MENDAERA

Focalist™ System

Instructions For Use

Mendaera, Inc.
700 South Claremont St., Suite 200
San Mateo, CA 94402 USA
www.mendaera.com
877-636-3237
support@mendaera.com

Trademark Acknowledgements

Product names mentioned in this manual may be trademarks of their respective owners.

Equipment / Software version

This user manual provides technical information about the use and operation of the Focalist™ System. The equipment described herein is designed to work with Software Version 25.10 and later.
Pictures of the user interface and equipment found in this manual may look different than in the current version of the Focalist System, but the content and instructions are applicable to all versions currently in use.

Disclaimer

To obtain a printed copy of this manual at no additional cost, contact support at support@mendaera.com.
To obtain an electronic copy of this manual, visit the 'Resources' page on www.mendaera.com.

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1 Chapter 1: Introduction

1.1 Document overview

This manual is intended to provide information to guide intended users in the safe and effective use of the Focalist System and applicable accessories. It is important that you read and understand all instructions in this manual before operating the system and pay careful attention to the warnings and cautions throughout the manual.

⚠ CAUTION *Federal (United States) law restricts this device to sale by or on the order of a physician or properly licensed practitioner.*

1.2 Intended use/indications for use

The system provides guidance for precise instrument placement of common interventional devices by positioning the device relative to the ultrasound transducer and the resulting image during a diagnostic or therapeutic procedure.

1.3 Intended patient population

This guidance system is intended for use with pediatric and adult patients.

1.4 Intended users

General purpose guidance systems should be used by clinicians medically trained in the use and interpretation of ultrasound for interventions. There are no other unique skills or user abilities required for the Focalist System. This may include, but is not limited to: Anesthesiologists, Interventional Radiologists, Nephrologists, Radiologists, Sonographers, and Surgeons.

The Focalist System's use environment is any clinical environment where the intended users typically perform ultrasound guided procedures. The use environment may include, but is not limited to operating rooms, hybrid imaging rooms, pre-op/post-op holding bay, and physician offices. The Focalist System is not MR safe and use of the system within 6 inches of the MR environment should be avoided. The Focalist System is not intended for use in an aircraft.

⚠ WARNING *The Focalist System is MR unsafe and may pose unacceptable risks to the patient, medical staff, or other persons within the MR environment. Using the Focalist System within 6 inches of other magnetically susceptible medical devices could lead to serious harm.*

1.5 Contraindications

There are no contraindications associated with the Focalist System. Reference the ultrasound probe manufacturer's Instructions for Use for any probe related contraindications.

1.6 Training

Training provided by Mendaera is limited to the use of the Focalist System and does not replace the clinical training and experience required to perform diagnostic and therapeutic ultrasound guided interventions.

1.7 Warnings, cautions, and notes

1.7.1 Symbols used in this document

WARNING	*A warning alerts the reader about a situation which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.*
CAUTION	*Alerts the reader about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse.*
NOTE	*Provides important information.*

1.7.2 Warnings, cautions, and notes

Warnings, cautions, and notes are listed below as well as throughout the document within the sections where they are applicable. Reference the ultrasound probe manufacturer's Instructions for Use for any probe related guidance, including warnings, cautions, and notes.

WARNING	*Always clamp the instrument adapter at the hub of the instrument. Failure to do so could result in inaccurate tip indicators and lead to serious patient injury.*
WARNING	*Do not over insert the instrument. Over inserting the instrument could result in serious patient injury.*
WARNING	*Do not let go of the instrument if the robot de-energizes while an instrument is inserted into the patient. Failure to maintain control of the instrument while the robot is de-energized could lead to serious harm to the patient.*
WARNING	*The Focalist System is MR unsafe and may pose unacceptable risks to the patient, medical staff, or other persons within the MR environment. Using the Focalist System within 6 inches of other magnetically susceptible medical devices could lead to serious harm.*
WARNING	*Do not attempt to service the Focalist System, including the battery. Doing so may result in damage to the Focalist System and/or injury to the operator or patient. Contact Mendaera Customer Support for service.*
WARNING	*Do not spill or allow fluids into the Focalist System's cart. Failure to comply may result in damage to the Focalist System, fire, electrical shock, or even death to the operator or patient.*
WARNING	*Do not modify the robot, cart, or other components specified for use with the Focalist System. Modification to the Focalist System may cause the system to perform improperly and/or may cause injury to the patient or operator.*

WARNING	*Always power the Focalist System according to the system specifications. Electrical shock to the patient and/or operator may result if voltages exceed the power requirements listed for the Focalist System.*
WARNING	*Always connect the Focalist System to a supply mains with protective earth. Electrical shock to the patient or operator and/or damage to the equipment may result if this guidance is not followed.*
WARNING	*Do not use the Focalist System in the presence of flammable gases or anesthetics. Doing so can result in a possible fire or explosion and/or result in injury to the patient or operator.*
WARNING	*Do not use cables, probes, devices, and/or other components other than those specified for use with the Focalist System. Do not use the Focalist System with devices that have emissions characteristics that are not aligned with the manufacturer's declaration and guidance regarding Electromagnetic Conformance. Failure to comply may result in increased electromagnetic emissions or decreased electromagnetic immunity of the Focalist System and cause the Focalist System to perform improperly, resulting in injury to the patient or operator.*
WARNING	*Do not connect multiple socket-outlets or extension cords to the Focalist System. Failure to comply may cause the system to perform improperly and/or may cause injury to the patient or operator.*
WARNING	*Always maintain (at minimum) a 30 cm separation distance between portable radio-frequency (RF) communication equipment (including peripherals such as antenna cables and external antennas) and any part of the Focalist System (including cables specified by the manufacturer). Failure to comply may cause the Focalist System to perform improperly and/or result in injury to the patient or operator.*
WARNING	*Avoid use of the Focalist System adjacent to or stacked with other equipment. Failure to comply may cause the Focalist System to perform improperly and/or result in injury to the patient or operator. If such use is necessary, the Focalist System and the other equipment should be observed to verify that they are operating normally.*

CAUTION	*Federal (United States) law restricts this device to sale by or on the order of a physician or properly licensed practitioner.*
CAUTION	*Ensure the gauge insert is snapped closed prior to instrument insertion. Failure to follow these instructions may result in inaccuracy between the instrument position and the guidezone and/or injury to the patient.*
CAUTION	*Ensure that the gray face of the instrument adapter is pointing towards the hub. Incorrect installation of the instrument adapter may result in sudden detachment of the adapter from the carriage, unintended motion of the instrument, and/or injury to the patient.*
CAUTION	*Avoid moving the probe following instrument insertion. Probe movement following instrument insertion could bend the instrument and result in inaccuracy between the instrument position and the guidezone and/or injury to the patient.*

CAUTION	*Remain aware of your instrument position at all times. The guidezone will widen when the instrument angle is adjusted after instrument insertion. To reset the guidezone, retract the instrument. Failure to comply may result in unintended motion of the instrument and/or injury to the patient.*
CAUTION	*Avoid applying excessive force to the cart at or above the cart handle. Excessive force applied to the cart, especially when moving around turns and on slopes, may cause the cart to tip over and result in injury to the patient and/or operator.*
CAUTION	*Ensure the selected instrument is within the instrument guide's maximum compatible length. Using an instrument longer than the maximum compatible length may result in inaccurate tip indicators and/or injury to the patient.*
CAUTION	*Ensure that heavy instruments are physically held or supported while they are connected to the system. Failure to do so may cause the robot to de-energize and lead to unintended motion of the instrument and/or injury to the patient.*
CAUTION	*Do not re-use a compromised sterile barrier. Re-using a compromised sterile barrier may result in an infection risk.*
CAUTION	*Always carefully inspect the Focalist System before and after use. Check the robot, cart, and other components for signs of damage such as cracks, chips, or abrasions. Use of damaged components may cause the Focalist System to perform improperly and/or result in injury to the patient or operator. If damage is suspected, discontinue use of the Focalist System and contact Mendaera Customer Support.*
CAUTION	*Do not use cables, probes, devices, and/or other components other than those specified for use with the Focalist System. Connecting devices improperly or substituting non-approved devices may cause the Focalist System to perform improperly and/or result in injury to the patient or operator.*
CAUTION	*Do not drop the Focalist System. Dropping the Focalist System may cause damage. Check the robot, cart, and other components for signs of damage such as cracks, chips, or abrasions. Do not use the system if there is any sign of damage. Use of damaged components may result in risk of electrical hazards, cause the Focalist System to perform improperly, and/or result in injury to the patient or operator.*

NOTE	*The selected target is not coupled to the underlying ultrasound image. If you move the ultrasound probe, the on-screen target will not maintain its relationship to the ultrasound image.*
NOTE	*Push the instrument from its hub to avoid the instrument slipping backwards relative to the adapter during insertion.*
NOTE	*Instruments will lose 3.1 cm of working length when attached to the universal adapter. Consider this loss of working length when selecting an instrument; choose an instrument of sufficient length to reach the target.*

NOTE	*Instruments from 14 to 25 gauge are compatible with the Focalist System.*
NOTE	*The instrument tip indicator may indicate any portion of the needle tip, depending on the type of bevel and its orientation as it passes through the insert.*
NOTE	*Do not submerge the electromechanical arm.*
NOTE	*Follow hospital, local, and state policies and guidelines for handling used medical devices.*
NOTE	*Store and operate the Focalist System only within the range of environmental conditions specified in the technical specifications. If operating or storing in an environment that is outside of these conditions, move the Focalist System to an environment that meets the environmental conditions.*
NOTE	*Follow all security and cybersecurity policies of your institution. If you do not know what these policies are, contact your information technology (IT) department.*
NOTE	*Consult with your IT/Security department to ensure that security and patient data protection is in accordance with the policy of your institution.*
NOTE	*Ensure the Focalist System is stored and operated only in a secure environment(s) which limit physical access to only authorized personnel.*
NOTE	*"Harmful interference" is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.*

1.8 Electrical safety

The Focalist System has been designed and tested to comply with IEC 60601-1-2 requirements for electromagnetic compatibility (EMC) with other devices.

Like other medical equipment, the Focalist System requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure EMC, the Focalist System must be installed and operated according to the EMC information provided in **Section 9.4** of this instruction for use.

1.9 Cybersecurity

To ensure cybersecurity, the Focalist System must be installed and operated according to the guidance in **Chapter 11** of this manual.

2 Chapter 2: System Overview

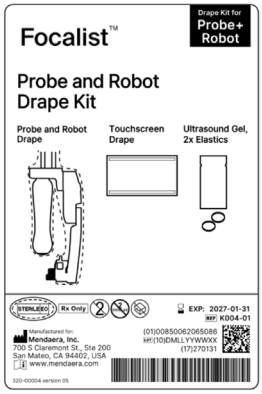
2.1 Overview

The Focalist System provides guidance for precise placement of common interventional devices by positioning the instrument relative to the ultrasound probe and the resulting image during a diagnostic or therapeutic procedure. The primary components of the Focalist System are the Robot (also “Electromechanical Arm”), Cart, Drape Kit, and Universal Instrument Guide Kit.

The system is used with compatible, commercially available, FDA-cleared ultrasound probes (see **Section 2.4**). The system uses standard ultrasound B-mode imaging, with optional Color Doppler, to support ultrasound-based planning and navigation. The system is also used with compatible instruments, as described in **Section 2.3**.

Robot

Cart



Drape Kit

Universal Instrument Guide Kit

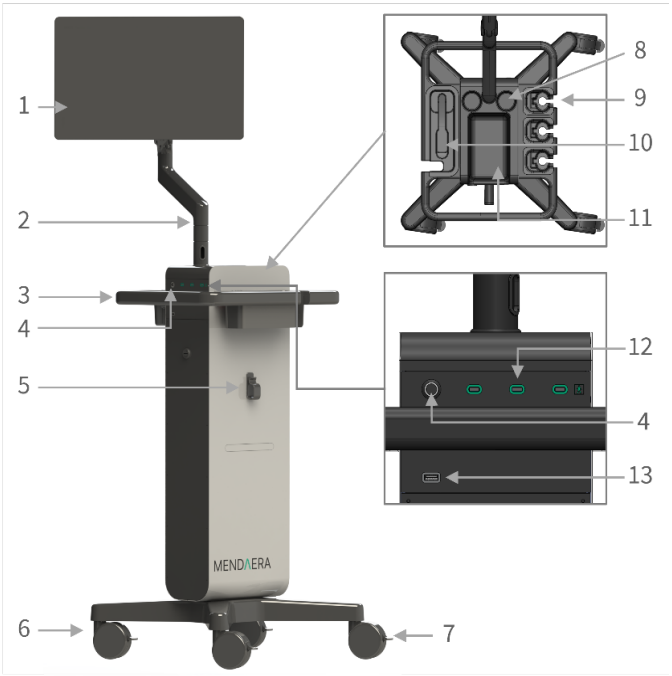
The Drape Kit comes in two variations: (1) Robot Drape Kit and (2) Probe and Robot Drape Kit. The Universal Instrument Guide Kit also comes in two variations: (1) Short, for interventional instruments up to 10 cm, and (2) Long, for interventional instruments up to 20 cm.

2.2 System description

2.2.1 Cart

The Focalist System cart is a portable piece of capital equipment that can be wheeled around and locked into place. The cart includes a computer that houses Focalist software for all system operations, and is home to all system controls, touchscreen monitor, storage for components, and power for the system and components including the robot and ultrasound probe. The cart contains a battery to enable use while disconnected from wall power.

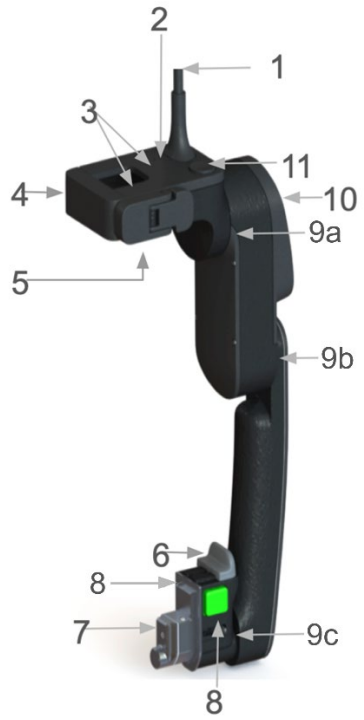
#	Description
1	Touchscreen monitor: Contains the graphical user interface (GUI) that displays ultrasound images and system settings and allows user to interact with system.
2	Adjustable monitor arm: Position monitor for best views
3	Cart handle: To move cart
4	Power button: Powers on monitor and cart
5	Cable management hooks: Typically used for robot and ultrasound cables.
6	Wheels (4x)
7	Wheel brake ON/OFF levers
8	Gel bottle storage (2x)
9	Probe holders (3x)
10	Robot storage
11	Additional miscellaneous storage
12	USB-C ports (3x): For robot and probes. Left to right corresponds to the numbers 1, 2, 3 respectively in the 'Devices' window on the GUI.
13	USB-A port: For compatible peripherals
14	HDMI port: Currently unavailable for use
15	Ethernet port
16	Power cable hooks: To manage power cord
17	Power cable connection point: For main power cable

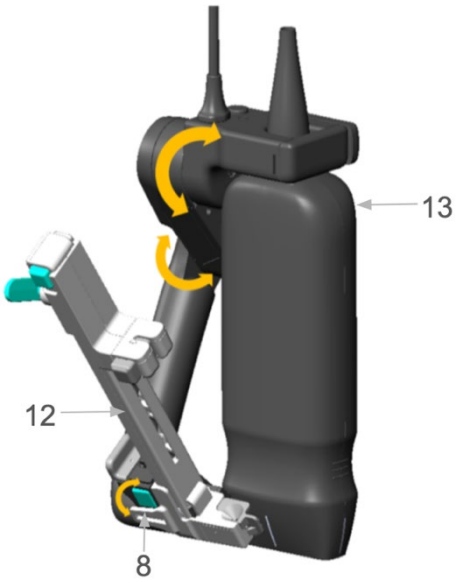


2.2.2 *Robot*

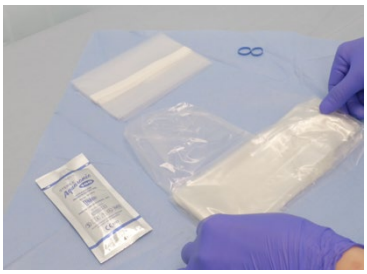
The Focalist System robot is a handheld device that attaches to a compatible ultrasound probe. It has three degrees of freedom to allow users to select desirable skin entry points and various trajectories for the interventional procedure. The top of the robot allows for attachment of the ultrasound probe in four positions to perform in-plane (parallel to the long axis of the ultrasound probe) and out-of-plane (perpendicular to the long axis of the ultrasound probe) placement of the instrument, on either the right or left sides of the probe. The user can manually readjust the position and orientation of the robot using the clutch buttons on the robot. The robot can also be controlled via user selections on the graphical user interface (GUI). The robot connects to and receives power from the cart via a USB-C cable.

#	Components
1	Robot USB-C cable: To connect robot to cart
2	LED indicator lights: • Dim white: Robot plugged in to cart successfully • Bright white: Probe attached to robot • Blue: Instrument guide attached to robot • Yellow: Robot in error state
3	Icons for probe orientation alignment: • In-plane: Solid square "■" • Out-of-plane: Empty circle "◯"
4	Robot latch door: Holds probe in place
5	Robot latch lock: Closes and locks robot latch door
6	Guide lock: Locks instrument guide to robot
7	Sterile mount: Interface to connect instrument guide
8	Green clutch buttons (x2): Press one or both buttons to manually adjust the position and orientation of the robot
9	Joints (x3): Offers 3 degrees of freedom
10	Side programmable button: single-press and/or press-and-hold can be programmed to capture a screenshot and/or a cine
11	Top programmable button: single-press and/or press-and-hold can be programmed to capture a screenshot and/or a cine
12	Instrument guide: Sterile single-use component that attaches to robot and the interventional instrument
13	Compatible ultrasound probe





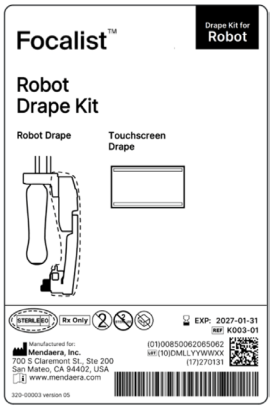
2.2.3 Drapes

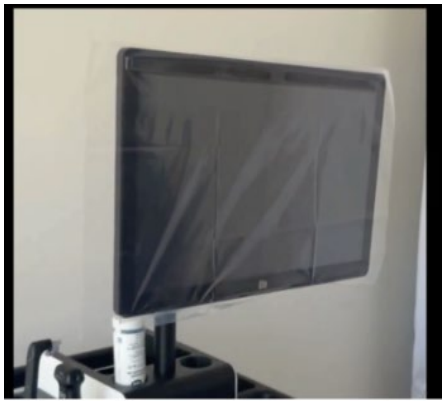


The Focalist System provides single-use, sterile drapes to cover the robot while it is in use. The Focalist System offers two draping kits based on the sterility requirements for the procedure. Both kits include a single-use drape to cover the entirety of the touchscreen to create a sterile barrier for touch interactions. Both kits are sterilized using ethylene oxide.

2.2.3.1 Robot Drape Kit: for clean technique

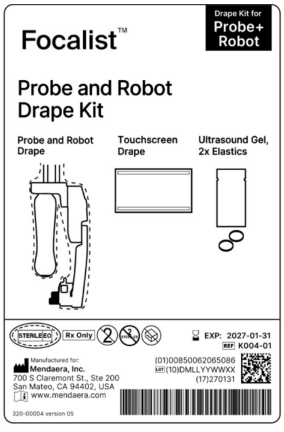
For a clean technique, the kit contains a drape to cover only the robot up to the connection point between the robot and the ultrasound probe.

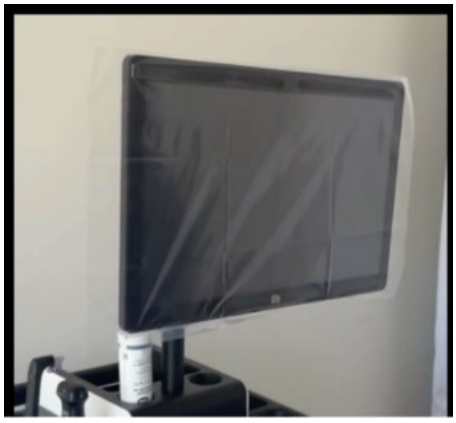




2.2.3.2 Probe and Robot Drape Kit: for sterile procedure

For a sterile procedure, the kit contains a drape that covers both the robot and the ultrasound probe. At the end of the drape, there is a sterile mount that allows for connection of the instrument guide.





2.2.4 *Universal Instrument Guide Kit*

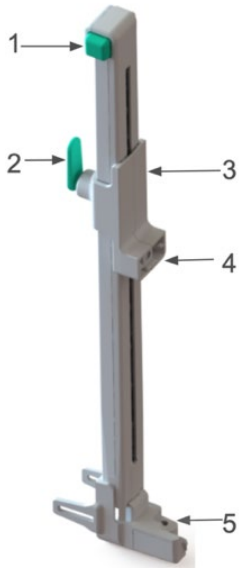
Mendaera offers a single-use, sterile, Universal Instrument Guide Kit that contains components needed to attach any preferred and compatible instrument to the robot including an instrument guide, universal instrument adapter, and a gauge insert tree. The Universal Instrument Guide Kit is sterilized using ethylene oxide. The kit is available in two size options:

- Short - for interventional instruments up to 10 cm of maximum compatible length
- Long - for interventional instruments up to 20 cm of maximum compatible length

2.2.4.1 *Instrument guide*

The instrument guide is a single-use sterile component that allows for attachment of an instrument. The instrument guide attaches to the robot, which moves the instrument guide into position for insertion of the instrument into the body. The user selects a short or long instrument guide kit to accommodate the length of the instrument being used in the procedure.

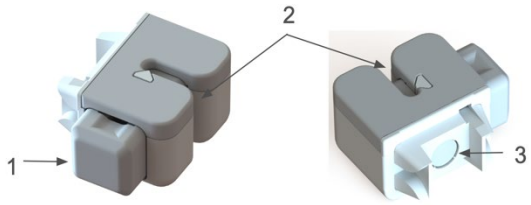
#	Description
1	Green guide adjustment button
2	Insertion lock for carriage: • To unlock: Keep the lever vertical • To lock: Rotate the lever approximately 45 degrees in either direction, or until it remains securely in place.
3	Carriage: Holds universal adapter and can be moved up or down to insert or retract the instrument
4	Universal adaptor connection point: Contains magnet for on and off attachment
5	Gauge insert hole: Attach size appropriate gauge insert



2.2.4.2 *Universal Instrument Adapter*

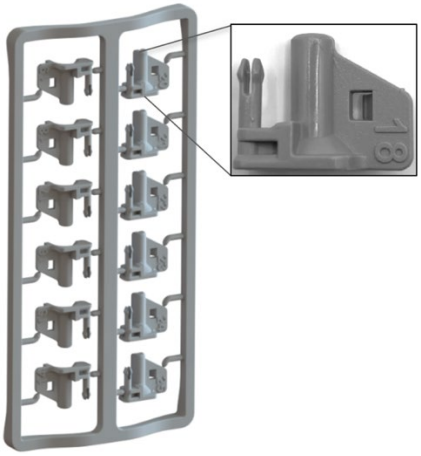
The Universal Instrument Adapter (also “adapter”) is a single-use sterile component that holds the preferred and compatible instrument and connects to the instrument guide by magnet.

#	Description
1	Adapter spring button: Push to insert and clamp instrument at the hub
2	Instrument slot: Clamps instrument
3	Instrument guide connection point: Magnet that attaches to a magnet on instrument guide



2.2.4.3 *Gauge insert tree*

The gauge insert is a single-use sterile component that attaches to the instrument guide to guide the instrument as its inserted into the body. A gauge insert tree is included in the instrument guide kit, with a variety of gauge insert size options to accommodate a variety of instrument gauge sizes. Gauge sizes are labeled on each insert and the appropriate gauge should be separated from the tree before use.



2.3 Compatible instruments

The Focalist System is compatible with most off-the-shelf percutaneous instruments, including needles up to a maximum length of 20 cm, from 14 to 25 gauge.

NOTE	*Instruments from 14 to 25 gauge are compatible with the Focalist System.*
NOTE	*Instruments will lose 3.1 cm of working length when attached to the universal adapter. Consider this loss of working length when selecting an instrument; choose an instrument of sufficient length to reach the target.*

2.4 Compatible ultrasound probes

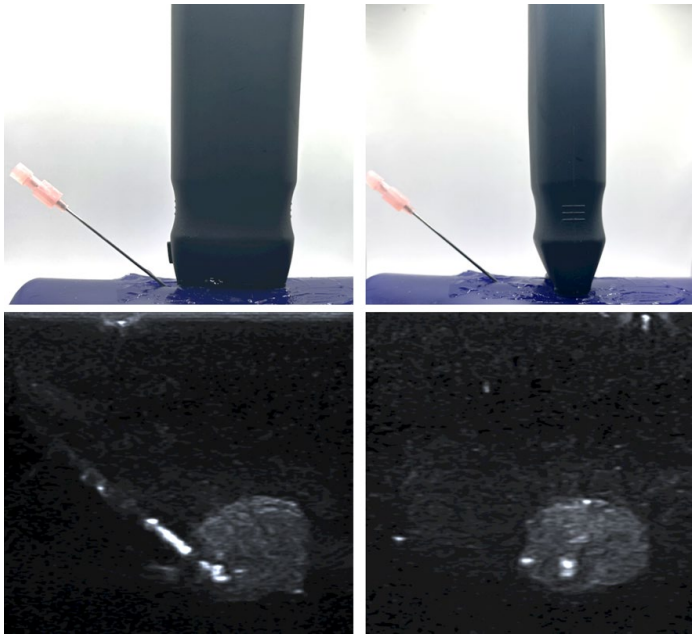
The FDA-cleared ultrasound systems listed in the table below are compatible with the Focalist System. Ultrasound systems not included in this table are not compatible with the Focalist System at this time. A website address to locate the instructions for use for the compatible ultrasound system is listed below; refer to the probe manufacturer for the latest documentation.

Ultrasound Systems	Probe Models	IFU location
EchoNous Kosmos	• Lexsa • Torso-One	Refer to the ultrasound probe manufacturer's documentation at www.echonous.com/mendaera.

2.5 Ultrasound intervention approaches: terminology as used in this manual

The Focalist System allows for either an in-plane or out-of-plane intervention approach, based on the axis of the interventional instrument in relation to the ultrasound plane. Terminology associated with these approaches as used in this manual are described here:

- In-plane approach (or "long-axis", "longitudinal"): the instrument is introduced in line with, or parallel to, the ultrasound probe and beam, the puncture is defined as "in-plane" (IP), and the instrument is intended to appear in its entirety on the ultrasound screen.
- Out-of-plane approach (or "short-axis, "transverse"): the instrument is introduced perpendicular to the ultrasound probe and beam, in the center of the probe, the puncture is defined as "out-of-plane" (OOP), and the instrument appears as a hyperechoic point on the ultrasound screen where it crosses the imaging plane



(Left) In-plane approach; (Right) Out-of-plane approach

3 Chapter 3: Graphical User Interface (GUI)

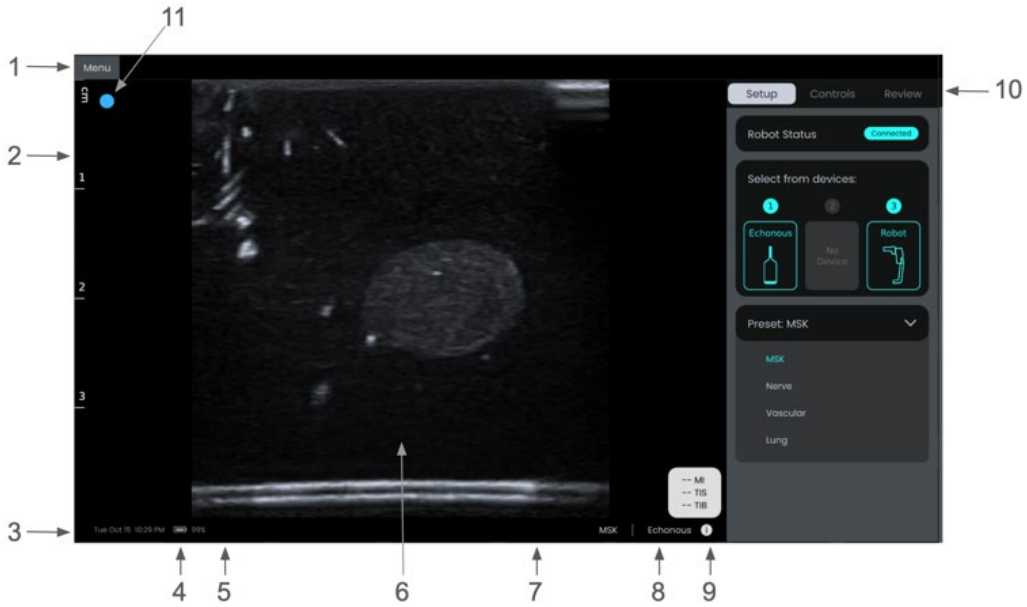
3.1 Intro to Focalist GUI

The Focalist System's graphical user interface (GUI) is located on the touchscreen monitor. From the GUI, users interact with the robotic system, and access and adjust various system functions, settings, and controls.
The following touch style conventions can be used with the Focalist touchscreen:

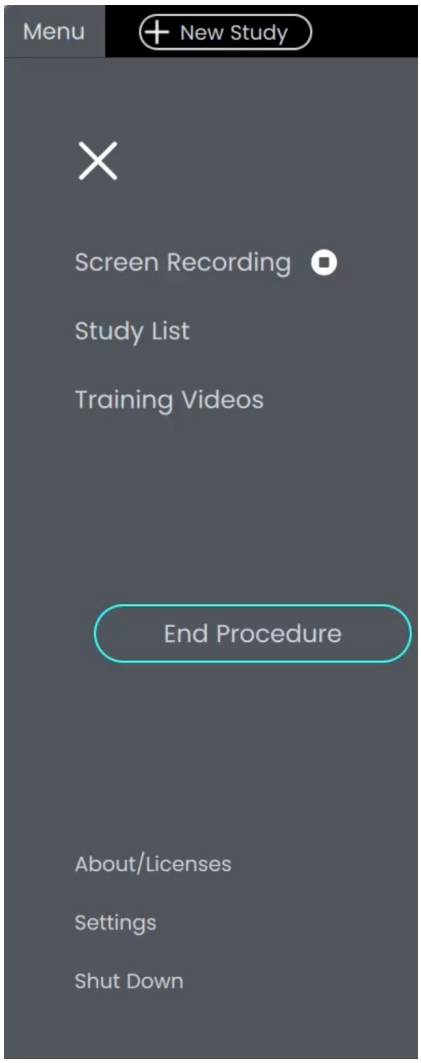
- "Tap" refers to touching the screen with your fingertip
- "Scroll" refers to swiping your fingertip on the screen vertically
- "Drag" refers to touching the screen with your fingertip and moving your finger across the screen without losing contact with the screen
- "Select" refers to tapping on the GUI icon or item

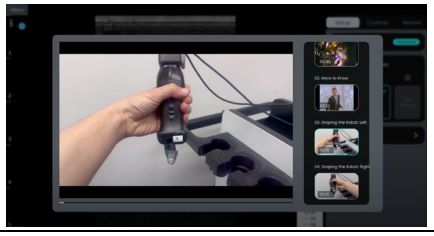
#	Description
1	Menu (see **Section 3.2**)
2	Ultrasound depth scale in centimeters
3	Date and time
4	Cart battery level: Shows percentage of battery remaining
5	Screen recording indicator: Shows red circle when "Recording"
6	Ultrasound image

#	Description (continued)
7	Selected ultrasound preset: Displays when user selects from dropdown (see **Section 3.3**)
8	Active ultrasound probe: Shows probe selected in Setup tab
9	Ultrasound acoustic information: information about the currently selected ultrasound preset
10	Setup, Control, and Review tabs (see next sections for more details)
11	Probe orientation mark

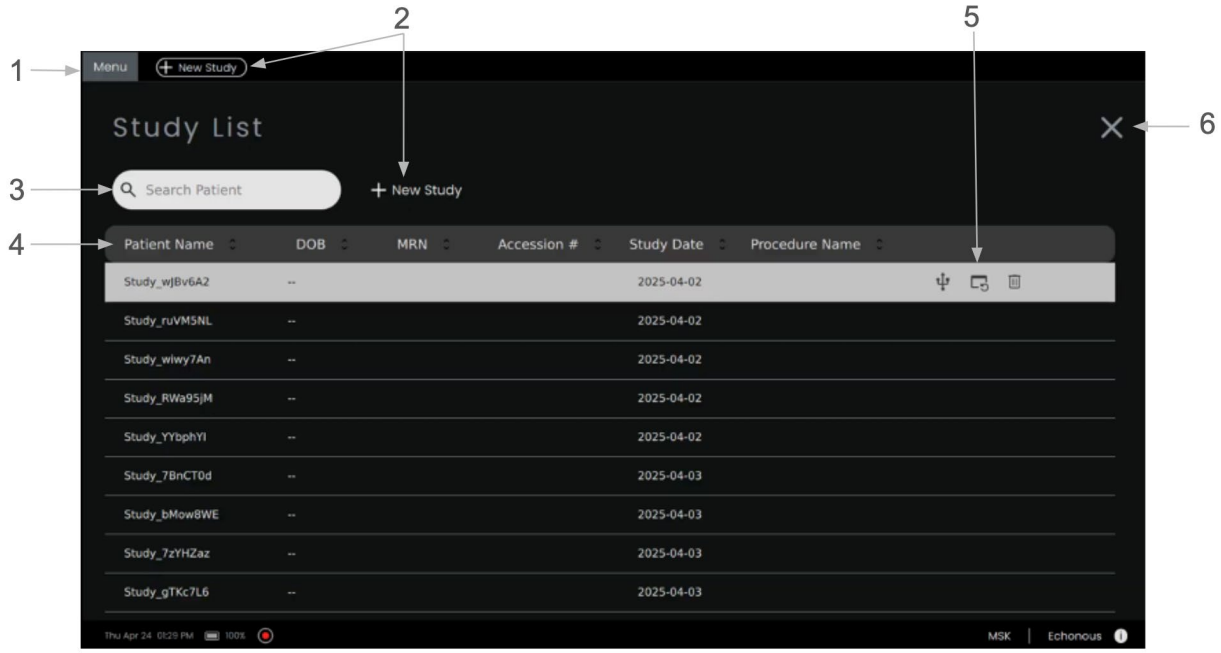


3.2 Menu



Features (activated by tapping)	Description / Capabilities
Screen Recording	Initiates screen recording of the entire GUI.. • Tap the play button to begin screen recording. • Press the “Stop” icon to stop the recording. Recordings cannot be exported by users in this release. Contact Mendaera support to request access.
Study List	Displays a list of studies. System automatically generates a study when media (screenshot/cine) is captured. See **Section 3.2.1** for details.
Training Videos	Allows the user to access a subset of training videos. • Scroll available videos to the right to select the desired video. • Tap outside the window to exit. 
End Procedure	Triggers an end to the procedure. Any media captured will be saved under a study with a software-generated patient name and study date.
About/ licenses	Displays software version.
Settings	Displays various system setting options. See **Section 3.2.2** for details.
Shut down	Displays options to power off or restart the system.

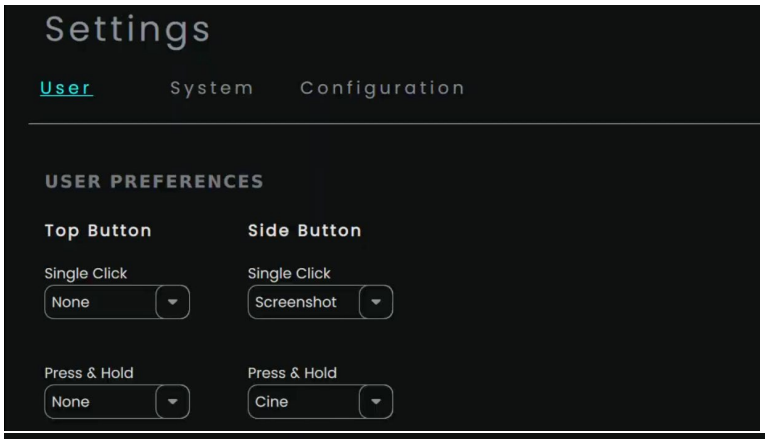
3.2.1 Study list

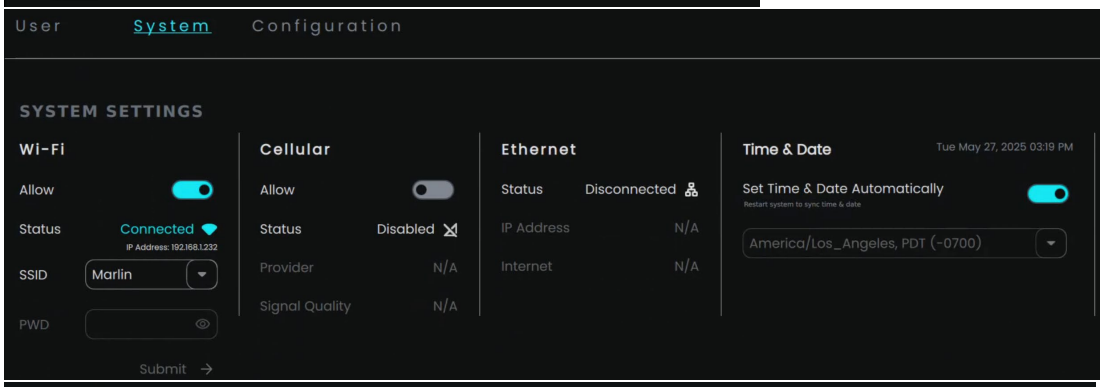


#	Description / Capabilities
1	Menu (see **Section 3.2**)
2	New Study: (Optional) Creates a new study with a software generated patient name in the format “Study_xxxxxxx” (where 'XXXXXXX' is a unique 7-character identifier). System automatically generates a study when media (screenshot/cine) is captured.
3	Search bar for patient names
4	Study list table that displays the software generated patient name and the study date. The list can be sorted by tapping on the up and down arrow (⇕).
5	Buttons to perform actions on the selected study
6	Tap on “X” to close the Study List page and return to procedure screen

#	Description (continued)
	USB export: Tap on the icon to initiate media export to an external USB drive
	Convert selection to the “Current Study”
	Delete the selected study

3.2.2 Settings





Features	Description / Capabilities
User	Dropdown shows options to program the top and side buttons on the robot to following actions: none, screenshot, cine
System	Tap to allow preferred network type: • Wi-Fi – Select a Wi-Fi network and enter the required username and password to connect.

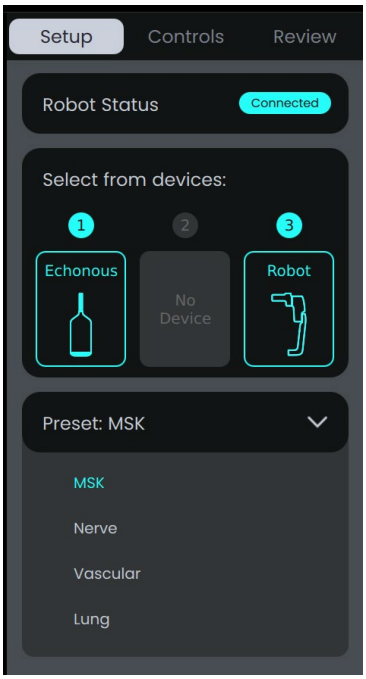
<table>
<tr><th>Features</th><th>Description / Capabilities</th></tr>
<tr><td></td><td>

Cellular – The cart comes equipped with a pre-installed SIM card for cellular connectivity.
When multiple connections are allowed, the system connects to only one network at a time, prioritizing in this order: Ethernet, then Wi-Fi, and finally Cellular. Only one network connection will be active at any given time.

Network Statuses:
<table>
<tr><td>INIT</td><td>The system is checking its settings to figure out the current network status.</td></tr>
<tr><td>DISABLED</td><td>The network (like Wi-Fi or cellular) is turned off—either by the user or automatically to avoid conflicts.</td></tr>
<tr><td>ENABLING</td><td>The system is turning the network on.</td></tr>
<tr><td>DISABLING</td><td>The system is turning the network off.</td></tr>
<tr><td>CONNECTING</td><td>The network is turned on, and the system is trying to connect to the internet.</td></tr>
<tr><td>CONNECTED</td><td>The system is successfully connected to the internet.</td></tr>
<tr><td>DISCONNECTED</td><td>The system tried to connect but failed, or it was connected and then lost the connection.</td></tr>
<tr><td>UNAVAILABLE</td><td>The system can't check the network status—usually because something is set up incorrectly.</td></tr>
<tr><td>FAULT</td><td>Something went wrong while starting or stopping the network.</td></tr>
</table>
</td></tr>
<tr><td>System – Time & Date</td><td>Tap to select preferred time zone displayed on the GUI</td></tr>
<tr><td>Configuration</td><td>Port 1, 2, 3 displays device connected from left to right respectively into the USB-C ports on the cart.
Tap on the arrow (→) to access the probe instructions for use.</td></tr>
</table>

3.3 Setup tab

The Setup tab is used to see the robot and probe connection status, and to select an ultrasound preset if available.

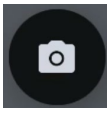
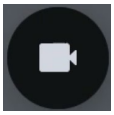
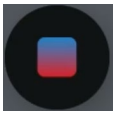
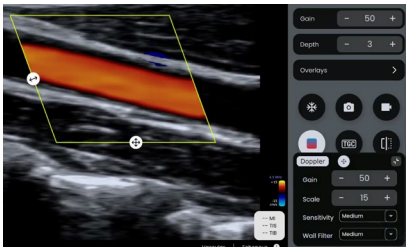
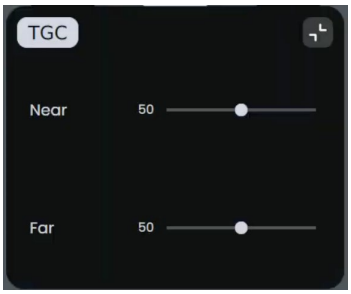


Features	Description / Capabilities
Robot Status	Robot status indicator: Displays “Connected” when robot is plugged in and ready for use, displays “Not Detected” when robot is disconnected or not ready for use.
Select from devices	1, 2, 3 displays devices connected from left to right respectively into the USB-C ports on the cart.
Preset	Dropdown shows Presets for the active ultrasound probe. Tap on the dropdown (>) to open the preset list, scroll by sliding finger vertically and tap to select the desired preset. Options will change based on the active ultrasound probe selected.

3.4 Controls tab

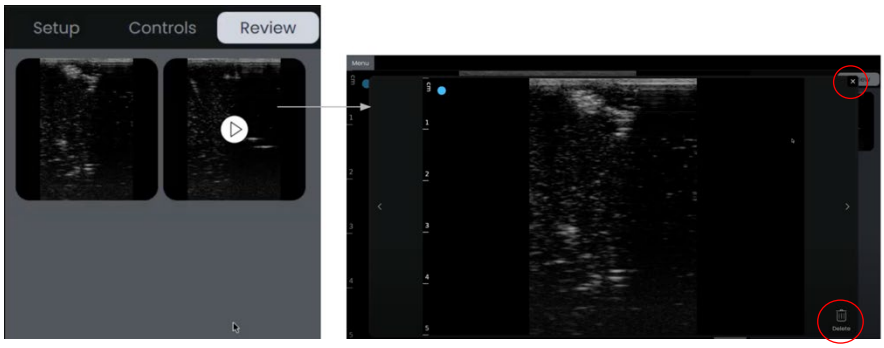
The Controls tab is used to access and modify system controls.

Feature	Capability and Use
Gain	Adjust the brightness of the ultrasound image. Tap the - / + to decrease/ increase the gain.
Depth	Adjust the imaging depth of the ultrasound probe. Tap the - / + to decrease/ increase the depth.
Overlays	Tap overlays to hide/show the midline, trajectory, and the instrument tip overlays on the live ultrasound image.
	Tap to freeze and unfreeze the live ultrasound image.

	Tap to capture a still frame of the ultrasound image.
	Tap to capture a prospective 10 second cine loop of the live ultrasound image.
	Tap to turn on and off the Color Doppler. A doppler window will appear to access doppler settings: Gain, Scale, Sensitivity and Wall Filter. 
	Tap to adjust the time gain control along near and far depth by sliding along the horizontal bars. Different options for TGC may appear for different ultrasound probes. 
	Tap to flip the live ultrasound image along the vertical axis.

3.5 Review tab

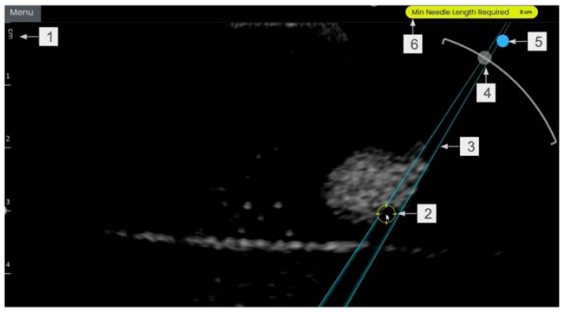
The Review tab is used to review still images and cine loops taken during the procedure (Screen Recordings are not saved here). It will be empty if no media was captured. Captured media can be reviewed by tapping on a thumbnail, which will open a new window on the screen. Delete an opened image/cine by tapping on the delete ( ) icon on the bottom right corner. Tap the cross (X) on the top right corner to close the window.

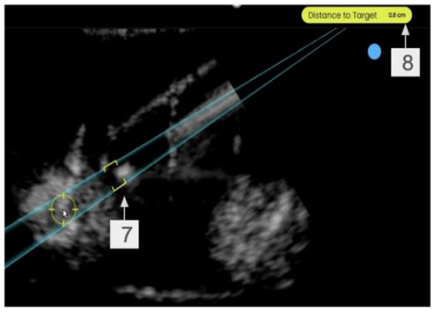


All images and cines will be saved under the software generated study name. To export images and cine loops to an external USB drive, navigate to the 'Study List' option in the menu. Only USB drives formatted as FAT32 are supported.

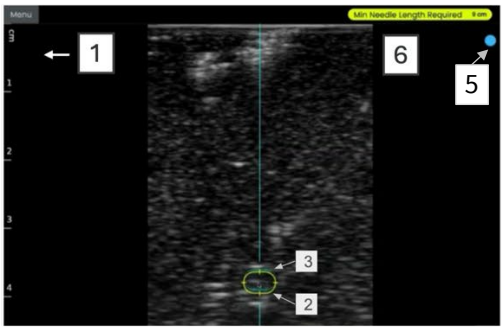
3.6 Live ultrasound image overlays

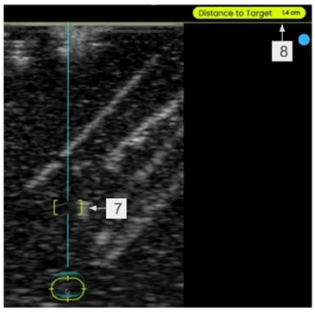
In-plane approach





Out-of-plane approach





#	Description
1	Ultrasound image depth scale in centimeters.
2	Virtual target location selected by the user; yellow circle for in-plane, yellow oval for out-of-plane.
3	Guidezone in-plane: blue lines represent anticipated instrument trajectory. Guidezone out-of-plane: blue oval represents anticipated intersection between the instrument and image plane. The trajectory error ranges from ±1.65mm to ±5.2mm depending on the insertion depth of the instrument. The planar error ranges from ±1.76mm to ±5.83mm depending on the insertion depth of the instrument.
4	Angle Adjustment with target lock: Adjust the instrument trajectory while maintaining the selected target. Dragging the angle adjustment will move the robot horizontally towards or away from the probe, depending on the angle selected. This feature is only available for the in-plane orientation.
5	Probe orientation mark: Corresponds to the physical orientation mark on the ultrasound probe.
6	Minimum needle length required: Only appears when a target has been selected and the needle has not yet been inserted. This value is based on the anticipated minimum distance from the end of the instrument guide to the selected target. The minimum needle length required value ranges from 3 cm to 20 cm, is rounded to the nearest 1 cm, and is accurate to the nearest 1 cm.
7	Instrument tip location, as estimated by software, continuously updates as the instrument is inserted/retracted. The color of the brackets can be yellow, blue, or red based on whether the system detects that the instrument tip location is before, at, or past the target location, respectively. The tip position error is ±1 mm.
8	Distance to target: Estimated distance from the instrument tip indicator to the center of the target icon. This value only appears if a target has been selected and the instrument is inserted. The distance to target value ranges from -17.1 cm to 17.1 cm and is rounded to the nearest 0.1 cm.

3.7 Auditory tones

For some notifications and functions, the Focalist System includes the following auditory single tones in addition to visual indicators:

- System errors and notifications displayed on GUI
- Instrument tip passes beyond the gauge insert
- Clutched button(s) are depressed

4 Chapter 4: Setup

This chapter provides step-by-step guidance to set up the Focalist System for a procedure.

⚠ WARNING	*Do not connect multiple socket-outlets or extension cords to the Focalist System. Failure to comply may cause the system to perform improperly and/or may cause injury to the patient or operator.*

⚠ CAUTION	*Always carefully inspect the Focalist System before and after use. Check the robot, cart, and other components for signs of damage such as cracks, chips, or abrasions. Use of damaged components may cause the Focalist System to perform improperly and/or result in injury to the patient or operator. If damage is suspected, discontinue use of the Focalist System and contact Mendaera Customer Support.*
⚠ CAUTION	*Do not use cables, probes, devices, and/or other components other than those specified for use with the Focalist System. Connecting devices improperly or substituting non-approved devices may cause the Focalist System to perform improperly and/or result in injury to the patient or operator.*

4.1 Cart placement and power on

1) Unlock the cart's wheels by pressing the "OFF" lever on the wheel brakes to move the cart.

2) Use the handle to push the cart to the desired location. Do not position the cart such that it is difficult to disconnect the main power cable from the power cable connection point.

3) Once positioned, lock the brakes of the cart by pressing "the ON" lever on the wheel brakes.

4) Position the cart monitor so that it is within arm's reach from your intended position for the procedure.

5) Ensure the cart is either plugged into a power outlet, or that the battery is sufficiently charged for the procedure.
Tip: Plug in the cart when not in use.

6) Power on the cart by pressing the power button on the front panel of the cart.

CAUTION *Avoid applying excessive force to the cart at or above the cart handle. Excessive force applied to the cart, especially when moving around turns and on slopes, may cause the cart to tip over and result in injury to the patient and/or operator.*

4.2 Plug in probe(s) and robot

1) Plug the ultrasound probe into any one of the USB-C ports on the cart's front panel. The ultrasound image will appear on screen when the probe has successfully connected.

2) Plug the robot cable to the robot.

3) Plug the robot into any available USB-C port on the cart's front panel, the "R" side of the cable connects to the cart. The LED indicator light on the top of the robot will turn dim white when the robot is successfully connected, and the "Robot Status" will show "Connected" on the Setup panel. Robot connection may take several seconds to appear.

4) Connected devices will appear on screen under "Select from devices" on the Setup panel. Ensure successful connections by ensuring that connected devices appear here.

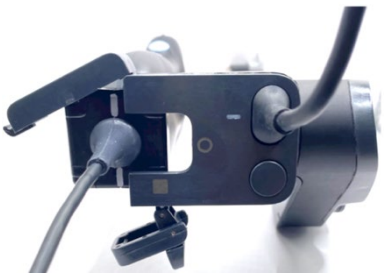
***Tip**: The USB-C ports on cart correspond (from left to right, respectively) with the 1, 2, and 3 positions under "Select from devices" on the "Setup" panel. When more than one probe is connected, tap on the probe to select it for imaging.*

4.3 Attach robot to the ultrasound probe

The system can be used to perform procedures using an in-plane or out-of-plane approach. To attach the probe:

1) Hold the robot in one hand and the probe in the other hand such that the cables are pointing up and the icons are visible on both the probe and robot.
2) Open the robot latch lock and the robot latch door.
3) Slide the top of the ultrasound probe into the top of the robot.

   a. For an in-plane approach, align the line (- -) markings on the probe with the filled square icon (▪) on the robot.



   b. For an out-of-plane approach, align the line (- -) markings on the probe with the circle outline icon (◯) on the robot.

4) Close the robot latch door and robot latch lock to secure the robot onto the probe. The LED will turn bright white, and the robot will energize and hold its position when the latch is properly closed.

4.4 Draping the system components

4.4.1 Prepare robot and probe for draping

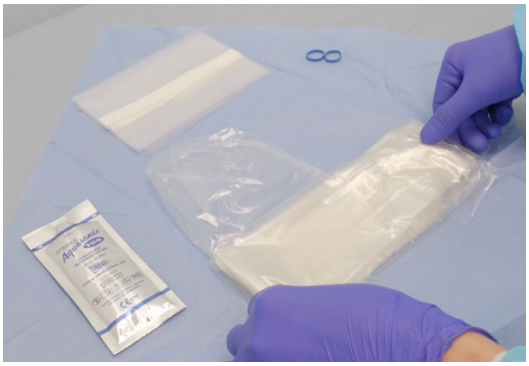
1) Hold the probe with your scanning hand and press the two green clutch buttons with your other hand to move the robot to the opposite side of the probe.

***Tip**: Keep about a 4-5 cm distance between the probe and the end of the robot to create enough space to drape the robot easily. An image will appear on the screen to show best position for draping.*

2) Place the probe and the robot in the cart holder such that the probe is pointing up.

***Tip:** If an assistant is available to help, skip the above step and have the assistant present the probe and robot to you with the gel on the probe when ready for draping.*

3) Choose the appropriate drape package and empty the contents onto the sterile field. Refer to **2.2.3 Drapes** for more information on drape package types.



4.4.2 Robot only drape setup (for clean technique)

1) Open the Robot Drape Kit onto a sterile field using sterile technique.

2) Place your thumb and index finger inside the pocket on the open end of the drape, such that the arrow is pointing away from your hand. The arrow indicates the direction that goes over the robot.

3) Place the drape over the robot to cover the entire length of the robot. Pull the drape up until the elastic has reached the top of the robot.

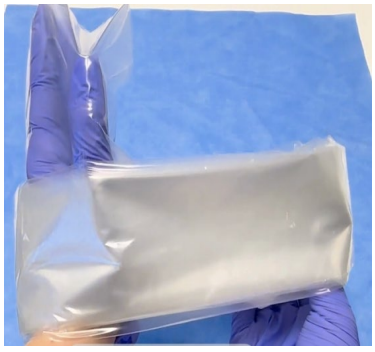
4) Press the gray sterile mount onto the silver end of the robot.

***Tip**: Attaching the gray sterile mount will NOT make a "click" sound; it is simply pressed on*

4.4.3 Probe and robot drape setup (for sterile procedure)

1) Open the Probe and Robot Drape kit onto a sterile field using sterile technique.

2) Place an appropriate amount of gel inside the drape and/or on the probe. Poor imaging may result if no gel is used.



3) Place one hand into the probe pocket, the other hand into the center of the drape folds and hold the drape taut.

4) Capture the probe through the drape with the hand in the probe pocket, while simultaneously using the other hand to capture the robot. Pull the drape over the entire length of the device and the cables

5) Pull the drape tightly over the probe face to remove wrinkles and air bubbles. Take care to avoid puncturing the drape.

6) Secure drape over the probe with enclosed elastics.

7) Press the gray sterile mount onto the silver end of the robot.

***Tip**: Attaching the gray sterile mount will NOT making a "click" sound; it is simply pressed on*

4.4.4 Touchscreen drape setup

1) Remove the adhesive strips from the screen drape and apply the drape to the touchscreen by applying the adhesive strips to the top and the bottom edge of the screen.

CAUTION	*Do not re-use a compromised sterile barrier. Re-using a compromised sterile barrier may result in an infection risk.*

4.5 Choose the appropriate instrument

Open the instrument to be used for the procedure in the sterile field.

NOTE	*Instruments from 14 to 25 gauge are compatible with the Focalist System.*
NOTE	*Instruments will lose 3.1 cm of working length when attached to the universal adapter. Consider this loss of working length when selecting an instrument; choose an instrument of sufficient length to reach the target.*

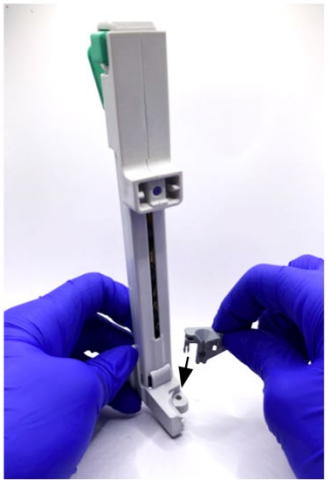
4.6 Set up the Universal Instrument Guide Kit

1) Open either the Short or Long Universal Instrument Guide Kit and place it onto a sterile field using sterile technique. Refer to **2.2.4 Universal Instrument Guide Kit** for more information on instrument length compatibility.

> **⚠ CAUTION** *Ensure the selected instrument is within the instrument guide's maximum compatible length. Using an instrument longer than the maximum compatible length may result in inaccurate tip indicators and/or injury to the patient.*

2) Choose and remove the appropriate size gauge insert from the gauge insert tree.

3) Insert the gauge insert: Hold the instrument guide with green button at the top. Place into the hole at the bottom of the instrument guide and snap it closed.



> **⚠ CAUTION** *Ensure the gauge insert is snapped closed prior to instrument insertion. Failure to follow these instructions may result in inaccuracy between the instrument position and the guidezone and/or injury to the patient.*

4) Install the instrument guide on the robot: Use the green clutch buttons to move the arm one to two centimeters away from the probe. Position the robot so that the gray guide lock is facing up and the gray sterile mount is facing towards you. Ensure that the gray guide lock is pushed away from the instrument guide toward the robot arm i.e. in the unlocked position.

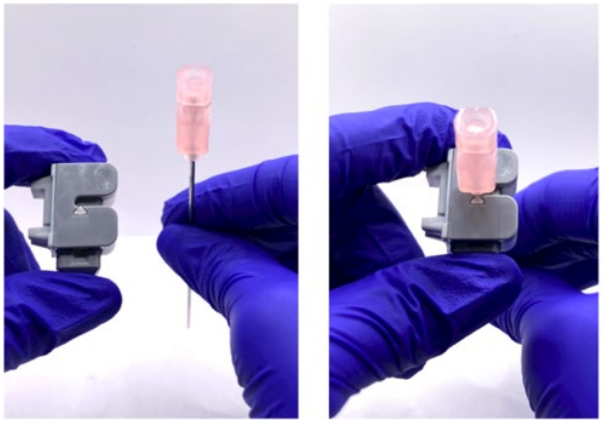
5) Slide the instrument guide onto the gray sterile mount.

6) Push the gray guide lock (under the drape) towards the instrument guide until it clicks into place. The guide is now locked on the robot.

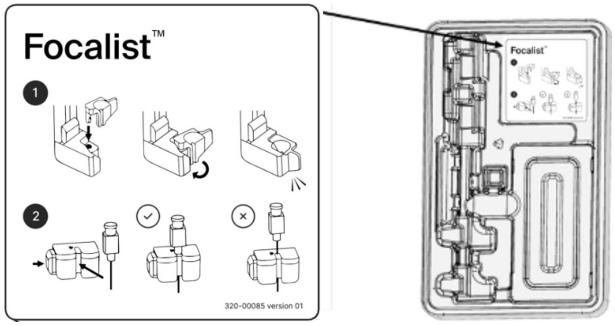
7) The LED on top of the robot arm will turn blue, indicating that the robot is ready for targeting.

4.7 Set up the Universal Adapter

1) Ensure the gray side of the universal adapter is facing up towards the instrument hub.
2) Push the adapter button on the side of the universal adapter and slide the instrument in, allowing it to clamp onto the shaft of the instrument touching the hub of the instrument.



***Tip**: The information sticker on the instrument guide kit highlights important steps before starting a procedure*



⚠ WARNING *Always clamp the instrument adapter at the hub of the instrument. Failure to do so could result in inaccurate tip indicators and lead to serious patient injury.*

⚠ CAUTION *Ensure that the gray face of the instrument adapter is pointing towards the hub. Incorrect installation of the instrument adapter may result in sudden detachment of the adapter from the carriage, unintended motion of the instrument, and/or injury to the patient.*

5 Chapter 5: Procedure

The Focalist System can perform in-plane or out-of-plane ultrasound-guided interventions. Decision for in-plane or out-of-plane should be made prior to setting up the system. Refer to **Section 4.3** for more information. This section describes how to perform targeting with the Focalist System.

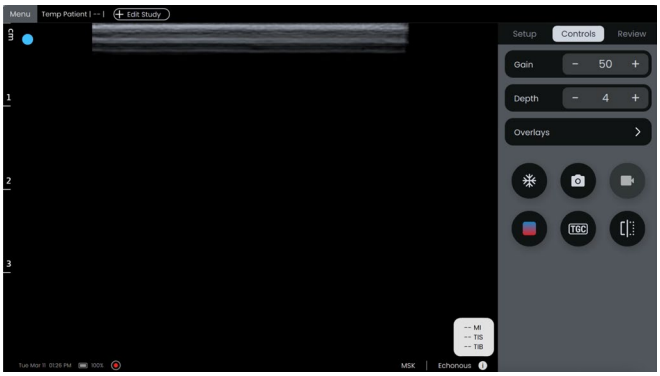
The region of the robot arm between joints 9a and 9c (indicated in **Section 0**) may reach up to 44 °C during normal use. It is recommended to avoid prolonged contact (greater than 10 minutes) between the specified region and the patient.

5.1 Optional steps to perform or check at the start of the procedure

1) Select the desired preset by scrolling through the list under the “Setup” tab on the right-side panel of the touchscreen.

2) Click on the “Controls” tab and adjust the ultrasound image gain and depth as desired, if the preset values are not acceptable.

3) Check the left-right orientation using the blue dot on the probe and the screen.



5.2 Prepare the instrument

1) Slide carriage to the top of the instrument guide.

2) Attach the instrument by inserting the prongs of the universal adapter into the connection point on the carriage. It will attach via a magnetic connection.

3) Ensure the instrument tip is inserted just past the opening of the gauge insert to cover the sharp tip before ready for use and so that the instrument can advance easily when ready to insert.

4) Lock carriage in place by moving the green insertion brake to approximately 45-degree angle in either direction or until lever retains position. Move brake to vertical position to unlock.

Tip: *When using a heavy instrument, such as a biopsy gun, attach the instrument to the guide only when ready to insert.*

⚠ CAUTION *Ensure that heavy instruments are physically held or supported while they are connected to the system. Failure to do so may cause the robot to de-energize and lead to unintended motion of the instrument and/or injury to the patient.*

5.3 In-plane procedure

1) Scan the patient and locate the desired anatomical target under live ultrasound imaging.

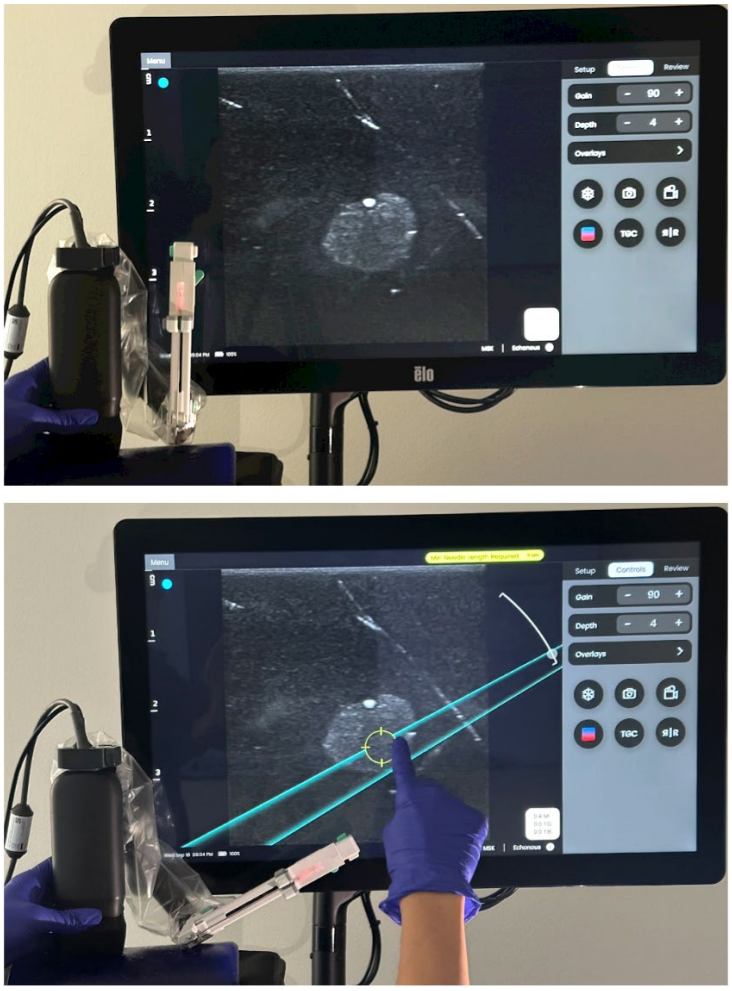
2) Once the target has been found, press the green clutch button(s) on the robot and lower the robot to the desired instrument entry site on the patient's skin.

Tip*: Lowering the robot to the skin maximizes the working length of the instrument.*

3) While holding the probe still, tap on the desired target on the live ultrasound image. A yellow target appears to indicate the tapped location.

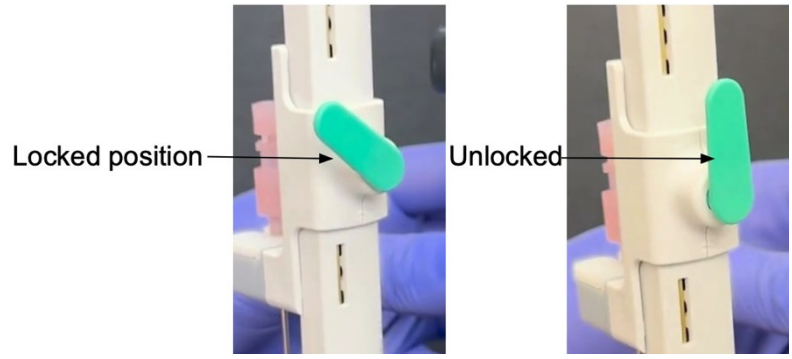
4) The robot will move and aim at the target and the Guidezone will align with the yellow target.

***Tip**: Re-tap or drag the existing target icon to adjust to a new target location. Press the green clutch buttons on the robot to clear the target and re-select as desired.*

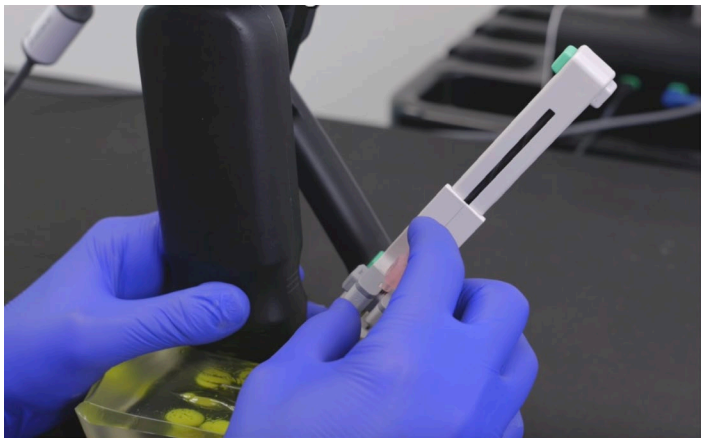


NOTE *The selected target is not coupled to the underlying ultrasound image. If you move the ultrasound probe, the on-screen target will not maintain its relationship to the ultrasound image.*

5) While continuing to hold the probe still, unlock the insertion brake by moving it to the vertical position.



6) Advance the instrument by pushing down on the instrument's hub.



CAUTION *Avoid moving the probe following instrument insertion. Probe movement following instrument insertion could bend the instrument and result in inaccuracy between the instrument position and the guidezone and/or injury to the patient.*

NOTE *Push the instrument from its hub to avoid the instrument slipping backwards relative to the adapter during insertion.*

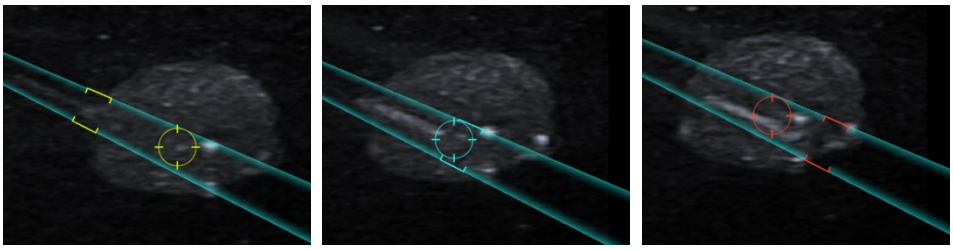
7) The instrument tip indicator, rectangular yellow brackets (for in-plane procedures), will be displayed on the screen to indicate the estimated instrument tip depth.

NOTE *The instrument tip indicator may indicate any portion of the needle tip, depending on the type of bevel and its orientation as it passes through the insert.*

8) If a target is selected, the instrument tip indicator color will change from yellow to:
    a. Blue, upon reaching the target indicator

b. Red, upon over insertion beyond the selected target location

9) The color of the border around the ultrasound image and the 'distance to target' indicator at the top right of the screen will also update to yellow, blue, or red, to correspond to the instrument tip indicators.



WARNING	*Do not over insert the instrument. Over inserting the instrument could result in serious patient injury.*
WARNING	*Do not let go of the instrument if the robot de-energizes while an instrument is inserted into the patient. Failure to maintain control of the instrument while the robot is de-energized could lead to serious harm to the patient.*

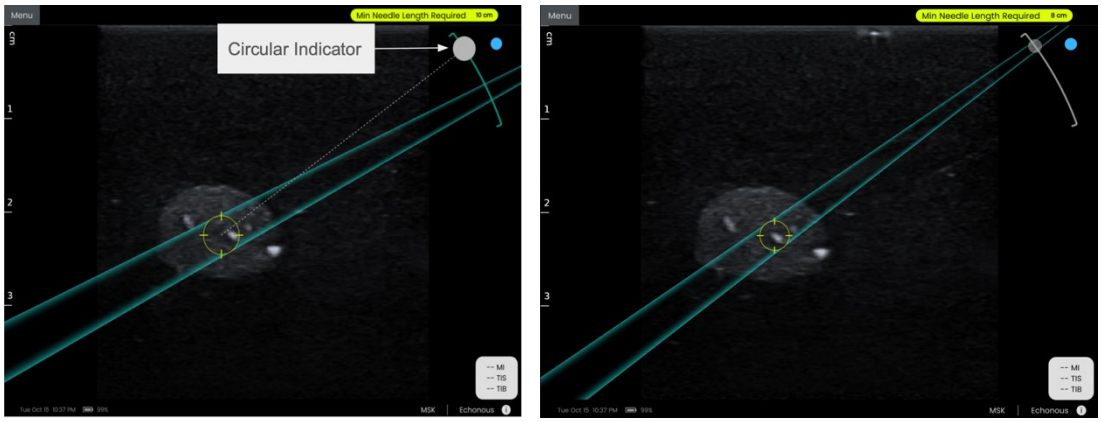
***Tip**: To prevent insertion or retraction of the instrument, engage the insertion brake.*

5.4 Adjusting trajectory for an in-plane procedure

Before inserting the needle, the insertion angle can be changed without changing the target. This is helpful for approaching anatomy from a specific angle or avoiding critical structures along the needle's path.

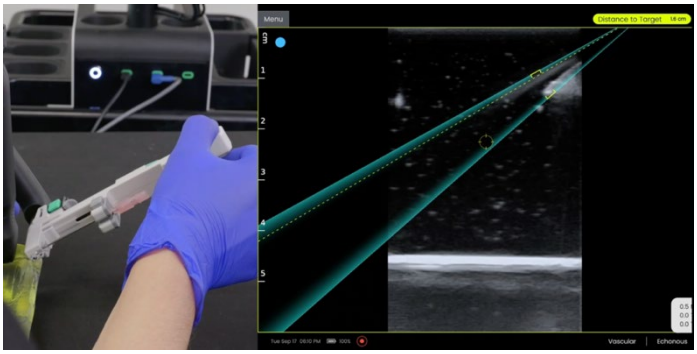
5.4.1 Adjusting instrument trajectory if a target is selected and the needle is not inserted

1) On the touchscreen, slide the circular indicator on the arc to choose a new trajectory while maintaining the selected target.
2) The robot will move to align to the new trajectory chosen. This will also change the instrument entry site.
3) The 'Min Needle Length Required' will update accordingly.



5.4.2 *Adjusting instrument angle using the pitch buttons*

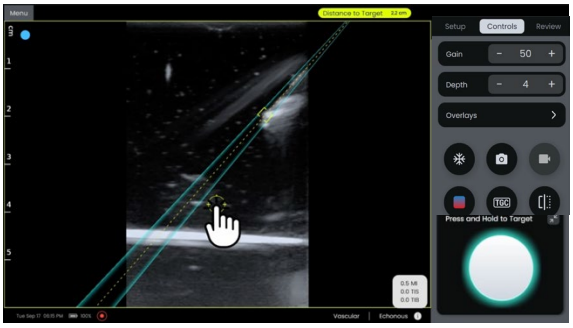
1) Press the green angle adjustment button at the top of the instrument guide and angle the guide to desired position. Releasing the button will lock the guide's position.
2) Guidezone will widen to include the new trajectory of the instrument insertion.
3) The target icon will dim indicating that the instrument trajectory was adjusted.
4) The 'Distance to Target' will update with respect to the new trajectory.



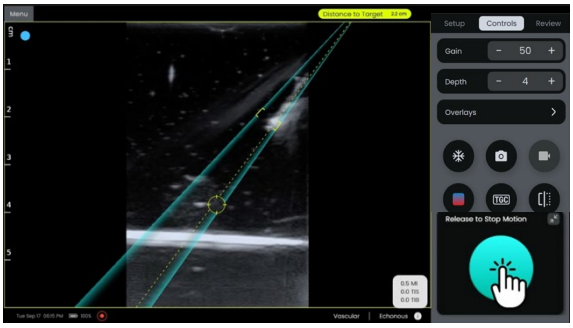
5.4.3 *Creating or changing a target when an instrument is inserted*

It is possible the needle could diverge from the Guidezone, for reasons such as needle deflection due to tissue resistance, manufacturing tolerance, and needle size. Thin needles may deflect more. A feature of the system allows you to adjust the needle angle after insertion, useful for correcting deflection or avoiding structures.

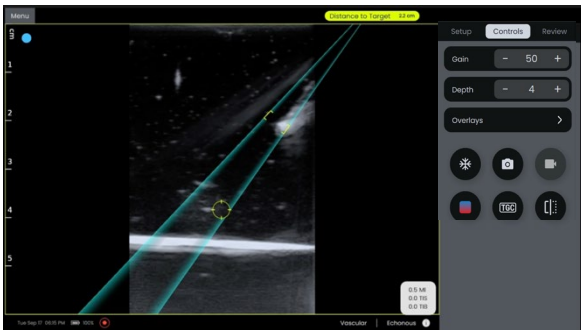
1) Click on the touchscreen for a new target location or drag the existing target icon to the new desired position.



2) Press and hold the circular button in the picture-in-picture window at the bottom right corner of the screen to aim at the new target.



3) The Guidezone will grow to include the new target location and the “Distance to Target” indicator will update. A dotted line will also appear to indicate trajectory movement.



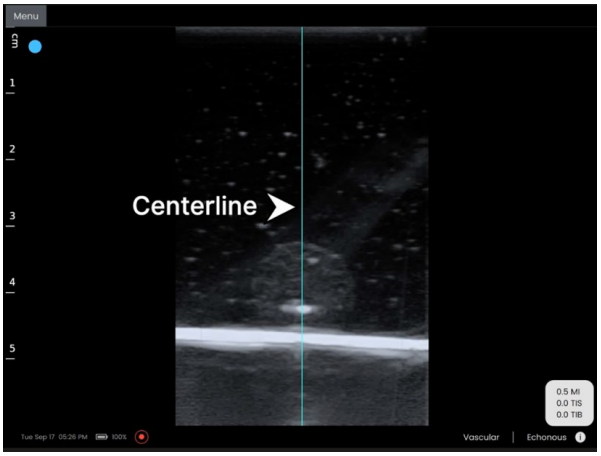
CAUTION *Remain aware of your instrument position at all times. The guidezone will widen when the instrument angle is adjusted after instrument insertion. To reset the guidezone, retract the instrument. Failure to comply may result in unintended motion of the instrument and/or injury to the patient.*

5.5 Out-of-plane procedure

1) Scan the patient and locate the desired anatomical target under live ultrasound imaging.

2) Move the probe such that the blue centerline on the screen intersects with the desired target.

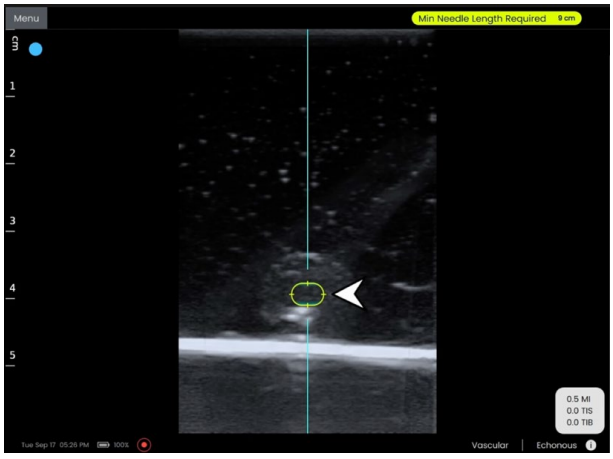
3) Once the target has been found, press the green clutch button(s) on the robot and lower the robot to the desired instrument entry site on the patient’s skin.



***Tip**: Lowering the robot to the skin maximizes the working length of the instrument.*

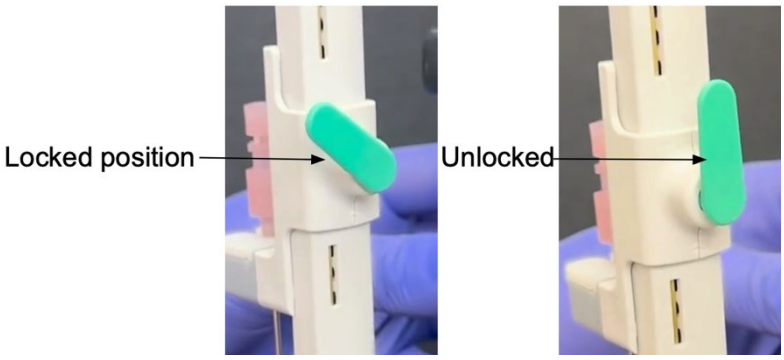
4) While holding the probe still, tap on the desired target on the live ultrasound image. A yellow target appears to indicate the tapped location.

5) The robot will move and aim at the target and the guidezone will align with the yellow target.



NOTE *The selected target is not coupled to the underlying ultrasound image. If you move the ultrasound probe, the on-screen target will not maintain its relationship to the ultrasound image.*

6) While continuing to hold the probe still, unlock the insertion brake by moving it to the vertical position.



7) Advance the instrument by pushing from the instrument's hub.

CAUTION *Avoid moving the probe following instrument insertion. Probe movement following instrument insertion could bend the instrument and result in inaccuracy between the instrument position and the guidezone and/or injury to the patient.*

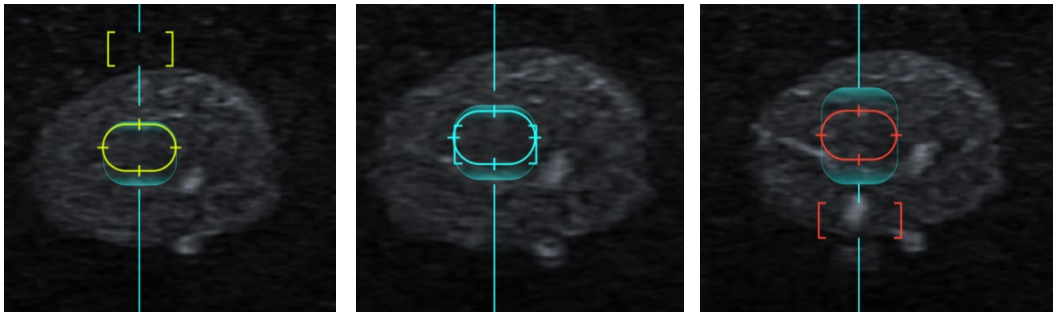
NOTE *Push the instrument from its hub to avoid the instrument slipping backwards relative to the adapter during insertion.*

8) The instrument tip indicator (rectangular yellow brackets for an out-of-plane approach) will be displayed on the screen to indicate the estimated instrument tip depth.

NOTE *The instrument tip indicator may indicate any portion of the needle tip, depending on the type of bevel and its orientation as it passes through the insert.*

9) If a target is selected, the instrument tip indicator color will change from yellow to:
    a. Blue - upon reaching the target indicator.
    b. Red - upon over insertion beyond the selected target location.

The color of the border around the ultrasound image and the 'distance to target' indicator at the top right of the screen will also update to yellow, blue, or red, to correspond to the instrument tip indicator.

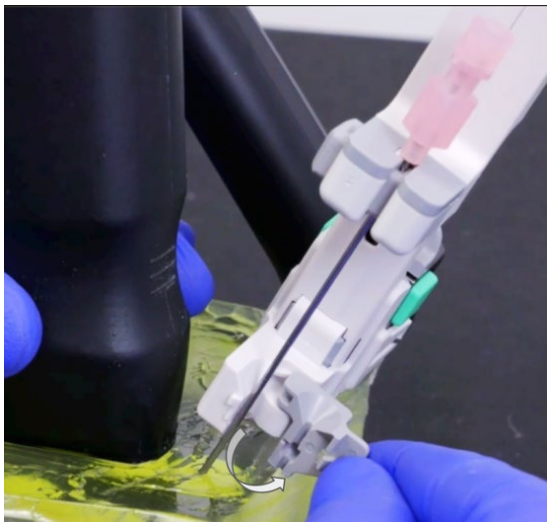


WARNING	*Do not over insert the instrument. Over inserting the instrument could result in serious patient injury.*
WARNING	*Do not let go of the instrument if the robot de-energizes while an instrument is inserted into the patient. Failure to maintain control of the instrument while the robot is de-energized could lead to serious harm to the patient.*

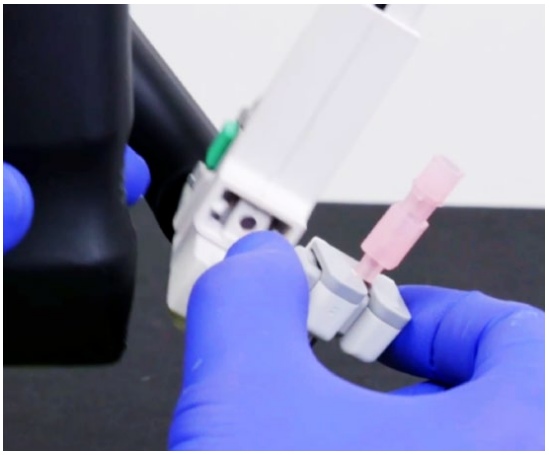
***Tip**: To prevent insertion or retraction of the instrument, engage the insertion brake.*

5.6 Disengaging the instrument from the robot

1) Open the gray insert on the instrument guide to expose the instrument shaft.



2) Carefully twist the instrument adapter off the instrument guide until the magnet is completely disconnected from the instrument guide carriage. The instrument is now disengaged from the robot.



Tip: *You should not press the button on the adapter, but it is a convenient grab point to gently pivot the adapter off the hub.*

5.7 Switching hands mid-procedure

1) Press the clutch buttons to unlock the robot arm.

2) Rotate the robot arm down under the probe. Rotate the instrument guide upside-down so that it clears the body of the probe.

3) Switch hands for holding the probe
4) Bring the instrument guide right-side up again.

Refer to **Chapter 7** for guidance on teardown, cleaning, and storage of the Focalist System.

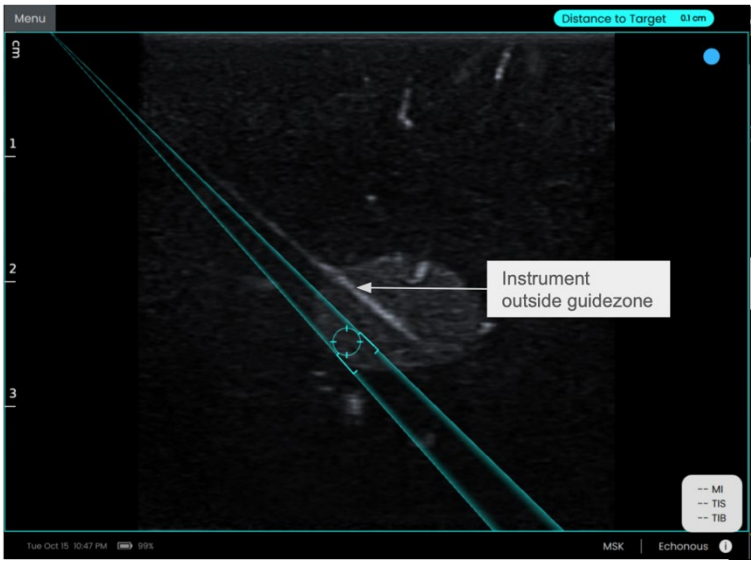
6 Chapter 6: Troubleshooting

6.1 Emergency scenarios

Scenario	Steps
Emergency Access to Patient Site	1. Retract instrument if inserted into patient 2. Put the robot and probe aside to access the patient site
Unexpected system motion	1. Retract instrument if inserted into patient 2. Move the robot away from the patient
Restarting system mid-procedure	1. Retract instrument if inserted into patient 2. Tap on “Menu” 3. Select “Shutdown” listed in the menu 4. Select “Restart” from the options provided in the pop-up window

6.2 Procedural troubleshooting

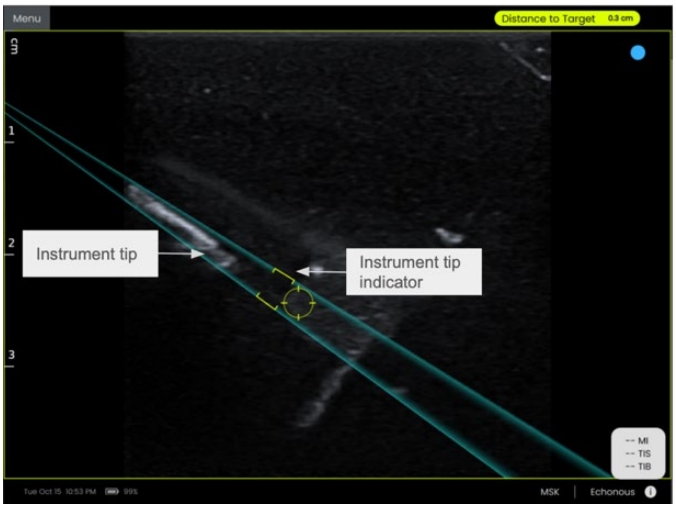
6.2.1 If the instrument does not follow the guidezone



- Check that the gauge insert is snapped shut
- Make sure the instrument is straight and not curved
- Ensure your probe hand doesn’t move when inserting the instrument
- If needle is deflecting in tissue, then compensate by adjusting the planned trajectory accordingly. Refer to **5.4 Adjusting Trajectory**.
- Variations in needle characteristics and tissue properties can lead to deviations from the intended needle path, such as:

- Needle barrel to needle clearance or strength
- Manufacturing tolerances
- Needle deflections due to tissue resistance during insertion
- Selection of needle size, as thinner needles are more susceptible to deflection

6.2.2 Depth indicator doesn't look accurate



Check the adapter has not detached from the instrument carriage and ensure to advance from the hub to avoid slippage.

6.3 System issues

Contact Mendaera Support at any time using the contact information in **6.4 Customer Support Contact**.

Issue	Troubleshooting Steps
Cart and Touchscreen	
System does not turn on after pressing power button	• Ensure the system is plugged into wall power for up to 8 hours for the battery to be fully charged prior to use. • Ensure battery has power and/or is plugged into wall. • Ensure the power button is depressed fully such that the LED around the button lights up to indicate success.
Blank screen or screen no longer updates	• Check that the cable connections at the back of the touchscreen monitor are fully plugged in and have not become loose during operation. • If issue persists, shut down the system, wait for 10-15 seconds, and reboot the system.

Issue	Troubleshooting Steps
Touchscreen unresponsive to touch	• Check that the cable connections at the back of the touchscreen monitor are fully plugged in and have not become loose during operation.
Probe and/or robot connected to cart but not detected on GUI	• Unplug and re-plug the device • If issue persists, unplug and re-plug into another USB-C port on the cart. • If issue persists, restart the system.
Robot	
Robot latch not latching while attaching to the probe	• Ensure the probe fully slides in the square slot. • Ensure drape is not getting caught inside the latch.
Robot unexpectedly de-energizes i.e. it's not holding its position	1. Check if there are any system notifications on the screen indicating recovery steps. 2. Retract the instrument. 3. Unplug and re-plug the robot. Choose a different USB-C port if necessary. 4. A notification will pop up indicating to complete robot setup. 5. Complete the robot setup by pressing the clutch buttons and rotating the three joints until the message disappears. 6. Continue with the procedure if the issue is resolved.
Robot is dropped	• Inspect the robot for visible damage.
Probe	
Probe issues	• Ensure probe is plugged into cart securely. • Refer to ultrasound probe manufacturer's IFU (Link/location provided in **2.4 Compatible Ultrasound Probes**).
Software	
System Faults on GUI not clearing	1. Check that all recovery steps provided on the GUI are completed correctly. 2. Perform a reboot: press and hold the power button until the system shuts down. Power on the system by pressing the power button. 3. If all recovery steps have been completed and the fault condition remains unresolved, the system will automatically escalate specific faults to a Critical Error after 10 seconds. Once escalated, the system

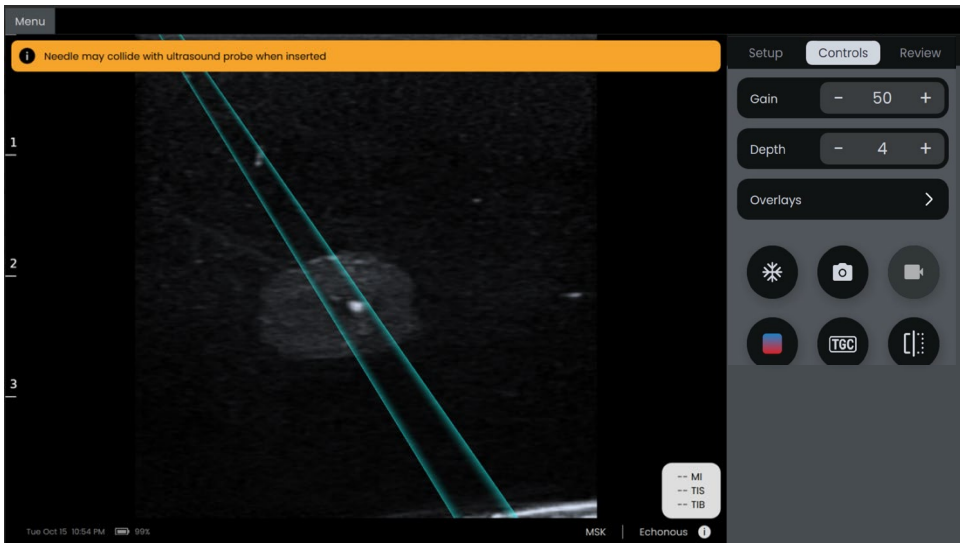
Issue	Troubleshooting Steps
	will display an option to restart. More information provided on the Critical Error state in **6.3.1.3 *Non-recoverable Errors***.
High system latency	If the system's latency exceeds the verified threshold of 300 milliseconds, a recoverable error message will be displayed. Refer to **Section 6.3.1.2** for more information on recoverable errors.
Hardware	
Package damaged	• Carefully inspect the components within the package for any damage. • If damage is observed, do not use the components. • If damage is observed or the components do not function as expected, contact Mendaera Customer Support.
Sterile package unintentionally opened	• Do not use a compromised sterile barrier. • Contact Mendaera Customer Support to order additional supply.
Expired consumables	• Do not use expired consumables. • Contact Mendaera Customer Support to order additional supply.

6.3.1 System faults on GUI

The system will notify the user of the system state through a notification banner or an error message pop-up window and an audible single tone.

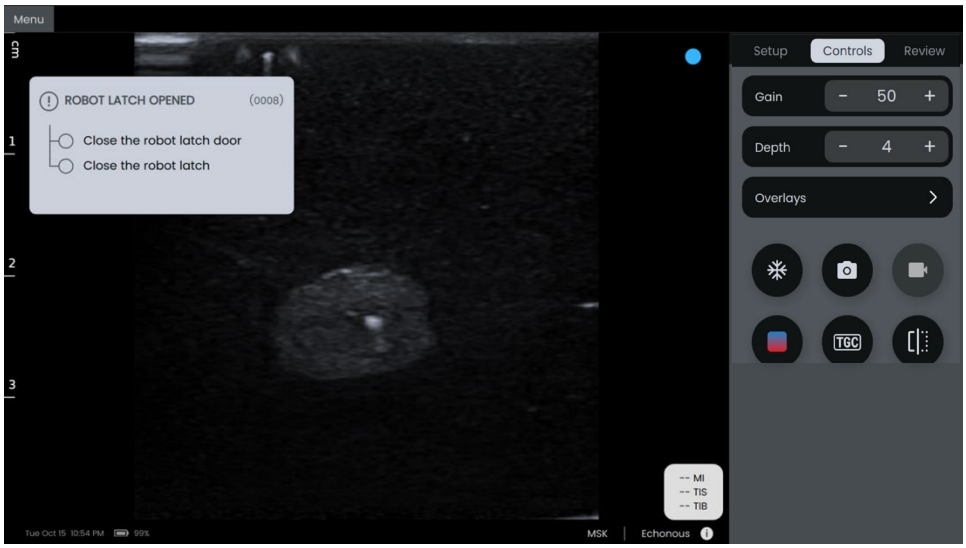
6.3.1.1 Notification

The system displays notifications in an orange banner, which will either persist until the user resolves the notification or will automatically clear after a few seconds.



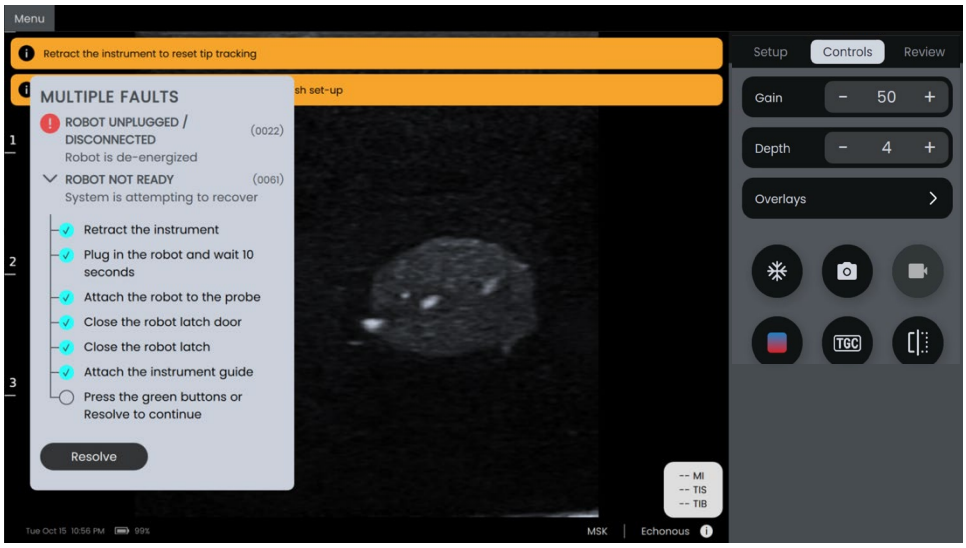
6.3.1.2 Recoverable errors

In the event of a recoverable error state, an error message banner will appear and list the recovery steps required.



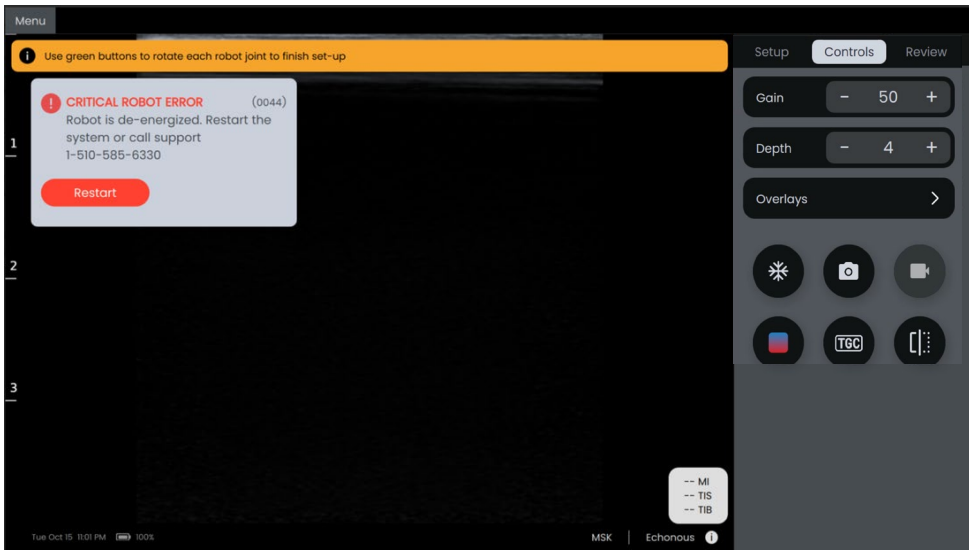
For some recoverable errors, the robot will de-energize (will not stay locked in its position) and the error message will notify the state. As you complete the recovery steps, the steps will be checked off and the banner will disappear automatically. Continue with the procedure.

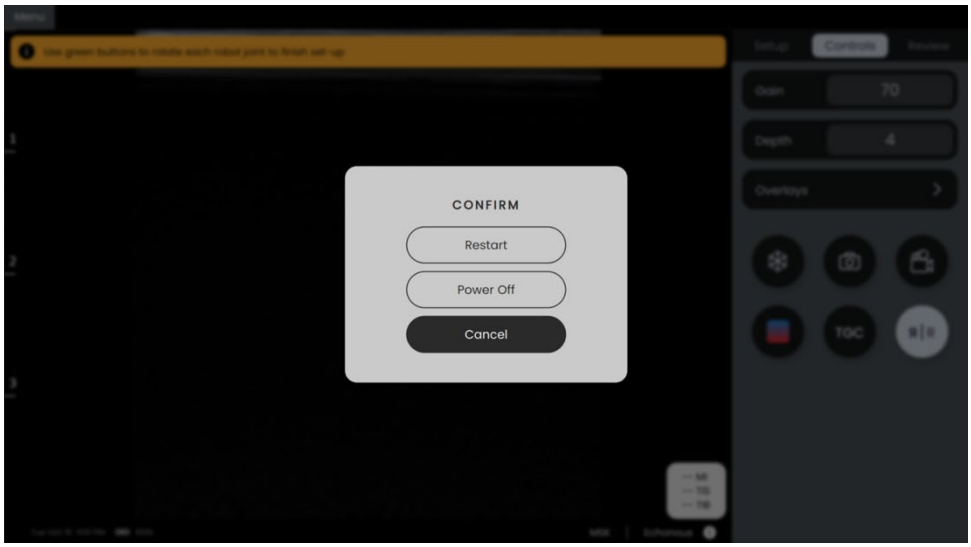
If all recovery steps have been completed and the fault condition remains unresolved, the system will automatically escalate specific faults to a Critical Error after 10 seconds. Once escalated, the system will display an option to restart. More information provided on the Critical Error state in **6.3.1.3 *Non-recoverable Errors***.



6.3.1.3 Non-recoverable errors

In the event of a non-recoverable error state, the handheld robot will de-energize and system shutdown/restart will be required. Retract the instrument if it inserted into the patient. Press the “Restart” button provided in the error message pop-up. Choose Restart to continue system usage or Power Off the system. During this error state, the ultrasound image is still live. The other GUI buttons will be deactivated.





WARNING *Do not let go of the instrument if the robot de-energizes while an instrument is inserted into the patient. Failure to maintain control of the instrument while the robot is de-energized could lead to serious harm to the patient.*

6.4 Customer support contact

Use the following information to contact Mendaera Customer Support, including to order products, report feedback or adverse events, and solicit information about products and services offered by Mendaera, Inc.

Mendaera, Inc.
700 South Claremont St., Suite 200
San Mateo, CA 94402 USA
877-636-3237
support@mendaera.com

Have the following information available when contacting Mendaera Customer Support.

- Serial/ lot number, product name, unique device identifier (UDI), and/or catalog number
- System version number
- Conditions under which the problem occurred
- Fault IDs and messages that have been displayed

7 Chapter 7: Teardown, Cleaning, and Storage

7.1 System teardown

1) Disconnect the instrument guide from the robot
    a. Push the gray lock (under the drape) on the robot away from the instrument guide until it releases the instrument guide.

2) Dispose of the consumables:
    a. Universal adapter
    b. Instrument guide
    c. Drapes
3) Unlatch the robot from the probe
4) If desired, from the menu options on the touchscreen, choose “Shutdown” to power down the system post use. The images and cines captured are not accessible once the system is shutdown.

CAUTION *Do not drop the Focalist System. Dropping the Focalist System may cause damage. Check the robot, cart, and other components for signs of damage such as cracks, chips, or abrasions. Do not use the system if there is any sign of damage. Use of damaged components may result in risk of electrical hazards, cause the Focalist System to perform improperly, and/or result in injury to the patient or operator.*

NOTE *Follow hospital, local, and state policies and guidelines for handling used medical devices.*

7.2 Robot cleaning and disinfection

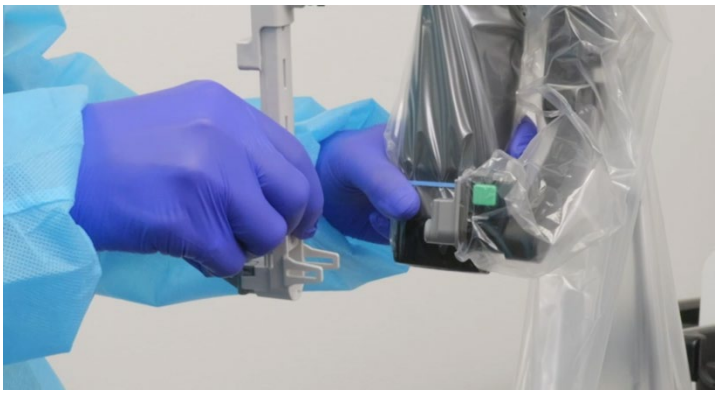
The robot has been demonstrated to be compatible with the following cleaning and disinfection agents:

- Super Sani-Cloth® Germicidal Disposable Wipes by PDI, Inc.
- Metrex CaviCide1 Surface Disinfectant Cleaner (Spray)

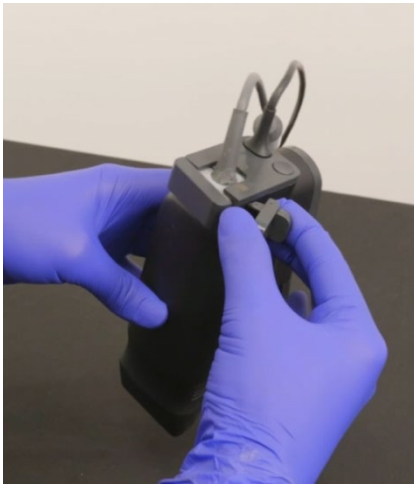
7.2.1 Cleaning - Robot

> **NOTE** *Do not submerge the electromechanical arm.*

1) Unplug the robot and compatible ultrasound probe from the cart.
2) Remove and discard the single-use sterile drape and instrument guide.

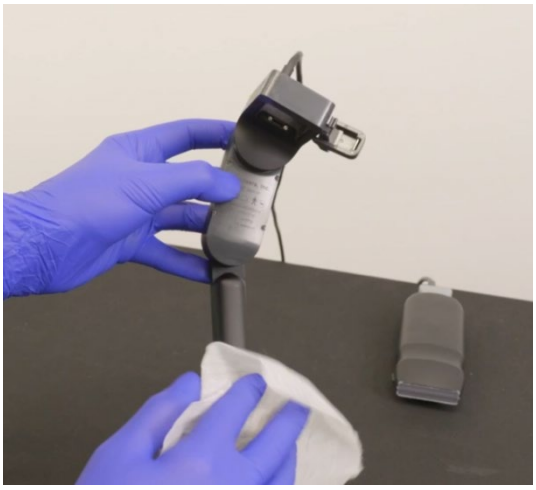



3) Remove any ultrasound gel and visible contaminants from the probe and robot by wiping them with a compatible disinfecting wipe or a clean lint-free cloth.
4) Unlatch the robot from the probe so that they can be cleaned separately. Compatible ultrasound probes should be cleaned as per the manufacturer's instructions.




5) Wipe the cable up to the connector with a fresh compatible disinfecting wipe or lint-free cloth until visibly clean.


6) Wipe the robot with the compatible disinfecting wipe or clean lint-free cloth until the robot is visibly clean. Clean the buttons, the probe latch at the top of the robot, the silver end of the robot and the green buttons. Rotate all joints to reach all surfaces.




7) Inspect the robot and cable in a well-lit area to ensure cleanliness. Change the wipes as necessary and repeat the above steps until the robot is visibly clean.

7.2.2 Disinfection - Robot

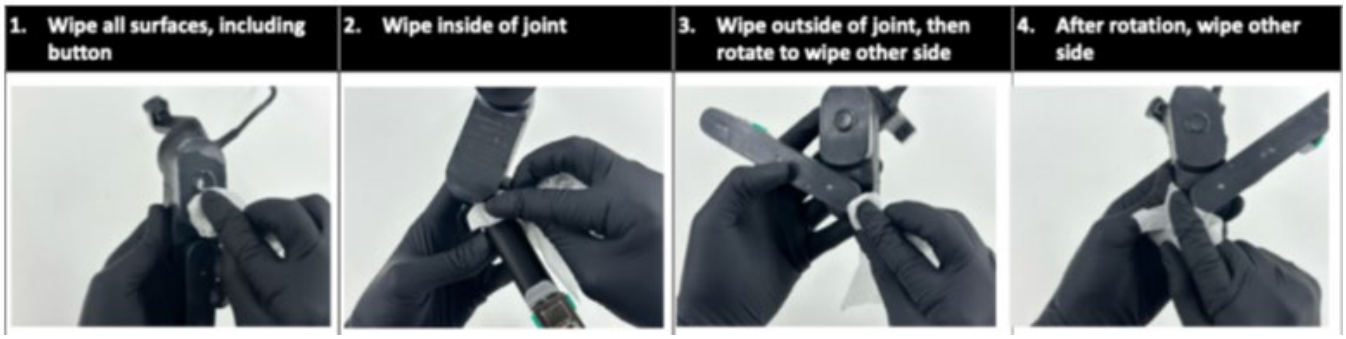
Disinfection of the robot can be accomplished by wiping then spraying the three robot segments pictured below, following the detailed instructions in this section.

NOTE *Do not submerge the electromechanical arm.*

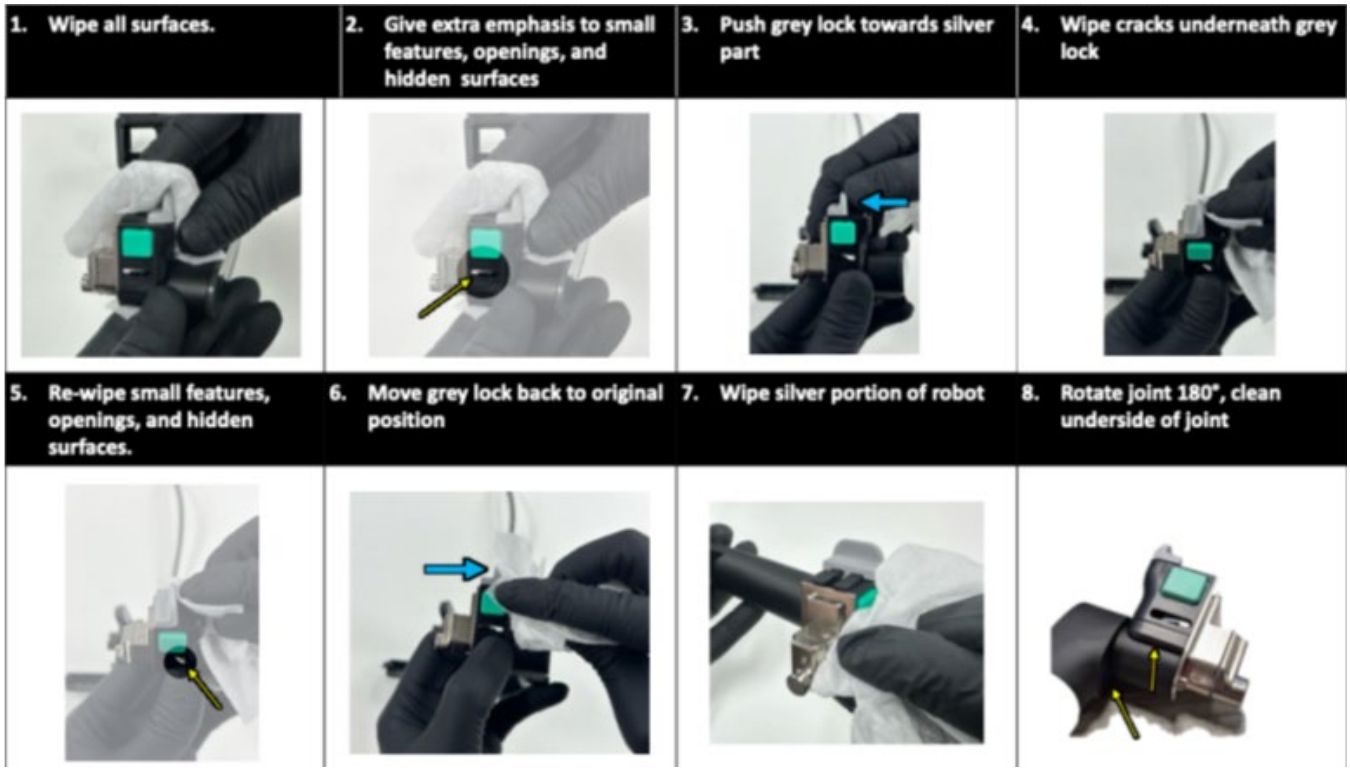
1) Before disinfection, clean the robot and its cable in accordance with the cleaning procedure above.
2) Wipe the robot with a compatible disinfecting wipe, following the instructions below. Ensure all surfaces remain visibly wet for 5 minutes, including seams, buttons, cracks, and recessed areas. Use additional wipes as needed.

i. Wipe the probe mounting feature and latch.

ii. Wipe the robot arm.



iii. Wipe the end effector.



3) Allow the robot to air dry.
4) Inspect the robot for signs of damage, such as cracks or dents. If any damage is found, contact Mendaera Customer Support.

> **⚠ CAUTION** *Always carefully inspect the Focalist System before and after use. Check the robot, cart, and other components for signs of damage such as cracks, chips, or abrasions. Use of damaged components may cause the Focalist System to perform improperly and/or result in injury to the patient or operator. If damage is suspected, discontinue use of the Focalist System and contact Mendaera Customer Support.*

7.3 Cart cleaning and disinfection

The cart has been demonstrated to be compatible with the following cleaning and disinfection agents:

- Super Sani-Cloth® Germicidal Disposable Wipes by PDI, Inc.
- Metrex CaviCide1 Surface Disinfectant Cleaner (Spray)

7.3.1 Cleaning - Cart

1) Power off and unplug the cart.
2) Remove the single use touchscreen cover.

3) Wipe visible dirt or contamination from exposed surfaces with a compatible disinfecting wipe or lint-free cloth until visibly clean. Focus on the touchscreen, handlebars, power button, and input/output panel. For stubborn stains, use a cloth with neutral detergent or water, then let the surface air dry.

1. Touchscreen	2. Handle	3. Power button	4. Input/Output panel
			

WARNING *Do not spill or allow fluids into the Focalist System's cart. Failure to comply may result in damage to the Focalist System, fire, electrical shock, or even death to the operator or patient.*

4) Visually inspect the cart in a well-lit area to ensure all surfaces are clean. If soil is still visible, repeat Step 3 until the cart is clean.

7.3.2 Disinfection - Cart

1) Before disinfection, clean the cart in accordance with the cleaning procedure above.
2) Wipe the cart with a compatible disinfecting wipe, using additional fresh wipes as needed. Focus on high-contact areas like the touchscreen, handle, power button, and input/output panel.

1. Touchscreen	2. Handle	3. Power button	4. Input/Output panel
			

3) Keep all surfaces visibly wet with disinfectant for 2 minutes, using additional wipes as needed.
4) Allow the cart to air dry.

⚠ CAUTION *Always carefully inspect the Focalist System before and after use. Check the robot, cart, and other components for signs of damage such as cracks, chips, or abrasions. Use of damaged components may cause the Focalist System to perform improperly and/or result in injury to the patient or operator. If damage is suspected, discontinue use of the Focalist System and contact Mendaera Customer Support.*

7.4 Storage

1) Stow the robot and the probe in the cart probe holders and robot storage.
2) Stow the monitor within the cart footprint.

3) Stow the cart power cable using the cable management hooks on the back of the cart.
4) Lock the cart wheels.
5) Plug in the cart to charge the backup battery as required.

WARNING	*Do not connect multiple socket-outlets or extension cords to the Focalist System. Failure to comply may cause the system to perform improperly and/or may cause injury to the patient or operator.*

CAUTION	*Always carefully inspect the Focalist System before and after use. Check the robot, cart, and other components for signs of damage such as cracks, chips, or abrasions. Use of damaged components may cause the Focalist System to perform improperly and/or result in injury to the patient or operator. If damage is suspected, discontinue use of the Focalist System and contact Mendaera Customer Support.*
CAUTION	*Avoid applying excessive force to the cart at or above the cart handle. Excessive force applied to the cart, especially when moving around turns and on slopes, may cause the cart to tip over and result in injury to the patient and/or operator.*

8 Chapter 8: Maintenance and Service

8.1 Maintenance

The Focalist System requires no routine maintenance or recurrent testing on either hardware or software components of the Focalist System.

If the system behaves in an abnormal manner or if damage is suspected, discontinue using the device immediately. Contact Mendaera Customer Support to arrange for repair or replacement.

Follow these steps to maintain the system in good condition:

- Avoid placing or storing the system in areas of excessive hot or cold temperatures or direct sunlight. Refer to **Section 9.3** for the acceptable environmental conditions for operating and storing the Focalist System.
- Avoid contamination by following the cleaning and disinfection instructions detailed in **Chapter 7**.
- Leave sufficient slack in the cables when wrapping around cable hooks to avoid damage to the cables.

8.2 Serviceability

There are no user-serviceable parts or modifications allowed to the system. Contact Mendaera Customer Support to arrange for repair or replacement by qualified service personnel.

WARNING	*Do not attempt to service the Focalist System, including the battery. Doing so may result in damage to the Focalist System and/or injury to the operator or patient. Contact Mendaera Customer Support for service.*
WARNING	*Do not modify the robot, cart, or other components specified for use with the Focalist System. Modification to the Focalist System may cause the system to perform improperly and/or may cause injury to the patient or operator.*

9 Appendix A: System Specifications

9.1 System specifications

Item	Cart
Dimensions (H x W x D)	1520 mm x 550 mm x 590 mm
Weight	75 kg
Power Requirements	100V - 240 V AC 50/60Hz Maximum 600VA

The Focalist System Cart requires mains power when not operating based on its internal battery. The mains power source must provide single-phase, AC current. When connecting the cart to mains power, use an AC power outlet which meets the power requirements in the table above.

Each of the USB Type-C ports on the Cart are capable of outputting 30W. The combined power consumption from all three USB-C ports simultaneously shall not exceed 80W.

Each USB Type-C is capable of outputting USB PD3.0 voltages of 5V at 3A, 9V at 3A, 15V at 2A, and 20V at 1.5A.

IT equipment connected to the system must be certified to IEC 60950-1 or IEC 62368-1.

WARNING	*Always power the Focalist System according to the system specifications. Electrical shock to the patient and/or operator may result if voltages exceed the power requirements listed for the Focalist System.*
WARNING	*Always connect the Focalist System to a supply mains with protective earth. Electrical shock to the patient and/or operator and/or damage to the equipment may result if this guidance is not followed.*

9.2 Wireless specifications

The Focalist System incorporates the following WiFi and cellular technology. See **Chapter 11** for network configuration and cybersecurity guidance.

Wireless Module	Technology	Frequencies (MHz)	Max RF Power (dBm)
WiFi	IEEE802.11 b/g/n/ax	2400 - 2483.5	20
	IEEE802.11 a/n/ac/ax	5150 - 5725	23
Cellular	2G Bands	GSM: 850	35.0
		GSM: 1900	33.0
	3G Bands	UMTS: 800/850/900/1700/1900/2100	25.0
	4G Bands	LTE-TDD: 1900/2300/2500/2600	25.0
		LTE-FDD: 700/800/850/900/1700/1800/1900/2100/2600	25.0

9.3 Environmental conditions

9.3.1 Environmental conditions: Operating

Temperature	10 °C to 25 °C
Humidity	30% to 75% Relative Humidity non-condensing
Atmospheric Pressure	The Focalist System shall function properly in atmospheric pressures ranging from 527mmHg (9,800 ft) to 774mmHg (-500 ft). For every 2,200 feet above sea level, the 25 °C operational temperature limit specified above will be reduced by 1 °C. (For example, the maximum operating temperature at 4,400 ft will be 23 °C and the maximum operating temperature at 8,800 ft will be 21 °C.)

The region of the robot arm between joints 9a and 9c (indicated in Section 2.2.2) may reach up to 44 °C during normal use. It is recommended to avoid prolonged contact (greater than 10 minutes) between the specified region and the patient.

9.3.2 Environmental conditions: Storage and Transport

The system can be stored or transported for up to 24 hours from -30 °C to 60 °C and 15-90% relative humidity. Exposure to temperature and relative humidity outside these ranges may damage the system.

WARNING	*Do not use the Focalist System in the presence of flammable gases or anesthetics. Doing so can result in a possible fire or explosion and/or result in injury to the patient or operator.*

NOTE	*Store and operate the Focalist System only within the range of environmental conditions specified in the technical specifications. If operating or storing in an environment that is outside of these conditions, move the Focalist System to an environment that meets the environmental conditions.*

9.4 Electromagnetic conformance

The system is classified as Group 1, Class A equipment in accordance with international standard CISPR 11 for radiated and conducted electromagnetic disturbances. Compliance with this standard and the emissions characteristics of this equipment makes the system suitable for use in industrial areas and hospitals. If the system is used in a residential environment (for which CISPR 11 Class B is typically required), the system might not offer adequate protection to radio-frequency communication services. You may need to take mitigation measures, such as relocating or re-orienting the equipment.

The following tables contain the Manufacturer's declaration and additional information required by IEC 60601-1-2.

WARNING	*Do not use cables, probes, devices, and/or other components other than those specified for use with the Focalist System. Do not use the Focalist System with devices that have emissions characteristics that are not aligned with the manufacturer's declaration and guidance regarding Electromagnetic Conformance. Failure to comply may result in increased electromagnetic emissions or decreased electromagnetic immunity of the Focalist System and cause the Focalist System to perform improperly, resulting in injury to the patient or operator.*
WARNING	*Always maintain (at minimum) a 30 cm separation distance between portable radio-frequency (RF) communication equipment (including peripherals such as antenna cables and external antennas) and any part of the Focalist System (including cables specified by the manufacturer). Failure to comply may cause the Focalist System to perform improperly and/or result in injury to the patient or operator.*
WARNING	*Avoid use of the Focalist System adjacent to or stacked with other equipment. Failure to comply may cause the Focalist System to perform improperly and/or result in injury to the patient or operator. If such use is necessary, the Focalist System and the other equipment should be observed to verify that they are operating normally.*

9.4.1 U.S. Federal Communications Commission (FCC) Part 15 compliance statement

This device complies with Part 15 of the FCC Rules per testing in accordance with FCC 15.107 Class A and 15.109 Class A. Operation is subject to the following two conditions:

- This device may not cause harmful interference.

- This device must accept any interference received, including interference that may cause unwanted operation.

This product does not contain any user-serviceable components. Any changes or modifications to this equipment not expressly approved by Mendaera may cause harmful RF interference and will invalidate the warranty and all applicable regulatory certifications and approvals, including authority to operate this device.

> **NOTE** *"Harmful interference" is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.*

9.4.2 Electromagnetic emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
Emission Test	**Compliance**	**Electromagnetic Environment Guidance**
RF emissions, CISPR 11 IEC 60601-1-2	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions, CISPR 11 IEC 60601-1-2	Class A	The system is suitable for use in all locations other than those in residential environments and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic Emission, IEC 61000-3-2	Class A	
Voltage Fluctuations and Flicker Emissions, IEC 6100-3-3	Complies	

9.4.3 Electromagnetic immunity

Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic Discharge IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Radiated Immunity and Proximity fields from RF wireless communications equipment IEC 61000-4-3	3V/m (80 MHz – 2.7 GHz)	3V/m (80 MHz – 2.7 GHz)	Refer to the guidance regarding recommended separation distances in this Instruction for Use.
	385 MHz (18 Hz Pulse Modulation)	27 V/m	
	450 MHz (FM +/ -5 kHz deviation 1 kHz sine)	28 V/m	
	710 MHz (217 Hz PM)	9 V/m	
	745 MHz (217 Hz PM)	9 V/m	
	780 MHz (217 Hz PM)	9 V/m	
	810 MHz (18 Hz PM)	9 V/m	
	870 MHz (18 Hz PM)	28 V/m	
	930 MHz (18 Hz PM)	28 V/m	
	1720 MHz (217 Hz PM)	28 V/m	
	1845 MHz (217 Hz PM)	28 V/m	
	1970 MHz (217 Hz PM)	28 V/m	
	2450 MHz (217 Hz PM)	28 V/m	
	5240 MHz (217 Hz PM)	9 V/m	
	5500 MHz (217 Hz PM)	9 V/m	
	5785 MHz (217 Hz PM)	9 V/m	
Electrical Fast Transient / Burst IEC 61000-4-4	±2kV (5/50 ns 100 kHz) for power supply lines ±1kV (5/50 ns 100 kHz) for HDMI I/O	±2kV (5/50 ns 100 kHz) for power supply lines ±1kV (5/50 ns 100 kHz) for HDMI I/O	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5kV, ±1kV, ±2kV common mode ±0.5kV, ±1kV differential mode	±0.5kV, ±1kV, ±2kV common mode ±0.5kV, ±1kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted Immunity IEC 61000-4-6	3 VRMS (0.15 – 80 MHz) 6 VRMS (ISM bands between 0.15 and 80 MHz) AM 80% at 1 kHz on AC Mains and HDMI I/O	3 VRMS (0.15 – 80 MHz) 6 VRMS (ISM bands between 0.15 and 80 MHz) AM 80% at 1 kHz on AC Mains and HDMI I/O	See Note below table.
Power Frequency Magnetic Fields Immunity IEC 61000-4-8	30 A/m (50 Hz or 60 Hz)	30 A/m (50 Hz or 60 Hz)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage Dips & Interrupts IEC 61000-4-11	0% for 0.5 cycle (At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°) 0% for 1 cycle (At 0°) 70% for 25/30 cycles (At 0°) 0% for 250/300 cycles	0% for 0.5 cycle (At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°) 0% for 1 cycle (At 0°) 70% for 25/30 cycles (At 0°) 0% for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment.
Proximity magnetic fields IEC 61000-4-39	134.2 kHz PM-2.1 kHz at 65 A/m 13.56 MHz PM-50 kHz at 7.5 A/m	134.2 kHz PM-2.1 kHz at 65 A/m 13.56 MHz PM-50 kHz at 7.5 A/m	Refer to the guidance regarding recommended separation distances in this instruction for Use.

NOTE: Electromagnetic interference may appear in many ways on the system and depends on the mode the equipment is operating in, the type of electromagnetic phenomena, and the intensity level of the phenomena.

Electromagnetic phenomena are not always present and may be transitory in nature. It may be difficult to identify the source of the interference.

9.5 Classifications

The system is classified according to IEC 60601-1 as follows:

Component	Type of protection against electrical shock	Degree of protection against electrical shock	Degree of protection against ingress of harmful ingress of water	Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Mode of operation
Cart	Class I when plugged into the wall. Internally powered when not plugged into the wall.	N/A	Ordinary protection	Not suitable	Continuous
Robot	N/A	BF	Ordinary protection	Not suitable	Continuous
Probe	Reference the ultrasound probe manufacturer's Instructions for Use for any probe related guidance and/or classifications.				

9.6 Essential performance

The Focalist System essential performance is:

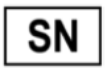
- The Focalist System shall not actively change the position of the electromechanical guide unless commanded by the user.
- The GUI shall display the live ultrasound image or inform the user that the image is not live.
- The handheld system shall allow reversion to manual instrument placement by retracting the instrument out of the patient or by disconnecting the instrument from the electromechanical guide.

9.7 Disposal

Dispose of all components in accordance with local regulations. This rule particularly applies to electronic components. Contact Mendaera Customer Support for additional guidance and support related to removal of products.

10 Appendix B: Symbols and Abbreviations

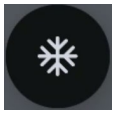
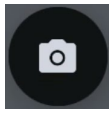
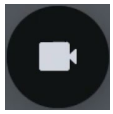
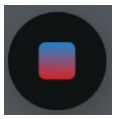
10.1 Symbols

Symbol	Title	Standard	Reference	Description
	Manufacturer name and location	ISO 15223-1	5.1.1	Indicates the medical device manufacturer and the location.
	Date of Manufacture	ISO 15223-1	5.1.3	Indicates the date of manufacture in the YYMMDD format.
	Grounding	ISO 7000/ IEC 60417	5017	Indicates a protective grounding terminal.
	Grounding	ISO 7000/ IEC60417	5019	Indicates protective earth terminals.
	Consult instructions for use or consult electronic instructions for use	ISO 15223-1	5.4.3	Indicates the need for the user to consult the instructions for use.
	Refer to instruction manual / booklet	ISO 7010	M002	To signify that the instruction manual/booklet must be read.
	Prescription use only	FDA 21 CFR Part 801.109	-	Federal (U.S.) law restricts this device for sale, distribution, and use by or on the order of a physician.
	Type BF applied part	IEC-60601-1	20	Indicates isolated patient connection (Type BF applied part).
	MR unsafe	ASTM F2503-1	F2503-13 3.1.14	Indicates an item which poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.
	Serial number	ISO 15223-1	5.1.7	Indicates the manufacturer's serial number so that a specific medical device can be identified.

Symbol	Title	Standard	Reference	Description
	Lot number	ISO 15223-1	5.1.5	Indicates manufacturer's batch code so that the batch or the lot can be identified.
	Reference number	ISO 15223-1	5.1.6	Indicates the manufacturer's catalog number so that the medical device can be identified.
	Do not re-use	ISO 15223-1	5.4.2	Indicates an item which is unacceptable to be re-used.
	Expiration date	ISO 15223-1	5.1.4	Indicates the expiration date.
	Sterilized using Ethylene oxide	ISO 15223-1	5.2.3	Indicates device is sterilized using ethylene oxide.
	Do not re-sterilize	ISO 15223-1	5.2.6	Indicates device should not be re-sterilized after it once has been sterilized.
	Keep dry	ISO 15223-1	5.3.4	Indicates device needs to be protected from moisture.
	Do not use if package is damaged	ISO 15223-1	5.2.8	Indicates a medical device that should not be used if the package has been damaged or opened.
	Single sterile barrier system	ISO 15223-1	5.2.11	Indicates there is a single sterile barrier system.
	Single sterile barrier system with protective packaging inside	ISO 15223-1	5.2.13	Indicates single sterile barrier system with protective packaging inside.
	Warning	ISO 7010	W001	Alerts the reader about a situation which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.

Symbol	Title	Standard	Reference	Description
	Caution	ISO 15223-1	5.4.4	Alerts the reader about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse.
	Note	-	-	Provides important information.
	Warning: Electricity	IEC 60417	6042	Indicates high current is present inside the enclosure even when the main power is off or disconnected.
	No pushing icon	ISO 7010	P017	Tipping danger. Do not lean on the system and take special care when moving the system. Always observe the guidance in this manual when moving the Focalist System.
	Temperature limit	ISO 15223-1	5.3.7	Indicates the maximum and minimum temperature limits at which the item shall be stored, transported or used.
	Humidity limit	ISO 15223-1	5.3.8	Indicates the acceptable upper and lower limits of relative humidity for transport and storage.

Additional Focalist System symbols not associated with specific standards

Symbol	Title	Description
MENDAERA	Company logos	Indicates the manufacturer's logo.
	Barcode	Indicates unique device identifier information.
	In-plane	Icon on the robot for in-plane probe orientation alignment.
	Out-of-plane	Icon on the robot for out-of-plane probe orientation alignment.
	R	Icon on the USB-C connector to indicate to the user which cable connects to the robot versus any other device such as an ultrasound probe.
	Freeze	GUI button to freeze and unfreeze the live ultrasound image.
	Image	GUI button to capture a still frame of the ultrasound image.
	Cine	GUI button to capture a prospective 10 second cine loop of the live ultrasound image.
	Doppler	GUI button to turn on and off the Color Doppler.
	TGC	GUI button to adjust the time gain control along near, mid, and far depth.
	Flip	GUI button to flip the live ultrasound image along the vertical axis.

Symbol	Title	Description
	Delete	GUI button to delete the selected image, cine or a study.
	Export media	GUI button to export media associated with the selected study to an external USB drive.
	Study	GUI button to designate the selected study as the current active study (allows to capture or review media captured under the study).

10.2 Abbreviations

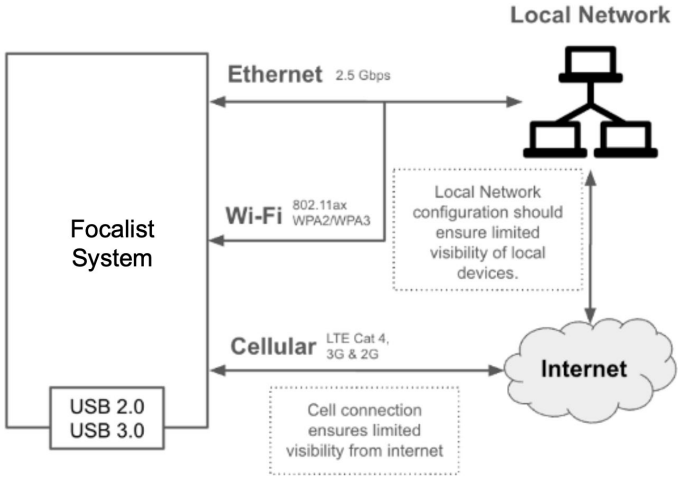
Abbreviation	Designation
°C	Degrees Celsius
°F	Degrees Fahrenheit
A	Ampere
AC	Alternating Current
ASTM	American Society for Testing and Materials
BF	Body Floating
CFR	Code of Federal Regulations
CISPR	Comité International Spécial des Perturbations Radioélectriques, which translates to the International Special Committee on Radio Interference
cm	Centimeter
DOB	Date of Birth
EMC	Electromagnetic compatibility
EOL	End of Life
EOS	End of Support
FCC	U.S. Federal Communications Commission
FDA	Food and Drug Administration
g	Gram
GUI	Graphical User Interface
HDMI I/O	High-Definition Multimedia Interface Input/Output
hr	Hour
HTTPS	Hypertext Transfer Protocol Secure
Hz	Hertz
IEC	International Electrotechnical Commission
IP	In-plane
ISM	Industrial, Scientific, and Medical
ISO	International Organization for Standardization
IT	Information Technology
K	Kelvin
kg	Kilogram
km	Kilometer
L	Liter
LED	Light-emitting Diode
m	Meter
Mbps	Megabits per second
Focalist	Focalist System
min	Minute
mL	Milliliter
mm	Millimeter
MR	Magnetic Resonance

Abbreviation	Designation
MRN	Medical Record Number
NAT	Network Address Translation
NTP	Network Time Protocol
OOP	Out-of-plane
PM	Pulse Modulation
RF	Radio-frequency
s	Second
SBOM	Software Bill of Materials
TLS	Transport Layer Security
USB-A	Universal Serial Bus Type-A
USB-C	Universal Serial Bus Type-C
V	Volt
VRMS	Root-mean-square voltage
Wi-Fi	Wireless Fidelity
WPA	Wi-Fi Protected Access

11 Appendix C: Cybersecurity

The section outlines guidance regarding connecting the Focalist System to a network.

- When connecting the device to a network via Wi-Fi or ethernet, use a private, internally segmented network to prevent unsolicited inbound internet traffic to the device. If network translation is required, configure NAT/firewalls to block external access unless explicitly approved. This safeguards inbound connections, limiting attack exposure and protecting device operations.
- The following network ports are used by the system to facilitate the indicated functionality. It is expected that these ports are open on the network that the system is connected to.
    - HTTPS communication for system software updates and log / telemetry upload: 443 (Outbound)
    - Network Time Protocol (NTP) communication for synchronizing the system clock: 123 (Outbound)
    - The following network ports are open for outbound connections on the system. However, they are not utilized for current functionality; as a result, they do not need to be open on the network the system is connected to: 53, 104, 2761, 2762, 11112.
- The diagram below illustrates how the Focalist System may be connected to networks.



- Use a network with at least 100 Mbps of bandwidth and a low latency (under ~50 ms round-trip). Keep time accurate (e.g., via NTP). Provide stable power and regularly apply patches for reliable operation. Encrypt data transport (WPA2/WPA3 for Wi-Fi and TLS for wired). Note that the WPA2 security standard contains known exploited vulnerabilities that can result in loss of confidentiality. The Focalist System contains mitigations against attacks. However, it is recommended that you keep network equipment up-to-date and use more secure connection protocols when possible.
- Configuration of the system includes parameters that control the system identity, what log data is securely uploaded periodically, and what network the system is connected to. The network configuration is configured by Mendaera Customer Support upon installation, in collaboration with the end-user. For all other parameters, the system is shipped pre-configured.
- Connection of the Focalist System to a network that includes other equipment could result in previously unidentified risks to patients, operators, or third parties.
- If the network characteristics do not meet the guidance in these Instructions for Use, this could render the Focalist System inoperable and/or result in injury to the patient, for example due to unintended motion of the robot.

- Changes to the network (to which the device is connected) could introduce new risks and require additional analysis. Changes to the network may include:
    - Changes in the IT-network configuration;
    - Connection of additional items to the IT-network;
    - Disconnecting items from the IT-network;
    - Update of equipment connected to the IT-network;
    - Upgrade of equipment connected to the IT-network; and
    - Changes in the visibility of devices on the network from outside devices.
- It is the responsibility of the customer to ensure any risks associated with non-conformance to the guidance in this Chapter are identified, analyzed, evaluated, and controlled.

The section below outlines measures implemented in the Focalist System to promote and/or ensure cybersecurity as well as guidance for users regarding cybersecurity.

- The system software includes a variety of security protections that ensure system safety, confidentiality, availability, and integrity. Key protections embedded in the system software include blocking network ports not necessary for critical functionality, file integrity monitoring, data encryption for user and patient information, and restrictions on devices that can be plugged in to the system.
- The system software monitors and logs unauthorized access or modification. Logs are securely uploaded to Mendaera for analysis. In the case of unauthorized modification of system files, the software will detect this on boot, notify the user, and shut down.
- In case of unauthorized modification to the system configuration or software, the system software will notify the user of unauthorized modification on boot and refuse to proceed to the main application. In this case, service by Mendaera Customer Support is required to restore the system to an authorized configuration. Contact Mendaera Customer Support at 877-636-3237 or support@mendaera.com.
- In the event of a cybersecurity event, contact Mendaera Customer Support at 877-636-3237 or support@mendaera.com.
- If service by Mendaera Customer Support is necessary for system recovery, the device configuration for identity and data management can be recovered from Mendaera servers as they are synchronized on initial device configuration.
- The system software logs system events into binary log files in a rolling buffer on the system hard drive. The log files are utilized by Mendaera Customer Support in cases where forensic analysis of a system is necessary. Certain log files are securely uploaded to Mendaera servers on a periodic basis to enable continuous analysis and alerting of anomalous security events.

The section below outlines additional support provided by Mendaera, Inc. to promote and/or ensure cybersecurity.

- Software updates are managed by the software itself and you will be notified by a Mendaera representative when a software update is available so that the update can be scheduled and coordinated with minimal disruption.
- Mendaera will maintain overall system support, including all third-party components, for the duration of the device's service life. In the event that a component reaches End of Life (EOL), Mendaera will continue to release patches or replace the affected software with a supported alternative whenever feasible, to preserve device security and functionality. However, at the End of Support (EOS) for the device or its components, Mendaera will no longer provide security patches or updates. Users are advised that cybersecurity risks may increase beyond this point. Mendaera will notify users of upcoming EOS/EOL dates

via electronic communication and provide guidance on risk mitigation strategies to ensure continued safe use.

- To decommission the system, contact Mendaera Customer Support to ensure that sensitive, confidential, and proprietary data is removed from the system.
- You can request the latest version of the SBOM by contacting Mendaera via email at support@mendaera.com. Requests will be fulfilled promptly, and the SBOM will be provided in a machine-readable format.

NOTE	*Follow all security and cybersecurity policies of your institution. If you do not know what these policies are, contact your information technology (IT) department.*
NOTE	*Consult with your IT/Security department to ensure that security and patient data protection is in accordance with the policy of your institution.*
NOTE	*Ensure the Focalist System is stored and operated only in a secure environment(s) which limit physical access to only authorized personnel.*