Not for Human Use – Not Evaluated by FDA

Evident Vascular™ Guidance System

USER MANUAL

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℞ ONLY **CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

History

Revision	Release Date	Change
LBL-0619, Rev 0	10/2025	Initial release
LBL-0619, Rev 1	10/2025	Updated content and additional features

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1 Introduction

How to Use this Manual

This manual explains how to operate and maintain the Evident Vascular™ Guidance System. It is important to read this manual and familiarize yourself with the workflow before operating the system. Contact your Evident Vascular, Inc. representative or Evident™ Technical Support Services if you have any questions.

User Manual Symbols, Icons and Text

The following table describes the symbols and icons used in this manual.

Icon	Text	Description
	*Information*	Provides important additional information
	Instruction	If a task or action can be performed using multiple methods, this icon indicates the use of the Tablet (e.g., pressing an icon or a button). All tasks or actions are performed on the Tablet unless otherwise indicated.
	Instruction	If a task or action can be performed using multiple methods, this icon indicates the use of finger gestures on the Tablet screen (e.g., pinch or drag).
	Instruction	If a task or action can be performed using multiple methods, this icon indicates a command using Evident™ Voice Assist.
	**CAUTION**	A hazard alert to inform of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient, damage to the equipment and/or loss of data. Follow the instruction or procedure correctly to avoid injury and/or damage.
	**WARNING**	A hazard alert to inform of a hazardous situation which, if not avoided, can result in serious injury or death. Follow the instruction or procedure correctly to avoid injury to the user or patient.

Related Documents

Peripheral imaging catheter Instructions For Use (IFU) can be found at https://evidentvascular.com/IFU.

Document	Description
Evident™ 14 Peripheral Imaging Catheter Instructions for Use (LBL-0546)	Provides information on the Evident 14 Peripheral Imaging Catheter and instruction for using the catheter with the Evident Vascular Guidance System.
Evident™ 35 Peripheral Imaging Catheter Instructions for Use (LBL-0547)	Provides information on the Evident 35 Peripheral Imaging Catheter and instruction for using the catheter with the Evident Vascular Guidance System.
Evident Vascular™ Guidance System Quick Reference Guide (LBL-1360)	Provides abbreviated information and instructions for common tasks using the Evident Vascular Guidance System.

2 Regulatory Information

Intended Use

The Evident Vascular Guidance System (EVGS) is intended for ultrasound examination of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.

The Evident Peripheral Imaging Catheters generate ultrasound images and are intended for ultrasound examination of peripheral vascular pathology only. The recommended use of each of these catheters may vary depending on the size and type of catheter. Refer to the Instructions for Use for all Evident Peripheral Imaging Catheters for additional information on recommended use.

Contraindications

Use of the Evident Vascular Guidance System is contraindicated in the presence of conditions that create unacceptable risk during catheterization. It is *not* to be used in coronary arteries.

Possible Adverse Events

The use of the Evident Peripheral Imaging Catheter – or any percutaneous intravascular catheter – could result in adverse reactions; the following complications may occur as a consequence of intravascular examination:

- Myocardial infarction
- Vessel occlusion
- Vessel dissection
- Perforation, rupture, or injury
- Restenosis
- Hemorrhage or hematoma
- Drug reactions
- Allergic reaction to contrast medium
- Hypotension/hypertension
- Infection/sepsis
- Vessel spasm
- Arteriovenous fistula
- Embolism
- Entry puncture site bleeding
- Vascular wall injury
- Vessel thrombosis
- Pseudoaneurysm (at site of catheter insertion)
- Renal insufficiency/failure
- Vessel aneurysm
- Vessel trauma requiring surgical repair or intervention
- Additional surgical intervention
- Death

Component Symbols

The following table lists the safety symbols found on the components. These symbols alert you to potential hazards.

Symbol	Description
	Catalog number
	Serial number
	Unique Device Identifier
	**CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a physician.
	Manufacturer
	Date of manufacture
	Waste Electrical and Electronic Equipment
	Wi-Fi
	Refer to Instruction Manual
	Do Not Push
	Do Not Step
	Power on/off

3 Warnings and Precautions

Evident Vascular Guidance System Console Warnings and Precautions

General Safety Warnings

- **WARNING:** To avoid electrical shock, do not remove any panels or covers. In the event of malfunction or system damage, power down the Guidance System, unplug from the power receptable and contact Evident Technical Support Services.
- **WARNING:** Do not modify this equipment. Any changes or modifications not expressly approved by Evident Vascular, Inc. could void the user's authority to operate this equipment under FCC regulations.
- **WARNING:** If you suspect malfunction or system damage, turn the system off, unplug the system from the power receptacle, and contact a qualified service person and Evident Vascular Technical Support Services.

Electrical Safety Warnings

- **WARNING:** The system must be properly grounded to avoid electrical shock. Connect only to power supply mains with protective earth.
- **WARNING:** Removing or defeating the protective earth conductor presents a risk of electric shock and is prohibited.
- **WARNING:** Do not connect a multiple socket–outlet or extension cord to the system. This may exceed safety limits of the system.
- **WARNING:** To prevent fire or shock hazard, do not expose the system to moisture or rain. Use a protective cover during transport in wet conditions.
- **WARNING:** If moisture enters the system, allow it to dry thoroughly before plugging the AC power cord into an electrical outlet.
- **WARNING:** If the Mains circuit breaker interrupts power to the system repeatedly, turn the system off, unplug it, and contact a qualified service person and Evident Vascular Technical Support Services.
- **WARNING:** To prevent compromising patient isolation, operators must not simultaneously touch the patient/catheter/guidewire and any part of the Mobile Cart, Workstation or connector interface.

EMC and Wireless Safety Warnings

- **WARNING:** Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC). Portable and mobile Radio Frequency (RF) communications equipment can affect performance of the system.
- **WARNING:** See Compliance for the recommended separation distances between RF communications equipment and the system.
- **WARNING:** Portable RF communications equipment (including antenna cables and external antennas) should be at least 30 cm (12 in) from any part of the System including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- **WARNING:** Maintain a minimum separation of **20 cm (8 in.)** between the wireless

transmitter and the human body during operation to comply with FCC exposure limits.

- **WARNING:** Operation of this wireless interface is restricted to healthcare facilities. Use outside of this environment may increase interference risk with other devices.
- **WARNING:** Wireless coexistence has been validated for healthcare environments per ANSI C63.27. Use in home or residential settings has not been evaluated.
- **WARNING:** The emissions characteristics make the system suitable for industrial and hospital use. Residential use may require mitigation measures.
- **WARNING:** Electrical Fast Transients on the AC line can result in a suspension of operation. If this occurs, turn the system off and back on to resume operation.

Environmental Hazards Warnings

- **WARNING:** An explosion risk may exist in areas with high concentrations of flammable anesthetics or cleaning agents. The probability of occurrence of the ignition of such anesthetic mixtures depends upon their concentration, the appropriate minimum ignition energy, the presence of high surface temperatures, and potential sparking.
- **WARNING:** Sparks from switches, connectors, fuses, or over-current releases can ignite such mixtures.
- **WARNING:** Do not power on the workstation in elevated atmospheric concentrations of flammable agents. If already running, do not power off.
- **WARNING:** This device is not intended for use in oxygen-rich environments.

Sterility Warning

- **WARNING:** Drape any part of the Evident Vascular Guidance system or components that may extend into sterile field or that interacts with a sterile user.

System User and Compatibility Warnings

- **WARNING:** The system can only be used with Evident™ Peripheral Imaging catheters and accessories.
- **WARNING:** Use of cables or accessories not approved by Evident Vascular, Inc. (e.g., power cords, adapters, ethernet/ video cables). Otherwise, degradation of the performance of this equipment could result.

Mechanical Safety and Handling Warnings

- **WARNING:** Avoid rolling the Mobile Cart over objects to prevent tipping and damage to the system.
- **WARNING:** Do not push the Mobile Cart at the neck- use the handles provided.
- **WARNING:** Do not push the Mobile Cart on unsafe slopes .
- **WARNING:** Do not put the Workstation on its side.
- **WARNING:** Position the Mobile Cart and power cord to minimize tripping hazards.
- **WARNING:** Keep fingers away from moving parts and joints on the Articulating Tablet Mount as well as the Mobile Cart.
- **WARNING:** Remove the Tablet from the Articulating Tablet Mount before clamping and unclamping it from the bedrail or storing the Articulating Tablet Mount.
- **WARNING:** When keeping the CIM on the Mobile cart instead of a bed rail, ensure casters are locked to avoid inadvertent removal of imaging catheter from patient.

Operational Precautions

- **CAUTION:** Stop imaging and withdraw the Evident Peripheral Imaging Catheter from the patient prior to defibrillation.
- **CAUTION:** Ensure catheter latch is engaged in the CIM receptacle before imaging.
- **CAUTION:** Do not disconnect the Evident Peripheral Imaging Catheter while imaging.
- **CAUTION:** Do not share user login credentials. All logins are traceable and part of the medical record.
- **CAUTION:** Installation of unauthorized software is prohibited and may impair performance or security.
- **CAUTION:** If you archive, the case will be deleted after 1 month. If not, the system will prompt you to archive when disk space falls below 20% of maximum capacity.
- **CAUTION:** The system must be shut down using the application software controls before switching off the main AC power switch. Pressing the main AC power switch or the tablet power button during recording may corrupt data. Wait at least 10 seconds before turning the system back ON.

Cleaning Precautions

- **CAUTION:** Never spray or otherwise apply any cleaner directly into the openings or seams of the Evident Vascular Guidance System or components. Always apply the cleaner to a soft cloth instead.
- **CAUTION:** Do not use harsh chemicals or cleaning solvents to clean the Evident Vascular Guidance System or its components. Never use acetone to clean the Evident Vascular Guidance System or its components.
- **CAUTION:** No portion of the Evident Vascular Guidance System or its components should be immersed in water or other fluids.

Electrical and Environmental Safety Precautions

- **CAUTION:** The product and its accessories are rated IPX0 – No protection against fluid ingress. Avoid spills or foreign material on components to prevent fire or electrical shock.
- **CAUTION:** No batteries are user replaceable.
- **CAUTION:** Do not block ventilation fans on the CIM or Workstation.
- **CAUTION:** To achieve proper grounding reliability, the power plug must be fully inserted into a Hospital Grade receptacle. If you are unsure, seek qualified technical assistance.
- **CAUTION:** To achieve appropriate transient overvoltage protection, use facility power systems compliant with Category II limits per IEC 60664-1.
- **CAUTION:** Avoid sudden temperature changes to prevent condensation. After exposure to cold, allow time for acclimation before plugging in.
- **CAUTION:** The Workstation should not be stacked with other equipment.

Wireless and EMC Precautions

- **CAUTION:** Never use the system nor accessories that you suspect may have been damaged.
- **CAUTION:** In case of abnormal system operation, follow shutdown and startup procedures in the User Manual.
- **CAUTION:** Do not roll equipment over the System Cable, AC power cord, ethernet cable or other connected cabling.
- **CAUTION:** Do not use excessive force when disconnecting the System Cable.
- **CAUTION:** The CIM should not be placed below an IV pole where liquids may drip into the catheter receptacle and cause damage.
- **CAUTION:** Ensure that Tablet is fully latched into the Tablet Mount before operating.

Peripheral Imaging Catheter Warnings and Precautions

Refer to the Evident Peripheral Imaging Catheter Instructions for Use at https://evidentvascular.com/IFU for a complete list of warnings and precautions associated with the peripheral imaging catheters.

4 Evident Vascular™ Guidance System

Evident Vascular Guidance System Overview

The Evident Vascular Guidance System (EVGS) is designed for ultrasound examinations of intravascular pathology. The EVGS supplies diagnostic information when used in conjunction with the Evident Peripheral Imaging Catheters during intravascular ultrasound (IVUS) imaging of peripheral vasculature. It is designed to be used as an adjunct to conventional angiographic procedures or endovascular therapy

The system includes the workstation computer that is the main system controller, running dedicated software. A single-use, sterile catheter, inserted into the vessel, produces the intravascular ultrasound images that are displayed on a tablet computer. The Evident™ Tablet serves as the primary user interface and can be mounted on the procedure table or on the mobile cart. The Catheter Interface Module (CIM) provides the connection between the workstation and the catheter via the System Cable. An optional auxiliary display can be connected to the workstation through an optical fiber cable.

There are two available installation options of the Evident Vascular Guidance System: a Mobile Cart and an Integrated Lab configuration with the key differences being the location of the Workstation (on cart or in procedure room) and the use of the Articulating Tablet Mount (ATM). For both options, all components will be installed and pre-connected by Evident Vascular, Inc.

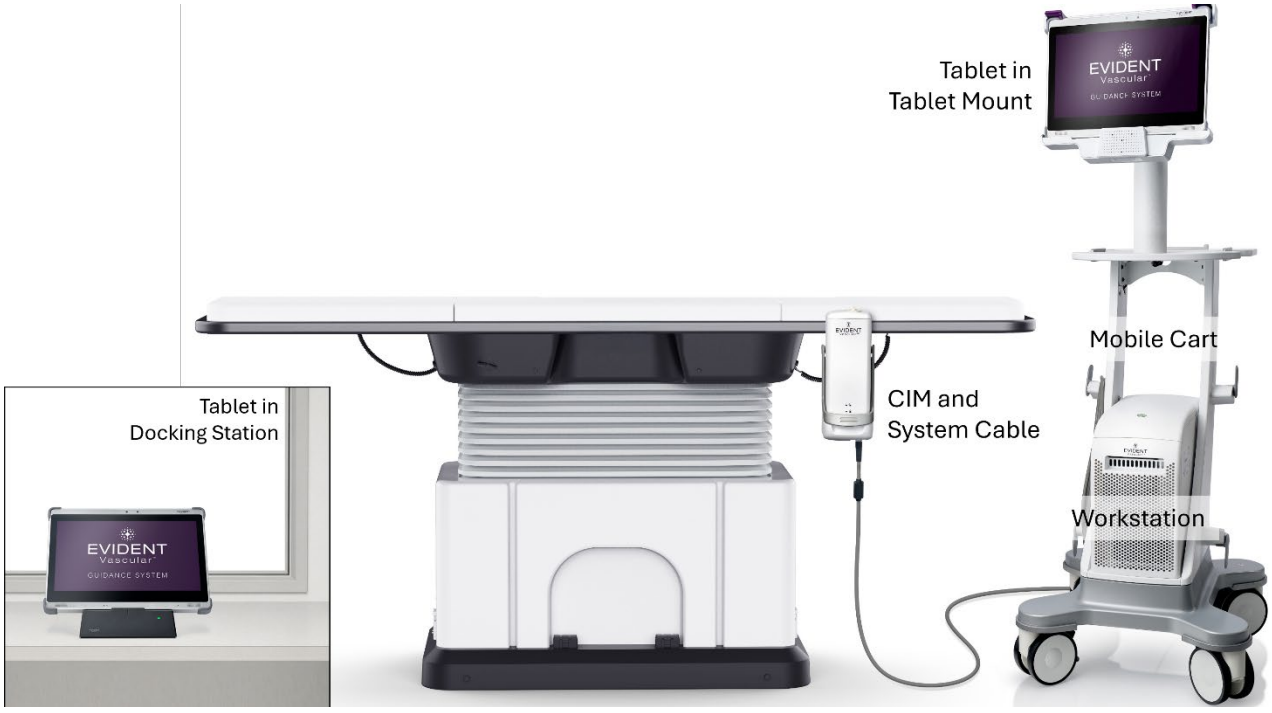

Figure 4-1 Evident Vascular Guidance System and Components (shown in Mobile Configuration)

Figure 4-2: Evident Vascular Guidance System (shown in Integrated Lab configuration)

Components of the Evident Vascular™ Guidance System

Evident™ Mobile Cart

The Evident Mobile Cart (shown in Figure 4-3) provides a place to mount the Workstation and the Tablet in the Mobile configuration. It also provides a rail on which to store the CIM, with hooks along the sides to wrap the Power Cord and System Cable when not in use. A locking caster on each wheel ensures the cart remains stationary during use and storage.

Evident™ Workstation

The Evident Workstation (shown in Figure 4-3 on the Mobile Cart) is the main controller and runs dedicated imaging software. The Workstation interfaces with the CIM, one or more Tablets, and an optional auxiliary display through a display cable. The user interacts solely through the Tablet. The Workstation is installed in the procedure room near the procedure table in the Integrated Lab or on the Mobile Cart in the Mobile configuration.

Figure 4-3: Mobile cart with Workstation, Tablet and Tablet Mount

Evident™ Tablet

The Evident Tablet (Figure 4-4) is a wireless touchscreen computer, compatible with Evident™ Voice Assist for hands-free operation. Two Tablets are provided with the Guidance System. The Tablet can be placed in the Tablet Mount, which can be attached to and powered by the Mobile Cart, the procedure table/bed rail (via the Articulating Tablet Mount), or a stationary docking station. The Tablet serves as the primary user interface. The Evident Vascular Guidance System can be operated with a single Tablet, but also supports the second Tablet, allowing a secondary user to assist and observe. When two Tablets are used, they mimic each other visually. Any actions performed on one Tablet are displayed on both. The Evident Tablets receive ultrasound image data streamed over Wi-Fi (or the provided optional ethernet cable included in the Cable Accessory Kit) and render the data to the real-time image display. The Tablet can be charged using the Tablet Mount (on the Mobile Cart or ATM) or the Docking Station.

Figure 4-4: Evident Tablet (shown in Tablet Mount)

Evident™ Tablet Mount

The Evident Tablet Mount (shown in Figure 4-4 with Tablet) is used to securely mount the Tablet on the Mobile Cart or to the procedure table bed rail, via the Evident™ Articulating Tablet Mount (ATM). The Tablet Mount has integrated microphones and electronics to support Evident™ Voice Assist. The Tablet Mount is powered by either the workstation (Mobile Cart configuration) or an AC power outlet through the ATM in the integrated lab configuration.

Evident™ Docking Station

The Evident Docking Station (shown in Figure 4-5 with Tablet) is used to charge a Tablet and can be in a fixed location, such as a procedure control room. A USB keyboard and mouse (not provided) may be connected to the Docking Station for use. The Docking Station does not support Evident Voice Assist.

Figure 4-5: Docking Station (shown with Tablet)

Evident™ Articulating Tablet Mount (ATM)

The Evident Articulating Tablet Mount (shown in Figure 4-6 with Tablet and Tablet Mount) is composed of an articulating arm and a Tablet Mount that is installed on the procedure table bed rail. The articulating arm allows for adjusting the position of the Tablet and Tablet Mount and is part of the Integrated Lab option only.

Figure 4-6: Articulating Tablet Mount (shown with Tablet)

Evident™ Catheter Interface Module (CIM)

The Evident Catheter Interface Module (shown in Figure 4-5 with System Cable) is a hardware interface between the workstation, via the system cable, and the single-use peripheral imaging catheter. The CIM connects to the catheter through its proximal hub connector. The CIM controls the catheter motor and transmits ultrasound signals between the catheter and the workstation. The CIM attaches to the procedure table bed rail.

System Cable

The 20-ft System Cable (shown in Figure 4-5 with CIM) connects the CIM to the Workstation.

Figure 4-7: Catheter Interface Module and System Cable

Evident™ Peripheral Imaging Catheters

The Evident Peripheral Imaging Catheters generate high-quality ultrasound images that are displayed on the Tablet. The imaging catheter is offered in two models that are optimized for various applications, procedures, and size of the vasculature:

- Evident™ 14 Peripheral Imaging Catheter
- Evident™ 35 Peripheral Imaging Catheter

Catheter Instructions for Use can be found at https://evidentvascular.com/IFU.

Cable Accessory Kit

The included Cable Accessory Kit contains the cables required for the operation of the Evident Vascular Guidance System, including connecting to an external auxiliary monitor:

	Quantity
Tablet Medical Grade Power Adapter	1
Medical Grade Ethernet Isolator	2
Ethernet Cable CAT6 Double Shielded 1ft Red	2
Ethernet Cable CAT6 Double Shielded 7ft Red	1
Ethernet Cable CAT6 Double Shielded 30ft Red	2
Active DP 1.2 to HDMI Adapter	1
HDMI 2.0 Optical Fiber Extender T/R	1
Armored Dual Fiber Cable	1
Workstation AC Power Cord, North America	1

Additional Supplies and Equipment

Imaging procedures should be performed in a fully equipped interventional lab. The following additional consumables and equipment may be needed for the imaging procedure and are not provided by Evident Vascular, Inc.:

- Sterile drape(s) suitable to cover the Tablet, Tablet Mount, and/or ATM to prevent contamination of the sterile field
- Standard catheterization lab auxiliary monitor for viewing IVUS images
- The Evident Vascular Guidance System supports the following USB devices only:
    - Keyboard/Mouse – Logitech MK270
    - USB Flash Drive – Samsung BAR Plus USB3.1 Flash Drive

WARNING: Use of cables or accessories not approved by Evident Vascular, Inc. (e.g., power cords, adapters, ethernet/ video cables). Otherwise, degradation of the performance of this equipment could result.

5 User Interface Overview (in progress)

The user interface (UI) has been designed for intuitive user interaction with the Evident Vascular Guidance System.

Display Layout

Figure 5-1 shows key features of the user interface and their location on the Tablet display:

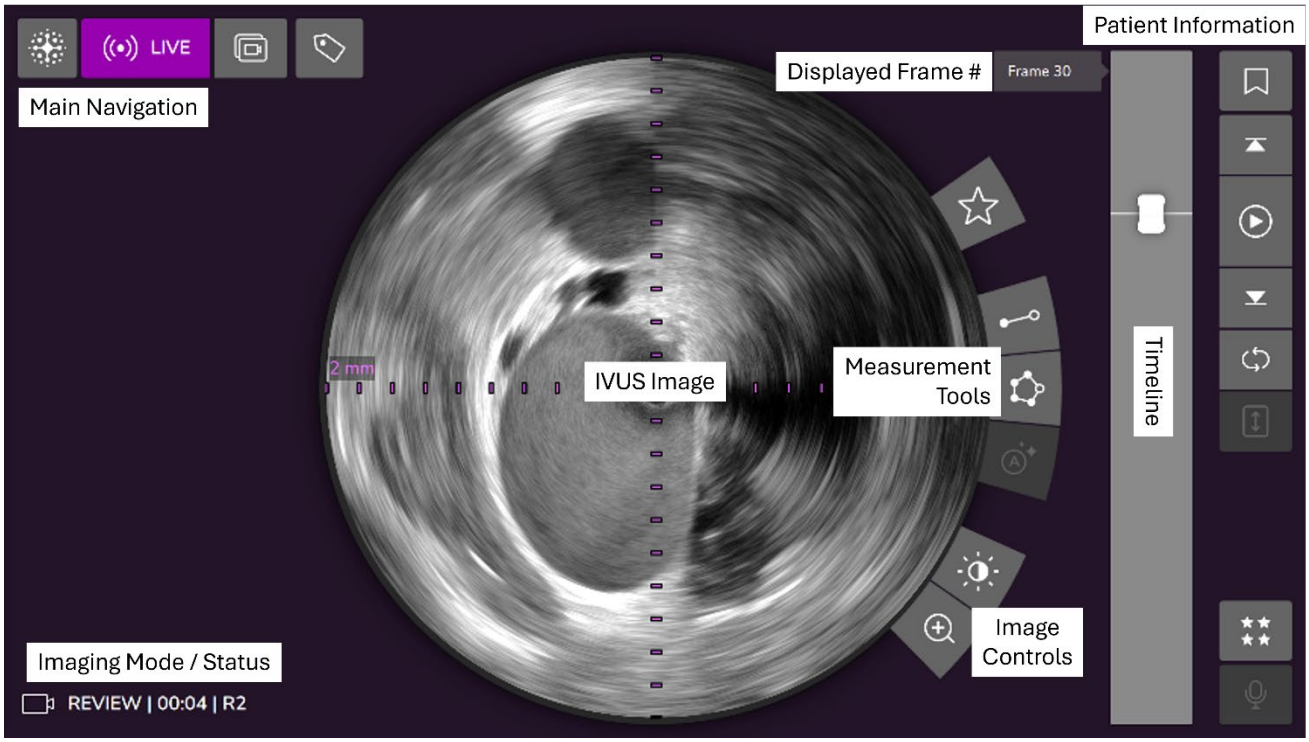

Figure 5-1: Review Screen layout showing the location of key information and tasks

Icons and Function

Icons represent functions, tasks or settings and act as a shortcut that can be activated with touch or hands-free commands (see Evident™ Voice Assist).

Icons appear as a white graphic on a dark or colored background. When the icon is selected (the task or function is active), it is inverted to a dark graphic on a white background.

The following table describes icons used in operation of the Evident Vascular Guidance System. For icons associated with hands-free commands, see Evident Voice™ Assist.

Icon	Name	Function
	System Menu	Opens System Menu
	System Shutdown	Shutting down Workstation and Tablet(s)
	List of Recordings	Shows all recordings in timed order
	Label	Add label to a frame
	Gain	Adjust Gain
	Zoom	Adjust Zoom
	Save	Tag a frame for archive
	Bookmark / Delete Bookmark	Mark a frame for later review
	Line Measurement	Measure a line
	Area Measurement	Measure an area
	Hide / Show Measurements	Toggle measurement panel off / on
	Lock / Unlock Area	Lock or unlock a measured area as reference
	Edit	Edit measurement

	Delete	Delete measurement
	Checkmark	Confirm measurement
	Dynamic Review	Review a short time span of frames to aid in measurement
	Summary View	View all recordings and frames tagged for archive
	Return to Home Screen	Return to Home Screen
	Return to Review Screen	Return to Review Screen
	Import	Import patients from connected PACS Worklist
	Export	Export/Archive case data to connected PACS
	Scroll the timeline	Allows more precise scrolling in longer recordings
	Review	Select a stored case to review

System Menu

- Press the System Icon  to access the System Menu panel. Depending on whether a case is in progress, there are several options:
  - System Information: provides information about the installed software version and information about a connected peripheral imaging catheter.
  - Help: Provides QR code to access electronic IFU, User Manual and Quick Reference Guide

- Case Information: Enter or edit patient information once case has been started.
- End Case: Ends current case and goes to Case Completed screen.
- Log Out: Logs current user out of the system and returns to Log In screen for next user.
- Shutdown: Shuts down the Guidance System (see Shut Down the Guidance System)

6 Evident™ Voice Assist

In addition to using the Tablet's touchscreen to interact with the EVGS, you can enable the Evident Voice Assist feature, allowing you to perform common tasks using your voice.

A directional microphone is built into the Tablet Mount to prioritize listening from a specific location, and the Evident Voice Assist feature can be enabled or disabled at any point during a case. Voice Assist is not functional with a Tablet in a Docking Station.

Evident Voice Assist Status Icons

The status of the voice assist feature is indicated by an icon (that also serves as a button) in the lower right corner of the Tablet. A list of icons and their descriptions is in the table below.

Evident Voice Assist Status Icons

Icon	Status	Description
	Not Detected	The hardware is not detected (i.e., the Tablet is not in a Tablet Mount)
	Muted	The system is muted; the user should press the button to enable or re-enable Evident Voice Assist
	Ready	The system is waiting for the wake word
	Voice Detected	The system has detected a voice while waiting for the wake word
	Active	The wake word has been recognized from the direction indicated by the purple shadow. The wake word has activated the voice assist feature. The system is actively listening for commands
	Active Voice Detected	The system has detected a voice while in the active state

The icons also have touch-enabled function:

- Short press: changes between Ready and Active status
- Long press: toggles between Muted and Ready

Enable Evident Voice Assist

When a case is started with a Tablet with detected hardware (i.e., Tablet Mount), Evident Voice Assist is started in the **Muted** status (Figure 6-1).

A wake word is a specific phrase that activates a voice assistant and lets the software know that a command is about to be spoken. The device then switches from passive to active listening.

*Evident Voice Assist determines which direction it heard "**ok**IVUS" and continues to listen only in the direction in which the wake word was spoken.*

- Press the status icon button in lower right corner to change from **Muted** to **Ready.**
- Say the wake word ***ok***IVUS™ (pronounced "OH-kay EYE-vuss") or press the status icon to change from **Ready** to **Active.**
- Voice Assist is **Active** (Figure 6-2):
    - The status icon changes to **Active** or **Active Voice Detected**, depending on whether a voice is detected at that time.
    - An animated white border on the outside of the display window frame will appear.
    - An overlay with "voice mode active" is shown for approximately 1.5 seconds then fades out.

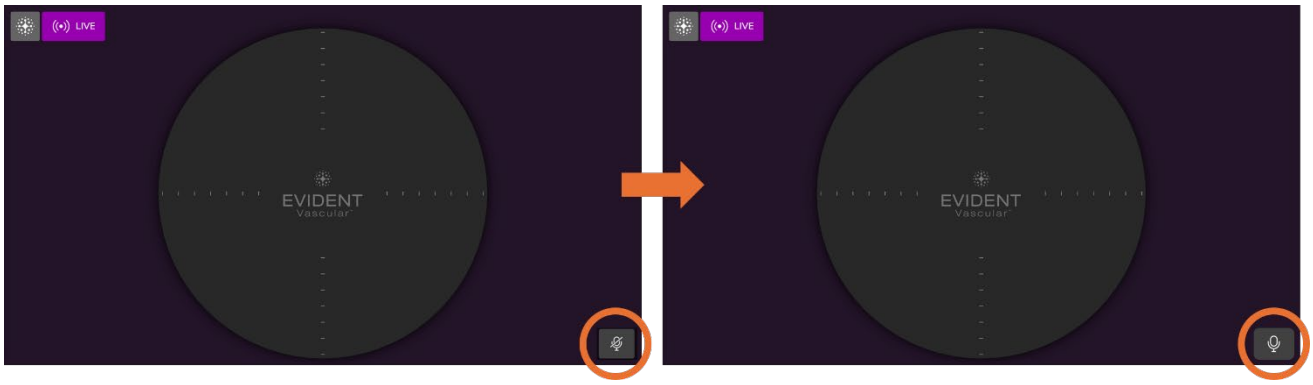

*Figure 6-1: Press the Evident Voice Assist **Muted** icon (left, circled) to change status to **Ready** (right, circled)*

*Figure 6-2: Evident Voice Assist in **Active** state, showing **Active** icon at bottom right and white border*

Once enabled, the interface stays in voice command mode for 60 seconds.

After the 60 seconds has elapsed with no additional commands, an overlay with “Voice Assist Disabled” appears. You must repeat the wake word before the next command, which restarts the timer.

Evident Voice Assist remains active during a recording; ending a recording restarts the 60-second timer.

Using Evident Voice Assist with Both Tablets

The first Tablet to receive the wake word is activated for Evident Voice Assist. The other Tablet will remain ready until the wake word is timed out, or the microphone button is pressed to return to **Ready** status. A short press on the microphone button will activate Evident Voice Assist on that Tablet and “override” any other Tablets.

Evident Voice Assist List of Commands

The following table lists the commands available in the Evident Voice Assist feature:

Action	Icon	Voice Command(s)
Wake word		"***ok***IVUS"
Start Live Imaging		• "Go live" • "Start imaging" • "Imaging On"
Stop Live Imaging		• "Freeze" • "Stop imaging" • "Imaging Off"
Start recording		• "Start recording" • "Recording On" • "Begin Recording"
Stop recording		• "Freeze" • "Stop recording" • "Recording Off"
Adjust zoom		• "Zoom in" • "Zoom out"
Adjust gain		• "Gain up" • "Gain down"
Add bookmark		• "Mark it" • "Bookmark that"
Replay recording		• "Start playback" • "Playback" • "Play recording"
Pause replay		• "Stop" • "Stop playback" • "Pause playback"
Save current frame		• "Save" • "Save frame" • "Save it" • "Save that"
Hide/Show Measurements		• "Hide measurements" • "Show measurements"
Stop Listening (Wait for Wake word)		• "Stop Listening"

Tips for Evident Voice Assist:

- Ensure voice assist is **Active** (status icon in lower right corner of Tablet)
- Speak clearly at a normal pace.
- Avoid crosstalk.
- Only repeat the wake word if necessary to re-enable the command mode.
- If a voice command is not recognized, pause and repeat the voice command.

7 Quick Start

Quick Start

1. **Workstation:**
   Connect to wall power
   Press power button on top

2. **Tablet(s):**
   Press and HOLD power button 3-5 seconds until display is active

3. **Log in** and **Start case**

4. **Connect** the catheter to CIM
   Advance to target site

5. **Go Live!** LIVE

8 Evident Vascular™ Guidance System Set Up

An Evident Vascular, Inc. Representative will install the Evident Vascular Guidance System before the first use. For installation information, please contact Evident Technical Support Services at info@evidentvascular.com.

Once the system is ready to operate, the following should be performed before each case.

WARNING: Inspect all components and connections for damage, wear, etc. before each use of the Guidance System. If any damage is noted, contact Evident Technical Support Services.

Guidance System Setup

Mobile Cart Setup (Mobile Configuration)

- Position the Mobile Cart in desired location near the procedure table. The cart should be close enough to the patient so the 20-ft System Cable can reach the CIM if attached to the bed rail.
- Lock the caster on each of the cart's wheels by depressing the lever on each caster.

Do not attempt to move the Mobile Cart once the casters have been locked.

- Connect Workstation to AC wall power.

Catheter Interface Module (CIM) Setup (both Mobile and Integrated Configurations)

- Ensure CIM is connected to Workstation with the System Cable:
  - The end of the System Cable with the right-angle connector should be connected to the appropriate port on the back of the Workstation (see Figure 8-1).
  - Align the red dot on the connector with the red dot on the port on the workstation and push firmly until the connector is fully seated.
- The other end of the System Cable should be connected to the bottom of the CIM.
  - Align the red dot on the connector with the red dot on the port on the CIM and push firmly until the connector is fully seated.

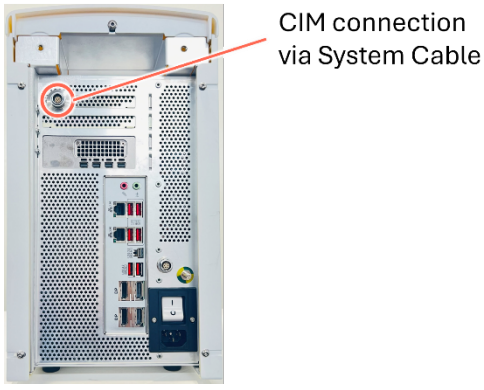

Figure 8-1: CIM/System Cable Connection on back of Workstation

Additional CIM Setup (Mobile Configuration)

- Remove CIM from cart:
  - Fully lift the handle to unlock the clamp.
  - Remove CIM from cart.

The CIM can remain on the mobile cart during use if a bed rail is not available for mounting. Ensure there is enough catheter working length in the sterile field for advancing and withdrawing the catheter without compromising catheter sterility.

WARNING: When keeping the CIM on the Mobile cart instead of a bed rail, ensure casters are locked to avoid inadvertent removal of imaging catheter from patient.

- Attach the CIM to the procedure table bed rail:
- Fully lift the handle to unlock the clamp (Figure 8-2a).
  - Angle the CIM so that the clamp is on the bed rail (Figure 8-2b).
- Fully lower handle to lock the CIM onto the bed rail (Figure 8-2c).

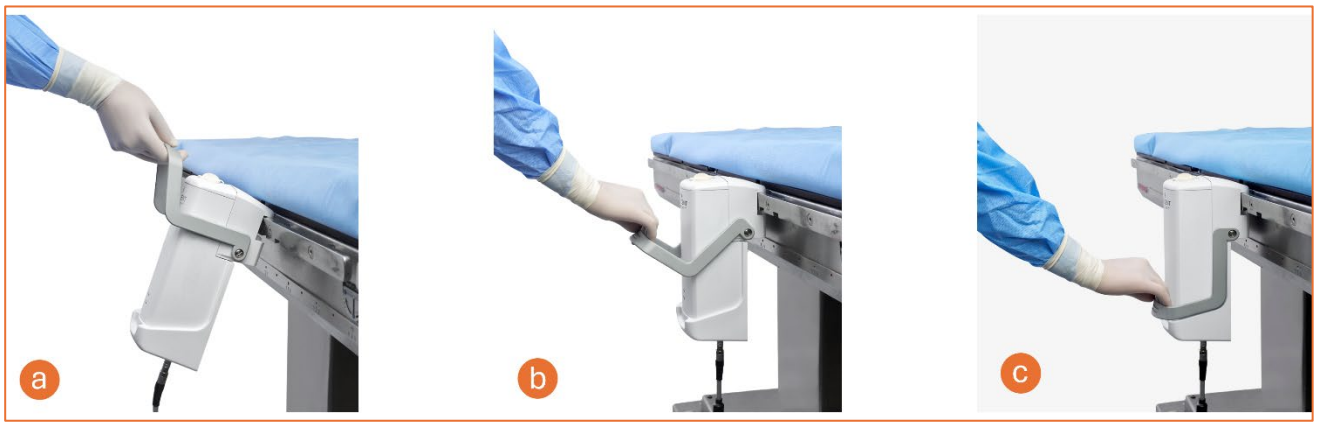

Figure 8-2: Attach the CIM to the procedure bed rail. With handle fully lifted (a), tilt the CIM on to the bed rail (b) then fully lower the handle (c).

Power Up the Guidance System

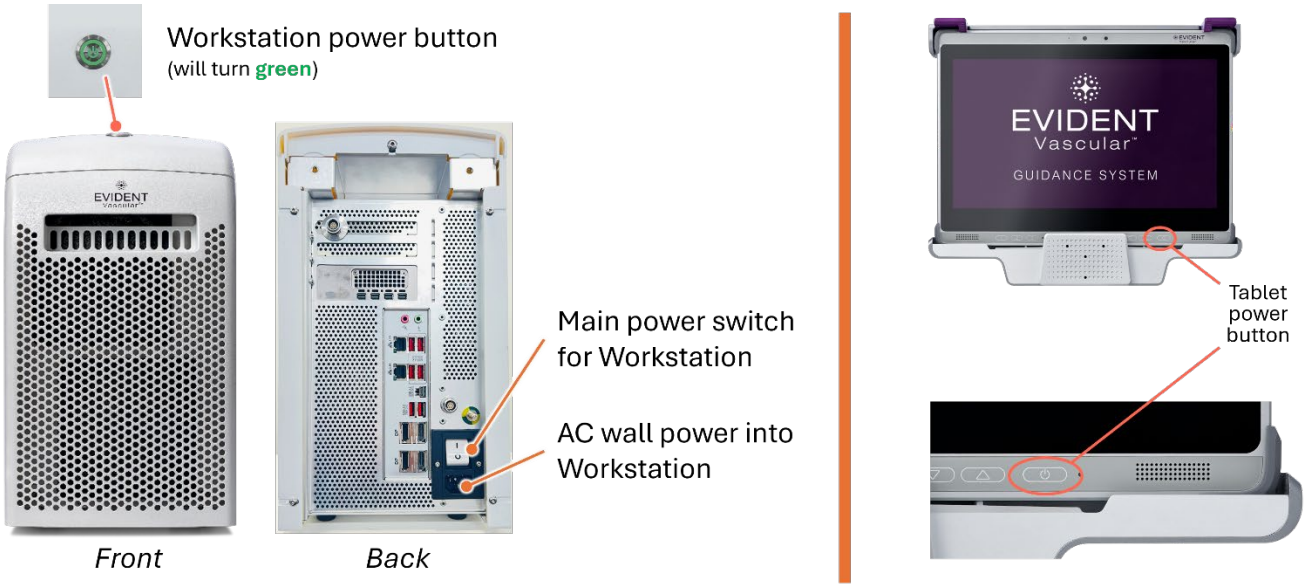

Figure 8-3: Power button and connection locations for the Evident Workstation (left) and Evident Tablet (right)

Power up Workstation

- Ensure Workstation is connected to AC wall power and that the main power switch on back of Workstation is on (Figure 8-3).
- Press the Power button located on top of the Workstation. The button will turn green to indicate it is on.
-

WARNING: if the Tablet and Tablet Mount (on Mobile Cart or Articulating Tablet Mount) are to be used in the sterile field, they must be draped to maintain the integrity of the sterile field.

Power up Tablet(s)

- The Tablet power button is located on lower right front of Tablet (Figure 8-3).
- Press and HOLD Tablet power button 3-5 seconds until Tablet display is active.
    - The Tablet(s) will display the Initializing screen and transition to the LogIn screen when boot up is complete(Figure 8-4).

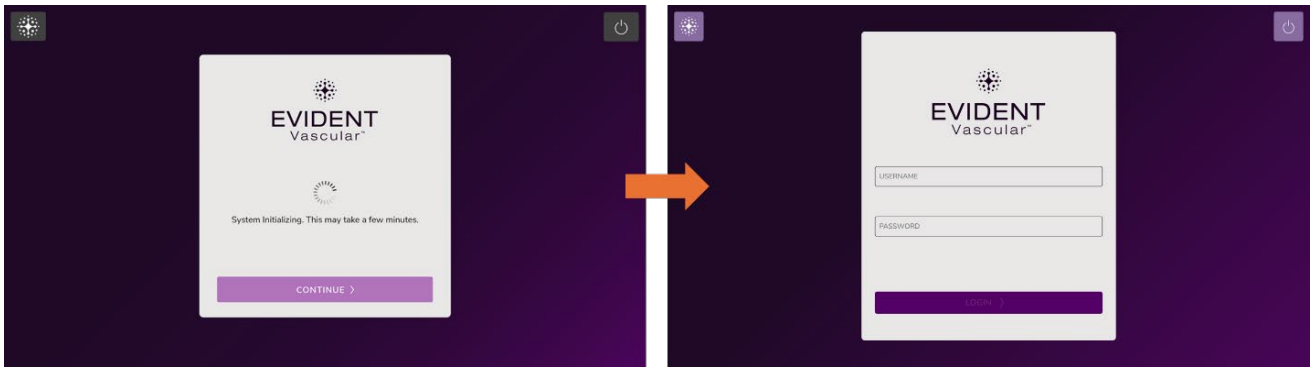

Figure 8-4: System Initializing (left) and System Login (right) screens

Tablet power indicator LED light status: the LED light will briefly turn blue while it is powering up and turn off when the display becomes active.

Tablet battery power is checked automatically during start up to ensure there is enough battery life. See Troubleshooting for error messages.

Tablet power indicator light status: the LED light will be green when the Tablet is fully charged. The Tablet charges through the Tablet Mount on the Mobile Cart or on the ATM, or on the Docking Station.

Optional Monitor Attachment for Mobile Configuration

You may wish to view the IVUS images on an auxiliary monitor. Only connections that are supplied or approved for use by Evident Vascular (see Additional Equipment Manufactured by Other Vendors) may be used. The fiber optic cabling will be pre-installed for the Integrated Lab Configuration and pre-connected for the Mobile Cart Configuration.

To connect an auxiliary monitor to the Mobile Cart:

- Workstation connection (Figure 8-5, left):
  - Ensure the Fiber Optic Extender that is labelled “Transmitter” is inserted into a Display Port on the Workstation
  - Connect the USB-A connector into an available USB port on the Workstation to provide power to the transmitting side of the cable.
- Monitor connection (Figure 85, right):
  - Connect the Fiber Optic Extender that is labelled “Receiver” into an HDMI port on the Auxiliary Monitor.
  - To power the receiving side of the cable, connect the USB-A connector into an available USB port on the Auxiliary Monitor, or to an external power source (not provided).

Fiber optic signals are sent in one direction only; it is important to distinguish the “Transmitter” connection from the “Receiver” connection.

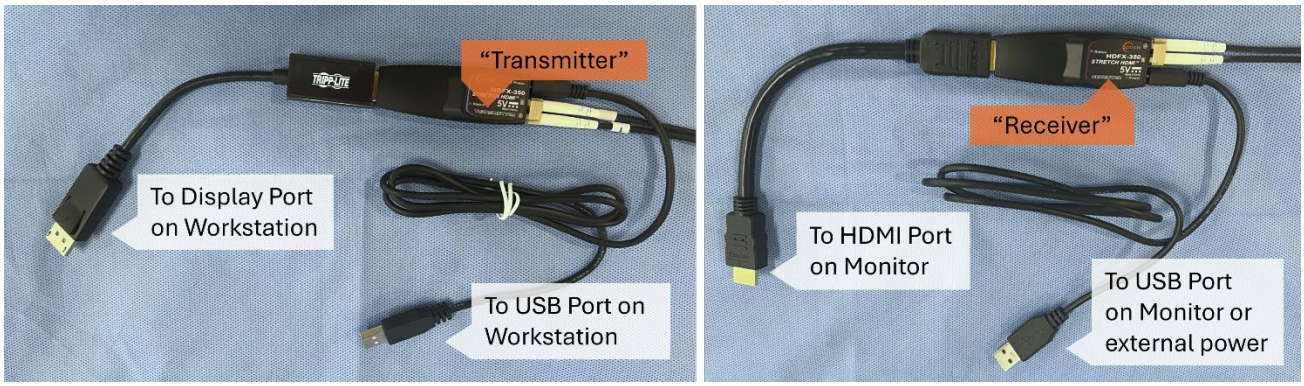

Figure 8-5: Auxiliary monitor connectors for Workstation (left), and monitor (right)

9 Starting a Case

Log In Screen

From the Login screen (Figure 9-1), you can:

- Access the System Menu (see System Menu)
- Shut down the Guidance System (see System Shutdown)
- Log into the Guidance System

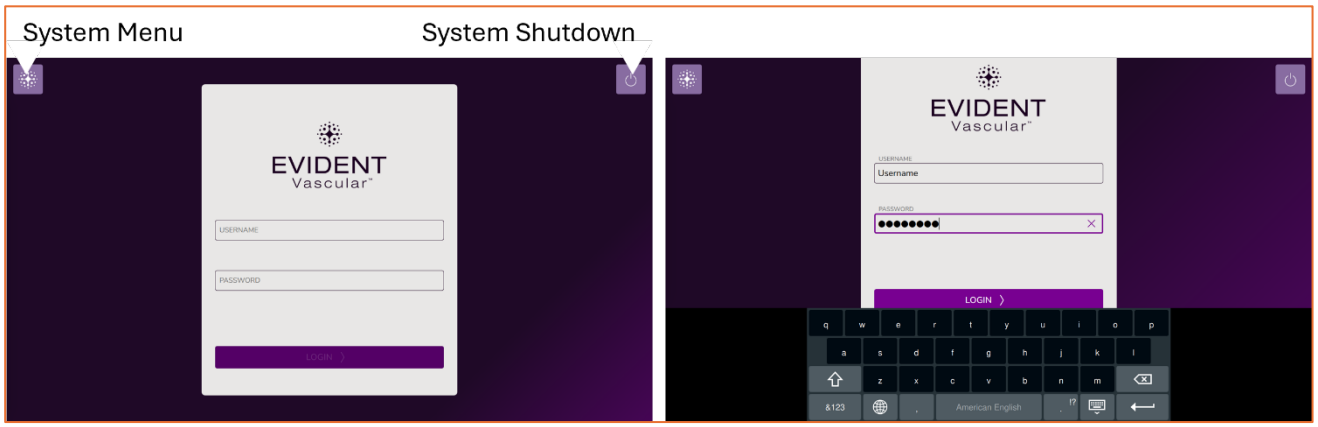

Figure 9-1: Login screen with System Menu and System Shutdown icons (left); press in either field to access keyboard (right)

Log In to the Guidance System

- Press one of the text fields to display the on-screen keyboard (Figure 9-1).
- Enter username and password.
- Press LOGIN.
- The Tablet(s) should display the Home screen (Figure 9-2).

Usernames and passwords are configured by Evident Vascular, Inc.; contact Evident Technical Support Services for assistance.

Home Screen

From the Home screen (Figure 9-2), you can:

- Access System Menu (see System Menu)
- Shutdown the Guidance System (see System Shutdown)
- Start a New Case
- Review, archive, or delete stored Cases (See Data Management).

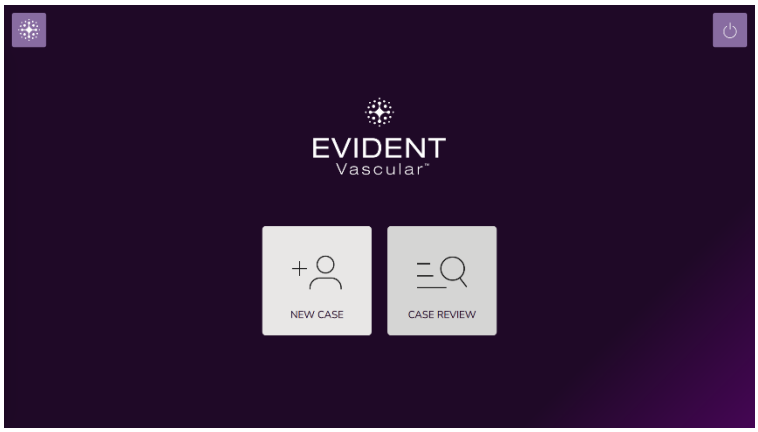

Figure 9-2: Home Screen

Start a New Case

To start a new case, select NEW CASE from the Home Screen and you will be directed to the Case Setup screen.

Case Setup

The Case Setup screen (Figure 9-3) allows you to enter case information before starting to image. This information is not required before starting the case, but you will be prompted to enter at least the Patient ID before ending a case that contains any recordings or saved images. You can enter or edit information at any time before ending the case in the Guidance System. There are three options for case setup:

- Start case without case information (Direct case start)
- Manual Entry
- Worklist

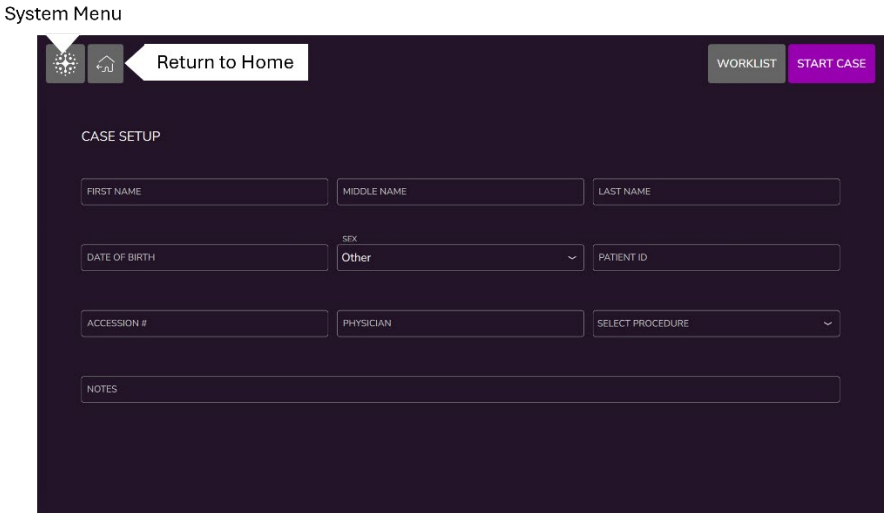

Figure 9-3: Case Setup screen

Direct Case Start

In certain situations, you may wish to defer entering case and patient details until after the case has been started.

- From the Case Setup screen (Figure 9-3), press START CASE.

> You will be prompted to enter patient ID before ending a case with recordings or saved images.

Manual Entry

- Touch any text field to bring up the keyboard.
- Enter the desired information.
- Select START CASE.

Worklist

The Evident Vascular Guidance System can pull case information from a connected PACS:

- Select WORKLIST from the Case Setup screen to display an imported worklist (Figure 9-4).
- To refresh the worklist, return to the Home Screen and re-select WORKLIST.
- Scroll through the list to locate the desired patient.
- Filter the list by typing in the appropriate fields and press SEARCH.
  - Press RESET to clear the search fields.
- Select the text line containing the desired patient's name.
- The case details will appear; select:
  - IMPORT icon to confirm.

> *Case information imported from a worklist, other than procedure type and notes, cannot be edited. Press RESET to clear data and re-enable editing of all fields.*

- Imported case data will be shown on the Case Setup screen to review and verify.
- Select START CASE.

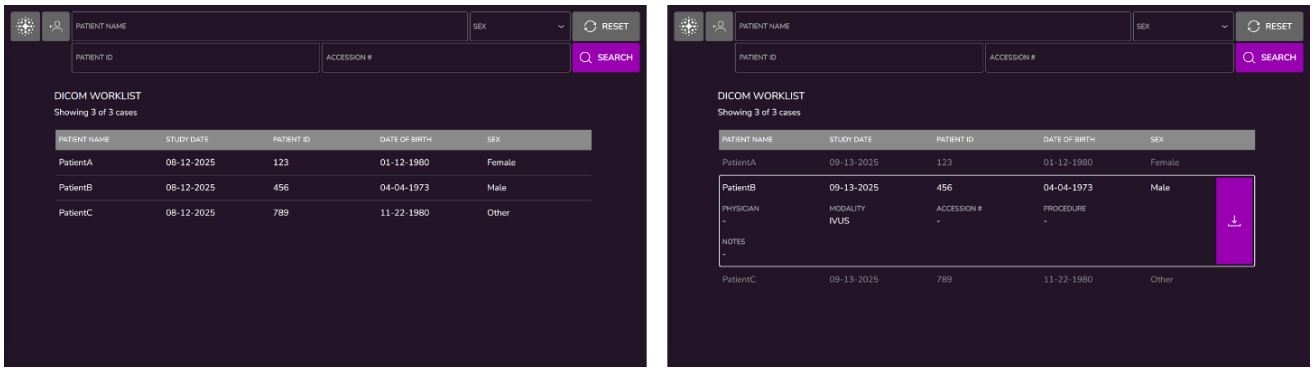

Figure 9-4: Worklist (left) and Worklist with selected case (right)

Enter or Edit Case Information After Case Start

At any time during the IVUS procedure:

- Press the System Menu icon.
- Press CASE INFORMATION.
- From the Case Information screen (Figure 9-5), you can:
  - Enter information directly, or
  - Press WORKLIST
    - Select patient.
    - Press CASE INFO to return, or
    - Press IMPORT to view and/or edit.
- CANCEL or SAVE.

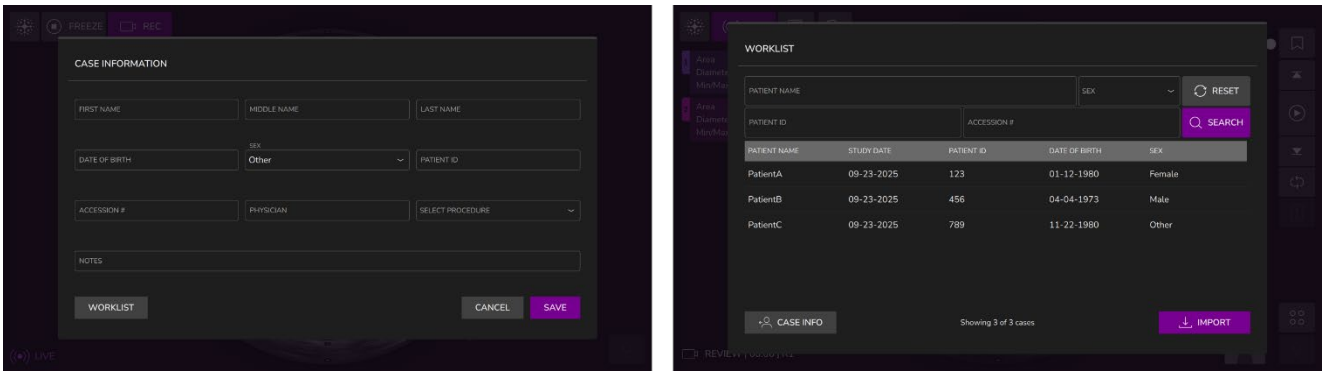

Figure 9-5: Case Information screen (left) and Worklist (right)

10 Connect the Evident™ Peripheral Imaging Catheter

Prepare the Peripheral Imaging Catheter

The Peripheral Imaging Catheter should be selected based on the needs of the procedure. Refer to the *Evident Peripheral Imaging Catheter Instructions for Use* at https://evidentvascular.com/IFU for information on preparing the Peripheral Imaging Catheter.

Connect the Catheter to the CIM

- Remove cap to CIM receptacle (Figure 10-1).
- Orient the Proximal Hub of the Imaging Catheter so that the latch aligns correctly with the CIM receptacle.
- Insert until you feel/hear the Hub click into the CIM.

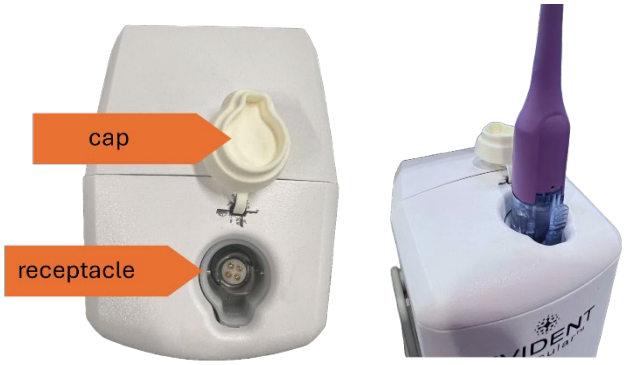

Figure 10-1: CIM top view with cap removed (left) and with catheter connected (right)

Confirm Proper Catheter and Function

Once the Peripheral Imaging Catheter is connected to the CIM, information about the specific catheter will appear (Figure 10-2). These messages detail the size and model of catheter, the catheter's transducer location and for model EV14P, the length of the RX guidewire lumen.

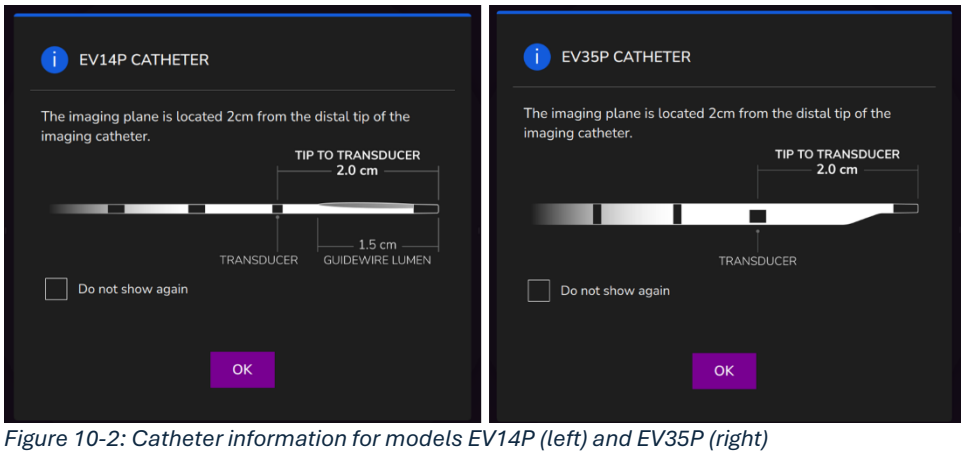

Figure 10-2: Catheter information for models EV14P (left) and EV35P (right)

The following screen (Figure 10-3) is displayed and the Evident Vascular Guidance System is ready for Live Imaging:

Figure 10-3: Ready to start Live Imaging

From the Ready screen (Figure 10-3), you can:

- Access the System Menu (see System Menu).
- Start Live Imaging (see Start Live Imaging).

11 Live Imaging

Once the catheter has been connected (see Connect the Evident Peripheral Imaging Catheter), insert and advance per the appropriate *Evident™ Peripheral Imaging Catheter Instructions for Use* (https//:evidentvascular.com/IFU). Once the catheter is in the desired location, you can begin imaging.

CAUTION: While inserting the catheter through a hemostasis valve into a guide or sheath, do not turn on imaging until after the catheter distal end is in the sheath or guide lumen.

Start Live Imaging

Figure 11-1: Ready for Live Imaging

You can start Live Imaging using the appropriate Tablet icon or Evident Voice Assist (see Evident™ Voice Assist):

Tablet

- Press LIVE to begin Live Imaging (Figure 11-1).

Evident Voice Assist

- Ensure Evident Voice Assist is active, and say one of the following commands to initiate Live Imaging:
  - "Go Live"
  - "Start Imaging"
  - "Imaging On"

During Live Imaging, the Live icon LIVE is displayed in the lower left corner of the screen.

Tools Available During Live Imaging

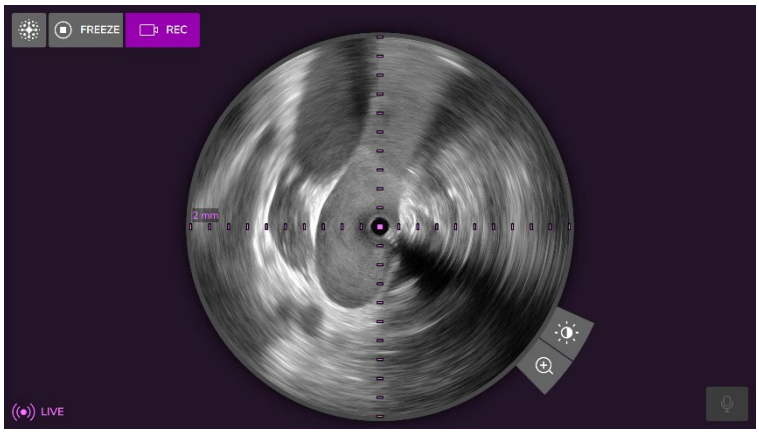

Figure 11-2: Live Imaging Screen

During Live Imaging (Figure 9-2), you can:

- Adjust the image gain (see Adjust Gain)
- Adjust the image zoom (see Adjust Zoom)
- Press FREEZE to pause the live image (see Freeze the Live Image)
- Press REC to begin recording data (see Start Recording)

Adjust Gain

You can adjust the brightness (“gain”) of the image during live imaging, recording and review.

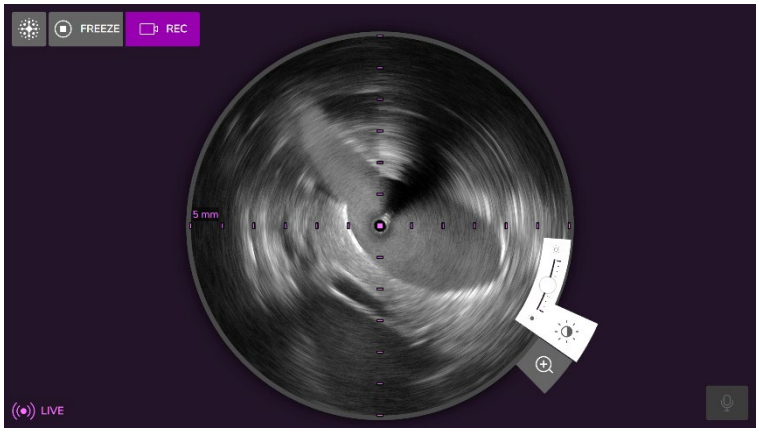

Figure 11-3: Adjusting Gain

You can adjust the gain using the appropriate Tablet icon, finger gestures or Evident Voice Assist (see Evident™ Voice Assist):

Tablet

- Press the Gain icon to reveal the slider control (Figure 11-3).
- Drag the slide up to increase gain (increase brightness), or
- Drag the slide down to decrease gain (decrease brightness)
  - The db value will be temporarily displayed in the center of the image.
- Tap the Gain icon again to close the slide; the slide will close automatically after several seconds of inactivity.

Gesture

- Press two fingers to the IVUS image and
- Drag both fingers up to increase gain or
  - Drag both fingers down to decrease gain.
- Tap the Gain icon again to close the slide; the slide will close automatically after several seconds of inactivity.

Evident Voice Assist

- Ensure Evident Voice Assist is active, and say the following command to increase gain:
  - “Gain Up”
- Say the following command to decrease gain:
  - “Gain Down”

Adjust Zoom

You can adjust the field of view (“zoom”) of the image during live imaging, recording and review.

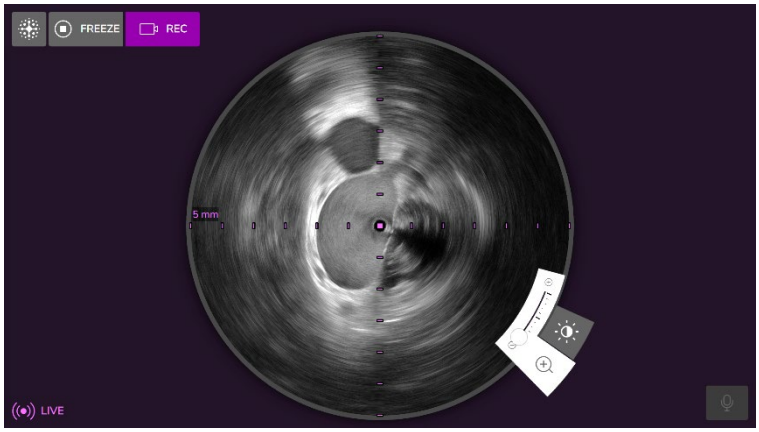

Figure 11-4: Adjusting Zoom

You can adjust the zoom using the appropriate Tablet icon, finger gestures or Evident Voice Assist (see Evident™ Voice Assist):

Tablet

- Press the Zoom icon to reveal the slide control (Figure 11-4).
- Drag the slide up to zoom in (increase magnification) and down to zoom out (decrease magnification).
  - The mm value will be temporarily displayed in the center of the image.
- Tap the Zoom icon again to close the slide; the slide will close automatically after several seconds of inactivity.

Gesture

- Press two fingers to the IVUS image and
  - Move them apart to zoom in, or
  - Pinch them together to zoom out.
- Tap the Zoom icon again to close the slide; the slide will close automatically after several seconds of inactivity.

Evident Voice Assist

- Ensure Evident Voice Assist is active, and say the following command to zoom in:
  - “Zoom In”
- Say the following command to zoom out:
  - “Zoom Out”

Freeze the Live Image

When Live Imaging is paused or "frozen," the last captured frame is displayed. You can freeze or pause Live Imaging using the appropriate Tablet icon or Evident Voice Assist (see Evident™ Voice Assist):

Tablet

- Press FREEZE

Evident Voice Assist

- Ensure Evident Voice Assist is active, and say one of the following commands to freeze or pause Live Imaging:
  - "Freeze"
  - "Stop imaging"
  - "Imaging Off"

When Live Imaging is paused or "frozen," the Tablet will display the Review Screen (Figure 11-5; see Review Images) with the last captured frame along with 0.5 seconds of previous imaging data.

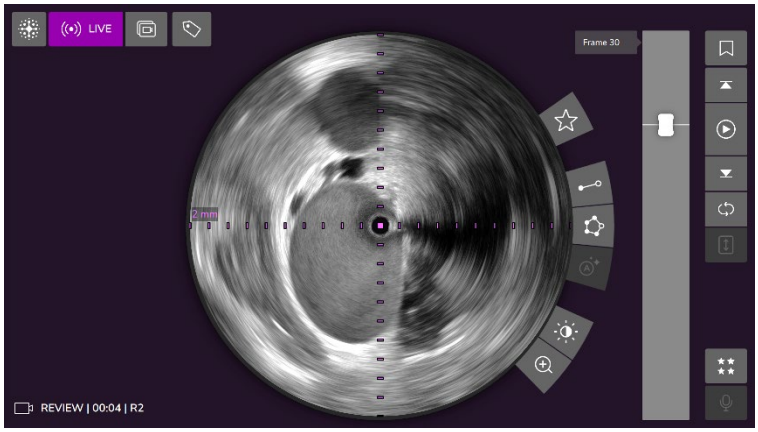

Figure 11-5: Review Screen

12 Recording Images

Recording Overview

From the Live Imaging screen (Figure 12-1), you can create a recording up to 3 minutes long.

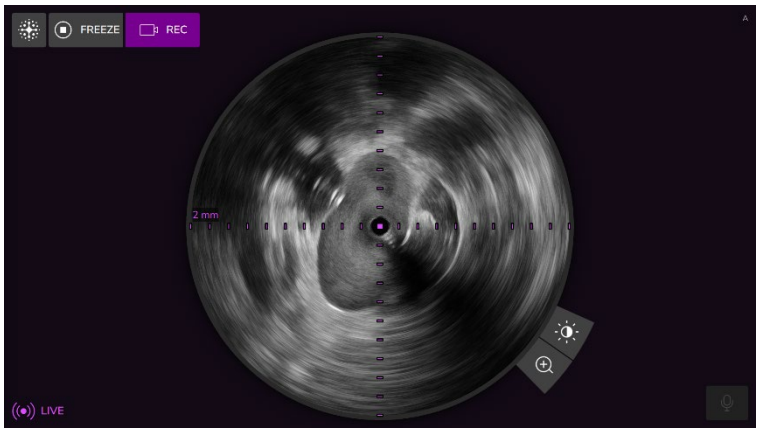

Figure 12-1: Live Imaging screen showing the REC (record) button

Start a Recording

You can initiate recording using the appropriate Tablet icon or Evident Voice Assist (see Evident™ Voice Assist):

Tablet

- Press REC  to begin recording

Evident Voice Assist

- Ensure Evident Voice Assist is active, and say one of the following commands to begin recording:
  - "Start Recording"
  - "Recording On"
  - "Begin Recording"

To indicate the Evident Vascular Guidance System is recording (Figure 12-2):

- The REC icon  and elapsed recording time are displayed in the lower left corner.
- A purple border circles around the live image.
- Recording timeline progress is shown on the right side of the display.

Recordings are limited to 3 minutes and will automatically be stopped once the limit is reached.

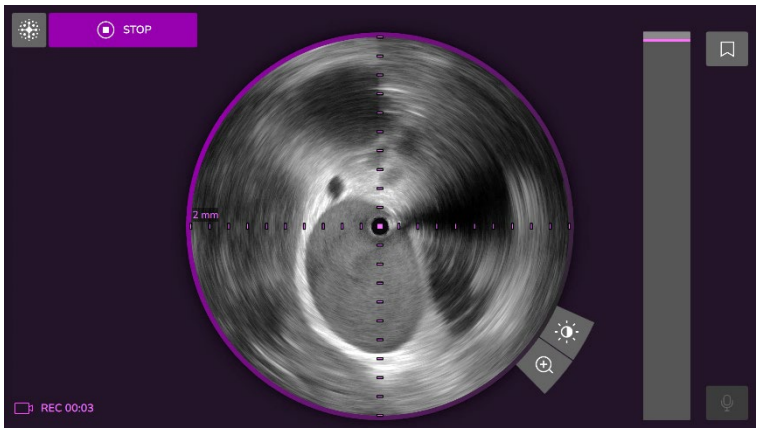

Figure 12-2: Recording

Tools Available During Recording

During recording (see Figure 12-2), you can:

- Adjust the image gain (see Adjust Gain)
- Adjust the image zoom (see Adjust Zoom)
- Add a Bookmark to mark the currently visible frame for later review (see Add a Bookmark)
- Stop recording (see Stop Recording)

Stop Recording

You can initiate recording using the appropriate Tablet icon or Evident Voice Assist (see Evident™ Voice Assist):

Tablet

- Press STOP to end recording

Evident Voice Assist

- Ensure Evident Voice Assist is active, and say one of the following commands to stop recording:
  - "Freeze"
  - "Stop Recording"
  - "Recording Off"

When recording is stopped, the Tablet will display the Review Screen and the first captured frame in the recording (see Review Images). All frames captured in the recording are available for review.

13 Review Images

Review Overview

The Evident Vascular Guidance System allows for immediate Review after freezing a Live Image or stopping a Recording. Freezing a Live Image displays a 0.5 second history of frame data in the Review screen. Stopping a Recording allows for review of all recorded frames. The Review features and tools are the same for pausing a Live Image or stopping a Recording.

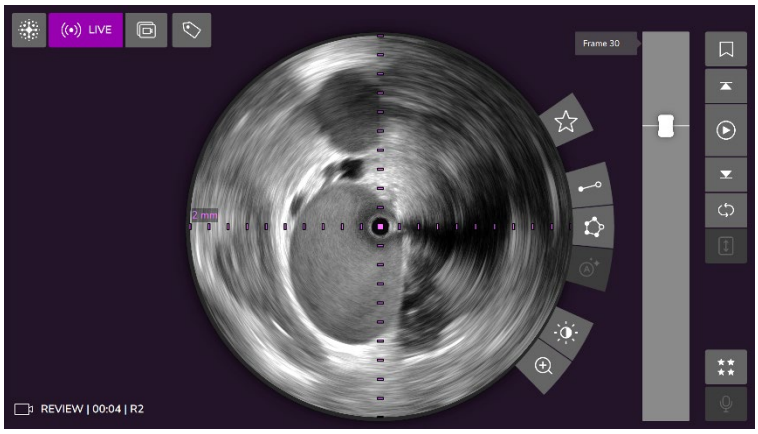

Figure 13-1: Review screen

During Review (Figure 13-1), you can:

- Adjust the image gain (see Adjust Gain)
- Adjust the image zoom (see Adjust Zoom)
- Add Labels to the frame (see Add a Label).
- Add a Bookmark to mark specific frames for later review (see Add a Bookmark)
- View the List of Recordings (see List of Recordings).
- Mark a specific frame as saved to include in exported data (see Save a Frame and Summary View).
- Navigate the Timeline on the right of the screen (see Navigate the Timeline)

Add a Label

You can add a label to any frame. There are labels from four pre-defined label categories and/or you may create a custom label. You can add up to a total of 64 characters per frame (includes pre-defined and custom labels).

Pre-Defined Labels

Tablet

- Press the Label tool near the upper left corner.
- The Frame Label(s) screen appears (Figure 13-2) , displaying pre-defined labels in 4 categories (Case Workflow, Side, Vessel, and Segment).
- Select the labels you wish to add by scrolling through the list and pressing the desired label.
    - Labels will be added in the sequence they are entered.
- Press:
    - RESET to clear all labels
    - CANCEL to discard any changes, or
    - SAVE to apply changes.

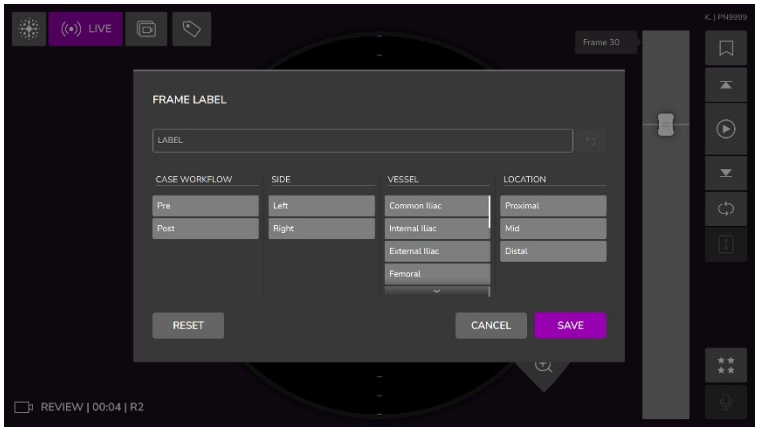

Figure 13-2: Add a Label

Custom Labels

You may also enter custom text.

Tablet

- Press in the LABEL field to open the keyboard (Figure 13-2).
- Enter the text for the custom label.
- Press:
    - RESET to clear all labels
    - CANCEL to discard any changes, or
- SAVE to apply changes.

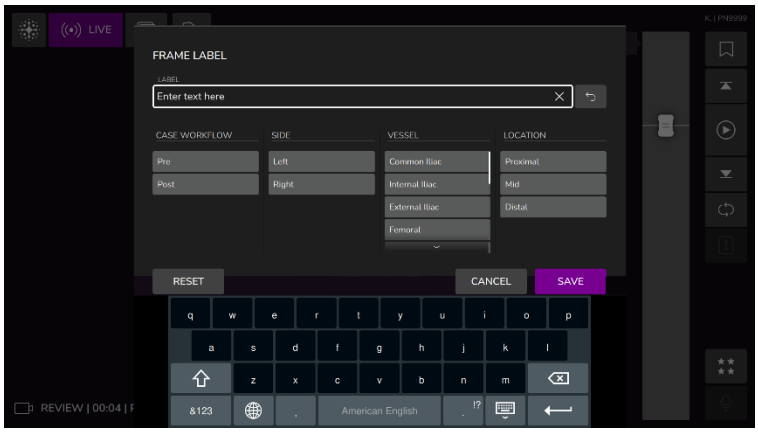

Figure 13-3: Example of a Custom Frame Label

If you wish to delete or change a label:

Tablet

- Press the label displayed on the frame.
- Press:
  - RESET to clear all labels
  - CANCEL to discard any changes, or
- SAVE to apply changes.

Add a Bookmark

You can bookmark (Figure 13-4) a frame of interest for later viewing. This does not save the image but serves as a placeholder for subsequent review.

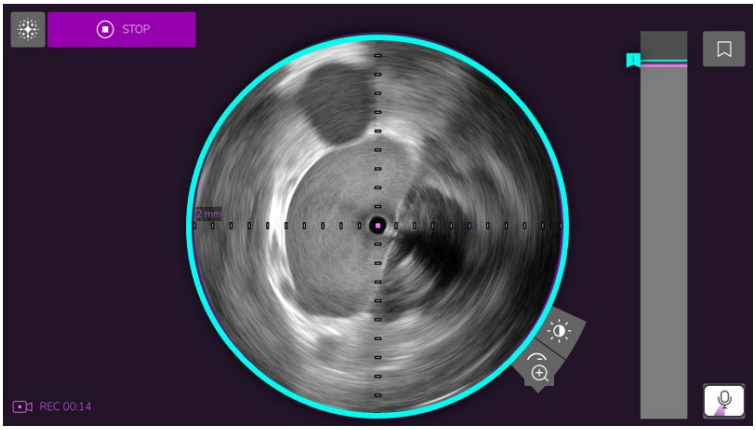

Figure 13-4: Example of Bookmark with colored outline around IVUS frame

You can add a bookmark using the appropriate Tablet icon or Evident Voice Assist (see Evident™ Voice Assist):

Tablet

- Press the bookmark tool in the top right corner of the display (Figure 13-4).

Evident Voice Assist

- Ensure Evident Voice Assist is active, and say one of the following commands to bookmark a frame:
  - "Mark It"
  - "Bookmark That"

Bookmarked frames appear as a teal line in the timeline (see Navigate the Timeline). A teal circle will flash around the image when the Bookmark Tool is selected. Each bookmarked frame is numbered in the order it was marked. Recordings are limited to 20 bookmarks.

You can delete the bookmark by selecting the Delete Bookmark Tool from the review screen once you freeze Live Imaging or stop Recording. To navigate to a bookmarked frame, press on the desired bookmark icon on the timeline (see Navigate the Timeline), then press the delete bookmark tool.

View the List of Recordings

You can view the list of recordings to select a specific recording to review.

From the Review screen:

- Press the List of Recordings icon to view the list (Figure 13-5).
- Press the Recording you wish to view; that Recording will be available in the Review Screen.

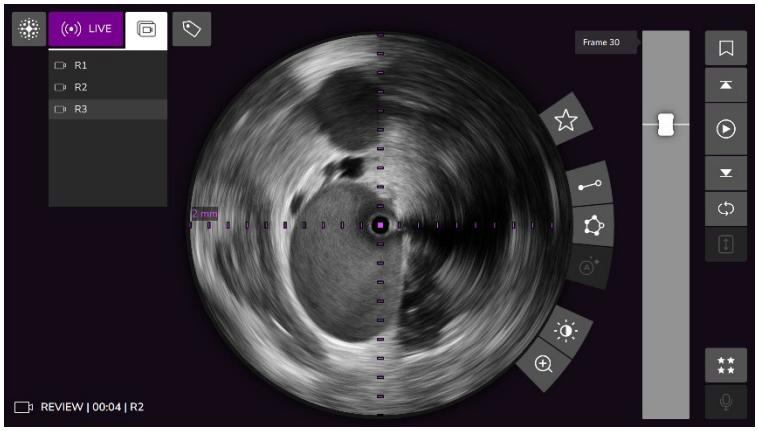

Figure 13-5: View List of Recordings

Save a Frame

The Save Frame feature tags a frame for export to PACS (see Archiving a Case). All Saved (tagged) frames appear in the Summary View (see Summary View). Recordings are limited to 20 saved frames. If modifications are made to a saved frame, those changes are still part of the tagged frame, and the frame does not need to be re-saved. You can save any frame of interest from the Review screen:

- When you freeze Live Imaging
- While reviewing a Recording
- After confirming a measurement (see Measurements)

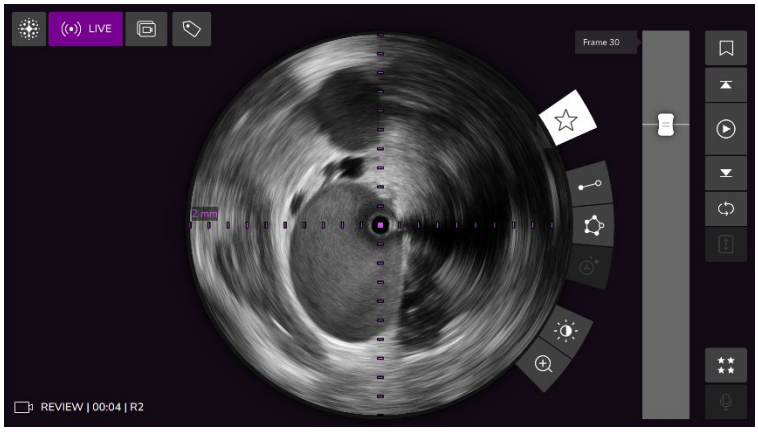

Figure 13-6: Save a Frame with Save Tool highlighted

You can save a frame using the appropriate Tablet icon or Evident Voice Assist (see Evident™ Voice Assist):

Tablet

- Press the Save icon ☆ above and to the right of the IVUS image (Figure 13-6).

Evident Voice Assist

- Ensure Evident Voice Assist is active, and say one of the following commands to save a frame:
  - "Save"
  - "Save Frame"
  - "Save It"
  - "Save That"

To indicate the frame has been stored, the Save Tool will be highlighted; saved frames also appear as a white line with a star to the right of the timeline (see Navigating the Timeline). Saved frames are automatically assigned an F# in the order in which they are saved (F1, F2, etc.). You can unsave a Saved Frame by navigating to the saved frame in the timeline and re-selecting the Save Tool (see Navigate the Timeline).If a numbered frame is unsaved, that F# is not reused.

Timeline Overview

The timeline represents a series of frames: either those frames available after freezing a Live image or frames within a Recording. After freezing a live image, the last 15 frames are captured in the timeline. After stopping a Recording, all frames are captured in the timeline.

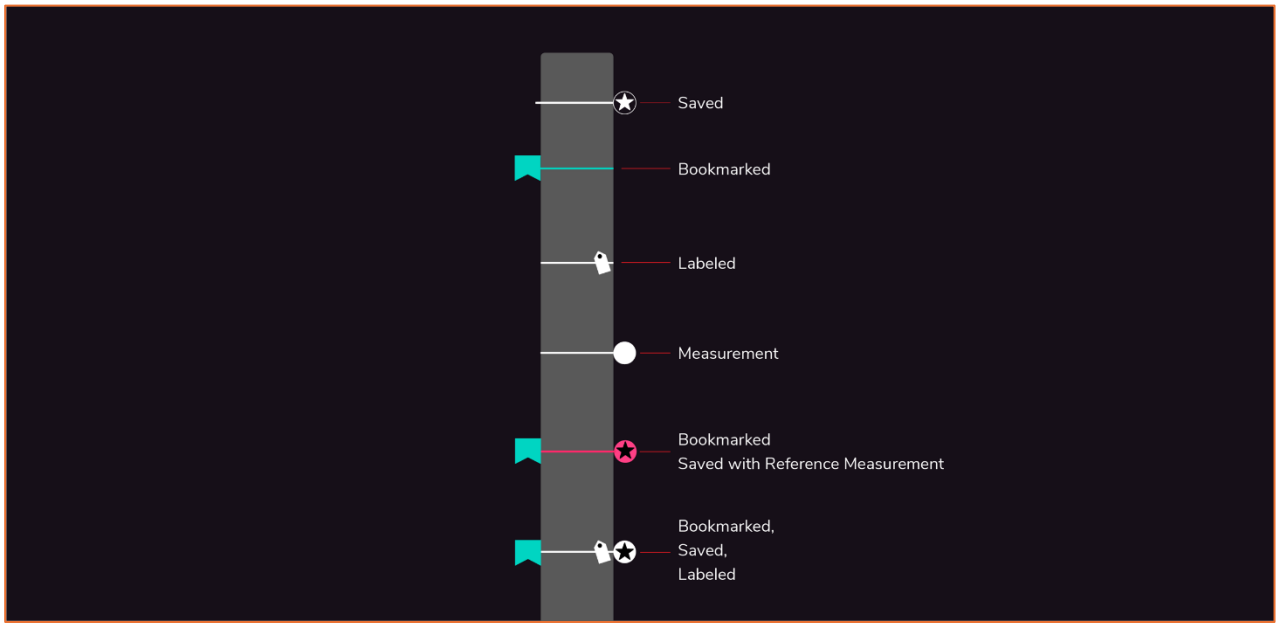

Figure 13-7: Timeline indicators

The timeline (Figure 13-7) is located on the right of the Tablet display. It displays icons for frames that are bookmarked, labeled, saved, and measured.

- Bookmarked frames:
  - Teal line with a bookmark icon containing the marked frame number in the sequence in which it was bookmarked.
  - See Bookmark
- Labeled frames:
  - White line with a label icon.
  - See Add a Label
- Saved frames:
  - White line with a save (star) icon.
  - See Save a Frame
- Measured frames:
  - White line with a circle, or
  - Locked area measurement: rose line with circle.
  - See Measurements

Within the timeline you can:

- Add a bookmark (See Add a Bookmark)
- You can navigate through the timeline to view images (see Navigate the Timeline)
- Zoom the timeline
- View Dynamic Review

Navigate the Timeline

You can navigate the using the Tablet or Evident Voice Assist (see Evident™ Voice Assist):

Tablet

- Tap within the timeline to view a specific frame.
- Use the up (back) and down (forward) arrow tools to scroll through the frames one at a time or hold an arrow to quickly scroll five frames at a time.
- Press and hold the timeline cursor to select and drag to a specific area in the timeline; the cursor will automatically snap to nearby bookmarks or saved frames when released.
- Press and hold the timeline and drag up or downward to pan through a zoomed-in timeline the entire recording, while the cursor remains stationary.

- Ensure Evident Voice Assist is active, and say one of the following commands to replay the recording:
  - “Start playback”
  - “Playback”
  - “Play Recording”
- Say one of the following commands to stop the replay of the recording:
  - “Stop”
  - “Stop Playback”
  - “Pause Playback”

Zoom the Timeline

For recordings over 10 seconds only, you can zoom the timeline. This centers 10 seconds of data around the timeline cursor. Press the Zoom Timeline Tool and then drag the timeline cursor up or down to review those frames.

Dynamic Review

Dynamic Review replays a short animation of IVUS images without moving the timeline cursor. Dynamic Review replays a total of 7 seconds, 3 seconds before the cursor position and 3 seconds after the cursor position, so that you can perform measurements (see Measurements) without having to manually scroll through a review of frames captured during Live Imaging or Recording. Press the Dynamic Review icon to review those frames.

14 Measurements

Measurements Overview

Measurements can be performed within the Review screen (after you pause Live Imaging or stop Recording). Measurement tools are located to the right of the image window in the Review screen (Figure 14-1). There are several measurements and features available in the software:

- Line
- Area
- Area difference
- Reference area

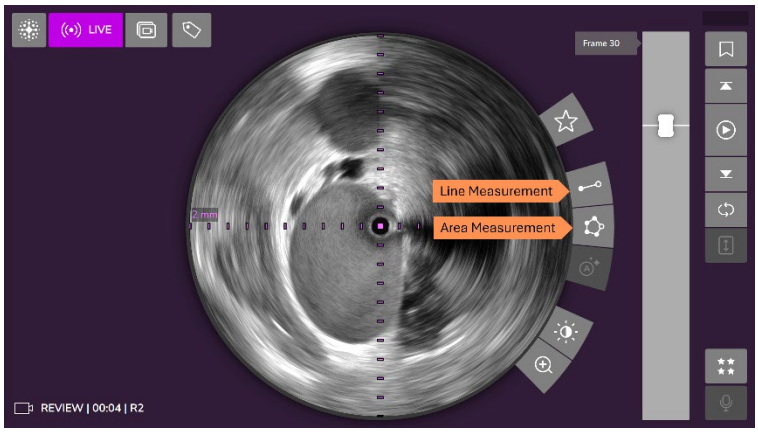

Figure 14-1: Review screen with labeled measuring tools

Line Measurement

You can measure a line between two points in the image using the caliper tool. The interface allows for 2 lines to be drawn consecutively (without having to re-select the caliper tool). You can create up to four line measurements per frame. Measurements are shown in millimeters (mm).

To measure a line:

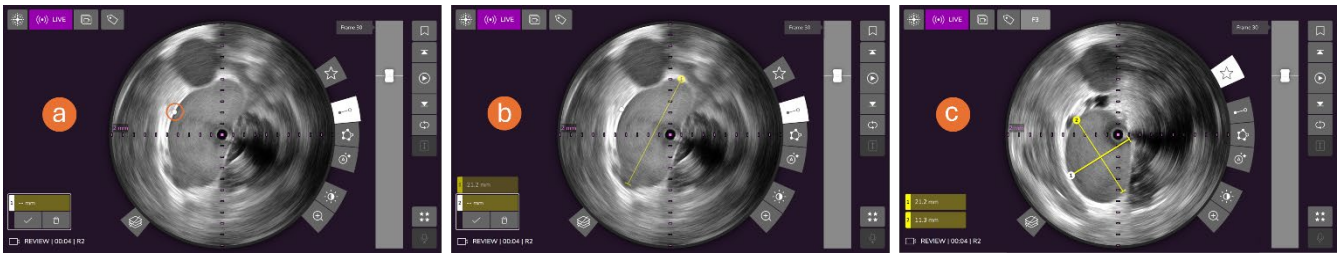

Figure 14-2: Line measurement and measurement panel; (a) shows first anchor point, (b) shows first line labeled as 1 with measurement, (c) shows both lines and measurements labeled as 1 and 2 with Save icon highlighted

Tablet

- Press the Caliper/Line Tool
- Touch a point on the image; each touch creates an anchor point, represented by a white dot on the screen (Figure 14-2a).
- Touch a second point; a line connecting the two points appears (Figure 14-2b)
- Repeat the steps to create a second line (Figure 14-2c).
- Measurements are displayed in the measurement panel to the lower left of the frame being measured. (Figure 14-2). Measurements can be edited, confirmed, and/or deleted within the panel.
- To adjust a measured line:
    - Press the line to reactivate the measurement, or
    - Press the Edit icon in the measurement panel.
    - Drag either anchor point to a new location, or
    - Delete an anchor point to the Delete icon in the center of the image.
- To tag the frame that includes the measurement for export/archival, press the Save icon (See Archive a Case).
- To delete a measurement, press the Delete icon in the panel or drag both points to the Delete icon in the center of the image.

Area Measurement

You can measure an area and a calculated average diameter in an image or compare area measurements within a recording using the Area tool. The Area tool allows you to:

- Measure an area and average diameter
- Lock an area as a reference
- Calculate the difference between two areas using the Area tool

The area measurement panel is displayed to the left of the frame being measured. You can create up to 2 areas per frame. Measurements are listed as area (mm^2), average diameter (mm), and min/max diameter (mm).

Measure an area

Tablet

- Press the Area tool icon.
- Touch the image using consecutive taps to outline the area you wish to draw and measure; each tap creates an anchor point (Figure 14-3a).
- Once there are enough anchor points, the area is closed by a line connecting all anchor points (Figure 14-3b).
- To adjust the area:
  - Drag any anchor point to a new location or drag it to the center to delete the point.
  - To add an anchor point, touch where you wish to add the point.
- To combine/merge two points into a single point, drag one anchor point close to another point.
  - To delete the area, press the Delete icon in the measurement panel.
- When you are satisfied with the area measurement, press the checkmark in the center of the circle or in the measurement panel to confirm (Figure 14-3b).

> *If you proceed to another task before pressing the checkmark, the measurement is automatically saved.*

- Measurements are displayed in the measurement panel to the left of the frame being measured. (Figure 14-3b). Measurements can be edited, confirmed, and/or deleted within the panel.
- If you wish to edit the area after it has been confirmed:
  - Long press on the area line on the image display to reactivate the editing measurement, or
  - Press the Edit icon in the measurement panel.
    - Adjust measurement as necessary.
- To tag the frame that includes the measurement for export/archival, press the Save icon. (See Archive a Case)
- To delete a measurement, press the Delete icon in the panel or drag all points to the Delete icon in the center of the image.

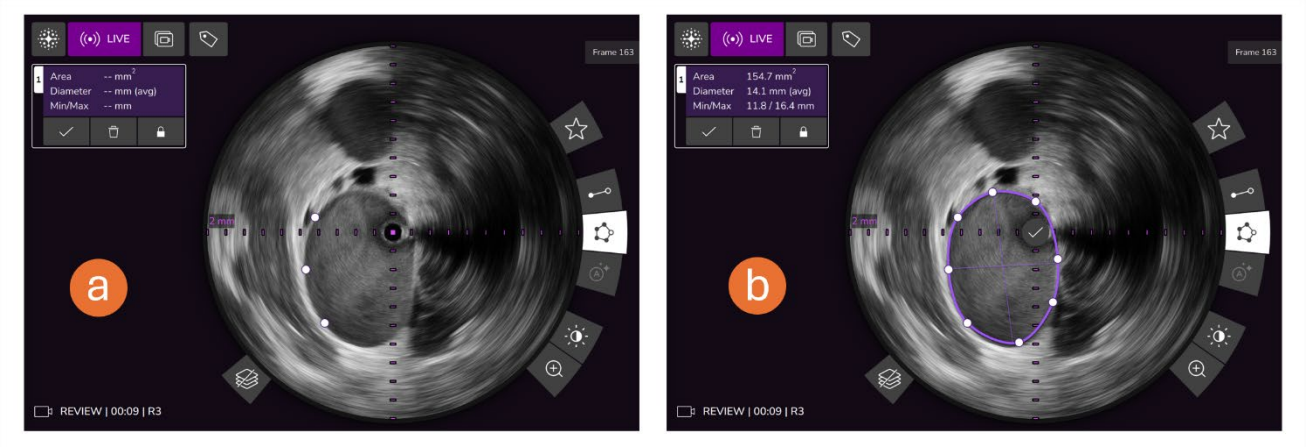

Figure 14-3: Measure a Single Area; (a) shows the first several anchor points, (b) shows the completed circle and measurements are displayed in the measurement panel.

Comparing Area Measurements

Lock an area for reference

Locking an area creates a reference area and keeps the measurement panel and tracing visible in every frame of the recording for comparison throughout the recording.

To lock an area:

Tablet

- After an area has been drawn, press the Lock icon in the measurement panel (Figure 14-4a).
- The Locked area shows in the timeline as a red line and circle (See Navigate the Timeline).
- To unlock, scroll to the frame in the timeline and press the unlock icon (Figure 14-4b).

Locking a second area within a recording overwrites the first locked reference area.

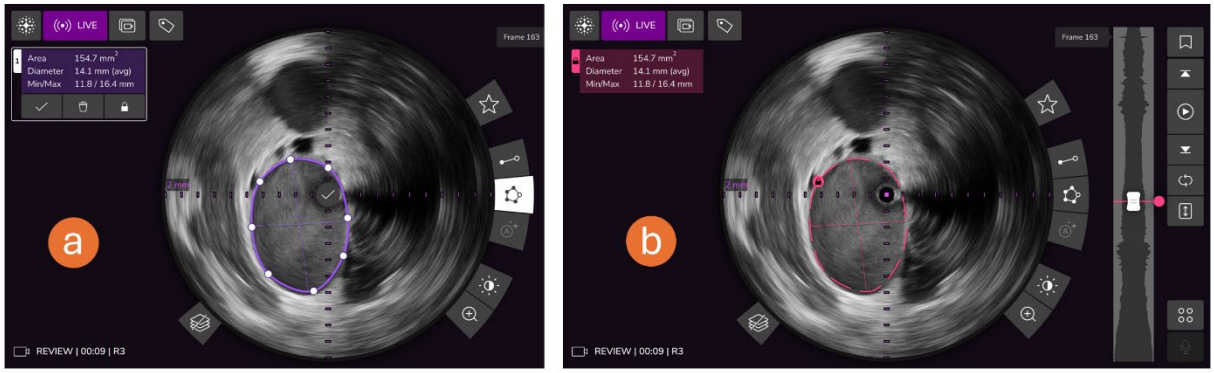

Figure 14-4: Lock an Area Measurement for Reference; (a) shows the drawn area with the Lock Tool available in the measurement panel, after pressing the Lock Tool, (b) shows the area in a different color with the lock symbol and is represented on the timeline with the same red-colored line and circle.

Measure Area Difference

This function measures the % area difference between the first two area measurements on a frame. The difference is displayed in the measurement panel. You can measure area difference between:

- Two areas within the same frame
- Two areas within the same recording

Compare two areas within the same frame (Figure 14-5)

This calculates the difference in areas within a single frame (such as stent apposition in the example below).

Tablet

- Draw an area (See Measure an Area) and confirm with checkmark .
- Re-select the Area Tool and draw a second area.
- The measurement panel will display the % difference. Confirm with checkmark.
- To tag the frame that includes the measurement for export/archive, press the Save icon (see Summary View).

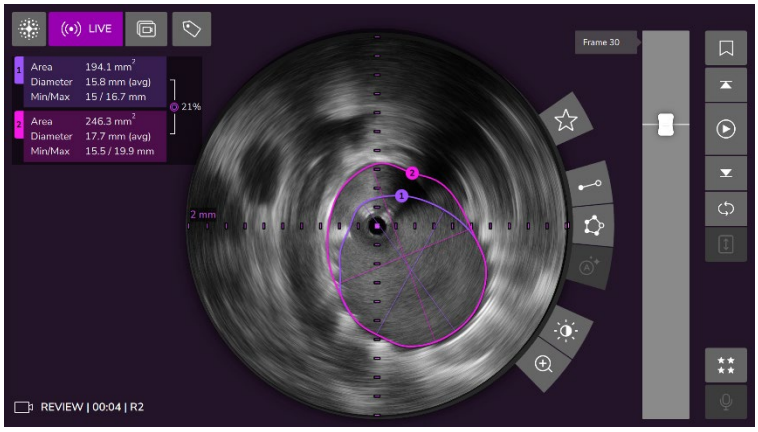

Figure 14-5: Measure Area Difference in Same Frame

Compare two areas within the same recording (Figure 14-6)

This calculates the difference between a locked reference area and another area in a different frame of the same recording (for example, measuring vessel stenosis).

Tablet

- Draw the first area (See Measure a Single Area); confirm with checkmark.
- Lock the first drawn area (See Lock an Area as Reference Diameter); press the lock icon .
- Scroll through the frames to the second area (See Navigate the Timeline).
- Draw the second area and confirm with checkmark.
- The measurement panel will display the % difference.
- To tag the frame that includes the measurement for export/archival, press the Save icon

(see Archive a Case).

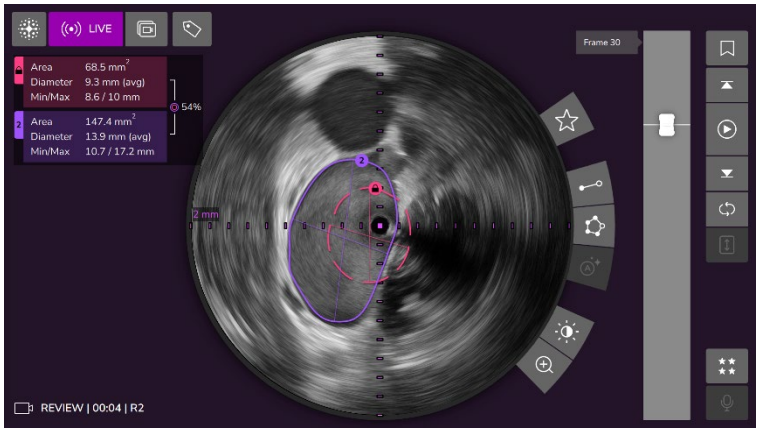

Figure 14-6: Measure Area Difference in Separate Frames

Measurement Panel and Overlay

Drawn measurements appear on the image and are numbered in the order in which they were drawn (Figure 14-7, left). Line measurements are yellow. The first area measurement in the frame is purple, the second is pink. A locked area is red and labeled with a lock. Calculated values are displayed in a measurement panel to the left of the frame being measured and colored to match the measurement. All measurement overlays can be toggled on and off to temporarily hide the measurements using the Tablet or with Evident™ Voice Assist. When toggled off (Figure 14-7, right), the drawn measurements are hidden from view, and the measurement panel is dimmed.

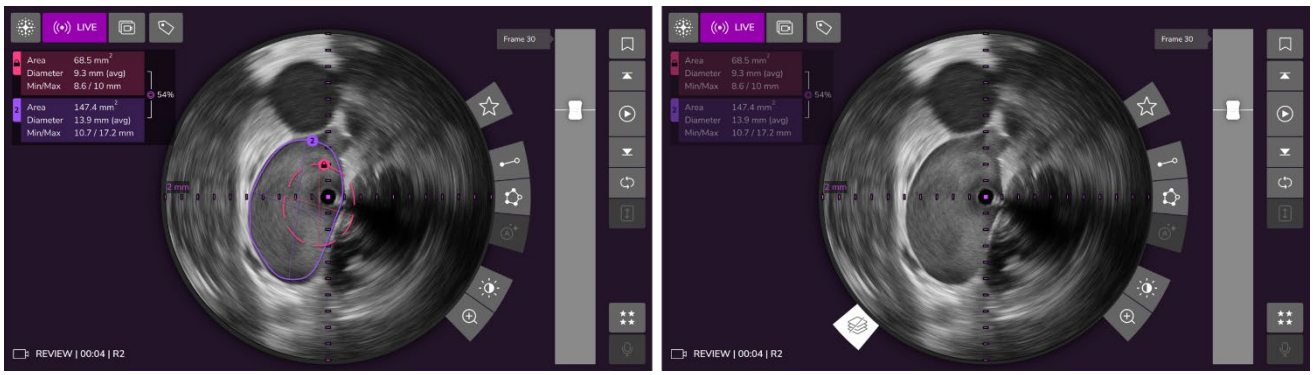

Figure 14-7: Measurement Panel and Overlay (left) and toggled off (right)

You can toggle the measurement overlay on and off using the appropriate Tablet icon or Evident Voice Assist (see Evident™ Voice Assist):

Tablet

- Press the Hide/Show Measurements icon to the lower left of the image.

Evident Voice Assist

- Ensure Evident Voice Assist is active, and say the following command to hide the measurement overlay:
    - “Hide Measurements”
- Say the following command to show the measurement overlay:
    - “Show Measurements”

15 Summary View

The Summary View allows you to view all recordings and saved (tagged) frames that will be exported during the Archive Case function (see Archive a Case). Summary View offers several display formats: a "report" and one-, two-, or four-frame displays (Figure 15-1). A scrollable browser is shown on the left side that shows a time ordered list of all the saved frames and recordings acquired in the case while the ultrasound image and associated data are shown on the right side. Measurement values are displayed in the one- and two-frame layouts only.

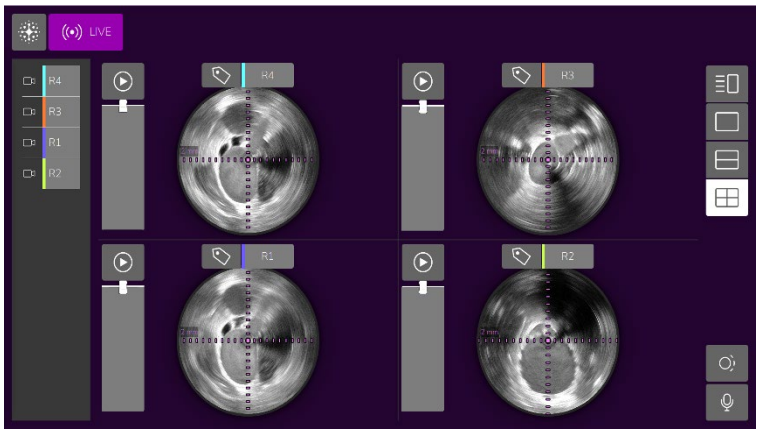

Figure 15-1: Summary View in four-frame layout

Access the Summary View by pressing the Summary View icon .

To navigate the Summary View:

- Scroll through the navigation list of saved frames and recordings on the left side.
- To select the image you want to review:
  - Touch a frame (F#) or a recording (R#) in the list on the left, or
  - Press the image on the right side if it is shown.
- The selected frame or recording appears on the right side with a white border (Figure 15-2) with the edit and delete icons in the upper right.

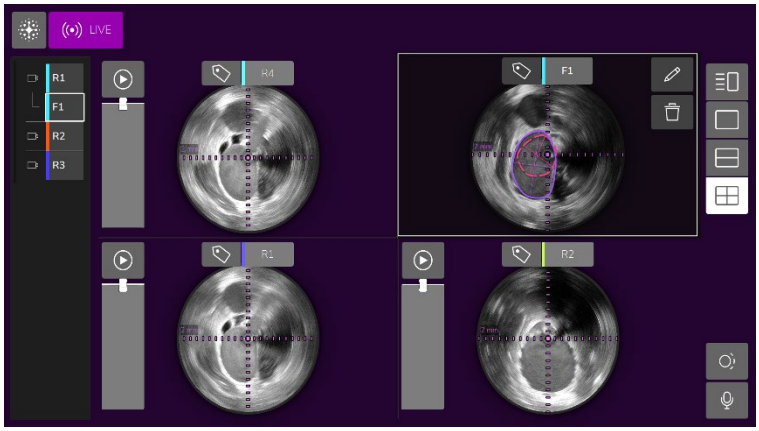

Figure 15-2: Summary View in four-frame layout with Frame 1 (F1) selected; edit and delete icons are displayed

- To add a label:
  - Press the Label tool ICON above the frame or recording.
  - Add a label (see Add a Label).
- To edit a *frame*:
  - Press the edit icon.
  - The Review Screen is opened to that frame in full screen.
  - All Review features are available including measurements.
- To edit a *recording*:
  - Press the edit icon.
  - The Review screen is opened to the first frame in the recording.
  - All Review features are available including measurements.
- To delete a *frame*:
  - Press the delete icon.
  - The frame is no longer separately tagged but remains in the original recording.
- To delete a *recording*:
  - Press the delete icon: this recording, including all associated frames and saved frames is deleted from the case.
  - CANCEL or YES, DELETE.
- To return to the summary view, press the Summary View  icon.
- To review a frame or recording in full screen:
  - Double tap the frame or recording image on the right side.
  - To return to the Summary View, press the Summary View  icon.
- To return to the Review screen, press the Return to Review  icon.

16 End the Case

End a Case

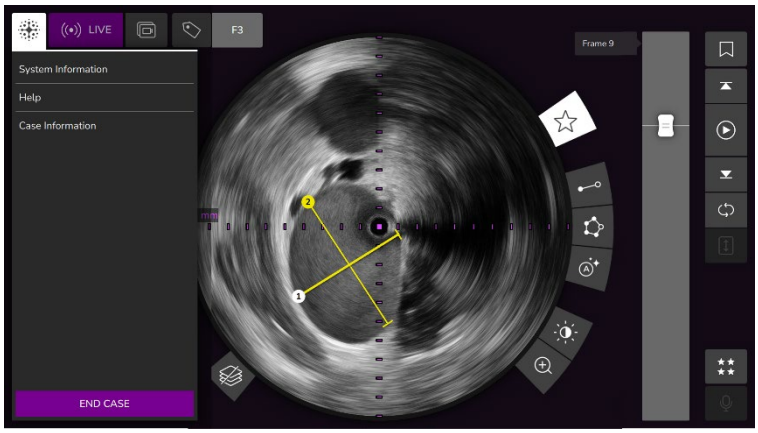

Figure 16-1: End a Case using System Menu

To end a case (Figure 16-1):

- Press the SYSTEM MENU icon.
- Press END CASE.
- CANCEL or END CASE.

End a Case with No Patient Information Entered

If no Patient ID was entered before starting the case, a system prompt will appear (Figure 16-2):

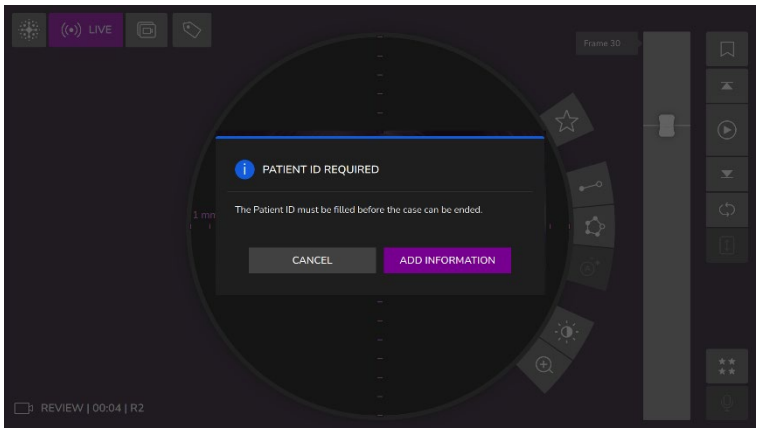

Figure 16-2: Prompt to enter case information

- Select ADD INFORMATION.
- You can select a patient from a Worklist or enter the information manually.
- Select END CASE.

When the case is ended, the display will show the Case Completed screen (Figure 16-3):

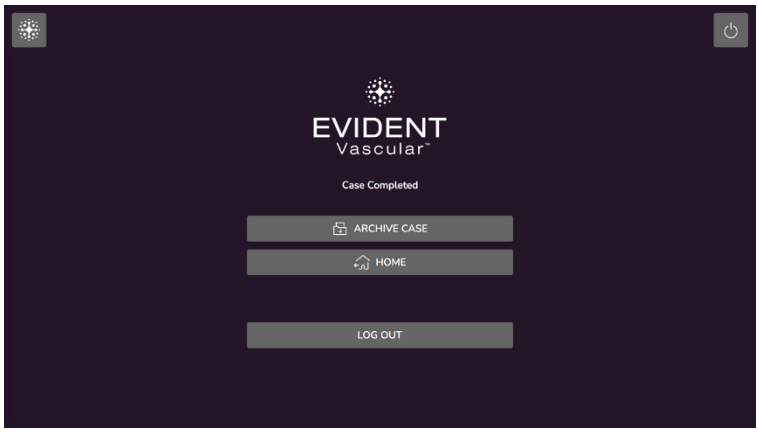

Figure 16-3: Case Completed screen

From the Case Complete Screen you can:

- Access the System Menu (see System Menu)
- Access the System Shutdown function (see System Shutdown)
- Archive the case (see Archive a Case)
- Return to the Home Screen
- Log Out: returns to Log In screen for next user (see Log In)

17 Data Management

Data Management Overview

Stored case data is saved locally on the Workstation. You can access this local data to:

- Review stored cases
- Delete stored cases
- Archive stored cases

From the Home Screen, select CASE REVIEW (Figure 17-1)

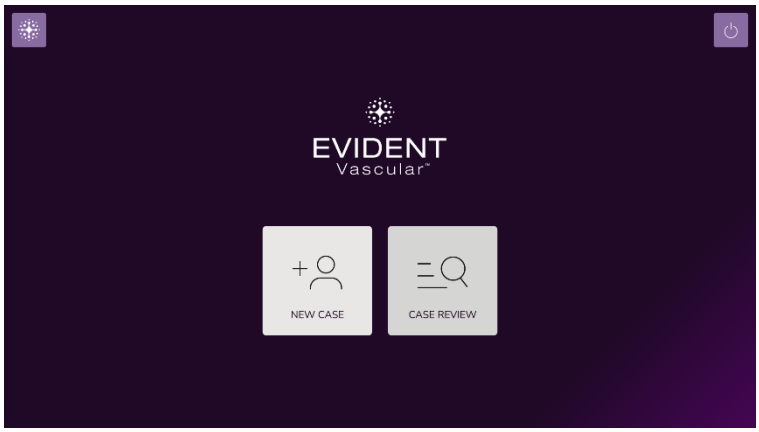

Figure 17-1: Home Screen

The only changes permitted after a case has ended are in the following Case Information fields:

- *Case type (Dropdown: Arterial, Venous, Other)*
- *Notes*

Review Stored Cases

- In the Case Review screen (Figure 17-2), select the case to review:
  - Scroll through the available stored cases.
  - To filter the list by category (i.e., Study Date, select the category to sort the available cases.
  - To search by patient name, press in the Patient Name field to enter search text.
  - To search by a date range, press in the Date Range field to select a time period from the drop-down menu.
- Touch the desired case and press the REVIEW icon.
  - You will see the Summary View screen for that case, but no additional measurements or modifications will be available (see Summary View).
- To return to the Case Review Screen, press CASE REVIEW at top left of the display.

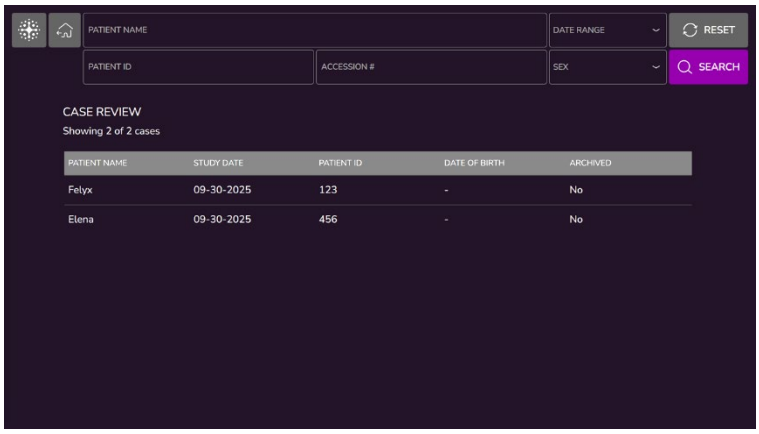

Figure 17-2: Case Review screen with list of stored cases

Delete Stored Cases

- In the Case Review screen (Figure 17-2), select the case to review:
  - Scroll through the available cases.
  - To filter the list by category (i.e., Study Date, select the category to sort the available cases.
  - To search by patient name, press in the Patient Name field to enter search text.
  - To search by a date range, press in the Date Range field to select a time period from the drop-down menu.
- Touch the desired case and press the DELETE icon (Figure 17-3).
  - CANCEL or YES, DELETE.
- The display returns to the Case Review screen.

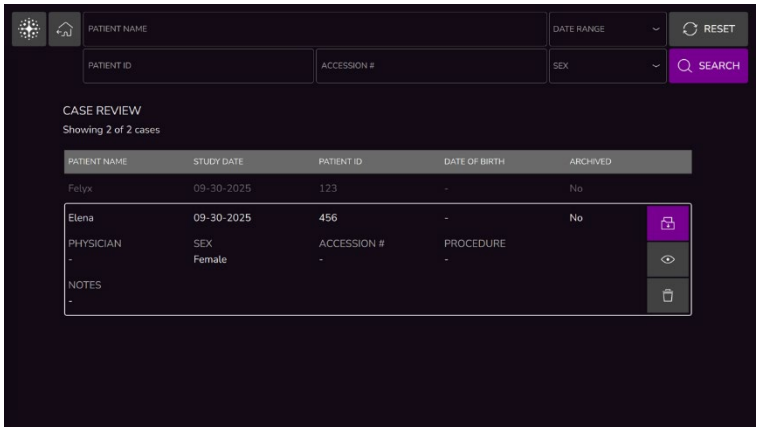

Figure 17-3: Case selected from Case Review list

Archive Stored Cases

In the Case Review screen (Figure 17-2), the archive status of each case (Yes or No) is listed in the rightmost column titled “ARCHIVED.”

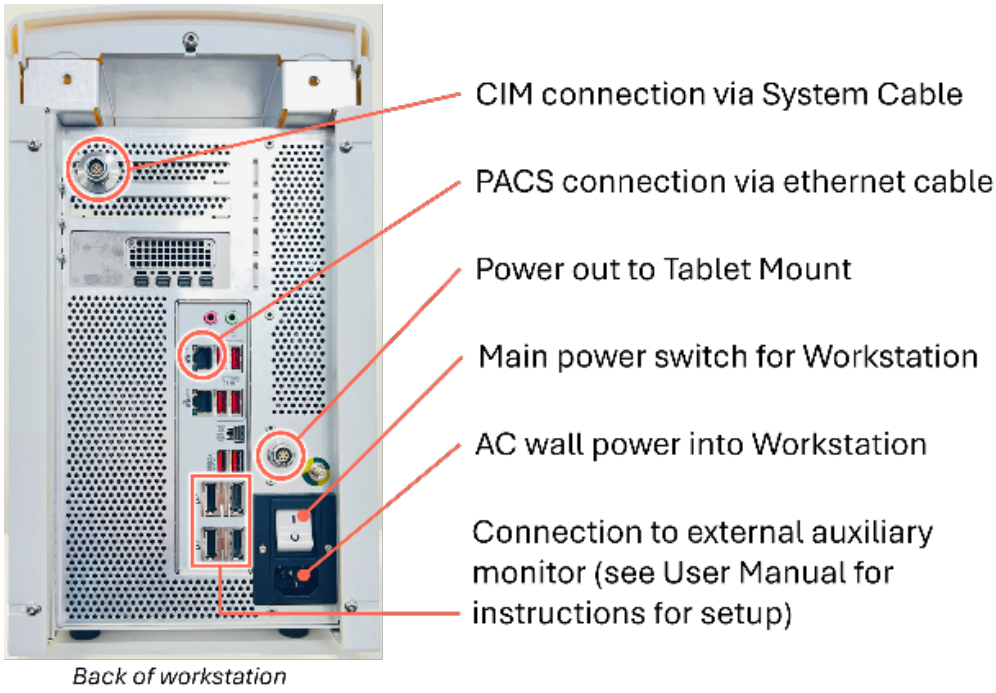

Figure 17-4: Back of Workstation showing connection ports

Archive a case to PACS from the Case Review Screen

- If the System is not configured for wireless archival, connect PACS ethernet cable to Workstation (Figure 17-4)
- Select the case to archive
  - Scroll through the available cases.
  - To filter the list by category (i.e., Study Date, select the category to sort the available cases.
  - To search by patient name, press in the Patient Name field to enter search text.
  - To search by a date range, press in the Date Range field to select a time period from the drop-down menu.
- Touch the desired case and press the EXPORT icon (Figure 17-5).
- From the drop-down lists (Figure 17-6):
  - Select Location: PACS
  - Select Compression: None (or per facility policy)
- CANCEL or EXPORT .
- The display returns to the Case Review screen.

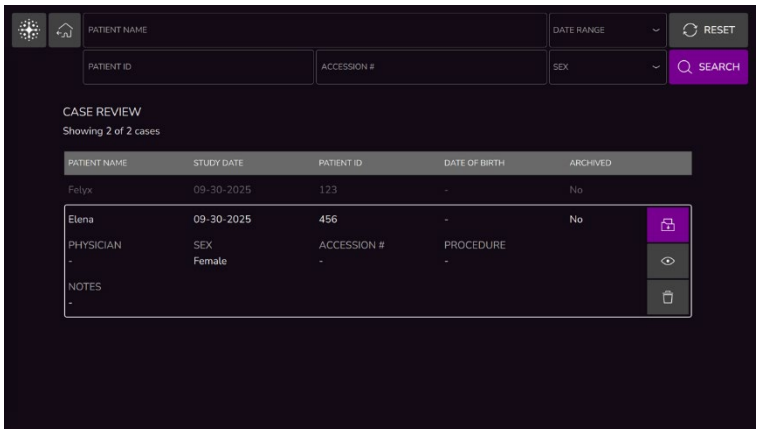

Figure 17-5: Case selected from Case Review list

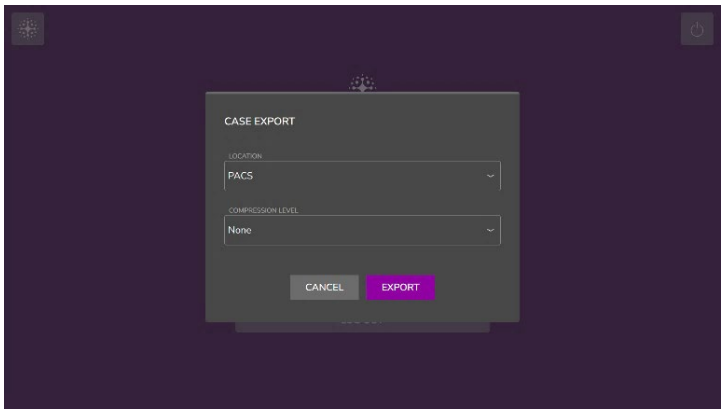

Figure 17-6: Drop-down menus for Case Export

Archive a case to PACS from the Case Completed Screen

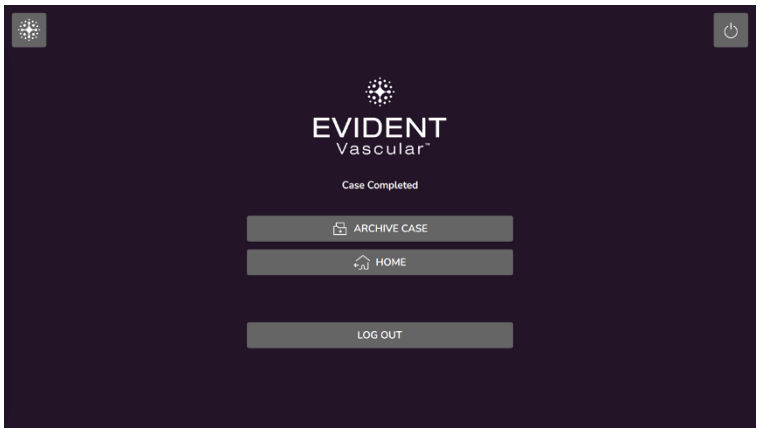

Figure 17-7: Case Completed Screen

To archive a case from the Case Completed screen (Figure 17-7):

- Select ARCHIVE CASE.
- From the drop-down lists (Figure 17-6):
  - Select Location: PACS
  - Select Compression: None (or per facility policy)
- CANCEL or ARCHIVE.
- The display returns to the Home screen.

Backing Up Data

The Evident Vascular Guidance System has two types of data: case data and configuration data. It does not support backing up (nor restoring) case data. It is highly recommended to archive case data to DICOM PACS and use a matching viewer to view legacy data. Configuration data will be backed up to NeuronSphere by Evident Vascular, Inc. after installation and subsequent configuration updates. To restore configuration data, contact Evident Technical Support Services.

18 Evident Vascular™ Guidance System Shutdown

There are two ways to shut down the Evident Vascular Guidance System: via the System Menu and via the System Shutdown. When the system shuts down, it also powers down any connected Tablet.

Shutdown the Guidance System

Before shutting down the system, ensure the current case has been ended (see End a Case).

- From the System Menu:
  - Press the System Menu Icon
  - Select Shutdown
  - CANCEL or SHUTDOWN

- From the Shutdown button:
  - Press the Power/Shutdown Icon to access the Shutdown prompt.
  - CANCEL or SHUTDOWN.

Case Recovery:

If an active case is terminated unexpectedly (i.e., power loss, system fault) the associated case data can be recovered and the case can be resumed if it was within an allowable time window.

If the system detects an incomplete case, a prompt is shown after user login.

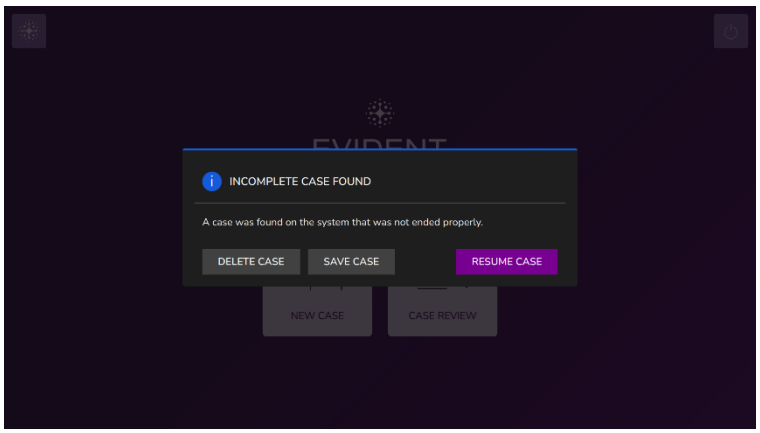

Figure 18-1: Incomplete Case Found (shown with options if system was restored within 2 hours)

The following options are available:

- DELETE CASE: removes case data from the system.
- SAVE CASE: stores the case and makes it available to review on the Case Review screen.
- RESUME CASE: *only available if the incomplete case is more than 2 hours old*. Reloads the case and allows you to acquire additional images, measurements, and any other actions.

19 Cleaning, Disconnection and Storage

Cleaning the Guidance System and Components

Before cleaning, shut down the Guidance System and unplug from the power receptacle.

Clean the Guidance System, Catheter Interface Module (CIM), and other parts as needed per the facility's policy and standard practice.

Always clean all components of the Guidance System which were in the patient vicinity.

CAUTION: Never spray or otherwise apply any cleaner directly into the openings or seams of the Evident Guidance System or components. Always apply the cleaner to a soft cloth instead.

CAUTION: Do not use harsh chemicals or cleaning solvents to clean the Evident Vascular Guidance System or its components. Never use acetone to clean the Guidance System or its components.

CAUTION: No portion of the Evident Vascular Guidance System or its components should be immersed in water or other fluids.

Disconnecting After Use

Mobile Cart Configuration:

- Ensure the Evident Vascular Guidance System is shut down and unplugged from the power receptacle.
    - Leave the Power Cord connected to Workstation.
    - Wrap the Power Cord around the side hooks on the cart.
- Remove the CIM from the procedure table bedrail and attach to rail on cart:
    - Replace cap to cover catheter receptacle.
    - Leave System Cable connected to CIM and to Workstation.
    - Fully lift the handle on the CIM to release the clamp.
    - Remove CIM from procedure table bedrail.
    - Place the CIM onto the cart's rail.
    - Lock the CIM onto the cart's rail by fully lowering the handle.
    - Wrap excess length of the System Cable around the side hooks on the cart.
- Leave Tablet in Tablet Mount.

Integrated Lab Configuration:

Both the Catheter Interface Module (CIM) and the Articulating Tablet Mount (ATM) are attached to the procedure bedrail during installation.

To temporarily remove the CIM from the procedure table bedrail:

- Shut down the Evident Vascular Guidance System.
- Leave System Cable connected to CIM and to Workstation.
    - If moving CIM away from Workstation, disconnect System Cable from CIM and wrap excess length of System Cable.
- Replace cap to cover the catheter receptacle.
- Fully lift the handle on the CIM to release the clamp.
- Remove CIM from procedure table bedrail.

To re-attach the CIM to the procedure table bedrail:

- To reconnect System Cable to CIM:
    - The end of the System Cable with the right-angle connector should be connected to the appropriate port on the back of the Workstation.
    - Align the red dot on the connector with the red dot on the port on the workstation and push firmly until the connector is fully seated.
- The other end of the System Cable should be connected to the bottom of the CIM.
    - Align the red dot on the connector with the red dot on the port on the CIM and push firmly until the connector is fully seated.
- Fully lift the handle to unlock the clamp.
- Angle the CIM so that the clamp is on the bed rail.
- Fully lower handle to lock the CIM onto the bed rail.

To remove Tablet from Tablet Mount:

- Holding the Tablet with both hands near the top corners, open the purple clips at the top of the Tablet Mount by pushing them upward with your thumbs.
- Remove the Tablet by pulling the Tablet toward you.

To replace the Tablet in the Tablet Mount:

- Holding the Tablet with both hands along the Tablet, center the bottom edge of the Tablet onto the Tablet Mount.
- Keeping the bottom edge of the Tablet in the Tablet Mount, push the Tablet with both hands until the purple clips close over the front top of the Tablet.

To remove Tablet from Docking Station:

- Holding the Tablet with both hands near the top corners, remove the Tablet by gently lifting the Tablet toward you.

To replace the Tablet in the Docking Station:

- Holding the Tablet with both hands along the Tablet, center the bottom edge of the Tablet onto Docking Station

To temporarily remove the ATM from the procedure table bedrail:

- Shut down the Guidance System and unplug from the power receptacle.
- Unplug the Tablet power adapter from the Tablet Mount.
- If attached, unplug the ethernet cable from the Tablet Mount.

WARNING: Remove the Tablet from the Articulating Tablet Mount before clamping and unclamping it from the bedrail or storing the Articulating Tablet Mount.

- Remove the Tablet from the Tablet Mount (see Remove Tablet from Tablet Mount)
- Loosen both knobs on the ATM base by turning counterclockwise.
- Holding onto the handle on the back of the Tablet Mount, push the release latch on the underside of the ATM base forward to unlock the clamp from the procedure table bedrail.

To mount the ATM on the procedure table bedrail:

WARNING: Remove the Tablet from the Articulating Tablet Mount before clamping and unclamping it from the bedrail or storing the Articulating Tablet Mount.

- Holding onto the handle on the back of the Tablet Mount, place the ATM base onto the bedrail from directly above the bedrail.
- The ATM base should engage to the bedrail.
- Hand-tighten both bolts on the ATM base by turning clockwise.
- Place the Tablet in the Tablet Mount (see Place Tablet in Tablet Mount)

Transport and Storage of the Mobile Cart

- Ensure the Evident Vascular Guidance System is shut down and unplugged from AC wall power.
- Ensure the CIM is attached to the rail on the Mobile Cart.
- Ensure the System Cable and Power Cord are wrapped around the hooks on the Mobile Cart.

WARNING: Keep fingers away from moving parts and joints on the Articulating Tablet Mount as well as the Mobile Cart.

- Turn cart neck so Tablet/Tablet Mount are facing the Mobile Cart handles.
- Unlock casters on each wheel.

WARNING: Do not push the Mobile Cart at the neck-use the handles provided.

WARNING: do not push the Mobile Cart on unsafe slopes.

- Using the handles on the front of the Mobile Cart, push the cart at a slow pace to the desired location.
- Ensure the storage location meets all requirements listed in Specifications.
- Lock the casters on each wheel.

20 Maintenance

The Evident Vascular Guidance System contains no user-serviceable parts.

WARNING: To avoid electrical shock, do not remove any panels or covers. In the event of malfunction or system damage, power down the Guidance System, unplug from the power receptable and contact Evident Technical Support Services.

Technical Support

If you need help, contact Evident Technical Support Services using one of the methods below.

Method	Contact Information
Website	www.evidentvascular.com/contact/
Email	info@evidentvascular.com
Telephone	(408) 785-2900

21 Troubleshooting

Troubleshooting Overview

This section details various alerts, pop-ups and use errors and are organized in order of workflow. The tables below list the message, possible cause(s), and action(s) to be taken by the user.

System Initialization

Standard Messages

Message	Cause	User Instructions
Initializing System	Waiting for the first heartbeat from all the locally launched apps	None required
Connecting to Workstation	This is a Tablet-specific message that indicates the tablet is waiting to connect to the Workstation.	Ensure the Tablet(s) is near the Workstation, and the Workstation is powered on. If this message persists for more than three minutes, power off the Tablets and Workstation, and restart.
Connecting to Tablets	This message is shown on the Workstation while it waits for clients to connect and on the Tablet once they are connected to a Workstation.	Ensure the Tablet(s) is near the Workstation, and the Workstation is powered on. If this message persists for more than three minutes, power off the Tablets and Workstation, and restart.
CIM Validating	The system is validating the CIM is ready for use.	None required

Failure Message

Message	Cause	User Instructions
Start-up Error *Unable to start the system. Re-start the system to resolve the issue. If the problem persists, contact Evident Technical Support Services.*	System initialization error	Power off the Tablets and Workstation, then restart. If the problem persists, contact Evident Technical Support Services.

Log In

User Messages

Message	Cause	User Instructions
Incorrect username or password	Validation failed with the username and password combination.	Ensure Caps Lock is turned off and try again.
Login disabled for 15 seconds due to too many attempts	Login lockout activated due to too many login failures in a row per the login policy.	Re-attempt after lockout has expired.
Login is temporarily disabled	Login attempt while the login lockout is active.	Re-attempt after lockout has expired.
Incorrect password	The password is incorrect for the specified user	Ensure Caps Lock is turned off and try again.

Status Messages

Status messages are intended to notify the user of a transient issue. These are intended to be minor issues that clear themselves with no user action required. However, the messages may caution the user to avoid certain actions or use caution when there is lag in image display or delays related to imaging. Status messages will clear when the transient issue has resolved.

Status messages (Figure 21-1) are shown at the bottom left corner with the icon and orange coloring.

Figure 21-1: Status message displayed at bottom of Tablet

Status Messages

Message	Cause	User Instructions
Imaging may be delayed due to image processing	Writing RawCINE data to disk is still in progress when user requests live imaging. This warning will auto-clear once output is complete.	None required
High CIM temperature detected. Ensure CIM is properly ventilated. If problem persists, contact Evident Technical Support Services	The CIM temperature has exceeded the warning threshold.	Ensure CIM is properly ventilated
System recovery in progress. Imaging is temporarily disabled.	System recovery is active, which makes imaging unavailable. The warning clears once the recovery is complete.	None required
Low tablet battery status detected. Please connect to a charger.	Low Tablet battery detected.	Charge Tablet on the dock
Catheter error detected. Slow catheter manipulation recommended.	Intermittent electrical connection with the catheter.	Reduce the pullback rate used to manipulate the catheter, if problem persists change
Image delay detected. Slow catheter manipulation recommended.	Image may be delayed or experiencing reduced frame rate.	Avoid rapid catheter manipulation
CIM validation in progress. Imaging temporarily disabled.	The system is validating the CIM is ready for use.	None required

Message Popups

Info / error messages are popups that block the workflow and require the user to press the “OK” button to acknowledge and continue. Most errors will be shown when they occur, while others are triggered by specific events. The system supports three levels of popups: information, errors, and faults. Information popups are typically confirmations, while errors and faults are due to an error condition. The informational popups (Figure 21-2, left) have a **blue** accent color with an info icon.

Figure 21-2: Informational Popups (left) and Error/Fault Message (right)

Errors and faults use a similar popup design but have a **red** accent color and button color to make them more prominent (Figure 21-2, right). Faults generally have a “shutdown” option as they are a severe issue that should stop a procedure.

Tablet Connection Messages

Message	Cause	User Instructions
Connection Error *Communication with Workstation interrupted. To continue to use this tablet, restart the system. If the problem persists, contact Evident™ Technical Support Services.*	The user may have moved the Tablet out of signal range, or there may be a system error.	Move the Tablet closer to the Mobile Cart
Connection Error *Communication with tablet(s) interrupted. To continue to use this tablet, restart the system. If the problem persists, contact Evident™ Technical Support Services.*	The user may have moved the Tablet out of signal range, or there may be a system error.	Move the Tablet closer to the Cart
Connection Disabled *Tablets cannot be connected to the workstation after a user has logged in. Please restart all systems together or return to login page and try again.*	The user attempted to connect a Tablet after the user logged in.	If the Tablet must be used, restart the system with the Tablet powered on and near the Cart.

General System Messages

Message	Cause	User Instructions
System Error *Live Imaging stopped. Please retry imaging. If the problem persists, contact Evident™ Technical Support Services.*	A software processing error occurred.	Retry imaging or restart the system.
System Error *High workstation temperature detected. Confirm workstation has suitable air flow. If the problem persists, contact*	The Workstation temperature is too high.	Check for blockages at Workstation fans. Ensure clear airflow to the front and back of the Workstation. Allow a few minutes to let the Workstation temperature go down, then continue.

Evident™ Technical Support Services.		
Configuration Error *Unable to initialize the system. Shutdown system and contact Evident™ Technical Support Services.*	A software configuration error occurred.	Restart the system, then try again.
System Error *An unrecoverable system error was detected. Restart the system to resolve the error. If the problem persists, contact Evident™ Technical Support Services.*	A system error occurred.	Restart the system, then try again.

CIM-Related Messages

Message	Cause	User Instructions
Live imaging unavailable. Please re-connect the CIM to enable imaging.	The CIM connection to the Workstation has an error.	Ensure the System Cable is firmly connected to the CIM and the Workstation. Allow some time for CIM Validation to complete, then try again.
High CIM temperature detected. Imaging disabled until acceptable temperature detected. Confirm CIM has suitable air flow.	The CIM is over temperature.	Check for blockages at CIM fans. Ensure clear airflow to the CIM fans. Allow a few minutes to let the CIM temperature go down, then continue.
Imaging not available. CIM recovery in process.	An internal error occurred with the CIM	Allow some time for CIM recovery to complete, then try again.
Live imaging not available. Reconnect or replace CIM. If problem persists, contact Evident™ Technical Support Services.	A motor error occurred with the CIM	Disconnect and reconnect the System Cable from the CIM. Ensure the System Cable connection to the Workstation is firmly connected. Allow some time for CIM Validation to complete, then try again.
An error was detected with the CIM. Please connect a new CIM.	A software error relating to the CIM occurred.	Disconnect and reconnect the System Cable from the CIM.

		Ensure the System Cable connection to the Workstation is firmly connected. Allow some time for CIM Validation to complete, then try again.

Catheter / Imaging Related Messages

Message	Cause	User Instructions
Live imaging unavailable. Please re-connect the catheter to enable imaging.	The catheter was not seated properly in the CIM, or there may be a sensor or latch issue.	Disconnect the Catheter from the CIM, ensure there is no foreign material in the CIM connection, or the Catheter connector, reconnect the Catheter to the CIM, then try again. If no improvement, replace the Catheter.
Recording stopped due to 3-minute limit.	The user attempted to record for more than 3 minutes.	None Required. If additional recording is needed, press Live to start live imaging, then press Record to start a new recording.
Live imaging stopped. Please retry imaging or connect a new catheter. If the problem persists, contact Evident™ Technical Support Services.	An error in the catheter signal was detected.	Retry imaging. If the problem persists, replace the Catheter.
Unable to start imaging, please try again. If the problem persists, contact Evident™ Technical Support Services.	A system error occurred.	Restart the System.
Please connect a catheter to enable imaging.	The user attempted to start imaging without a connected catheter.	Connect a catheter. If a catheter is already connected, retry the connection. If problem persists, replace the catheter or contact Evident Technical Support Services

Please connect a CIM to enable imaging.	The user attempted to start imaging without a connected CIM.	Connect the CIM using the System Cable. Ensure the System Cable is firmly connected to the CIM and the Workstation. Allow some time for CIM Validation to complete, then try again. If problem persists, contact Evident Technical Support Services.
Error detected with CIM. Please replace CIM with a valid CIM to enable imaging.	A CIM error occurred.	Contact Evident Technical Support Services.
Imaging unavailable. Please restart the system to enable imaging.	A system error occurred.	Restart the System. If problem persists, contact Evident™ Technical Support Services.
Unable to start imaging. Retry imaging and if the problem persists, contact Evident™ Technical Support Services.	A system error occurred.	

DICOM-Related Messages

Message	Cause	User Instruction
DICOM archive failed. Try again and if problem persists, contact Evident™ Technical Support Services.	DICOM export either returned a failure status, or the operation timed out.	Ensure the PACS network connection is properly configured, and if connected via ethernet cable, the cable is connected to the Workstation.
Unable to communicate with worklist server. Please ensure server is running and network settings are configured properly.	A connection to the PACS system is unavailable.	Ensure the PACS network connection is properly configured, and if connected via ethernet cable, the cable is connected to the Workstation.
Failed to load worklist, please try again. If the problem persists, contact Evident™ Technical Support Services.	A connection to the PACS system may be unavailable, or it may be misconfigured.	Ensure the PACS network connection is properly configured, and if connected via ethernet cable, the cable is connected to the Workstation.

Unable to load the selected case. If the problem persists, contact Evident™ Technical Support Services.	The data for the selected case may not match that of the PACS system.	Ensure the PACS network connection is properly configured, and if connected via ethernet cable, the cable is connected to the Workstation.
Unable to communicate with PACS server. Check connection and try again.	A connection to the PACS system may be unavailable, or it may be misconfigured.	Ensure the PACS network connection is properly configured, and if connected via ethernet cable, the cable is connected to the Workstation.

Annotation-Related Messages

Message	Cause	User Instruction
The maximum number of saved frames per recording has been reached. Please remove an existing saved frame to add a new one.	The user attempted to save more frames than the allowed limit.	Remove a saved frame from the currently active recording to save any additional frames.
The maximum number of bookmarks per recording has been reached. Please remove an existing bookmark to add a new one.	The user attempted to add more bookmarks than the allowed limit.	Remove a bookmark from the currently active recording to save any additional frames.
The maximum number of bookmarks per recording has been reached.	The user attempted to add more bookmarks than the allowed limit.	Remove a bookmark from the currently active recording to save any additional frames.

Tablet Battery-Related Messages

Message	Cause	User Instruction
The tablets have insufficient battery status to start a case. Please connect them to a charger and try again.	Tablet battery is insufficient	Connect the Tablet(s) to a power source. This can be the Tablet Mount, ATM, or the Docking Station. Once the Tablet is connected to power, try again.
One or more tablets have a low battery status. Please connect them to a charger.	Tablet battery is insufficient	Connect the Tablet(s) to a power source. This can be the Tablet Mount, ATM or the Docking Station. Once the

		Tablet is connected to power, try again.
Low tablet battery status detected. Please connect to a charger.	Tablet battery is insufficient	Connect the Tablet(s) to a power source. This can be the Tablet Mount, ATM or the Docking Station. Once the Tablet is connected to power, the warning message will resolve.

Case Recovery-Related Messages

Message	Cause	User Instructions
Features such as review and export may not be available for this case. If the problem persists, contact Evident™ Technical Support Services.	System or disk error	Try resuming the feature. If the problem persists, contact Evident Technical Support Services.
Unable to resume the case. If the problem persists, contact Evident™ Technical Support Services.	System or disk error	Try resuming the case. If the problem persists, contact Evident Technical Support Services.
Unable to load the selected case. If the problem persists, contact Evident™ Technical Support Services.	System or disk error	Try to reload the case. If the problem persists, contact Evident Technical Support Services.
A case was found on the system that was not ended properly.	Case not ended properly, possibly due to forced system shutdown.	Press SAVE to end the case, RESUME to reload and continue the case, or DELETE to delete the case.

Catheter Setup Screen Messages

The Catheter Setup Screen also displays the catheter status with titles, messages, and an associated image (Figure 21-3).

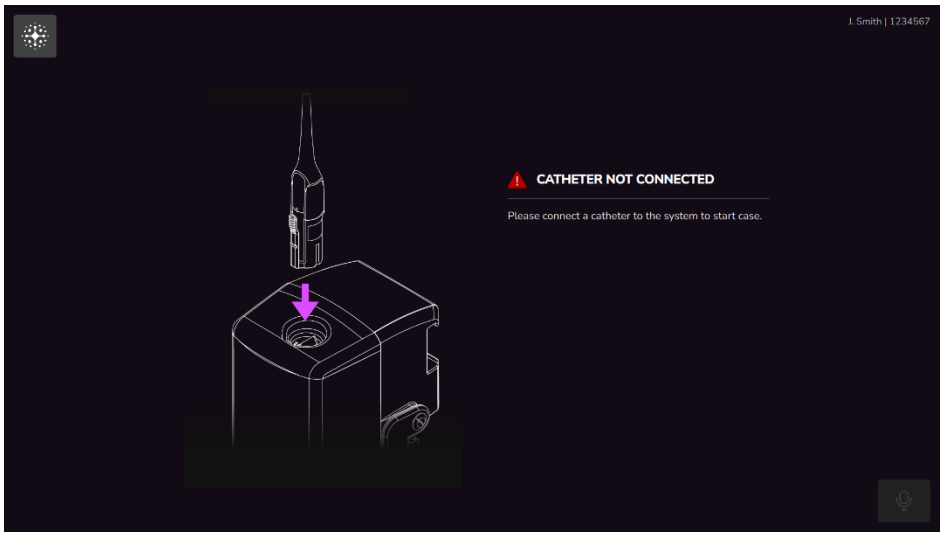

Figure 21-3: Catheter Setup Screen with Message

Catheter Setup Related Messages

Message	Cause	User Instruction
The catheter has exceeded its use limit. Please connect a new catheter.	The connected Catheter has exceeded its single-use duration and can no longer be used with the System.	Connect a new catheter
Live imaging stopped. Reconnect the catheter or connect a new catheter. If the problem persists, contact Evident™ Technical Support Services.	A data processing error occurred.	Reconnect the catheter or connect a new catheter
Catheter has exceeded use limits. Please connect a new catheter.	The catheter has been used, and it is past its use limit.	Connect a new catheter
Live imaging unavailable. Reconnect the catheter or connect a new catheter. If the problem persists, contact Evident™ Technical Support Services.	A catheter data or configuration error occurred.	Disconnect the Catheter from the CIM, ensure there is no foreign material in the CIM connection, or the Catheter connector, reconnect the Catheter to the CIM, then try again. If there is no improvement, replace the Catheter.

Connected catheter is not supported. Please connect a new catheter.	The catheter is not supported by the system.	Disconnect the Catheter from the CIM, ensure there is no foreign material in the CIM connection, or the Catheter connector, reconnect the Catheter to the CIM, then try again. If there is no improvement, replace the Catheter.
An error was detected with the catheter. Please connect a new catheter.	A catheter data or configuration error occurred.	Disconnect the Catheter from the CIM, ensure there is no foreign material in the CIM connection, or the Catheter connector, reconnect the Catheter to the CIM, then try again. If there is no improvement, replace the Catheter.

22 Cybersecurity

To ensure safe and secure operation of the Evident Vascular Guidance System, users must follow recommended cybersecurity practices. The following information is intended for system integrators, clinical engineers, and hospital IT staff to support secure deployment, configuration, operation, maintenance, and decommissioning of the Evident Vascular Guidance System.

Recommended Cybersecurity Controls

Antivirus / Malware Protection

The Evident Vascular Guidance System does not include antivirus / malware protection software. The integrity of the software is provided by a secure boot configuration (see below).

It is suggested that the Evident Vascular Guidance System is installed behind a firewall with antivirus/malware protection.

- Use anti-malware protection and endpoint detection solutions on the host network.
- Isolate the Evident Vascular Guidance System Workstation on a VLAN or secure subnet.
- Configure host-based and network firewalls to limit inbound/outbound connections to essential services only.

Secure Boot

The Evident Vascular Guidance System Workstation and Tablets are configured with a Secure Boot security feature. It is designed to protect the integrity of the medical device during the startup process. It ensures that only verified and authorized software components are executed when the device is powered on.

When the device is turned on, Secure Boot performs a cryptographic verification of each component in the boot sequence –starting from the motherboard firmware, through the bootloader, and up to the Linux kernel. Only components that are digitally signed with trusted certificates are allowed to run. If any unauthorized or tampered software is detected, the boot process is halted to prevent potential security breaches.

Secure Boot operates transparently and requires no user interaction during normal operation. In the event of a boot failure due to verification issues, the device will display an error message and halt startup. Contact the Evident Vascular Service Team if this occurs.

User Management

The Evident Vascular Guidance System supports two types of users:

- Clinical User
- Service User

The Clinical User has access to the clinical function and can perform imaging and diagnostic activities. The Service User has additional capabilities to configure and maintain the system.

Initial users and passwords will be created by an FSE at install time. To add users later, or to change/reset a password, the FSE is required.

Password Policies

The Evident Vascular Guidance System enforces a minimal set of requirements for a strong password:

- Minimum length of 6 characters
- Maximum length of 24 characters
- At least one lowercase, uppercase, number, and special character

The HDO is responsible for maintaining password policies that keep them safe, which includes, but is not limited to:

- Maintain password policies on accounts used to access the system:
  - No shared or default passwords
- Follow password strength policies, which might go beyond what the software is enforcing.

Network Ports and Interfaces

External Interfaces – Workstation

Interface	Direction	Function	Notes
Wi-Fi, 6 GHz Channel or Ethernet (RJ45)	Bi-directional, Workstation to Tablet	Time synchronization of Tablets with Workstation	
		IVUS image data and control	Connection is WPA-3 secured and only possible between system components.
		Time synchronization of Evident Vascular Guidance System with internet time	Connection is WPA-3 secured, requires access to internet and configured NTP servers
Wi-Fi, 2.4 GHz Channel or Ethernet (RJ45)	Bi-directional, Workstation to external network	Upload of system log files	Connection is WPA-3 secured, requires connection to a server in AWS, TLS 1.3
		Download of Software Updates	
		Upload of case information (optional for approved Evident Vascular, Inc. partners)	
		DICOM image transfer to PACS and loading of DICOM worklist information	Requires PACS connectivity, TLS 1.3 is optional (configured by FSE)
USB 3	Bi-directional	FSE Use Only – For Software Updates	Note: Only select USB devices will function, including mouse, keyboard, USB stick/drive.
HDMI / DisplayPort	Output	Secondary display	Optional configuration. EVGS Cable Accessory Kit includes a DisplayPort to HDMI adapter.

External Interfaces – Tablet / Docking Station

Interface	Direction	Function	Notes
Wi-Fi, 6 GHz Channel or Ethernet (RJ45)	Bi-directional, Workstation to Tablet	Time synchronization of Tablets with Workstation	
		IVUS image data and control	Connection is WPA-3 secured and only possible between system components.
USB 3 – USB Types A/C port	Bi-directional	Optional; User-provided Keyboard, Mouse, and USB stick/drive	Note: Only approved USB devices will function, including mouse, keyboard, USB stick/drive. See Additional Supplies and Equipment

Supporting Infrastructure Requirements

- **Network**: WPA3 Wi-Fi or shielded Cat5e Ethernet; PACS/VLAN access recommended.
- **Internet Access**: HDO-supplied Firewall protection with antivirus/malware detection
- **Encryption**: TLS 1.3 for PACS transfers (optional).
- **Time Sync**: Use of NTP for Workstation time is recommended. Tablets will use NTP to synchronize with Workstation time.
- **Access Control**: On system user login with password. The user is expected to follow best password management practices.

Software and Firmware Updates

Users will be notified of *available software and firmware* updates via an Evident Vascular, Inc. representative. Software/firmware updates are digitally signed and delivered via secure download.

Security Event Logging and Anomalous Conditions

The EVGS logs key events to a log file on the Workstation. These events include the following:

- User Management - Creating Users
- User Management - Deleting Users
- User Management - Modifying Users (incl. password reset)
- Access Control - Successful Login
- Access Control - Failed Login
- Access Control - Login Delay (after 3 failed login attempts)
- Access Control - User Logged Out

The logs are retained on the Workstation and uploaded to NeuronSphere between cases.

Users should report anomalous behavior to Evident Vascular Technical Support Services for review of log information on NeuronSphere for further troubleshooting.

SBOM and Software Component Information

An up-to-date machine-readable Software Bill of Materials (SBOM) is available upon request by authorized hospital IT staff.

Evident Vascular
142 Charcot Ave
San Jose, CA 95131 USA
Info@evidentvascular.com
+ 1 (408) 785-6511
The SBOM contains open-source, commercial, and proprietary components, including end-of-support timelines. The SBOM will be in CycloneDX format in a JSON data structure. Other formats and data structures are available upon request, including SPDX format.

Protection of Critical Functions

In the event the Evident Vascular Guidance System detects a severe cybersecurity issue, it enters the system fault mode and:

- disables system operation (including stopping imaging and CIM motor rotation),
- displays a notification to the user of the fault condition, and
- only allows the user to shut down the system.

To recover from this mode the user should power down all components and restart the system. If the issue persists, please contact Evident Vascular Technical Support Services.

Backup and Restore

The Evident Vascular Guidance System does not have a backup/restore functionality for case or patient data. It is recommended to archive case data to DICOM PACS. For additional data management-related features, see Data Management.

Configuration Recovery

Device settings and configurations are retained locally. Evident Vascular Field Service Engineers can modify them at time of installation and back those up to NeuronSphere. If needed, Evident Vascular Technical Support Services can restore the settings.

Secure Default Configuration

Devices with the following secure defaults:

- The system components, Workstation and Tablets, are paired at manufacturing.
- Initial login can only be done by a Field Service Engineer during setup.
- WPA3 Wi-Fi required for Tablets
- Unused ports have been disabled, where applicable
- IT staff may contact support for a full configuration guide.

Forensic Logging and Evidence

Local log files include timestamps, event codes, and system status.

Log format is compatible with hospital SIEM tools (CSV export available).

Logs are stored in encrypted partitions and rotated every 30 days.

End of Support / End of Life (EOS/EOL)

Evident Vascular, Inc. will notify users at least 12 months before EOS. After EOS, no security updates will be provided. Evident Vascular, Inc. will inform you on the steps to decommission and / or replace the system.

Secure Decommissioning

Removal of PHI / PII and HDO-specific information requires the help of Evident Vascular, Inc. To decommission a system, please call Evident Vascular Technical Support Services and the system will be reset to factory defaults.

MDS^2 and Customer Security Documentation

Evident Vascular, Inc. customers can request a Manufacturer Disclosure Statement for Medical Device Security (MDS^2). Please contact an Evident Vascular representative.

Maintenance schedule

Evident Vascular, Inc. will monitor CISA's "Known Exploited Vulnerabilities" catalog on a regular basis. If any vulnerabilities that might impact the system are identified, Evident Vascular, Inc. will reach out to the customer and with a plan on how this vulnerability will be addressed. If a software update is required, Evident Vascular, Inc. will communicate the planned timeline for the new software release and rollout to the customer.

Coordinated Vulnerability Disclosure (CVD) Process

If a potential vulnerability is discovered by an external party, the party should follow Evident Vascular's Coordinated Vulnerability Disclosure process, which complies with the ISO/IEC 29147:2018 "Information technology — Security techniques — Vulnerability disclosure" standard. A description of the process is provided below:

1. Evident Vascular, Inc. will take receipt of a potential vulnerability report. This should include a detailed description of the vulnerability, steps to reproduce it, and the reporting person's contact information.
2. Within five business days, Evident Vascular, Inc. will confirm that we have received your submission and provide you with the name of a contact person.
3. Evident Vascular, Inc. will notify the appropriate security engineers who may want to follow up with the person reporting the vulnerability to improve understanding of what was found, or to

confirm technical details.

4. Evident Vascular, Inc. shall investigate the reported potential vulnerability.
5. Evident Vascular, Inc. shall conduct a risk analysis to determine appropriate actions to take, if any.
6. Evident Vascular, Inc. shall provide the initial reporting party with a summary of findings.
7. Evident Vascular, Inc. may publicly acknowledge your contribution to improving the security of our products and services, subject to your agreement.

23 Specifications

Evident Vascular Guidance System Component Specifications

Component	Specification
Evident Mobile Cart	
Dimensions (nominal position)	H: 151 cm W: 70 cm D: 82 cm
Weight	Loaded: 81 kg Unloaded: 65 kg
Evident Tablet	
Display size, resolution	33.8 cm LCD, 1920 x 1080
Dimensions	H: 27 cm W: 34 cm D: 2.5 cm
Weight	2 kg
Evident Docking Station	
Dimensions	H: 11 cm W: 19 cm D: 17 cm
Weight	1.3 kg
Connections	RJ45 Ethernet port, DP, HDMI, Power
Evident Workstation	
Dimensions	H: 41 cm W: 21 cm D: 39 cm
Weight	9 kg
Connections	System Cable, AC power, Tablet power, DP, USB, Ethernet
Evident Articulating Tablet Mount	
Dimensions (nominal position)	H: 57 cm W: 56 cm D: 57 cm
Weight	5 kg
Connections	Power

Evident Catheter Interface Module	
Dimensions	H: 27 cm W: 13 cm D: 14 cm
Weight	2kg
Connections	Catheter receptacle, System Cable
System Cable	
Length	6 m

Environmental Conditions

Storage/Shipping (non-operating)

Temperature: -30°C to 60°C
Humidity: RH 15 to 90%, non-condensing
Pressure/Altitude: 101 kPa to 59.5 kPa (equivalent to 0-4267m)

Operating

Temperature: 10°C to 35°C
Humidity: RH 15 to 85%, non-condensing
Pressure/Altitude: 101 kPa to 71.0 kPa (equivalent to 0-3000m)
Fluid ingress: IPX0 – no controls

Catheter Acoustic Outputs

The acoustic output power for the diagnostic imaging brightness mode (B-mode) is static for each catheter, and the operator cannot adjust the output power. Ultrasound is only emitted from the catheter when the user selects Live Imaging or Recording through the user interface. When the Evident Vascular Guidance System is not in the live imaging operating mode there is no power emitted. The Evident Vascular Guidance System and Evident Peripheral Imaging Catheters have been tested and are in compliance with the Acoustic Output Display Standard, and maximum outputs are below the FDA limits for ultrasound equipment. Values reported are consistent with requirements set forth per IEC 60601-2-37, “Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment”.

Evident 35 Peripheral Imaging Catheter

Acoustic Output Parameter	Description	B-Mode
$I_{SPTA,3}$ (mW/cm^2)	Derated intensity, Spatial Peak Temporal Average	24.02
MI	Mechanical index	0.45
TI	Thermal index	0.68
f_c (MHz)	Center frequency	17.48

Evident 14 Peripheral Imaging Catheter

Acoustic Output Parameter	Description	B-Mode
$I_{SPTA,3}$ (mW/cm^2)	Derated intensity, Spatial Peak Temporal Average	9.55
MI	Mechanical index	0.36
TI	Thermal index	8.87×10^{-2}
f_c (MHz)	Center frequency	23.38

- Intensities have maximum overall uncertainty ±37.5%
- MI and TI are estimated in tissue

Essential Performance - Catheter Operating Temperatures

Operating temperatures of the Evident Peripheral Imaging Catheters have been tested per IEC 60601-2-37, “Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment” when operating in the live imaging mode when the catheters are in air and under physiologic conditions through simulated use testing. Maximum outputs are below limits set by compliance standards.

Evident 35 Peripheral Imaging Catheter

Environment	Temperature rise (˚C)
In air	21.58 +/- 0.4 ˚C
Simulated use	4.26 +/- 0.4 ˚C

Evident 14 Peripheral Imaging Catheter

Environment	Temperature rise (˚C)
In air	16.58 +/- 0.4 ˚C
Simulated use	3.49 +/- 0.4 ˚C

Measurement Accuracy

Accuracy of measurements taken with the Evident Vascular Guidance System are as follows:

Linear Measurements	+/- 0.3mm or +/- 10%, whichever is larger
Area Measurements	+/- 1.5 mm^2 or +/- 20%, whichever is larger

Abbreviations

Abbreviation	Definition
AC	Alternating Current
ASC	Ambulatory Surgery Center
ANSI	American National Standards Institute
ATM	Articulating Tablet Mount: attaches the Tablet and Tablet Mount to the procedure table bedrail in the Integrated Lab Configuration
BOM	Bill of Materials
CIM	Catheter Interface Module: connection between the Peripheral Imaging Catheter and the Workstation
CISA	Cybersecurity & Infrastructure Security Agency
DC	Direct Current
DICOM	Digital Imaging and Communication in Medicine
DP	Display Port
EOL	End of Life
EOS	End of Support
EVGS	Evident Vascular™ Guidance System
FCC	Federal Communications Commission
FSE	Field Service Engineer or other service staff
HDMI	High-Definition Multimedia Interface
HDO	Health Delivery Organization, e.g., a hospital or OBL
HIS	Hospital Information System
HW	Hardware
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization

IVUS	Intravascular Ultrasound
NTP	Network Time Protocol
OBL	Office-Based Lab
PACS	Picture Archiving and Communication System
PHI	Personal Health Information
PII	Personally Identifiable Information
SBOM	Software Bill of Materials
SW	Software
USB	Universal Serial Bus
VLAN	Virtual Local Area Network

24 Compliance

FCC Compliance Statement

This device complies with **Part 15 of the FCC Rules**. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Interference Guidance (FCC Part 15)

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a healthcare installation.

If interference occurs, the user is encouraged to take one or more of the following actions:

- Reorient or relocate the receiving antenna.
- Increase the separation between this equipment and the affected device.
- Connect the equipment into an outlet on a circuit different from that to which the affected device is connected.
- Consult Evident Vascular or qualified service personnel for assistance.

Frequency Bands of Operation

The wireless link between the Workstation and Tablet operates in the **5 GHz U-NII bands** using fixed channels:

Band	Channel	Center Frequency	Bandwidth
U-NII-1	42	5.210 GHz	80 MHz
U-NII-3	155	5.775 GHz	80 MHz

Wireless and Regulatory Compliance

Region / Authority	Standard / Directive	Scope / Frequency Band	Certification ID
FCC (USA)	FCC Part 15 Subpart C	2.4 GHz WLAN, Bluetooth	**N6C-PCEAX**
	FCC Part 15 Subpart E	U-NII-1/2A/2C/3/4 (5 GHz, no DFS master), 6 GHz Dual Client[1]	
ISED (Canada)	RSS-247	2.4 GHz WLAN, Bluetooth	**4908A-PCEAX**
	RSS-247	U-NII-1/2A/2C/3 (5 GHz, no DFS master)	

Region / Authority	Standard / Directive	Scope / Frequency Band	Certification ID
	RSS-248	6 GHz Client[1]	
ETSI (EU)	EN 300 328	2.4 GHz WLAN, Bluetooth	—
	EN 301 893	5 GHz WLAN (W52/W53/W56 without DFS master)	—
	EN 300 440	5.8 GHz (Master/Slave)	—
	EN 303 687 (Draft)[2]	6 GHz Client	—
Ofcom (UK)	EN 300 328	2.4 GHz WLAN, Bluetooth	—
	EN 301 893	5 GHz WLAN (W52/W53/W56 without DFS master)	—
	VNS 2030/8/3	5.8 GHz	—
	EN 303 687 (Draft)[2]	6 GHz Client	—

[1] Applies to 6 GHz client devices only.
[2] Draft standard subject to revision.

Mode of Operation

Duty Cycle: Continuous Operation.

Declarations for Electromagnetic Compatibility (EMC) and Associated Risks

The Evident Vascular™ Guidance System complies with the requirements of IEC 60601-1-2:2020. The system was tested to the following standards. The system is designed for use in a clinic/hospital non-protected electromagnetic environment. If used in a hospital, it should not be located in parts of the hospital where there are any HF Surgical or magnetic resonance systems used.

Essential Performance

The Essential Performance of the Evident Vascular™ Guidance System is to generate a real-time intravascular image without noticeable artefacts, elevated image noise, or distortion that supports a trained user's diagnosis.

Measurements that support a diagnosis include:

1) measuring linear distances in an image with an accuracy of no worse than +/- 0.3mm or +/- 10% whichever is greater.

2) measuring an area in an image with an accuracy of no worse than +/- 1.5mm2 or +/- 20% whichever is greater

Noise, Artifacts, Distortion

The System shall be free from noise on a waveform or artifacts or distortion in an image or error of a displayed numeric value which cannot be attributed to a physiological effect and which may alter the diagnosis.

Numerical Values

The System shall be free from the display of incorrect numerical values associated with the diagnosis to be performed.

Unintended or Excessive Output

The System shall be free from the production of unintended or excessive ultrasound output.

Unintended or Excessive Surface Temperature

The System shall be free from the production of unintended or excessive transducer assembly surface temperature.

Unintended or Uncontrolled Motion

The System shall be free from the production of unintended or uncontrolled motion of transducer assemblies intended for intra-corporeal use.

Should these functions fail to work as intended, discontinue use and contact Evident™ Technical Support Services. To help ensure the system functions as intended as it pertains to electromagnetic performance, follow all the instructions in this manual and contact Evident™ Technical Support Services for any repairs. Do not modify the system. Simple trouble shooting measures as it pertains to EMC are noted at the end of this section.

EMC Compliance

Emissions (Class A, Group 1)	CISPR 11:2015 +AMD1:2016+AMD2:2019 (Radiated Emissions)
	CISPR 11:2015 +AMD1:2016+AMD2:2019 (Conducted Emissions)
	IEC 61000-3-2:2018 +AMD1:2020 (Harmonic distortion)
	IEC 61000-3-3:2013 +AMD1:2017 +AMD2:2021 (Voltage fluctuations and flicker)
The EMISSIONS characteristics of this equipment make it suitable for use in hospitals only. 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.	
Immunity	IEC 61000-4-2:2008 – ESD immunity (± 2, 4, 8 & 15kV Air discharge; ±8kV Contact discharge)
	IEC 61000-4-3:2020 – Radiated immunity (3V/m f) (80 MHz to 2.7 GHz); IMMUNITY to RF wireless communications 9-28V/m, see table 9 for
	IEC 61000-4-4:2012 – EFT immunity (± 2 kV)
	IEC 61000-4-5:2014 +A1:2017 – Surge immunity (L-L: ± 0,5 kV, ± 1 kV; L_G ± 0,5 kV, ± 1 kV, ± 2 kV)
	IEC 61000-4-6:2013 – Conducted immunity (3V m; 0.15 MHz - 80 MHz; 6V m 0.15 MHz - 80 MHz)
	IEC 61000-4-8:2009 – Magnetic immunity (30 A/m)
	IEC 61000-4-39:2017 - Radiated fields in close proximity immunity: tested at CW 8A, 134.2KHz 65A, 13.56MHz 7.5A
	IEC 61000-4-11:2020 –Voltage dips, short interruptions, and voltage variations immunity: tested at 0 % UT; at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°; and 0 % UT; 1 cycle and 70 % UT; 25/30 cycles
	IEC 61000-4-11:2020 –Voltage dips, short interruptions, and voltage variations immunity: tested at 0 % UT; 250/300 cycle
The normal test levels for Professional Healthcare equipment as specified in tables 4, 5, 7, 8 and 9 of IEC 60601-1-2 were applied for the immunity tests noted above.	

Appendix A: Warranty Statement

Limited Warranty Statement

Evident Vascular warrants that the Evident Vascular Guidance System and its associated components (including Workstation, CIM, Mobile Cart, System Cable, Tablet, Tablet Mount, Articulating Tablet Mount and Software) shall be free from defects in materials and workmanship under normal use and service for a period of **one (1) year** from the date of shipment.

Warranty Coverage Includes:

- Repair or replacement of defective parts at no charge.
- Technical support for hardware and software issues.
- Software updates released during the warranty period.

Exclusions:

- Damage resulting from misuse, unauthorized modifications, or improper maintenance.
- Consumables such as disposable catheters, unless otherwise specified.
- Third-party accessories not supplied or approved by the manufacturer.

Claim Procedure: Warranty claims must be submitted in writing within the warranty period. The device must be returned to the manufacturer or authorized service center, freight prepaid, with proof of purchase and a description of the issue.

Limitation of Liability: The manufacturer shall not be liable for any indirect, incidental, or consequential damage arising from the use or inability to use the device. This warranty is exclusive and in lieu of all other warranties, whether express or implied.

Appendix B: Manufacturer Disclosure Statement for Medical Device Security (MDS^2)

Device Name: Evident Vascular™ Guidance System

Manufacturer: Evident Vascular, Inc.

Device Category: Intravascular Ultrasound Imaging

Software Version: [version XX.YY]

Date of Disclosure: September 23, 2025

1. Device Description & Connectivity

Intended Use: Real-time intravascular imaging for diagnostic and interventional procedures.

Deployment Mode: Operates as a standalone system or integrates with hospital networks via DICOM.

Connectivity: Wireless module; Ethernet module (disabled by default).

Remote Access: No remote access enabled by default. Remote diagnostics available via secure VPN upon request.

2. Electronic Protected Health Information (ePHI)

ePHI Stored: Patient ID, imaging data, timestamps.

Storage Type: Persistent (internal SSD); encrypted.

Data Export: USB (encrypted), DICOM over network.

Data Retention: Configurable retention policy; default is XX days.

3. Security Features

Authentication: Role-based access control; password complexity enforced.

Audit Logging: System logs user access, configuration changes, and data exports.

Encryption:

At rest: AES-256 encryption

In transit: TLS 1.2 for DICOM transfers

Auto Logoff: Enabled after 10 minutes of inactivity (configurable).

Malware Protection: Embedded OS hardened; no third-party software installation permitted.

4. Software & Firmware Management

Update Mechanism: Evident Vascular Field Service Engineer.

Patch Management: Security patches released as needed.

5. Risk Management & Compliance

HIPAA Compliance: Designed to meet HIPAA Security Rule requirements.

FDA Clearance: Not evaluated by FDA.

Vulnerability Disclosure: Coordinated via Evident Vascular, Inc. cybersecurity response team.

ISAO Participation: Member of Medical Device ISAO.

6. Additional Notes

Network Diagram: Available upon request.

Security Documentation: Full MDS^2 form and cybersecurity white paper available under NDA.