activate the hydrophilic coating by injecting saline into the hoop or wiping the distal segment with gauze moistened with saline.
2. **SO:** Fill the provided 3 ml syringe with heparinized saline and attach to the catheter purge port. Purge the lumen of the catheter with saline until 3-5 drops exit the distal purge exit.
3. **SO:** Leave the purge syringe connected so that the catheter lumen can be repurged if necessary.

CAUTION! Do not remove the syringe from the catheter purge port to prevent air from entering the purge lumen and to allow repurging as necessary.

Inserting and Positioning the Catheter

➤ To insert the Vis-Rx Micro-Imaging Catheter:

1. **SO:** Insert the guidewire into the guidewire lumen of the Vis-Rx Micro-Imaging Catheter and advance the imaging catheter over the guidewire. Use the insertion depth gauges at 90 cm and 100 cm as guides for when the imaging catheter will exit the guide catheter.

WARNING! Leave the guidewire engaged with this catheter at all times during use.

CAUTIONS!

- Use a guidewire with a maximum outer diameter of 0.014" (0.36 mm) and a guide catheter with a minimum inner diameter of 0.068" (1.73 mm).
- Make sure the PIM motor is NOT running and not imaging when inserting the Vis-Rx Micro-Imaging Catheter into the guide catheter.

➤ To advance and position the imaging catheter:

Note — There are three radiopaque markers on the catheter:

1. The most distal marker, the **tip marker**, is located 4 mm proximal to the tip of the catheter and is affixed to the catheter sheath.
2. The **lens marker** is located 5 mm distal to the lens on the imaging core. Place the lens marker distal to your target image area.
3. There is an additional **pullback marker** placed 50 mm proximal to the lens on the imaging core.

---

1. **SO:** Using fluoroscopy, position the imaging catheter in the region of interest, using the radiopaque markers at the tip, imaging lens, and 50 mm marker proximal to the lens for guidance.

WARNINGS!

- If resistance is encountered during advancement or withdrawal of the Vis-Rx Micro-Imaging Catheter stop manipulation and evaluate under fluoroscopy. If the cause of resistance cannot be determined or mitigated, carefully remove the catheter and guidewire together.
- Observe all advancement and movement of the imaging catheter in the vasculature under fluoroscopy.
- If the imaging catheter becomes kinked, stop manipulating it to avoid vessel injury or imaging catheter damage.
- To avoid blood vessel damage, maintain the position of the guidewire when manipulating the imaging catheter in the vessel.

CAUTIONS!

- To avoid catheter damage, make sure the PIM motor is NOT running when inserting the Vis-Rx Micro-Imaging Catheter into the guide catheter.
- Always advance and withdraw the imaging catheter slowly.
- To ensure imaging of the selected anatomy, do not move the guide wire after the imaging catheter is in position.

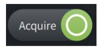
Confirming Imaging Settings

This section provides instructions for confirming imaging settings.

When confirming imaging settings, you are prompted to select the **Pullback Settings**. **Pullback Settings** include:

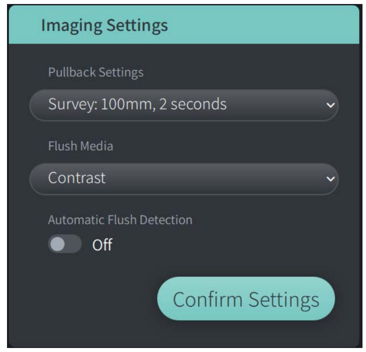
- Survey: 100mm, 2 seconds
- Short Survey: 50mm, 1 second
- High Density: 50mm, 2 seconds
- One Second Imaging™: 100mm, 1 second

➤ To confirm imaging settings:

1. **NSO:** When ready, select  on the touchscreen. If the catheter has not yet been connected, the system provides user guidance, as shown in Figure 6-1 on page 6-3.

   The **Imaging Settings** screen is displayed, as shown in Figure 6-2.

Figure 6-2 Confirm Settings



2. **NSO:** Specify the following settings in the **Imaging Settings** window:
   - Select the **Pullback Settings**, as described above.
   - Confirm the default **Flush Media** type or select another **Flush Media** type.
   - In the **Automatic Flush Detection** section, select **ON** for automatic detection, or **OFF** for manual detection.

Notes

- **Automatic Flush Detection (ON)** is the setting in which the system triggers a pullback automatically when a brief sequence of clearing is detected as a result of contrast injection. If clearing is not detected within 15 seconds after being enabled, the system displays a Timeout error. You can initiate pullback manually when in Automatic mode by selecting  on the touchscreen or by pressing the **GO** button on the PIM.
- **Automatic Flush Detection (OFF)** is the manual setting. After clearing is observed, select  on the touchscreen or press the **GO** button on the PIM to start the pullback. If you do not initiate the pullback within 15 seconds after the system is enabled, the system displays a Timeout error.

WARNING! Selecting the wrong flush media can cause measurement errors which could lead to incorrect treatment. Prior to acquisition, make sure the media identified in the **Pullback Settings** window matches the media you are using.

---

3. **NSO:** Select **Confirm Settings** to continue.

Preparing the Flush Media

CAUTIONS!

- Refer to the contrast media's instructions for general warnings and precautions relating to contrast media.
- Make sure to use the contrast media and injectors according to injection specifications given by the manufacturers.

Note — The flush media source (injector or syringe) should be connected to the Y-connector on the guide catheter.

➤ To prepare the flush media:

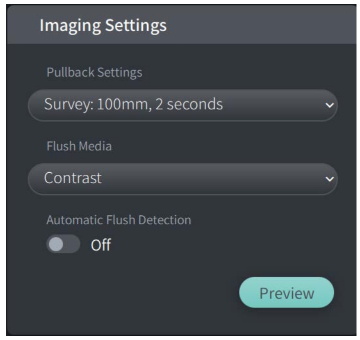
1. **SO:** Depending on the type of flush media injection, do one of the following:
   - If using an **automated injector**, ensure the selected flush media is loaded in the injector and set the flush rate to 4 ml/sec or less, with a total volume of 16 ml or less and pressure limit of 300 psi (2068 kPa).
   - If using a **manual injection**, prepare a coronary control syringe capable of injecting up to 4 ml/sec for 3 to 4 seconds.

WARNING! Excessive flush rate and pressure may damage the blood vessel or devices used with the Vis-Rx Micro-Imaging Catheter. Low flush rate may result in a faint image.

Beginning Preview (Optional)

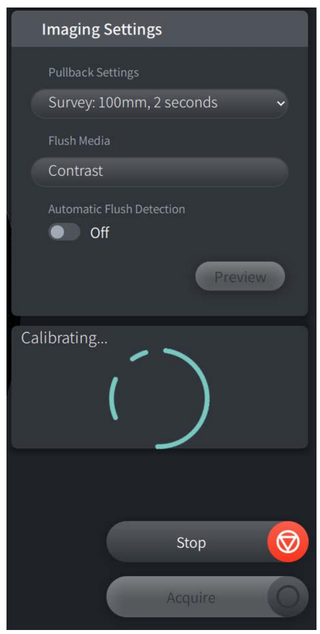
Perform the following *optional* steps in **Preview** to confirm the position of the catheter within the vessel.

Figure 6-3 Imaging Settings-Preview



1. **NSO:** When the catheter is in position, select **Preview** (Figure 6-3). Upon selecting **Preview**, the PIM will activate and the HF-OCT image is displayed. A **Calibration** window (Figure 6-4) is also displayed for approximately 5 seconds.
2. **SO:** If necessary, use the 3 ml purge syringe to eliminate any blood from the catheter lumen.

Figure 6-4 Calibration window



Delivering 5 ml Flush Media to Confirm Alignment

Optionally, you can deliver flush media to confirm alignment of the guide catheter with the vessel.

➤ **To deliver flush media and confirm alignment:**

1. **SO:** Deliver approximately 5 ml of flush media via the Y-connector to fill the guide catheter with the flush media and to ensure proper guide catheter alignment with the ostium under fluoroscopic guidance.

CAUTIONS!

- To help ensure successful imaging, the guide catheter should be oriented to preferentially direct the flush media flow to the target artery.
- To help ensure successful imaging, do not use a guide catheter with side holes.

---

2. Proceed to **Enable** step, or press **STOP** on the touchscreen (or on the PIM) to exit Preview mode.

Enabling the Start of High-Speed Rotation

➤ **To enable the system to start high-speed rotation:**

1. **NSO:** With confirmation of proper guide position and imaging catheter position, select **ENABLE** on the Gentuity High-Frequency OCT Imaging System touchscreen (or press the green **GO** button on the PIM) to start high-speed PIM rotation.

When the PIM reaches full speed and the catheter is calibrated, the system is ready for pullback. The 15-second clock begins, and the system prompts for injection of the flush media.

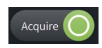
Note — If you do not inject the flush media and initiate pullback within 15 seconds, the PIM rotation stops completely and a Timeout window is displayed. Select **Okay** and then select **Enable** to enable the system when ready to image.

Injecting Flush Media and Initiating Pullback

WARNING! Before injecting flush media, be sure that the hemostasis valve is tightened to reduce the risk of unintended catheter movement or leaking of flush media during injection.

➤ To inject the flush media and initiate pullback:

1. **SO:** Inject the flush media into the target artery via the Y-connector on the guide catheter.
2. **NSO:** Depending on the selected Automatic Flush Detection setting, do one of the following:
   - **Automatic Flush Detection (ON)**: The system automatically initiates pullback when clearing is detected. Alternatively, you can manually initiate pullback prior to the automatic trigger by selecting 

 on the touchscreen or by pressing the green **GO** button on the PIM.
   - **Automatic Flush Detection (OFF)**: Select 

 on the touchscreen or press the green **GO** button on the PIM to initiate pullback and start capturing images once the blood is removed and a clear image displays (1-2 seconds after injecting the flush media).

The image displays after completion of the pullback. The optical imaging core returns to the distal position within the sheath for further imaging.

CAUTION! If the optical imaging core encounters resistance while returning to the distal position within the sheath (due to a kink or blockage), the Advance Force Limiter will buckle to absorb the forward motion. If this occurs, carefully remove the imaging catheter from the guide catheter. Replace with a new catheter if further imaging is required.

Notes

- **SO:** Do not remove the catheter until you confirm the image is acceptable.
- **NSO:** Do not disconnect the catheter from the PIM until no more HF-OCT images are required.

Removing the Catheter

After confirming that the image or images are acceptable, perform the steps in this section to remove the catheter.

➤ To remove the catheter

1. **SO:** Under fluoroscopy, carefully remove the catheter from the guide catheter, checking the condition of the catheter, guidewire, and guide catheter during withdrawal.

WARNING! To avoid vessel damage or catheter damage, do not push the guide catheter further into the blood vessel when removing the catheter.

2. **SO:** After removing the catheter from the patient, use the 3 ml purge syringe to purge the Vis-Rx Micro-Imaging Catheter until 3-5 drops of saline exit from the purge exit. Keep the purge syringe connected throughout the procedure.
3. **SO:** Wipe the distal section of the catheter with saline to remove the external blood and flush media.

WARNING! Do not disconnect the Vis-Rx Micro-Imaging Catheter from the PIM until the procedure is complete to avoid a sterility breach.

When the catheter is removed the from the guide catheter and no further imaging is required, it may be disconnected from the PIM.

➤ To disconnect the catheter from the PIM

1. **NSO:** Hold the catheter connector and unlock the optical connection by turning it counter-clockwise to the UNLOCKED position.
2. **NSO:** Grasp the pullback connector (by squeezing both sides) to remove the catheter from the PIM.
3. **NSO:** Place the protective port cover on the PIM to prevent damage to the catheter and pullback connection ports on the PIM.

CAUTIONS!

- When there is no catheter connected to the PIM, be sure the PIM connector cover is securely in place to protect from dirt and damage.
- Do not touch the internal optics of the optical connector on the catheter or on the PIM.
- Protect the PIM connection ports and the catheter connectors from fluids.

4. **NSO:** Dispose of the catheter in accordance with accepted medical practice and applicable laws and regulations.

WARNING! The catheter is intended for one time use only. Do not reuse, re-sterilize, or reprocess.

Completing the Exam

Note — Images and all measurements and annotations are automatically saved with the patient record and are available when the record is reopened.

When the exam is complete, perform the following steps:

1. Shut down the system using the **Shut Down** button.
2. Before moving the system:
    - Release the PIM from the bed rail and place it in the PIM cradle on the Gentuity High-Frequency OCT Imaging System. The PIM must be placed in the cradle so that the connection ports are facing down.

CAUTION! Always store the PIM with the PIM connector cover facing down.

- If necessary disconnect the power cord from AC power.
- Wrap the PIM cord around the rear handle so that it does not drag on the floor.

Note — To save time powering up the system, it is recommended that you leave the power switch on the back of the system in the ON position when finished using the system.

Chapter 7
Reviewing HF-OCT Recordings

This chapter provides information and instructions for reviewing the HF-OCT recordings. It includes details about the Image screen used to view and review pullback images, the view modes, and information and instructions for exporting files during review.

Overview

Review mode is immediately available following a pullback.

When reviewing recordings, the default Image screen shows a 2D image of the pullback, the lumen profile display, and if connected, the angio image acquired during pullback. Lateral (L-Mode) and 3D views are also available.

Notes

- To optimize the view of the lumen/vessel and surrounding tissue, use the pinch and zoom gestures to zoom in and out of the 2D image.
- You can also size the panels in the Image screen to increase or reduce the size of the content in the panel.

Image Screen

Use the Image screen to view the pullback images. Figure 7-1 shows the Image screen and its elements, and Table 7-1 lists and describes each item in the Image screen.

Figure 7-1 Image Screen

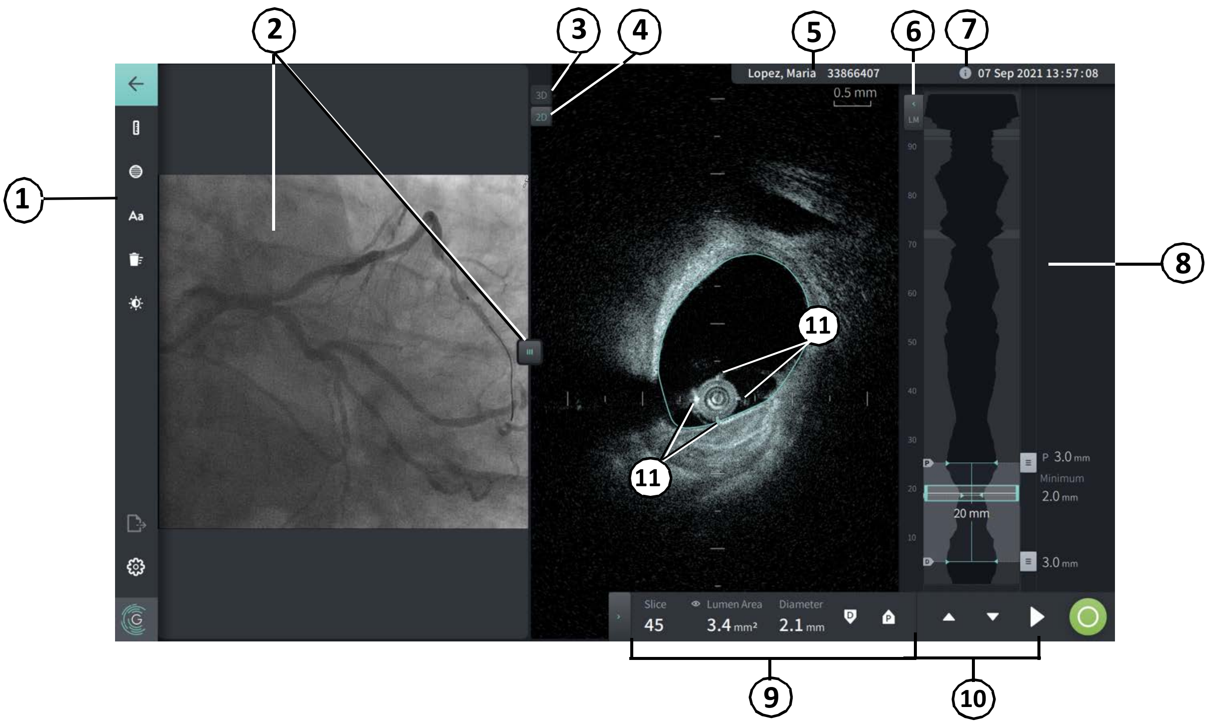


Table 7-1 Image Screen

Item	Name	Description	For more information, see:
1	Menu Bar	Provides an icon to return to the previous screen, tools for adding measurements, annotations, and adjusting the contrast and brightness, and access to the **Settings** window and Export functions.	"Menu Bar" on page 7-4
2	Angio Image Display and resizing tool	If connected during acquisition, this section displays the angiogram acquired at the time of pullback. Use the resizing tool to show, hide, and change the size of the angio image display.	"Angio View" on page 7-5
3	3D View tab	A control to view the 3-dimensional image of the lumen display of the acquired vessel.	"3D View" on page 7-15
4	2D View tab	Displays a two-dimensional image of the vessel during playback.	"2D View" on page 7-6
5	Patient Information title bar	Displays the patient name, patient ID, and in the far right corner, the date and time of the pullback	"Accessing the Patient List" on page 5-1

Table 7-1 Image Screen

Item	Name	Description	For more information, see:
6	LM View tab	A control to view and hide the L-Mode display.	"L-Mode View" on page 7-14
7	Pullback Information Icon	When clicked, opens the Pullback Information window to view details about the displayed pullback.	"Viewing Pullback Information" on page 7-17
8	Lumen Profile Display	Shows the relative size of the lumen area throughout the pullback.	"Lumen Profile Display" on page 7-8
9	Current Slice Information Panel	Provides automated lumen measurements on the displayed 2D image.	"Current Slice Information Panel" on page 7-7
10	Playback Controls	Controls to playback the HF-OCT recording.	"Playback Controls" on page 7-10
11	Calibration Fiducials	The four lines around the catheter provide a visual indication of the expected catheter size when correctly calibrated.	--

Menu Bar

The Menu Bar, shown in Figure 7-2, is located on the left side of screens in the Gentuity High-Frequency OCT Imaging System during review. Table 7-2 lists and describes the elements of the Menu Bar.

Figure 7-2 Menu Bar

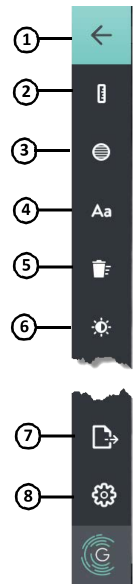


Table 7-2 Menu Bar

Item	Name	Description
1	Back icon	Returns to the previous screen
2	Linear measurement tool	Provides tools to add measurements and annotations to the image. For more information about the tools, see “Measurements and Annotations” on page 8-1.
3	Area measurement tool	
4	Annotation tool	
5	Delete icon	Deletes all user-generated measurements and annotations in the pullback. Confirmation is required.
6	Image Adjustment	Lets you adjust the contrast and brightness of the displayed image.
7	Export icon	Opens the **Export** window. For more information about exporting patient records, see “Exporting Patient Records” on page 5-8 and “Exporting Files During Review” on page 7-18.
8	Settings icon	Opens the **Settings** window to configure system settings. For more information, see “Configuring System Settings” on page 4-8.

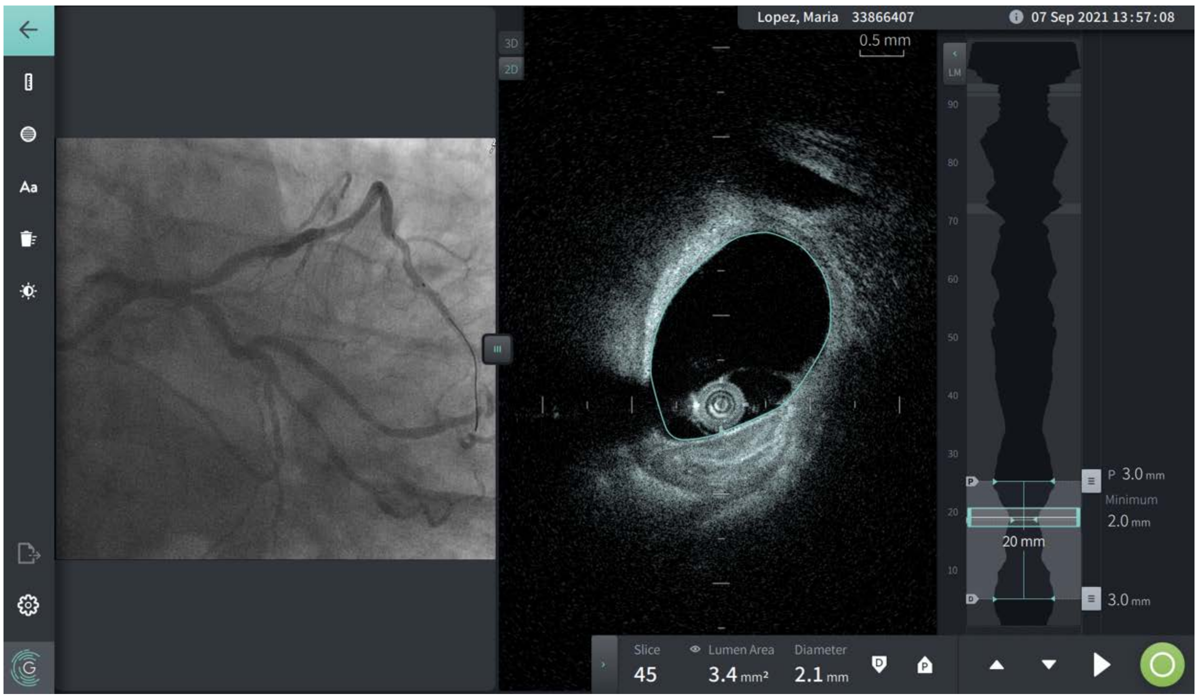
Angio View

If connected to an angiography system video output during acquisition, the left side of the Image screen displays the angiogram acquired at the time of pullback.

Use the resizing tool ||| to resize, expand, and collapse the Angio view.

For more information on connecting an angiography system video output, see “Connecting Video Input from an Angiography System” on page 4-4.

Figure 7-3 Angiogram View

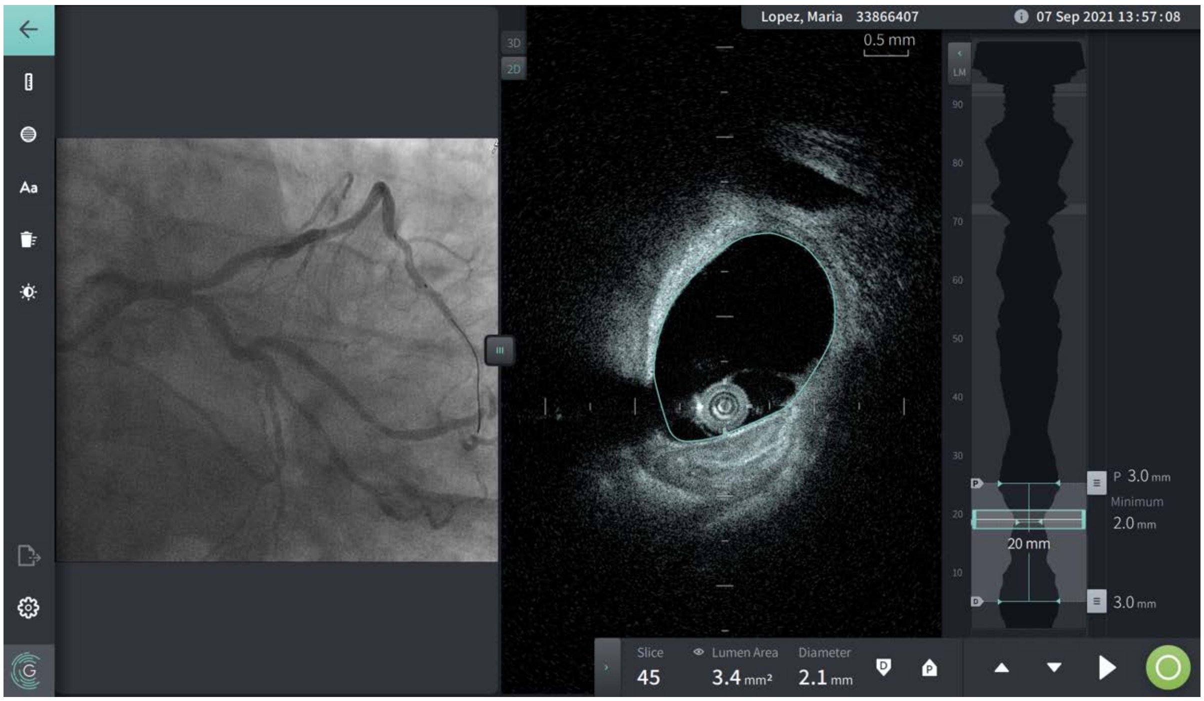


2D View

During the HF-OCT pullback recording, the system captures a 3-dimensional volume which is rendered into 2-dimensional slices, or cross-sections, for viewing.

In each 2D slice, the system identifies the lumen boundary and draws a lumen trace. The lumen area and diameter are determined from this trace.

Figure 7-4 2D View



➤ **To edit the lumen trace and move the points:**

1. Tap or click on the lumen trace to show the control points and enable editing.
2. To make adjustments, press and hold a move point and then drag the point to the new location as needed. You can eliminate an unwanted point by dragging it to a neighboring point to combine the two points. Add additional points by tapping or clicking the area in which you want to add a point.
3. Tap or click somewhere else on the screen to hide the control points.

Current Slice Information Panel

After the HF-OCT image is acquired, the software automatically detects the lumen boundary in each cross-sectional slice and displays the area and the diameter for each slice based on the displayed lumen trace, as shown in Figure 7-4 and Figure 7-5.

Based on the lumen trace, the system calculates the area. The diameter is derived from a circle with the same area as the trace.

Notes

- The number of slices may vary slightly for pullbacks that are of the same distance and duration.
- Image artifacts, such as residual blood from incomplete flushing or sew-up artifact, can affect individual slices of the image. When making a precise measurement, select a slice that is free from artifacts.

Table 7-3 lists and describes the elements in the Current Slice Information Panel.

Figure 7-5 Current Slice Information Panel

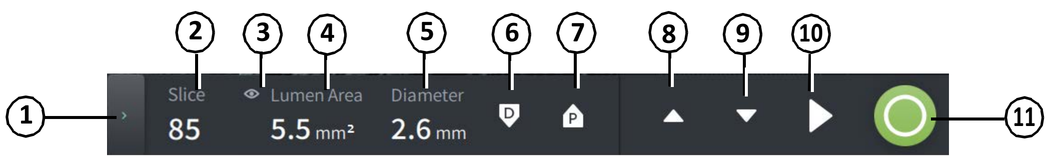


Table 7-3 Current Slice Information Panel

Item	Description
1	Control to show and hide the Current Slice Information Panel
2	Current slice
3	Control to show and hide the lumen trace boundary on the 2D view
4	Lumen area value
5	Lumen diameter value
6	Control to mark a distal reference slice on the lumen profile
7	Control to mark a proximal reference slice on the lumen profile
8	When playing, the control to fast-forward through the slices; when paused, the control to advance to the next slice
9	When paused, the control to reverse to the previous slice
10	When playing, a control to pause the playing of the pullback; when paused, the control to play the pullback
11	Control to enter the image acquisition workflow to acquire another pullback

For more information on the playback controls, including what is visible when paused and when playing, see “Playback Controls” on page 7-10.

Lumen Profile Display

The Lumen Profile display, on the right side of the Image screen, shows the relative area of the vessel lumen along the length of the vessel based on the automatically detected lumen boundary for each 2D view.

The Lumen Profile display is shown with the proximal portion of the vessel at the top and the distal at the bottom of the screen.

CAUTION! Cardiac motion relative to the catheter can cause lengthening and shortening of longitudinal segments of the Lumen Profile and L-Mode, or can create a jagged appearance of the reconstructed image. Do not rely solely on the Lumen Profile or L-Mode for longitudinal measurements.

You can perform the following actions on the Lumen Profile display:

- To adjust the current slice, drag the Current Slice Marker (shown in Figure 7-6 below) to the desired location or touch an area in the Lumen Profile to move directly to that location.
- To identify a region of interest within the Lumen Profile, adjust the Proximal and Distal reference slices. When adjusting the reference slice location, the corresponding 2D view is displayed.
- To designate a slice as proximal or distal, navigate to the desired slice and use the markers in the Current Slice Information Panel accordingly. For details, see "Current Slice Information Panel" on page 7-7.

The Lumen Profile display shows the lumen diameter at the Proximal and Distal reference slices and the longitudinal distance between these references. In addition, the system identifies the slice with the smallest lumen diameter between these two references, labeled as the **Minimum** (minimum lumen diameter) on the Lumen Profile display.

Figure 7-6 shows the elements in Lumen Profile. Table 7-4 lists and describes the elements.

Figure 7-6 Lumen Profile Display

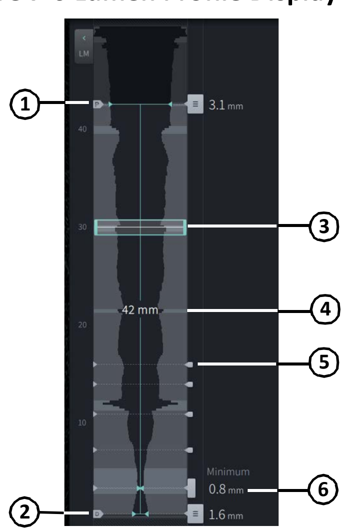


Table 7-4 Lumen Profile Display

Item	Name	Description
1	Proximal Slice Reference Marker	Defines the proximal end of an area of interest and provides the lumen diameter for that slice. Select the Proximal Slice Reference Marker and drag it up and down the Lumen Profile Display to adjust proximal slice area of interest. Alternatively, move to a slice in the 2D view and select to mark that slice as the Proximal Slice Reference.
2	Distal Slice Reference Marker	Defines the distal end of an area of interest and provides the lumen diameter for that slice. Select the Distal Slice Reference Marker and drag it up and down the Lumen Profile Display to adjust distal slice area of interest. Alternatively, move to a slice and select to mark that slice as the Distal Slice Reference.
3	Current Slice Indicator	The current slice indicator shows the location of the currently displayed 2D image in the pullback. Select anywhere in the Current Slice Indicator to drag it up and down the Lumen Profile Display to navigate to different sections of the pullback, or touch anywhere on the Lumen Profile to jump to that slice. Use the Current Slice Indicator control to navigate to different sections of the pullback. As you drag it, the 2D image updates to match the location and the values in the Current Slice Information Panel are updated to display information about the slice. You can also use the slice controls to step forward and backward through the slices:
4	Longitudinal Distance	Indicates the longitudinal distance between the proximal and distal reference slices
5	Measurement/ Annotation Marker	Indicates a slice where the user has added a manual measurement or annotation.
6	Minimum	Indicates the slice with minimal lumen boundary area between the Proximal and Distal Slice Reference Markers and displays the lumen diameter of that minimum slice. The Minimum indicator is automatically set as the narrowest section of the Lumen Profile Display between the Proximal and Distal Slice Reference Markers and will adjust as needed if you adjust the Proximal and Distal Slice Markers.

Note — The marks along the outsides of the Lumen Profile Display indicate where measurements and/or annotations are located on the pullback. For more information, see “Measurements and Annotations” on page 8-1.

Playback Controls

Use the playback controls when viewing an HF-OCT recording to play and pause the playback.

Controls When Playing

When a pullback is playing, the following controls are available, as shown in Figure 7-7.

Figure 7-7 Controls While Pullback is Playing

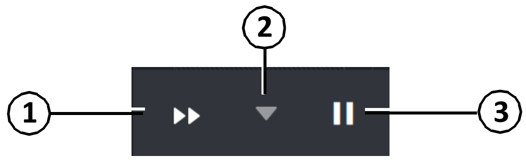


Table 7-5 Controls While Pullback is Playing

Item	Description
1	Fast-forward. Each click/tap changes the speed of the play. Speeds include regular (no number showing), 2x, 4x, 1/2x, and 3/4x speed.
2	Unavailable while playing
3	Pause

Controls When Paused

When a pullback is paused, the following controls are available, as shown in Figure 7-8.

Figure 7-8 Controls While Pullback is Paused

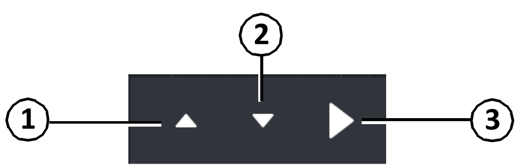


Table 7-6 Controls While Pullback is Paused

Item	Description
1	Advance to next slice
2	Reverse to previous slice
3	Play

Navigating the Pullback

There are several ways to navigate in the pullback:

- Touch anywhere in the Lumen Profile to navigate to a specific slice. See Table 7-4 on page 7-9 for more information.
- Drag the Current Slice Indicator to navigate to a different section of the pullback. See Table 7-5 on page 7-10 for more information.
- Use the Play and Pause controls as described in “Playback Controls” on page 7-10.
- Use the arrow keys on the keyboard or the arrow keys as described in Table 7-3 on page 7-7.

Areas of Uncertainty

When the software detects an unusual lumen shape, such as where a side branch originates or where residual blood obscures the lumen, the slice is identified as *low confidence.*

Figure 7-9 shows an example of an area of uncertainty. In 2D images, the system has several indicators to display low confidence in the automatically detected lumen boundary. Table 7-7 describes the indicators.

You can manually adjust the lumen boundary by touching the boundary and adjusting the control points. When you have adjusted the boundary, it is no longer marked as low confidence.

CAUTION! Use caution when interpreting the low confidence slices. If measurements are present, you can manually adjust the lumen trace to more accurately identify the lumen boundary.

Figure 7-9 Areas of Uncertainty

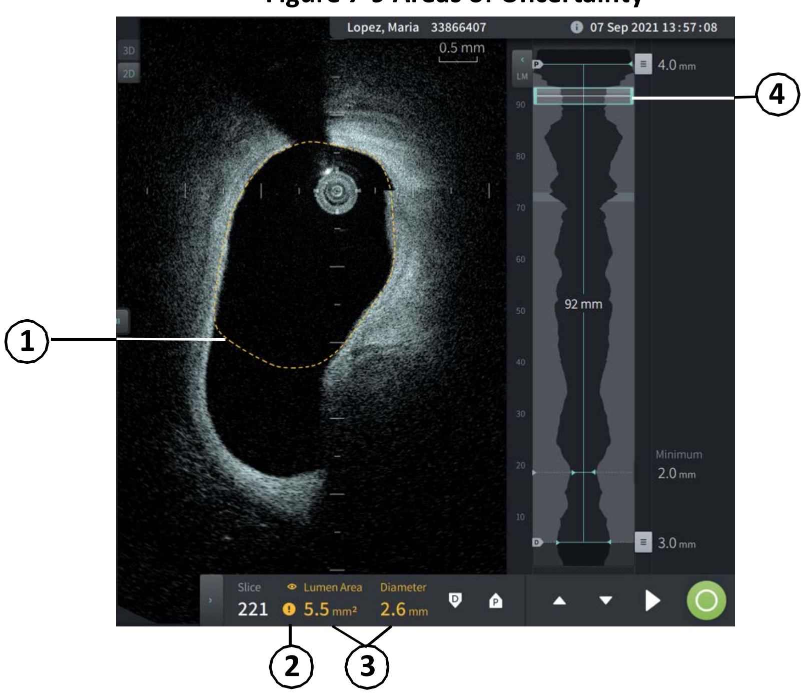


Table 7-7 Areas of Uncertainty

Item	Description
1	Lumen Trace is outlined in a dotted yellow line
2	Area of uncertainty icon is displayed in the panel
3	Current slice information is displayed in yellow text
4	Lumen Profile shows a lighter shade of gray to indicate a low confidence section

In some rare cases, one or more slices of the pullback may have very low confidence. If this occurs, automated and manual measurements are disabled for those individual slices, and those slices cannot be used as the references or identified as the minimum. There are several indicators of a very low confidence slice, as shown in Figure 7-10. Table 7-8 describes the indicators.

Figure 7-10 Very Low Confidence Slice

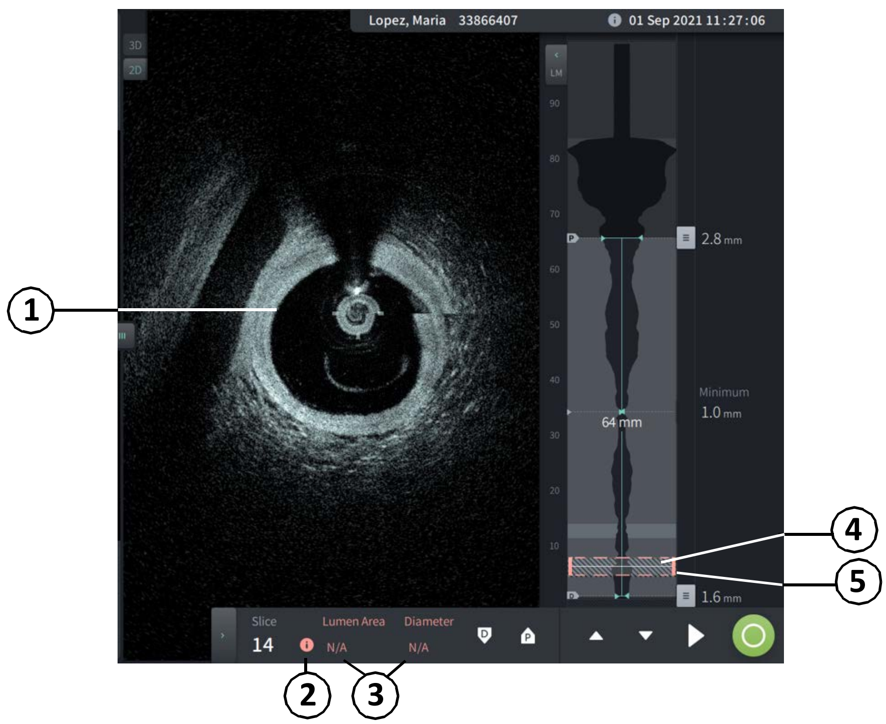


Table 7-8 Very Low Confidence Slice

Item	Description
1	No Lumen Trace is displayed
2	Very low confidence icon is displayed in the panel
3	Current slice information is marked N/A
4	Lumen Profile shows a cross-hatch pattern to indicate a very low confidence section
5	Current slice indicator is outlined in dotted red

Additional View Modes

The Gentuity High-Frequency OCT Imaging System lets you select from the following additional viewing modes:

- L-Mode
- 3D Mode

Limitations

Consider the following limitations when viewing the L-Mode:

- When viewing the pullback, note that the display appears aligned rotationally around the catheter and straight. This is due to the method of image reconstruction.
- Note that the center of the catheter, not the center of the lumen, is the center of the image.

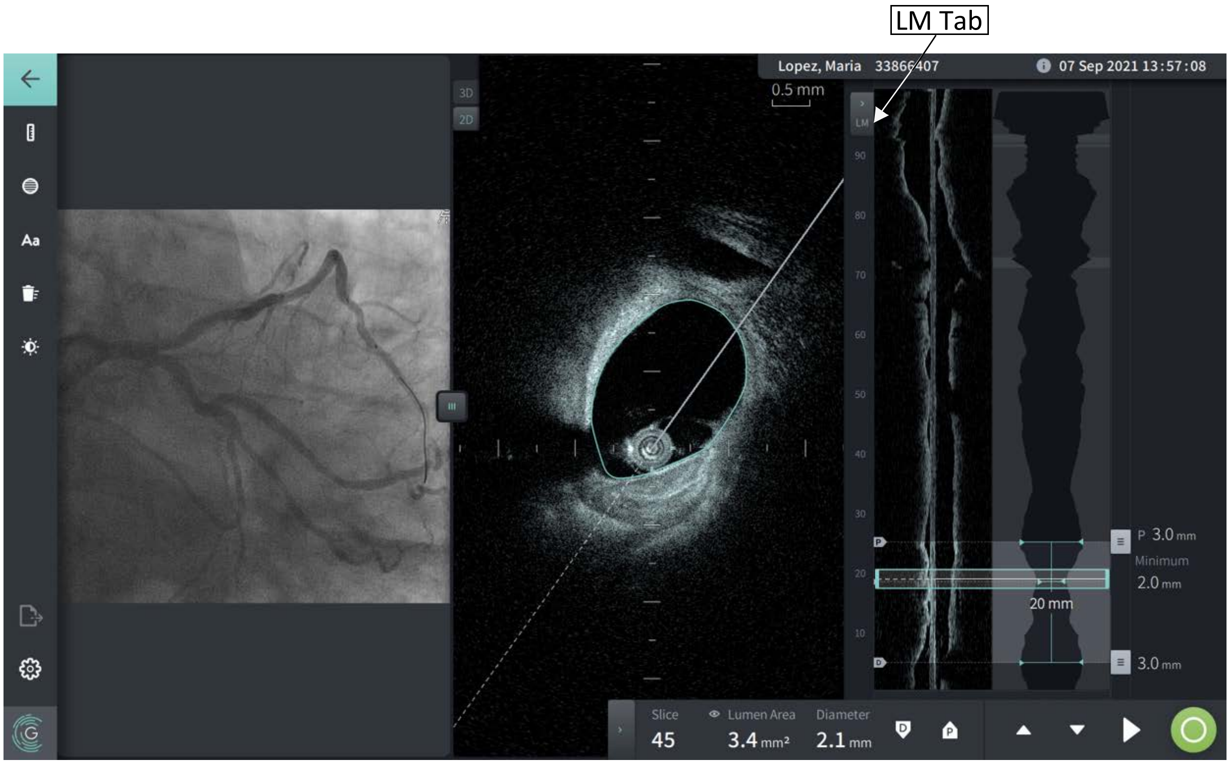
CAUTION! Because image data is displayed centered around the catheter, off-center catheter locations can make the lumen appear significantly smaller than actual diameter in some L-Mode views. When viewing in L-Mode, rotate the cut-plane to avoid image misinterpretation.

L-Mode View

L-Mode view displays a user-selectable, single cut plane image centered on the catheter, made along the length of the pullback and orthogonal to the 2D image. You may change the cut plane by dragging the cut plane indicator on the 2D image.

To show and hide the L-Mode view, use the LM tab < and > controls, as shown.

Figure 7-11 L-Mode View



3D View

The 3D view (Figure 7-12) is based on the longitudinal cut line and gives you a view of the vessel as if it was cut open length-wise.

- Use the 3D/2D tab selector to switch between 3D view and 2D view.
- Rotate the 3D image by rotating the cut plane line or dragging the 3D image.
- Maximize the zoom setting to display Fly-Through view. For more information, see “Fly-Through View” on page 7-16.

Note — You can zoom the 3D view as needed.

Figure 7-12 3D View

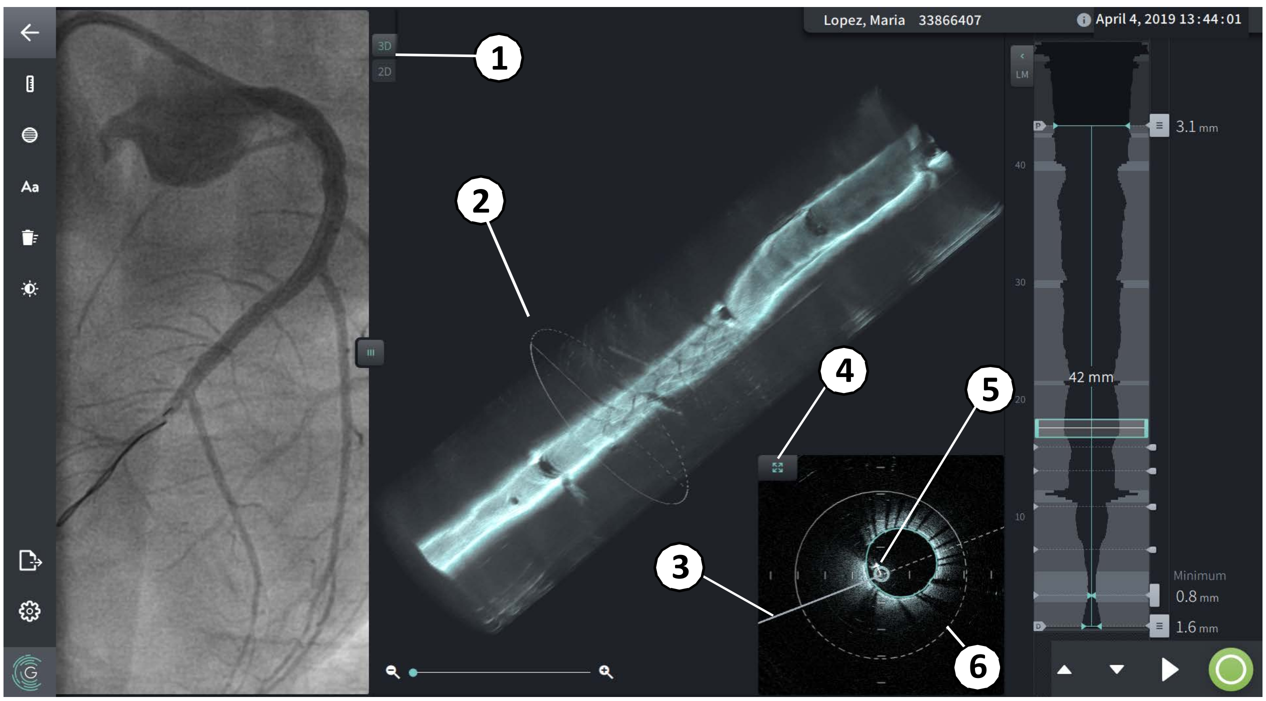


Table 7-9 3D View Components

Item	Description
1	3D/2D tab selector
2	Indicates location in vessel and can be rotated to change the 3D view
3	Cut plane; can also be rotated to change the 3D view
4	Icon to close the 3D view and restore the full 2D image
5	Small white arrow indicates direction of view into the 3D vessel
6	Dashed line indicates cutaway; solid line indicates the part of the vessel currently displayed

Fly-Through View

The Fly-Through view (Figure 7-13) is displayed when zoom is maximized in 3D view. Fly-Through view enables you to see the inside of the Lumen wall and move through the vessel by adjusting the location on the Lumen Profile display.

Figure 7-13 Fly-Through View

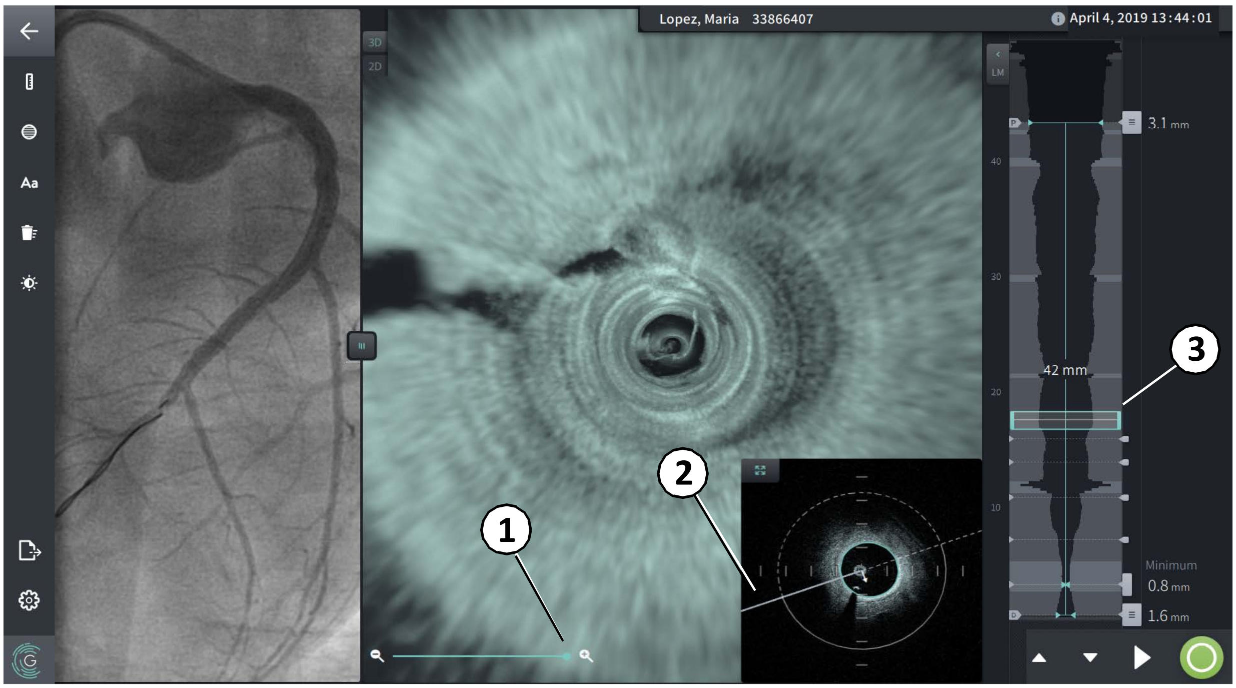


Table 7-10 Fly-Through Components

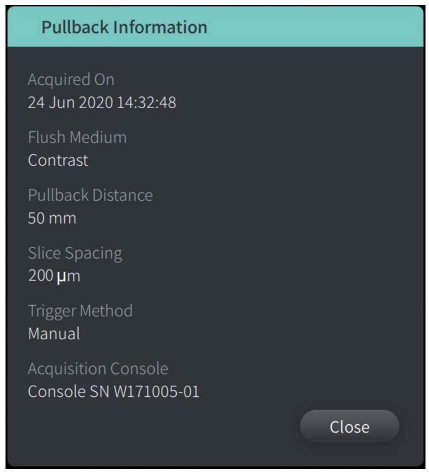
Item	Description
1	Maximize Zoom to display the Fly-Through view. You can also maximize zoom using the scroll wheel on the mouse or by pinching out on the touchscreen.
2	Cut plane; can be adjusted to rotate through Fly-Through view.
3	Use the slider on the Lumen Profile display to navigate through the vessel.

Viewing Pullback Information

Use the Pullback Information icon ( ) to view the **Pullback Information** window as shown in Figure 7-14. The icon is located in the upper right corner of the Image screen, to the left of the pullback date and time.

The **Pullback Information** window shows detail about the pullback including the date and time it was acquired, the flush medium, pullback distance, slice spacing, trigger method, and the serial number of the acquisition console.

Figure 7-14 Pullback Information window



➤ To view pullback information:

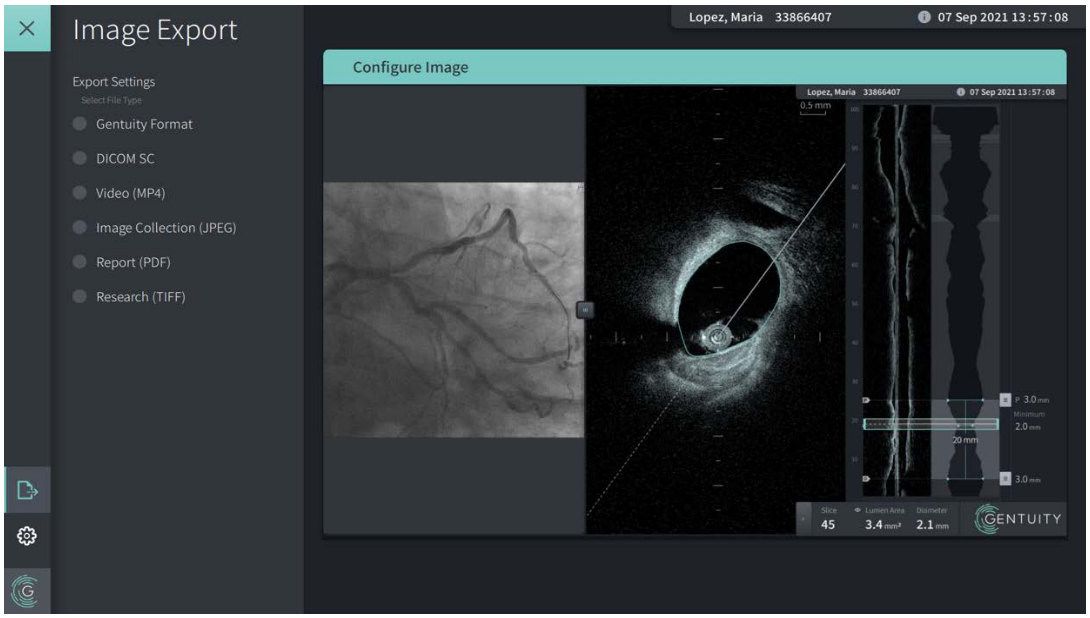
1. Open the pullback to view. The pullback is displayed in the Image screen.
2. Click the Pullback Information icon ( ) to open the **Pullback Information** window.
3. When finished, click **Close**.

Exporting Files During Review

When reviewing pullbacks, you can export the files during the review. The system displays the **Configure Image** screen (Figure 7-15) which shows the currently displayed image and allows you to change the composition of the display before exporting it.

CAUTION! To minimize the risk of cybersecurity threats, only use USB drives with trusted computers running anti-virus and anti-malware software.

Figure 7-15 Export Review Window



➤ **To export files during review:**

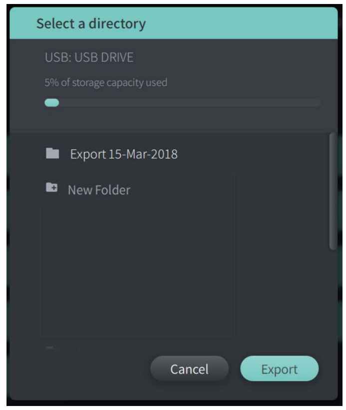
1. Open the pullback for review.
2. Zoom the image for better clarity.

Note — You can adjust the image as needed before exporting.

---

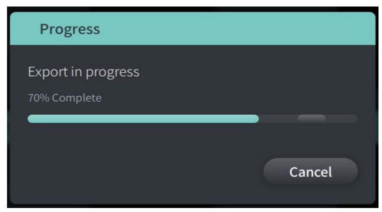
3. Perform measurements and annotations as needed. For details, see "Measurements and Annotations" on page 8-1.
4. Make sure the USB drive is inserted into the USB port on the system.
5. Select [export icon] to display the **Image Export** menu.
6. In the **Configure Image** window, zoom and make adjustments as needed.
7. In the **Image Export** section, select the file format and export options. For details, see "Exporting Patient Records" on page 5-8.
8. Select **Export**. The **Select a Directory** window is displayed, prompting you to select a directory or to create a new folder for the archive.

Figure 7-16 Select a Directory window



9. Select an existing directory on the USB drive, or select **New Folder** and enter the name of the new folder.
10. Select **Export**. The **Progress** window is displayed as the record is exporting from the system to the USB drive.

Figure 7-17 Progress window



11. Allow the export to continue, or select **Cancel** to cancel the export.

Note — For details on file naming conventions for exported files, see “About File Naming Conventions” on page 5-16.

Chapter 8
Measurements and Annotations

This chapter provides information and instructions for performing linear and area measurements and for adding annotations to images in the pullback.

Measurements and Annotations in the Image Files

Measurements and annotations that are added to images do not change the underlying image data. The unannotated image is always preserved and can be reviewed without the measurements and annotations. Measurements and annotations added during the procedure are preserved in the file.

CAUTIONS!

- If you want to make measurements on files which will be exported in standard formats (such as MP4, JPEG, and PDF), you must make the measurements BEFORE exporting the images.
- Using non-OCT software to measure standard format images will not produce accurate measurements.
- Do not use images that have been exported in standard formats (such as MP4, JPEG, and PDF) for clinical decision making. This format uses compression methods that may degrade the image quality.

Notes

- All measurements and annotations can be made in the 2D view of the HF-OCT image, but only longitudinal measurements can be made in the Lumen Profile and the L-Mode views. No measurements are allowed in the 3D view.
- Measurements are not allowed in slices with very low confidence (see “Areas of Uncertainty” on page 7-11). Move to an adjacent slice to make measurements.

Measurement and Annotation Tools

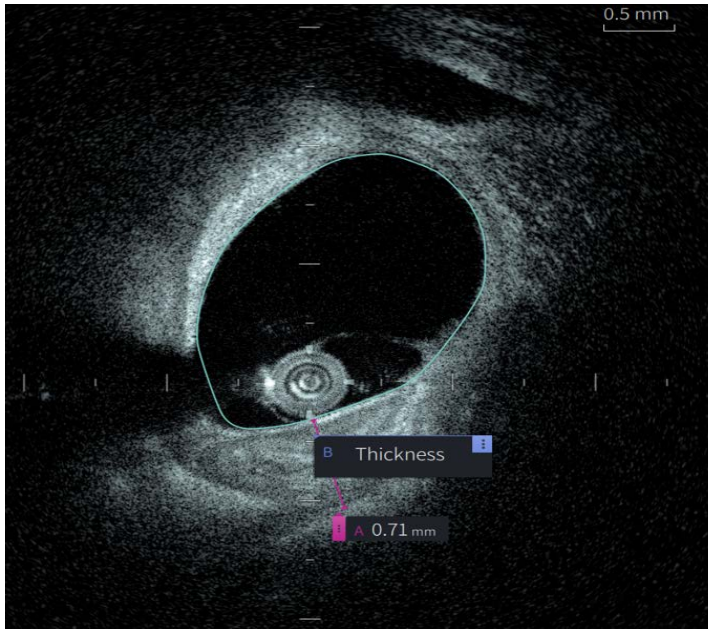
As measurements and annotations are added to the image, they are labeled with successive control letters (A, B, C, and so on). Table 8-1 lists and describes the measurement and annotation tools.

Table 8-1 Measurement and Annotation Tools

Tool Icon	Name	Description
	Linear measurement	Lets you perform a linear measurement by placing two calipers on the image.
	Area Measurement	Lets you perform an area measurement by tracing the outline of an area. The system calculates the area within the user-defined trace.
	Annotations	Add annotations/notes/comments to image. **CAUTION:** Do not use personally identifiable information in annotations. Annotations do NOT get anonymized.
	Delete All	Deletes all measurements and annotations from the current pullback.
	Image Adjustment	Adjust the image’s contrast and brightness.

Note — Measurements are indicated with a small marker in the Lumen Profile display on the right side of the screen.

Figure 8-1 Measurements and Annotations



Techniques to Improve Measurement Accuracy

Follow these guidelines to improve measurement accuracy:

- Before making measurements, use the zoom function to zoom into the region of interest until you can clearly see borders and other features you want to measure.
- Place the measurement cursor on the image, using the same measurement technique each time you perform the same type of measurement.
- Use the mouse to make fine adjustments when placing endpoints.

Measurements and Annotations in L-Mode View

All annotations and measurements can be made in the 2D area of the image window. Only longitudinal measurements, useful for determining vessel segment length, are permitted in the L-Mode view and Lumen Profile view.

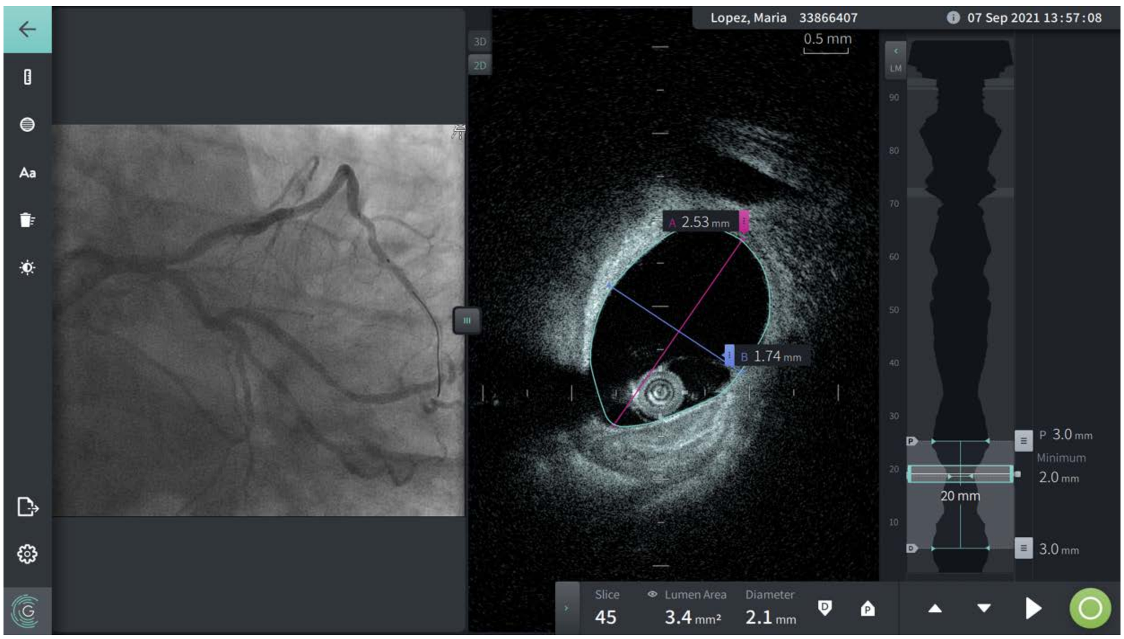
Linear Measurements

The system calculates and displays length as the distance in millimeters (mm) between two points placed on an image in either the 2D or L-Mode views.

As you perform each measurement or annotation, the results are labeled alphabetically and shown in a Measurement Result Tag associated with that measurement, as shown in Figure 8-2.

For more information, see “Measurement Results Tag” on page 8-8.

Figure 8-2 Linear Measurements



Performing a Linear Measurement

Measurement markers are displayed on the Lumen Profile Display, as shown in Figure 7-6 on page 7-8.

Tip — Zoom the image in the area of interest before making any measurements.

➤ To perform a linear measurement:

1. With the slice displayed in image review, select the linear measurement icon: 
2. Touch or click the start of the linear measurement. A caliper is displayed on the image.
3. Touch or click the end of the linear measurement. A second caliper is displayed on the image, connecting the line. The linear measurement tag is displayed on the image with the value.
4. Do any of the following:
    - To make adjustments to either end point, touch and hold to display the caliper and then drag the point to the new location.

- To delete the measurement, touch or click the measurement's delete icon.
- To show or hide the measurement tag tools, touch or click the icon.
- To show or hide only the measurement tag (for example, F 3.56 mm) touch or click the show icon or hide icon.
- To complete the measurement, touch or click in another area of the image.

5. To perform another linear measurement, repeat the steps above.

Note — To delete ALL measurements and annotations from the pullback, select in the menu bar on the left side of the screen. A message is displayed prompting you to confirm the deletion.

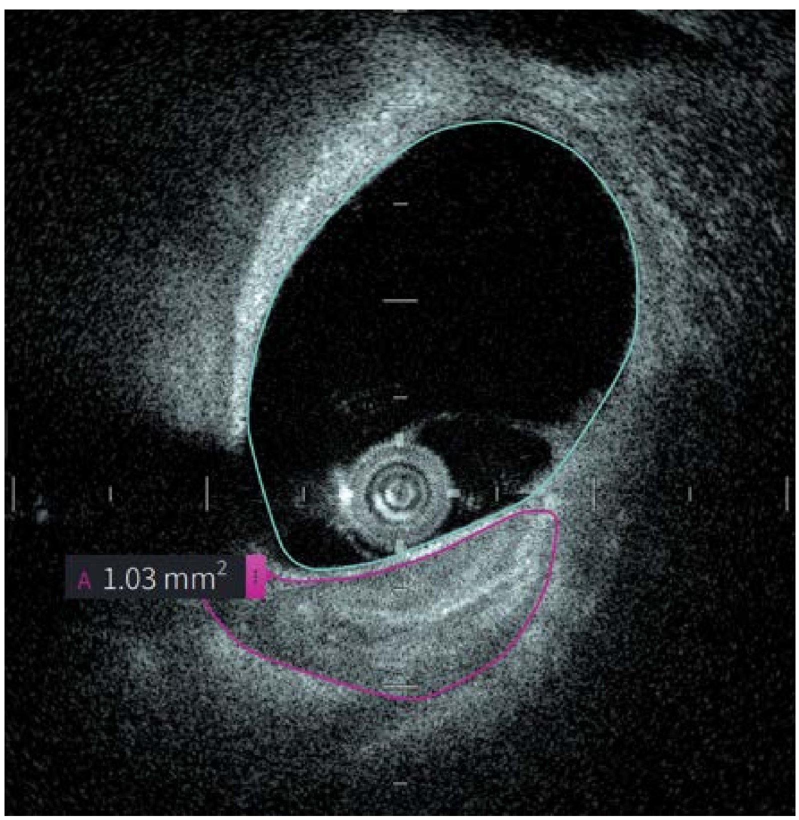
Area Measurements

You can manually create a closed area trace of a feature in 2D view. The area is calculated using Green's Theorem, and is displayed in the slice in mm^2.

As you perform each area measurement, the results are shown in the Measurements Results Tag, as shown in Figure 8-3.

For more information, see "Measurement Results Tag" on page 8-8.

Figure 8-3 Area Measurements



Performing an Area Measurement

Measurement markers are displayed on the Lumen Profile Display, as shown in Figure 7-6 on page 7-8.

Tip — Zoom the image in the area of interest before making any measurements.

➤ To perform an area measurement:

1. With the slice displayed in image review, select the area measurement icon:
2. Drag your finger around the area to be defined or click and drag the mouse.
3. To make adjustments, press and hold a caliper point and then drag the point to the new location as needed. You can eliminate an unwanted point by dragging it to a neighboring point to combine the two points. Add additional points by tapping or clicking the area in which you want to add a point.
4. Do any of the following:
   - To delete the area measurement, touch or click the measurement's delete icon.
   - To show or hide the measurement tag tools, touch or click the icon.
   - To show or hide only the measurement tag (for example, F 3.56 mm) touch or click the show icon or hide icon.
   - To complete the measurement, touch or click in another area of the image.
5. To perform another area measurement, repeat the steps above.

Note — To delete ALL measurements and annotations from the pullback, select in the menu bar on the left side of the screen. A message is displayed prompting you to confirm the deletion.

Annotations

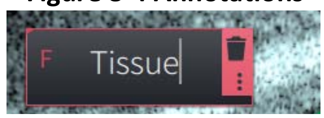
Use the annotation tool and system keyboard to add notes to the image.

As you enter each annotation, the annotations are labeled alphabetically in the Measurements Results Tag, starting with the next available letter, as shown in Figure 8-3.

For more information, see “Measurement Results Tag” on page 8-8.

CAUTION! Do not use personally identifiable information in annotations. Annotations are not changed for an anonymized export.

Figure 8-4 Annotations



Adding Annotations

Annotations and measurement markers are displayed on the Lumen Profile Display, as shown in Figure 7-6 on page 7-8.

If necessary, zoom the image in the area of interest before adding any annotations.

➤ To add an annotation:

1. With the slice displayed in image review, select the annotation tool icon: .
2. Touch or click the area where you want to add the annotation. The annotation tag is displayed on the image.
3. Enter the annotation text in the note field. To add a line break, press the **Shift** + **Enter** keys.
4. Do any of the following:
   - To edit the text, touch or click the text area and re-enter the text.
   - To delete the annotation, select the annotation and touch or click the delete icon.
   - To complete the annotation, touch or click in another area of the image.
   - To move the annotation, drag it to the new location.
5. To add another annotation, repeat the steps above.

Note — To delete ALL measurements and annotations from the HF-OCT recording, select in the menu bar on the left side of the screen. A message is displayed prompting you to confirm the deletion.

Measurement Results Tag

As you perform each linear or trace measurement, or add an annotation, the Measurement Results Tag is displayed, as shown in Figure 8-5. Table 8-2 lists and describes the tag.

Figure 8-5 Measurement Results Tag

Table 8-2 Measurement Results Tag

Item	Description
1	Measurement or annotation label.
2	Measurement value or text entry for annotations.
3	Click this icon to access additional tag tools (callouts 4 and 5) and to edit the measurement or annotation.
4	Deletes the measurement or annotation.
5	Shows and hides the tag for the user-generated measurement. The line or area remains visible, but the tag is hidden. When you click the user-generated line or area, the tag reappears, along with the and icons. This icon is only visible for user-generated measurements. It does not appear for annotations.

Chapter 9
Cleaning the System

This chapter provides information and instructions for cleaning the Gentuity High-Frequency OCT Imaging System and the PIM.

Overview

Cleaning the Gentuity High-Frequency OCT Imaging System consists of:

- Cleaning the system surfaces
- Cleaning the PIM and its cable

Routine Cleaning Procedures

Follow your facility's standard cleaning schedule for medical devices, or clean the Gentuity High-Frequency OCT Imaging System at least every 30 days under normal operation.

Items Required for Cleaning

The following items are recommended for cleaning the Gentuity High-Frequency OCT Imaging System:

- Dry cloth
- Lint-free, non-abrasive cloth
- Mild detergent
- Disinfectant wipe, Glutaraldehyde 3.4% Cidex Solution, or 70% Isopropyl Alcohol (IPA)

Cleaning the System

➤ To clean the system:

1. Turn off the Gentuity High-Frequency OCT Imaging System and unplug the power cable from the wall outlet.
2. Using a dry cloth, or a dry cloth that is slightly dampened with water, clean the system surfaces, keyboard, mouse, and keyboard/mouse tray.
3. Using a lint-free, non-abrasive cloth, clean the monitors' LCD surface.
4. Clean exposed system cables with a soft cloth, moistened with water or a mild detergent.

Cleaning the PIM

CAUTIONS!

- When there is no catheter connected to the PIM, be sure the PIM connector cover is securely in place to protect from dirt and damage.
- Protect the PIM connection ports and the catheter connectors from fluids.

➤ To clean the PIM:

1. Make sure the cover is on to protect the optical connections.
2. Clean the PIM and the PIM optical cable with a disinfectant wipe or with Glutaraldehyde 3.4% Cidex Solution or 70% IPA, and a soft cloth.
3. Use the PIM cradle to store the PIM when not in use.

CAUTION! Always store the store the PIM with the PIM connector cover facing down.

Chapter 10
Support and Maintenance

This chapter provides information about service and support for the Gentuity High-Frequency OCT Imaging System. It also includes details on troubleshooting.

Note — There is no regular maintenance required for the Gentuity High-Frequency OCT Imaging System and there are no user-serviceable parts on the system or on the catheter.

Contact Information

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FAX: 978-319-4632
General Inquiries: info@gentuity.com
Support and Service: support@gentuity.com
Website: www.gentuity.com

Troubleshooting

Table 10-1 lists issues and resolutions for troubleshooting during an HF-OCT procedure.

Note — If there are any concerns or issues while the PIM motor is spinning, use the red **STOP** button on the PIM or the **STOP** button on the touchscreen to stop all PIM rotation and pullback.

Table 10-1 Troubleshooting

<table>
<tr><th>Issue</th><th>Resolution</th></tr>
<tr><td>No image</td><td rowspan="3">Ensure adequate amount of flush delivery. For details, see “Preparing the Flush Media” on page 6-8 and “Delivering 5 ml Flush Media to Confirm Alignment” on page 6-9.
If the problem persists, remove the catheter and replace it with a new catheter.</td></tr>
<tr><td>Unstable image</td></tr>
<tr><td>Vibration</td></tr>
<tr><td>Faint image</td><td>Disconnect and reconnect the catheter to the PIM.</td></tr>
<tr><td rowspan="2">System does not power on properly</td><td>Remove the PIM from the PIM cradle and try restarting the system again.</td></tr>
<tr><td>The fuse(s) may need replacement. Replacement fuses are available (T5.0 (240V) - 5x20mm). Contact Gentuity Support.</td></tr>
<tr><td>Catheter connection error</td><td>Disconnect the catheter from the PIM and turn off the system. Power the system back on and re-connect the catheter to the PIM. If the problem persists, contact Gentuity Support.</td></tr>
<tr><td>Forgotten password</td><td>If an Administrator Password has been set, that password will also allow you to log on. An Administrator can reset the password. For details, see “About the Administrator Password” on page 4-9.
If an Administrator Password has not be set, contact Gentuity Support to reset the password. For details on contacting support, see “Contact Information” on page 10-1.</td></tr>
</table>

Disposal

WARNING! The Vis-Rx Micro-Imaging Catheter is intended for one time use only. Do not reuse, re-sterilize, or reprocess.

The Vis-Rx Micro-Imaging Catheter is a single-use item and should be disposed of after use according to your institution's biomedical waste disposal policies.

When the Gentuity High-Frequency OCT Imaging System reaches its end-of-life, disposal must be in accordance with local laws.

Chapter 11
Specifications

This chapter lists the technical specifications for the Gentuity High-Frequency OCT Imaging System.

System Specifications

This section lists the system specifications.

System Height and Weight

Table 11-1 System Height and Weight

Item	Specification
Console, including PIM (total weight)	< 70 kg (159 lb)
Maximum height (top of monitor)	155 cm (61 in)
Maximum height without monitor	115 cm (45 in)
Maximum width (base)	65 cm (26 in)
Wheel diameter (4 wheels)	10 cm (4 in)
PIM Umbilical Cable length	3.0 m (118 in)

Monitors

Table 11-2 Monitors

Item	Specification
Display Monitor	
Style	LCD
Size	24” diagonal
Format	Wide screen
Operator Monitor	
Style	LCD Touchscreen
Size	15” diagonal
Format	Wide screen

Environmental Specifications

Table 11-3 Environmental Specifications

Condition	Parameter	Range
Transport and Storage	Temperature	-10°C to 45°C
	Humidity	20% RH to 95% RH (Non-condensing)
	Pressure	700 to 1060 hPa (0.7 to 1.05 atm)
Operating	Temperature	10°C to 30°C
	Humidity	20% RH to 85% RH (Non-condensing)
	Pressure	700 to 1060 hPa (0.7 to 1.05 atm)

System Optical Specifications

Table 11-4 System Optical Specifications: Swept Source and Visible Laser

Specification	Description/Parameter
Swept Source	
Center Wavelength	1310 nm
Wavelength Sweep	≥ 70 nm, FWHM
Sweep Rate	200 kHz
Power, ex PIM	Class 1 laser output
Maximum Output Power*	< 0.5 W
Visible Laser	
Visible Laser Wavelength	650 nm
Visible Laser Power, ex PIM	Class 1 laser output
Maximum Output Power*	< 390 µW
* Per IEC-60825-1:2014, measured per Condition 1 and Condition 3	

Clinical Imaging Specifications

Table 11-5 Clinical Imaging Specifications

Specification	Description/Parameter
Vessel Diameter Range	1.3 mm to 6.0 mm
Pullback Length	100 mm or 50 mm
Axial Resolution	≤ 20 um in tissue

Electrical Specifications

Table 11-6 Electrical Specifications

Specification	Description/Parameter
Power Supply Input	100-240V AC, 50/60 Hz, 5A Max @ 100V AC
Power Cord	3 M (9 ft) cord, nominal
Voltage Withstand (PIM)	Type CF and Defib Safe
Voltage Withstand (Console)	Per IEC 60601-1

Note — Replacement fuses are available (T5.0 (240V) - 5x20mm). The system console requires two fuses. For more information, contact Gentuity Customer Support.

Safety Standards Compliance

The Gentuity High-Frequency OCT Imaging System complies with the following national and international standards:

- EN 60601-1-2 (2015) (Europe)
- IEC 60601-1-2 (2014) (US and International)

Chapter 12
Glossary of Symbols

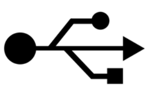
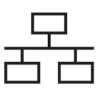
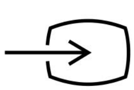
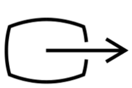
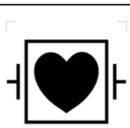
This chapter lists and describes the symbols and icons that appear on the Gentuity High-Frequency OCT Imaging System and the Vis-Rx Micro-Imaging Catheter and their packaging.

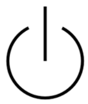
System Symbols

Table 12-1 lists and describes the symbols that may appear on the Gentuity High-Frequency OCT Imaging System.

Table 12-1 System Symbols

Symbol	Title	Explanatory Text	Reference to Standard	Designated or Reference Number
EC REP	Authorized representative in the European Community/ European Union	Indicates the authorized representative in the European Community/ European Union	Reference 1	5.1.2
UK RP	United Kingdom Responsible Person	Indicates the person who acts on the manufacturer's behalf in the United Kingdom for UK MDR	--	--
UDI	Unique device identifier	Indicates a carrier that contains unique device identifier information	Reference 1	5.7.10
MD	Medical device	Indicates this item is a medical device	Reference 1	5.7.7
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified	Reference 1	5.1.6
	Date of manufacture	Indicates the date when the medical device was manufactured	Reference 1	5.1.3
	Country of manufacture	Indicates the country where the medical device was manufactured	Reference 1	5.1.11

Symbol	Title	Explanatory Text	Reference to Standard	Designated or Reference Number
SN	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	Reference 1	5.1.7
100-250 V ~ 50/60 Hz 5A T5.0 (250V) - Type 5x20mm	Fuse	Identifies the location of the fuse	Reference 2	5016
	Equipotential	Identifies the equipotential grounding post	Reference 2	5021
	Refer to instruction manual	Indicates that the instruction manual must be read	Reference 2	ISO-7010-M002
	Bureau Veritas NRTL	Electrical Safety Testing Laboratory	--	--
	Manufacturer	Indicates the medical device manufacturer	Reference 1	5.1.1
TRIGGER	Not used	--	--	--
	USB	Indicates the port for USB (Universal Serial Bus) compatible devices		
REMOTE	Not used	--	--	--
	Computer network	Identifies the connecting terminal to the computer network	Reference 2	5988
	Video input	Identifies video equipment input controls and connecting terminals	Reference 2	5525B
	Video output	Identifies video equipment output controls and connecting terminals	Reference 2	5529B
	Defibrillation Proof	Identifies a defibrillation-proof type CF applied part complying with IEC 60601-1	Reference 2	5336

Symbol	Title	Explanatory Text	Reference to Standard	Designated or Reference Number
	Standby	Identifies the switch by means of which the equipment is switched on in order to bring it into the stand-by condition	Reference 2	5009

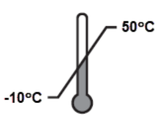
Reference 1: ISO 15223-1:2021

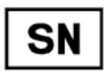
Reference 2: IEC TR 60878:2022

System Console Packaging Symbols

Table 12-2 lists and describes the symbols that may appear on the Gentuity High-Frequency OCT Imaging System packaging.

Table 12-2 System Console Packaging Symbols

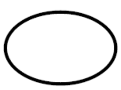
Symbol	Title	Explanatory Text	Reference to Standard	Designated or Reference Number
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified	Reference 1	5.1.6
	Keep dry	Indicates a medical device that needs to be protected from moisture	Reference 1	5.3.4
	This way up	Indicates the correct upright position	Reference 2	0623
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully	Reference 1	5.3.1
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed	Reference 1	5.3.7
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed	Reference 2	5.3.8
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be exposed	Reference 2	5.3.9
	Date of manufacture	Indicates the date when the medical device was manufactured	Reference 1	5.1.3

Symbol	Title	Explanatory Text	Reference to Standard	Designated or Reference Number
	Country of manufacture	Indicates the country where the medical device was manufactured	Reference 1	5.1.11
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	Reference 1	5.1.7
	Manufacturer	Indicates the medical device manufacturer	Reference 1	5.1.1
Reference 1: ISO 15223-1:2021 **Reference 2:** IEC TR 60878:2022				

Catheter Packaging Symbols

Table 12-3 lists and describes the symbols that may appear on the Vis-Rx Micro-Imaging Catheter.

Table 12-3 Catheter Packaging Symbols

Symbol	Title	Explanatory Text	Reference to Standard	Designated or Reference Number
EC REP	Authorized representative in the European Community/ European Union	Indicates the authorized representative in the European Community/ European Union	Reference 1	5.1.2
UK RP	United Kingdom Responsible Person	Indicates the person who acts on the manufacturer's behalf in the United Kingdom for UK MDR	--	--
MD	Medical device	Indicates this item is a medical device	Reference 1	5.7.7
	Single sterile barrier system with protective packaging inside	Indicates a single sterile barrier system with protective packaging inside	Reference 1	5.2.13
	Single sterile barrier system	Indicates a single sterile barrier system	Reference 1	5.2.11
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	Reference 1	5.4.4
	Date of manufacture	Indicates the date when the medical device was manufactured	Reference 1	5.1.3
	Country of manufacture	Indicates the country where the medical device was manufactured	Reference 1	5.1.11

Symbol	Title	Explanatory Text	Reference to Standard	Designated or Reference Number
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified	Reference 1	5.1.6
LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	Reference 1	5.1.5
	Consult instructions for use	Indicates the need for the user to consult the instructions for use	Reference 1	5.4.3
	Keep dry	Indicates a medical device that needs to be protected from moisture	Reference 1	5.3.4
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened	Reference 1	5.2.8
	Do not re-use	Indicates a medical device that is intended for use on a single patient during a single procedure	Reference 1	5.4.2
	Do not resterilize	Indicates a medical device that is not to be resterilized	Reference 1	5.2.6
	Keep away from sunlight	Indicates a medical device that needs protection from light sources	Reference 1	5.3.2
STERILE R	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation	Reference 1	5.2.4
STERILE EO	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide	Reference 1	5.2.3
	Use by date	Indicates the date after which the medical device is not to be used	Reference 1	5.1.4

Symbol	Title	Explanatory Text	Reference to Standard	Designated or Reference Number
	Quantity	Indicates the quantity of an item contained in the package	--	--
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed	Reference 1	5.3.9
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed	Reference 1	5.3.7
	Guide Catheter compatibility	Defines the minimum guide catheter inner diameter	--	--
	Guidewire compatibility	Defines the maximum guidewire outer diameter	--	--
	Packaging unit	Indicates the number of pieces in the package	Reference 2	2794
	Injection syringe	Indicates a reference to an injection syringe	Reference 2	5382
	Remove before use	Indicates a part which should be removed before using the catheter	--	--
	Open here	Indicates the location where the package can be opened	--	--

Reference 1: ISO 15223-1:2021

Reference 2: IEC TR 60878:2022

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