IntraGuide Ultrasound System

Instructions for Use

Manufactured by:

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1 Table of Contents

2 Introduction

This user manual describes the **IntraGuide** ultrasound system (REF 2501)**.**

This user manual details the system's hardware, components, user interface, and guidelines for maintenance and disinfection. Additionally, it covers the **IntraGuide** user interface, including its structure, controls, and usage for ultrasound imaging.

Explanation of Symbols Used in the IFU:

The CAUTION symbol is used together with information where there is a conceivable risk of malfunction or damage of the equipment.

The WARNING symbol is used together with information where there is a conceivable risk of harm to the user or patient if the warning is ignored.

	**CAUTION:** United States federal law restricts this device to be used by, or on the order of, a licensed physician.

2.1 Intended Use

IntraGuide is a general-purpose diagnostic ultrasound imaging system intended for ultrasound imaging, measurements and display and analysis of the human body. It is intended to be used in a hospital or medical clinic.

2.2 Intended Users

IntraGuide is intended for use by qualified and trained healthcare professionals.

	**CAUTION:** United States federal law restricts this device to be used by, or on the order of, a licensed physician.

2.3 Product Description

IntraGuide ultrasound system consists of an ultrasound beamformer (IntraGuide Box), compatible ultrasound probes, IntraGuide PC, IntraGuide software and a trolley. The IntraGuide Box is connected to the Windows-based IntraGuide PC on which the IntraGuide software is installed. All hardware components are mounted on a trolley.

IntraGuide Software controls the operation of the ultrasound system. AURA provides the latest IntraGuide Software together with your system.

The IntraGuide Software includes a state-of-the-art graphical user interface (GUI) with menus, buttons, control elements, indicators and navigation icons that allow the operator to control the system, adjust ultrasound image quality, view images, and perform measurements.

The IntraGuide Software also provides a software function called ClipGuide that users must activate before use. When the function is turned on, it assists healthcare professionals in efficiently locating previously implanted breast biopsy clips. The ClipGuide software function was validated for use with the FDA cleared biopsy marker Tumark Vision (K201863, HOLOGIC, formerly SOMATEX).

2.4 Indications and Contraindications

2.4.1 Indications for Use General Ultrasound

IntraGuide is indicated for clinical applications including abdominal (GYN and Urology), thoracic/pleural, small organ (breast, testes, thyroid), vascular, peripheral vascular, musculoskeletal (conventional and superficial) adult cardiac, intraoperative and interventional guidance.
The operating mode of the IntraGuide is B-mode.

	**CONTRAINDICATION**: The IntraGuide is contraindicated for: - fetal ultrasound - ophthalmic use or any application that causes the acoustic beam to pass through the eye

2.4.2 Indications for Use ClipGuide

The ClipGuide software function is indicated for locating biopsy clips in real-time ultrasound images for review by healthcare professionals during outpatient follow-up evaluations (e.g., pre-surgical therapy monitoring), planning for interventional procedures (e.g., identifying biopsy clip before placement of localization device), and planning for surgical procedures (e.g., identifying biopsy location before breast-conserving surgery).

ClipGuide is indicated for

- Female patients with a previously placed biopsy marker that is compatible with ClipGuide.
- all breast sizes and densities
- all ethnicities

	**CONTRAINDICATION**: ClipGuide is contraindicated for: - localization of biopsy clips that are placed deeper than 50 mm - biopsy clips outside of breast (e.g. axilla) - female patients with breast implants - male patients - female patients who had a previous surgery in the imaged area

2.5 Essential Performance

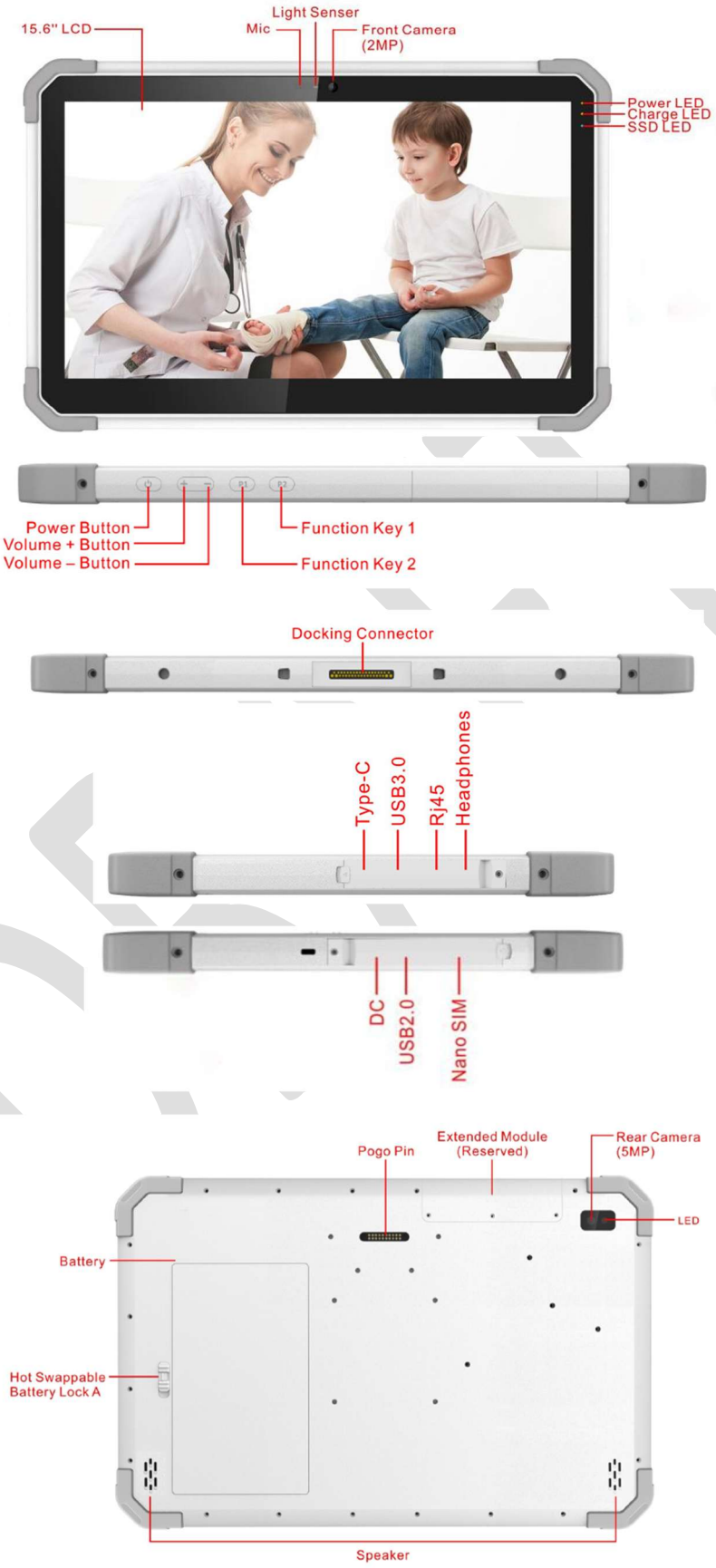
The essential performance of the IntraGuide ultrasound system is the ability to provide **real-time B-mode diagnostic ultrasound imaging** with sufficient image quality for clinical interpretation.

2.6 System Overview

Part	Description
User Manual	This document
IntraGuide Box	Ultrasound unit (beamformer) with its AC/DC power supply and AC power cable
IntraGuide PC	Tablet PC with touchscreen with IntraGuide Software with its AC/DC power supply AC power cable and an inserted battery pack
Ultrasound Probe (Transducer)	Linear 40 mm probe 5-12 MHz (L12-5N40-A4)
USB Cable	Connecting the PC with the beamformer.
Trolley	A mobile trolley on wheels that holds all other system parts. It also features a basket for consumables and the probe.

Table 1: System Parts

2.6.1 IntraGuide PC



The IntraGuide PC has one small, permanent, internal battery and one hot-swappable battery pack. When hot-swappable battery pack has low voltage and needs to be replaced, the built-in small battery will power the tablet for up to 10 minutes.

To charge the battery pack, make sure that the power cable is connected to the IntraGuide PC and connect the AC power cable to mains (wall outlet).

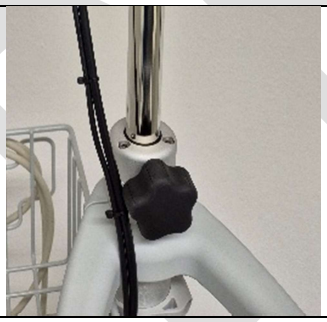
⚠	**CAUTION**: Battery life naturally degrades over time. Failure to follow instructions for recommended operating temperatures, charge and discharge rates, and other instructions may accelerate battery decay rates.

To check the battery charge level, use the battery indicator in the IntraGuide software. See 8.3.1 Battery

For checking the battery status after removing the battery pack, press the Battery Status Button (1)

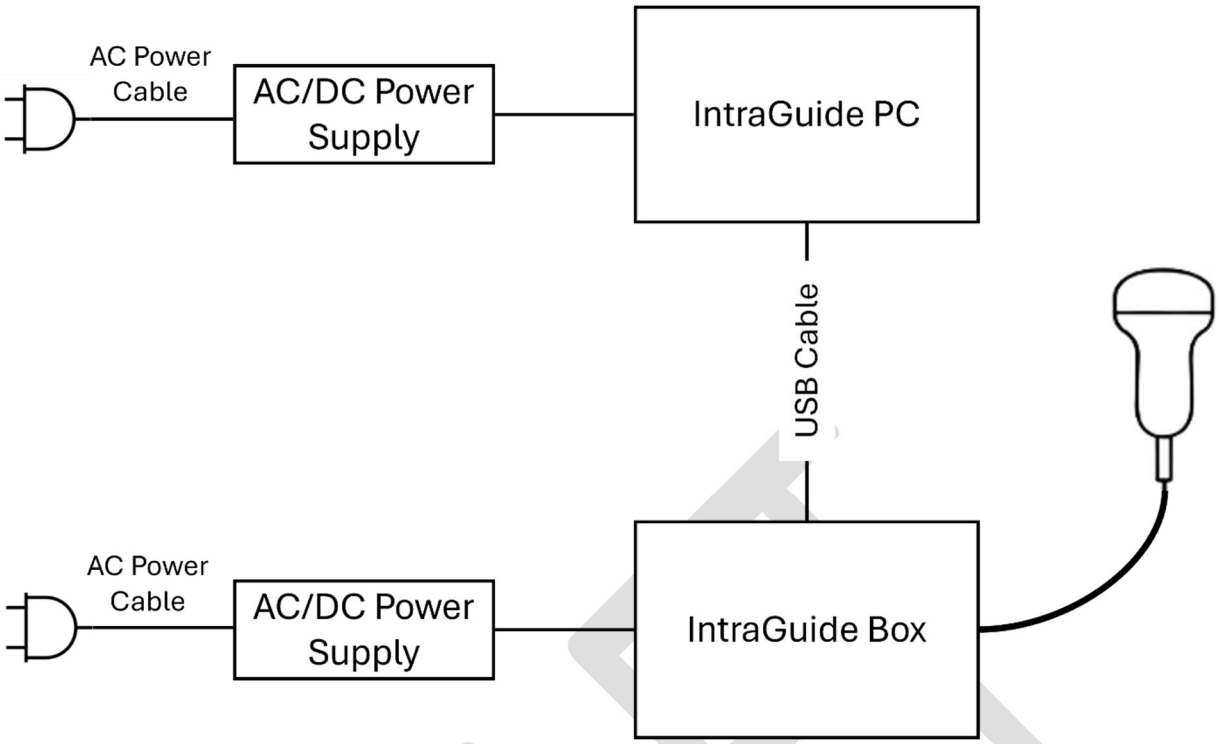
2.6.2 Trolley

The trolley allows you to change the tilt of the height and tilt of the screen of the IntraGuide PC.

To change the height of the screen, release this knob, adjust height and fasten the knob again.	To change the tilt of the screen, release this handle, adjust the tilt and fasten the handle again.
	

2.6.3 Component connections

This diagram illustrates the system's component connections, showing the relationship between the IntraGuide PC running the IntraGuide Software, the IntraGuide Box, the Ultrasound Probe, and the External AC/DC Power Supplies.



2.7 Technical Specifications

Technology	Specification
Imaging Mode	B mode
Ultrasound Imaging	• Ultrasound image canvas is 1000 x 800 pixels • Gray scale: 256 • Color scale: 256 • Full motion and full-size real-time ultrasound imaging, up to 120 fps (depending on selected scanning depth, angle, focusing mode, Lines Density setting, computer speed) • "FREEZE" mode
Depth Selection	30-90 mm
Transducer	Linear 40 mm probe with a frequency range 5-12 MHz.
Focusing	• Transmit: variable, 8 zones • Receive: point to point, dynamic
Image Settings Controls	• Focus • Depth • Dynamic range control • Overall gain control • Acoustic power control
Ultrasound Software	IntraGuide Software version 1.0.0.0 or newer
Dimensions on the system	Footprint: 63.3 cm x 63.3 cm (24.9 inch x 24.9 inch) Height: Adjustable between 131.5 cm (51.8 inch) and 168.5 cm (66.3 inch)
Weight with trolley	TBD
Power Consumption	• IntraGuide PC: 19 VDC, 3.15 A Max via external AC/DC medical grade power supply (100-240 VAC, 50-60 Hz), Class II, Delta Electronics, Inc. MEA-065A19C

	• IntraGuide Box: 12 VDC, 3.5 A Max via external AC/DC medical grade power supply (100-240 VAC, 50- 60 Hz), Class II, XP Power AKM65US12C2
Electromechanical Safety	IEC 60601-1 Medical electrical equipment part 1: General Requirements for safety Class II Type BF applied part
EMC/EMI standards	IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance IEC TR 60601-4-2: Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity
Ultrasound Exposure	IEC 60601-2-37 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment CEI/IEC 61157:1992, International Electrotechnical Commission, Requirements for The Declaration of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment AIUM/NEMA: Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment.1992
Degree of protection (watertight)	IntraGuide Box IPX0 Ultrasound Probe IPX7 IntraGuide PC IP54
Applied part	Ultrasound Probe 
Operational Environment	Nominal Operational Environment • Hospital or clinic • Temperature: 10-35°C (50-95°F) • Relative humidity: 10%-85% • Atmospheric pressure: 80-106 kPa (600-795 mmHg)
Screen	Resolution: 1920 x 1080 Full HD resolution (16:9) Size: 15.6"
Communication	WiFi module (disabled): 802.11 a/b/g/n/ax, 2.4G & 5G Bluetooth (disabled): Bluetooth 5.2
Battery	Hot-swappable Battery-Pack: Li-ion Polymer, 11.4V 5840 mAh 66.348 Wh, Internal Battery: Li-ion Polymer
Expected service life	10 years

Table 2: Technical Specifications

3 Safety

3.1 General warnings

	**WARNING**: Please read this information thoroughly before using IntraGuide.

	**WARNING:** The IntraGuide system is intended to be used only by appropriately qualified and trained users.

	WARNING: The device packaging shall be opened and the system assembled only by authorized personnel. Unauthorized opening or assembly may result in electric shock, system damage, fire or unsafe operation.

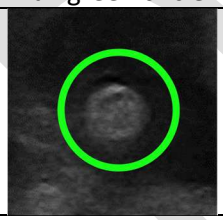
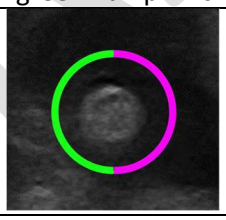
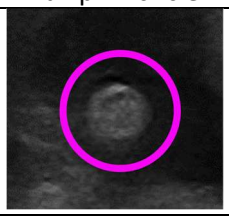
	WARNING: In the event of detecting a discrepancy or malfunction that may impact patient safety, immediately turn the power off, unplug the system from mains (wall outlet). Then inform the local dealer and the manufacturer.

	WARNING: The usage of the device for applications outside of the intended use may lead to patient harm. Use the system only for applications within the intended use

	CAUTION: Installing unauthorized or third-party software on the IntraGuide PC may cause the system to malfunction and will void warranty.

3.2 Warnings and information related to ClipGuide

ClipGuide relies on a real-time machine learning (ML) algorithm that analyzes each frame of ultrasound imaging. If the algorithm assumes that a biopsy marker is present in the image, a circle is displayed around the assumed structure. There are three distinct visualization patterns for the circle.

Full green circle	Half green half pink circle	Full pink circle
		

	CAUTION: Review section 5 Information on ClipGuide (Model Card) for detailed and important information on ClipGuide performance.

	WARNING: The ClipGuide software feature is indicated only for the Tumark® Vision (SOMATEX® / HOLOGIC®) biopsy markers. The ClipGuide feature must not be used for other biopsy marker types.

	**WARNING:** The ClipGuide software feature may provide visualization in locations without biopsy marker. Review the information on sensitivity and specificity of the biopsy marker visualization algorithm (See section 5 Information on ClipGuide (Model Card)). Always visually confirm the presence of a biopsy marker in the visualized region before making diagnostic or therapeutic decisions.

	**WARNING**: The ClipGuide Software feature may provide false visualization if other interventional devices are in the field of view (e.g. biopsy needles, localization wires). While using ClipGuide, position the ultrasound probe to not have other interventional devices in the field-of-view. Always visually confirm the presence of a biopsy marker in the visualized region before making diagnostic or therapeutic decisions.

	**WARNING:** ClipGuide visualizes only one biopsy marker at a time. If there are two biopsy markers in one frame, only one will be visualized.

3.3 Electrical Safety

IntraGuide System complies with the applicable medical equipment requirements and meets IEC 60601-1, Class II Type BF safety requirements. Further, it is compliant with IEC 60601-2-37 requirements.
The IntraGuide system consists of two electrical subsystems – the IntraGuide PC and the IntraGuide Box with the ultrasound probe – each of the subsystems has its own power supply. The IntraGuide PC also has an in-built battery and a hot-swappable battery pack.
To avoid electrical shock only use the supplied cables and AC/DC power supplies and connect them to properly earthed mains (wall outlets).
If the system is left unused for a long period of time without being switched on it is recommended to disconnect it from a power supply.
Do not interrupt the system startup and while IntraGuide software is being loaded. The time for booting is approximately 1 minute.

To avoid the risk of electrical shock and fire hazard:

- Before using the system, inspect the IntraGuide's housing and cables and do not use the IntraGuide System if the transducer or the cable is damaged.
- Before using the transducer, inspect the transducer face, housing, and cable and do not use the transducer if the transducer or the cable is damaged.
- Always disconnect the system from AC power before cleaning.
- Do not use any transducer that has been immersed into a liquid.
- Inspect the power supply, AC power supply cable and electrical plug on a regular basis to ensure they are not damaged.
- Do not supply power to the system from unapproved AC power supply. Use only power supplies that were supplied by AURA.
- Only use accessories and peripherals recommended by AURA, see6.3 Peripherals and Compatibility.

- Do not use a three pin - two pin adapter.
- All system components should be operated within specified voltage limits.

	**WARNING:** To avoid the risk of electrical shock do not open or disassemble the system components. Only qualified personnel shall perform service and repair of the system and its components. Opening the casing of the device will void product warranty.

	**WARNING:** Do not position the device in a position where it is difficult to disconnect the device from the mains (wall outlet) to safely terminate operation of the device.

3.4 Equipment Protection

To protect your ultrasound system, transducer and accessories, please follow these precautions:

	**WARNING:** Do not spill liquids on the system.

	**WARNING:** Do not pull on the ultrasound probe and its cable. Exercising force on the ultrasound probe cable may cause permanent damage to the probe connector and impact image quality.

	**CAUTION:** Excessive bending or twisting of electrical cables can cause failure or intermittent operation.

	**CAUTION:** Unplugging the device from the mains (wall outlet) while it is running may cause damage to the system. Always shut down the system before you unplug it from the mains (wall outlet).

	**CAUTION:** Ultrasound probe that dropped may be damaged and provide worse image quality. Always perform a quality assurance procedure after the ultrasound probe has been dropped.

3.5 Biological Safety

Observe the following precautions related to biological safety:

- Only use the provided ultrasound probe from the delivery kit.
- Do not use the system if it displays erratic or inconsistent behavior.
- Interruptions to the scanning sequence are signs of hardware failure that must be corrected before use.
- Artifacts may be indications of hardware and/or software errors that shall be investigated, contact the AURA service team in such an event.
- Perform ultrasound procedures prudently, using the ALARA (As Low as Reasonably Achievable) principle.

NOTE: IntraGuide System, and the ultrasound probe specifically, do not contain natural rubber latex.

	**WARNING:** The ultrasound probe is not sterile. For procedures that require a sterile field, a sterile probe cover shall be used.

	**WARNING**: Some probe covers may contain talc and natural rubber latex. Examine the package labeling to confirm latex content. We recommend that healthcare professionals identify latex sensitive patients, and refer to the FDA's March 29, 1991 Medical Alert on Latex products. Be prepared to treat allergic reactions promptly

3.6 Ultrasound Exposure and ALARA Principle

Perform ultrasound procedures prudently, use the ALARA (As Low as Reasonably Achievable) principle. The interactive system features or user controls that may affect the acoustic output are:

- acoustic output control (i.e. Power);
- transmit frequency;
- scanning depth;
- transmit focal length (i.e. Focus).

The default output level is based on device settings that yield an optimum image for the type of patient examination and do not exceed FDA recommended limits.

Once an optimal image is achieved, the need for increasing acoustic output or prolonging the exposure cannot be justified. Whenever possible, controls and other presets should be used to optimize the image before increasing the acoustic output level. Follow the ALARA principle during all patient examinations. The AURA devices employ the ALARA principle in configuring factory defaults and presets.

Ultrasound waves used in diagnostic systems have frequencies ranging from 2 MHz to 18 MHz. Sound waves with such frequencies are weakened in the air, so can be measured, for example, in water. Ultrasound waves sent by a converter are so weak (medium intensity less than 100 mW/cm²), that, according to International Electrotechnical Commission (IEC 1157) standards (well within AIUM/NEMA standards), they do not have any impact on patient health (however any unnecessary exposure should be avoided).

	**Caution:** Ultrasound imaging of gas-containing anatomical regions (such as lung or intestine) may be associated with gas-body effects. Users should be aware of these effects and apply the ALARA principle when imaging such regions.

3.7 Measurement Accuracy

The accuracy of measurements is determined not only by IntraGuide System but also by proper use of medical protocol.
Distance is displayed to 0.1 mm. The following general assumptions can be made about the accuracy of any ultrasound system:

- Velocity of sound is constant - 1540 m/s
- Velocity of sound uncertainty is 5%
- Measurement accuracy is based on the root-mean-square combination of all independent sources of error
- RMS errors are due to velocity of sound uncertainty, pixel error, and typical transducer geometry

3.8 Electromagnetic Compatibility

The IntraGuide ultrasound system was tested according to the recommendations of IEC 60601-1-2 requirements for electromagnetic compatibility and of IEC TR 60601-4-2: Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems. Under normal conditions, the system maintains essential performance, which includes real-time B-mode imaging with sufficient quality for clinical interpretation.

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

	**WARNING**: The IntraGuide PC contains magnets. Magnetic fields may interfere with pacemakers, defibrillators, or other devices. Maintain a minimum distance of 15 cm (6 inch) between the IntraGuide PC and a magnetically sensitive device.

	**WARNING:** Do not stack the IntraGuide Ultrasound System on or near other equipment and do not position it in close proximity to other devices.

Stacking or placing the system adjacent to other equipment may result in electromagnetic interference (EMI), which can lead to **loss or degradation of essential performance**.

In particular, portable and mobile RF communications equipment, including antennas, can affect the operation of medical electrical equipment.

Effects of Electromagnetic Disturbances

- **Image Quality Degradation**: The ultrasound image may show artifacts, noise, or reduced resolution, making anatomical structures difficult to visualize.
- **Delayed or Interrupted Imaging**: The live image may freeze unexpectedly or refresh slowly.
- **User Interface Response Issues**: Touch controls may become sluggish or temporarily unresponsive.
- **System Warnings**: Indicators such as “No Probe” or error messages may appear.

Operator Actions

- **Pause the Procedure**: If image quality is compromised, do not proceed with diagnostic or interventional steps.
- **Check Environment**: Move the system away from strong RF sources (e.g., electrosurgical units, mobile phones in close proximity).
- **Verify Recovery**: Once interference ceases, confirm that image quality and system responsiveness have returned to normal before resuming use.
- **Contact Support**: If normal operation does not resume, shut down the system and contact AURA service.

Preventive Measures

- Maintain recommended separation distances between the IntraGuide system and RF transmitters:

Rated Maximum Output Power of Transmitter	Separation Distance
0.01 W	12 cm
0.1 W	38 cm
1 W	120 cm
10 W	3.8 m

	**WARNING:** Use only the supplied cables and AC/DC power supply. Other cables and accessories may negatively impact electromagnetic compatibility of the IntraGuide system and may severely damage the system or cause harm.

3.9 Cybersecurity

Connection of the system to an IT network that includes other equipment could result in previously unidentified risks to patient, operator or third parties. The responsible organization should identify, evaluate and control these risks. Subsequent changes to the IT network could introduce new risks and require additional analysis. Changes to the IT network include - changes to 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 and upgrade of equipment connected to the IT network.

4 Labeling

Table 3 describes the purpose and location of symbols and marking and other important information provided on the equipment.

Symbol or marking	Description	Location
	Power On/Off Indicator	IntraGuide PC upper side IntraGuide Software
	*CE Mark* - a declaration by the manufacturer that the respective component complies with the relevant directives and standards as issued by the European Union	Label IntraGuide PC Label IntraGuide Box
	*Type BF Equipment IEC 878-02-03* - indicates BF type equipment which provides a particular degree of protection against electric shocks, particularly regarding allowable LEAKAGE CURRENT and reliability of the PROTECTIVE EARTH CONNECTION if present	Label Ultrasound Probe
	This symbol indicates that additional information or instructions are available in the manual and should be consulted for further guidance	Label IntraGuide Label Ultrasound Probe
	This symbol indicates that the user must consult the instructions for use before operating the device	Label IntraGuide
	This symbol indicates separate collection for electrical and electronic equipment	IntraGuide Box rear panel
	USB connector	IntraGuide Box rear panel
	DC power input of the IntraGuide Box	IntraGuide Box rear panel

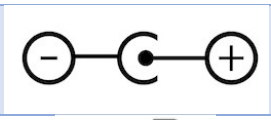
	DC power input of the IntraGuide PC	Label IntraGuide PC
	Manufacturer name and address	Label IntraGuide
	Model/Catalog Number	Label IntraGuide Label Ultrasound Probe
	Date of Manufacture (YYMMDD)	Label IntraGuide Label Ultrasound Probe
	Serial number	Label IntraGuide Label Ultrasound Probe
	Protection (watertight)	Label Ultrasound Probe
	UDI GS1 Data Matrix	Label IntraGuide
	Medical Device	Label IntraGuide
	The symbol indicating separate collection for electrical and electronic equipment (Annex IV of Directive 2002/96/EC)	Label IntraGuide Label Ultrasound Probe Label IntraGuide PC
	This is a certification mark employed on electronic products manufactured or sold in the United States which certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission.	Label IntraGuide PC

Table 4: Labeling

5 Information on ClipGuide (Model Card)

The information below intends to communicate information about the ClipGuide, which is an ML-feature of the IntraGuide ultrasound system.

ML Model Information	
Name	ClipGuide for Tumark Vision
Model version or identifier	TV_0.8.2.0
Release Date	December 01, 2025
Model UDI	(01)4262555910074(11)251201(8012)TV_0.8.2.0
Model Architecture	TBC
Clinical indications and contraindications	See 2.4.2 Indications for Use ClipGuide
Clinical workflow phase	ClipGuide is intended to be used during these procedures alongside the breast cancer treatment pathway:

<table>
<tr><td></td><td>

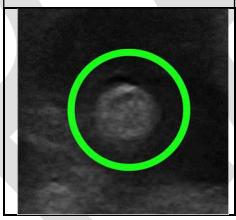
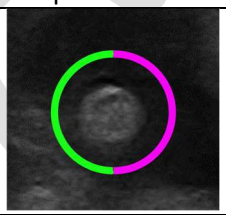
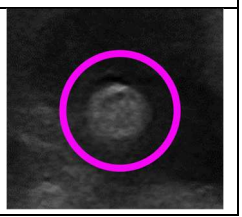
outpatient follow-up evaluations of the breast, e.g. pre-surgical therapy monitoring, where the healthcare professional searches for the previously placed breast biopsy clip
planning for interventional procedures, e.g. identifying biopsy clip position before placement of localization device
planning for surgical procedures, e.g. identifying biopsy clip position before breast-conserving surgery

ClipGuide is not intended to be used for these procedures:

ClipGuide is not intended to provide guidance for needle insertion (e.g. biopsy needle, needle with a preloaded localization device, needle with preloaded biopsy clip)

</td></tr>
<tr><td>Inputs and outputs of the model and contribution to healthcare decisions or actions.</td><td>
Input to ClipGuide is ultrasound image data. The ML-model analyzes each acquired ultrasound frame.

Output of the ML-model are coordinates of structures identified as biopsy clips and the ML-model probability for these structures. Coordinates with an ML-model probability above a pre-determined threshold are being visualized with a circle by the ClipGuide software feature. Only the structure with the highest ML-model probability is being visualized if there are more structures in one frame with ML-model probability above the threshold.

How to interpret visualizations in practice.
The ClipGuide visualization has three distinct patterns:
<table>
<tr><td>Full green circle</td><td>Half-green/half-pink circle</td><td>Full pink circle</td></tr>
<tr><td>  </td><td>  </td><td>  </td></tr>
</table>

The assignment of the categories has been calibrated on all frames of the testing dataset which is representative for the intended use cases of ClipGuide.
Full green circle will be shown on the upper 33% of frames when frames are sorted by probability of the ML-model.
Full pink circle will be shown on the lower 33% of frames when frames are sorted by probability of the ML-model.
Half-green/half-pink circle is an intermediate visualization which will be shown for frames where the probability of the ML-model is between the green (higher probability) and pink (lower probability).

A short tone is played for visualizations with green and half-green/half-pink circle. No tone is played with pink circle.The volume of the tone follows the tablet’s current volume setting.
</td></tr>
</table>

	The overlay and tone are **assistive cues**—they do not replace clinical judgment. Always verify the target visually in the ultrasound image before acting.
Potential risks associated with the model, the data, and the outputs	**False positive visualization of structures that are not the Tumark Vision biopsy clip.** By the nature of the ML-model, ClipGuide may also visualize structures that are not the Tumark Vision. In the test dataset, which is representative for the intended use cases of ClipGuide, this has been observed in 0.91% of all XYZ frames that did or did not contain the Tumark Vision biopsy clip. Not visualization of Tumark Vision biopsy clip. By the nature of the ML-model, ClipGuide may also not visualize the biopsy clip even though a trained health-care professional would be able to identify the biopsy clip in the image frame. In the test dataset, which is representative for the intended use cases of ClipGuide, this has been observed in 7.3% of XYZ frames, that contained Tumark Vision biopsy clip.
Degree of automation compared to the current standard of care, including whether the device supports or automates decision making.	The ClipGuide visualization assists healthcare professionals in finding breast biopsy clips during ultrasound imaging faster The ClipGuide is not intended to automate the decision making of a healthcare professional.
Performance and Limitations	
Performance Metrics	Sensitivity (Recall): 0.827, 95% CI [0.754, 0.9] Specificity: 0.996, 95% CI [0.994, 0.999] Precision: 0.942, 95% CI [0.889, 0.994] F1 score: 0.867, 95% CI [0.8, 0.934] Negative predictive value: 0.804 [0.735, 0.873] The above performance metrics are weighted averages of ML-model performance in 75 imaging sessions. To establish the average performance metrics, session-specific performance was evaluated across all individual frames separately for each ultrasound imaging session in the test set. The above performance metrics represent across-session averages, weighted by the number of frames in each session, and 95% confidence intervals. The metrics represent the model performance at the pre-determined probability threshold above which model detections are visualized.
Performance Evidence	The ML model evaluation was performed in an internal verification procedure. There is currently no published data on ClipGuide performance.
Known failure modes 	The following are cases where the device input will not align with the data used in development and validation. These cases are not part of the intended use of the ClipGuide algorithm, and the respective data was not part of training and testing. Using ClipGuide in such cases may lead to unreliable results. These cases include:

	• ultrasound images with interventional devices (e.g. biopsy needles, localization wires, localization seeds) in the imaging frame • ultrasound images with two or more biopsy clips in one frame • ultrasound images from the axilla or any other anatomy outside of the female breast • ultrasound images where the biopsy clip would be deeper than 5 cm • ultrasound images of non-anatomical structures (such as ultrasound gel, ultrasound phantoms) • Ultrasound images with other biopsy clips then **Tumark® Vision (SOMATEX® / HOLOGIC®)** • Ultrasound images with image settings or acquisition parameters outside of the pre-defined ranges selectable via the IntraGuide UI while ClipGuide is enabled

Known and potential biases 	The following cases are part of the intended use of the ClipGuide algorithm but were underrepresented in the training and testing dataset due to their low prevalence in the target population. While subgroup analyses of the respective demographic subgroups did not reveal statistically significant differences in ClipGuide performance between groups, they are potential sources of bias.
	• Biopsy clips placed deeper than 2 cm .
	• The ultrasound images for training and testing were recorded from BI-RADS 4-6 patients. BI-RADS 1-3 classified patients were not included.
	• Certain demographic factors, specifically
	  ○ Ethnicities other than White
	  ○ BMI below 18.5
	  ○ Breast size DD and above

Development	
Methods used to establish and ensure that the model meets the intended use and user requirements	**Design Control** in accordance with FDA Quality System Regulation (21 CFR Part 820), ensuring systematic planning, verification, and validation throughout the product lifecycle. **Interface Development and Testing** aligned with IEC 62366 addressing user interface design and mitigating risks related to usability and human factors. **Risk analysis and management** alongside the ML-mode development aligned with ISO 14971 **Artificial Intelligence Development** following FDA guidance documents, including *"Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning-Based Software as a Medical Device (SaMD)"* and related best practices, ensuring transparency, performance, and safety of AI components. **Software Development** is conducted in compliance with **IEC 62304**, ensuring a structured software lifecycle with rigorous risk management, verification, and validation activities.

Data Characterization of data used to develop the device	[Data sources (e.g., clinical trials, public or proprietary databases) including details on any devices used to collect data.] [Data types used (e.g., structured numerical data, structured categorical data, unstructured text, images, time-series data, or a combination).] [Relevant details including the sample size, effect size, data quality, reference standard, diversity, and representativeness.]
Limitations in the model development	Model development: • Overfitting: If not properly managed, model training can result in overfitting to the training data, thus degrading model performance on unseen data. During training, regularization, early-stopping criteria and hyperparameter optimization were employed to limit the risk of overfitting. • Image quality and acquisition parameters: Image quality can influence model performance. During model training, data augmentation was used to mimic a variety of image acquisition parameters. Further, the IntraGuide software limits the range of image parameters adjustable to the user such that reliable model performance is ensured. • Real-time requirement limiting model complexity
Data Characterization for data used to test the device	ClipGuide was developed using ultrasound data collected at clinical sites under approved research protocols, operated with the same system configuration as the final product. Cases for ultrasound data collection reflected workflow steps after a **Tumark® Vision (SOMATEX® / HOLOGIC®)** clip had been placed – outpatient follow-up procedures, intervention or surgery planning and imaging during surgical procedures. Collected data for training and validation included both "clip in frame" and "no-clip in frame" examples. To check that ClipGuide generalizes beyond the training set, performance was verified on a **separate set of patients not used for training**. **Train/test split and independence.** To avoid data leakage and to assess generalization, the **train–tuning set** consists of patients from a **single site** used only for training, while the **independent test set** comes **from several external sites** and is **sequestered** from the training process (no overlapping patients or sites).
Limitations in the model performance testing	Performance evaluation: Data bias: The training (and testing) data contained imbalances across various patient demographics and attributes (e.g., scanning site, age, ethnicity, breast size, breast density), meaning that certain subgroups were underrepresented compared to others. Subgroup analyses were performed to assess potential bias introduced by training/testing on unbalanced data. These analyses revealed no significant differences between subgroups, indicating that the model generalizes well even to underrepresented patient groups.
ML-Model Lifecycle	
Description of information that could	There are no known risk related to the product lifecycle of the ML-model.

impact risks and patient outcomes, across the product lifecycle	
Details regarding how the model is deployed and updated	The ML-model is frozen and is not self-learning. The ML-model is updated in regular intervals with updates of the IntraGuide software. The updates are performed on-site by authorized service personal.

6 System Overview

6.1 Principle of Operation

The ultrasound imaging system is based on the effect of ultrasound wave reflection from the tissue edges with different acoustic impedance levels. Ultrasound waves sent out by the transducer head are emitted into the patient's body. Reflections from the specific types of tissue and their external surface/edges cause partial reflections of the propagating sound wave. The return echo comes back to the transducer head and after being detected and amplified is displayed on the monitor screen as a pixel combination with various shades of brightness creating an ultrasound image. Components and Modifications

IntraGuide Box:

- Excite electric pulses to fire the transducer unit in the ultrasound probe;
- Ultrasound echo signals pre-amplification;
- compensation of the ultrasound attenuation due to travel depth;
- re-ordering the receiving signal sequence and focusing by applying the appropriate time delays;
- shifting the center frequency of BPF (band pass filter) to follow the frequency shift that occurs according to the travel depth;
- the ultrasound signal compression by means of Log Amplifier, detection of the echo signal envelope

Ultrasound Probe:

The transducer unit of the ultrasound probe is a piezoelectric transformer which provides the acoustical pulse used to examine the medium and is used for both transmission and reception (the transducer is used in pulse-echo mode). A voltage waveform is applied to the transducers of the transducer unit and then converted into an acoustic waveform (inverse piezoelectric effect). An acoustic pulse is then partially transmitted and partially reflected by the intervening soft tissues structures in the body. The reflected acoustic waveform is received by the same transducer unit and is converted into a voltage waveform (direct piezoelectric effect). The transducer unit consists of many piezoelectric elements.

The probe enclosure has an indentationto indicate the orientation of the ultrasound probe.

6.2 Network Connectivity

IntraGuide system operates **standalone**. It does **not** connect to the internet or hospital networks, and no patient data are transmitted over wired or wireless interfaces. Network adapters are **not used** during

normal operation. Software updates, when required, are performed **offline** by AURA field service personnel using approved media. There are no user-configurable network settings.

	WARNING: Connection of the system to an IT network that includes other equipment could result in previously unidentified risks to patient, operator or third parties. The responsible organization should identify, evaluate and control these risks. Subsequent changes to the IT network could introduce new risks and require additional analysis. Changes to the IT network include – changes to 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 and update of equipment connected to the IT network.

6.3 Peripherals and Compatibility

Optionally recommended trolley accessories are external battery and battery holder. Compatible probe sleeve covers for the L12-5N40-A4 ultrasound probe:

- Ecolab / Microtek ULTRACOVER Surgical Probe Covers - T-Shaped Ultrasound Probe Cover - PC3687 × 1
- SHEATHES 5-2435 KIT Invasive (Ultrasound Probe Cover Kit – 20 ml Sterile Gel and 2 Sterile Elastics)
- Palmedic Probetection™ 1238-02

Always consult regulatory approval with the manufacturer

7 System Startup and Shutdown

This section provides instructions to start (power on) the IntraGuide system and to safely shut it down after use.

7.1 Startup:

1. Press the **power button** on the IntraGuide PC (tablet PC) to turn on the system. Ensure the tablet PC is connected to its power supply or has sufficient battery charge before powering on.
2. Allow the system to boot up. The **IntraGuide software** will launch automatically – no user login or manual software start is required.
3. Wait for the IntraGuide interface to fully load (boot-up is typically completed within approximately one minute). Once the software is running, the system is ready for operation.

NOTE: The system's hardware components (IntraGuide Box, ultrasound probe, and all connecting cables) are pre-assembled and pre-connected by the manufacturer. **No user assembly or cable connection is required during startup.** If the system does not function as expected upon power-up, refer to the **Troubleshooting** section for guidance on checking component connections.

7.2 Shutdown:

1. Tap the on-screen **Shutdown** button (power icon) in the IntraGuide interface to initiate system shutdown.

Figure X: Shutdown button in the IntraGuide interface.

2. A confirmation prompt will appear on the screen. Confirm the shutdown command when prompted by taping on **"Shut down"** in the dialog
3. The IntraGuide software will close and the IntraGuide PC (tablet) will power off automatically. Do not take any other action; the system will shut down on its own.

NOTE: Always shut down the system using the IntraGuide on-screen Shutdown command. The shutdown procedure is managed entirely within the IntraGuide software, which ensures that the application closes safely, and the IntraGuide PC powers down properly. This integrated shutdown process helps prevent data loss or hardware issues by powering off the software and hardware together.

8 Software User Interface

The IntraGuide application runs **full screen upon system startup** and is optimized for **touch** operation on the tablet PC (no mouse or keyboard). The main screen presents the live B-mode image in the center, the **Image Settings** panel on the right (Power, Focus, Gain, Dynamic Range, Depth), the **Freeze/Unfreeze** control at the bottom, and a **status bar** at the top showing Battery status, Disk Space, Probe status, and **ClipGuide: ON/OFF**.

The left-docked ClipGuide panel provides guidance features. The **ClipGuide** panel is **visible by default** and remains active during use; if you open the **Presets** panel, it occupies the same left dock and **temporarily covers** ClipGuide (closing Presets restores it). When **ClipGuide is ON**, the **Presets** button is **disabled**. To open Presets, first **deactivate ClipGuide**. Audio feedback is available for ClipGuide detection and follows the tablet's **system volume**, which can be adjusted via the on-screen **Sound** control.

The layout is consistent across the application to keep essential controls and indicators always in view. Subsequent subsections describe each control group and workflow.

8.1 Ultrasound Image

8.1.1 Freeze/Unfreeze

The **Freeze/Unfreeze** control pauses and resumes real-time ultrasound acquisition. Freezing the image is useful when a stable frame is needed for inspection before proceeding (Cine playback is **not** available)

8.1.1.1 Freezing the image

When the **Freeze** button on the main screen is tapped, the system pauses acquisition and holds the current frame on screen. The button label changes to **Unfreeze**, indicating the paused state.

- The live image stops updating while frozen.
- Safety/status readouts (e.g., MI/TIS) stop changing until acquisition resumes.
- ClipGuide assistance is suspended while frozen and resumes with live imaging.

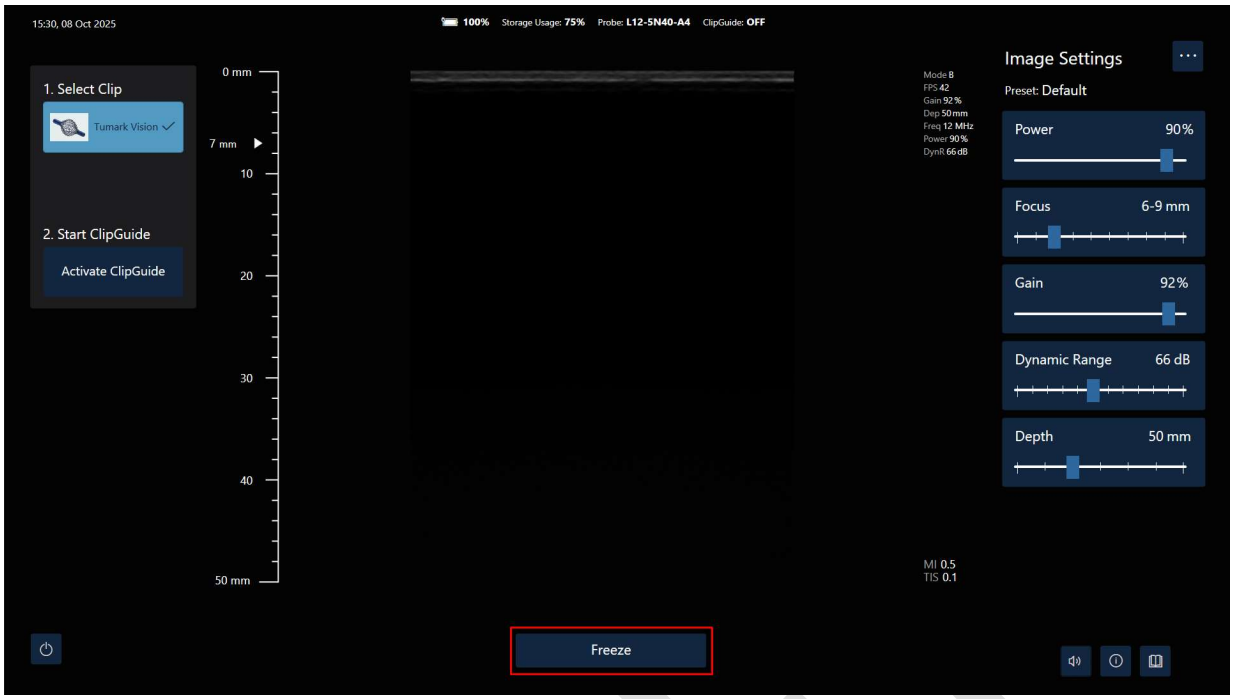


Figure 8.2.1: Freeze button in the IntraGuide UI

8.1.1.2 Unfreeze (Resuming live imaging)

Tap **Unfreeze** to immediately return to real-time scanning. The button text switches back to **Freeze**, MI/TIS resume updating, and ClipGuide (if previously enabled) continues running.

8.1.1.3 Automatic freeze (power-saving)

If no user interaction occurs for a period of inactivity (10 **minutes**), the software may **automatically freeze** acquisition to help **prolong the ultrasound probe's lifetime**. To resume scanning, tap **Unfreeze**.

8.2 Ultrasound Image Settings

The **Image Settings** panel (right side of the screen) provides touch controls to adjust the live ultrasound image. Settings take effect immediately and are listed below **in the same top-to-bottom order shown in the GUI**. Use your finger to **drag the slider handle**; the current value is shown next to each control on screen.

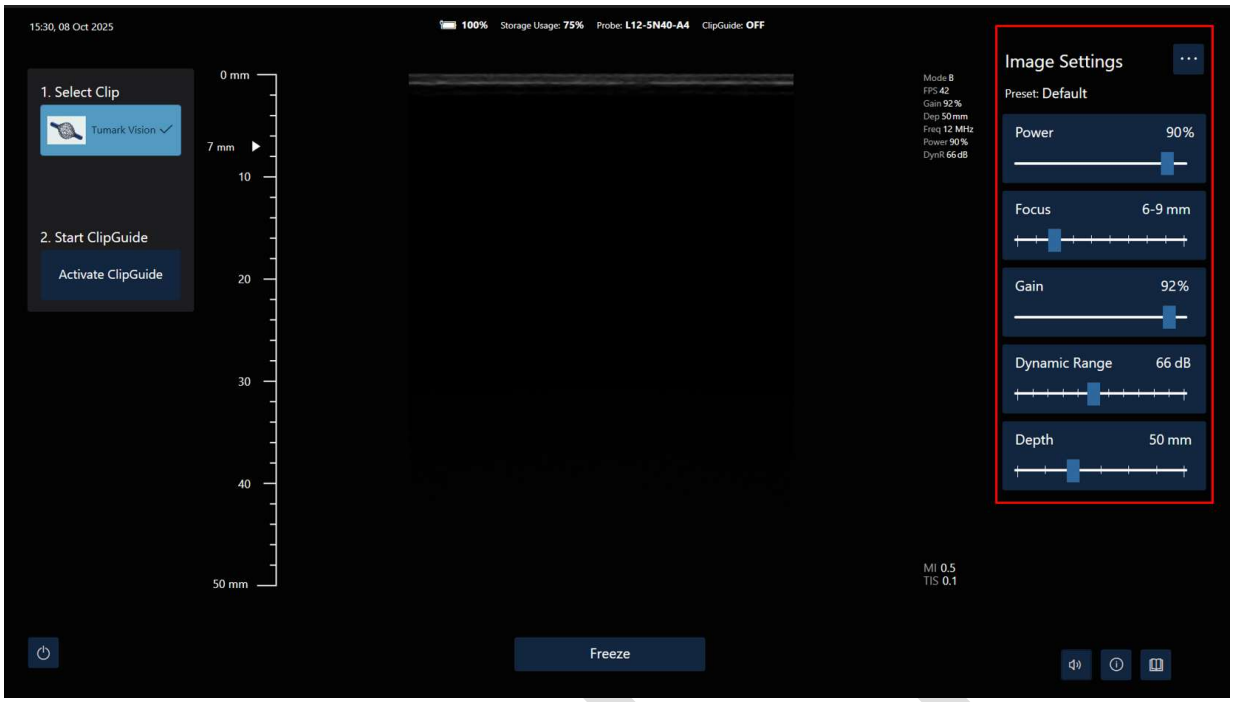


Figure 8.1.0: Location of the ultrasound Image Settings in the GUI

8.2.1 Power

Purpose. Adjust the acoustic output delivered by the transducer. Increasing Power can brighten the image by sending a stronger signal; decreasing Power reduces output.

How to adjust. Drag the **Power** slider to the desired level. The current value is displayed.

Figure 8.1.1: Power control as shown in the Image Settings panel.

Notes/Safety. Follow ALARA principles—use the **lowest output** that achieves adequate image quality. Power changes may be reflected in on-screen safety indicators (e.g., MI/TIS), where available.

8.2.2 Focus

Purpose. Sets the focal zone depth so that structures near that depth appear with optimal lateral resolution.

How to adjust. Drag the **Focus** slider to move the focal zone to the region of interest. The current depth is shown on screen in millimeters.

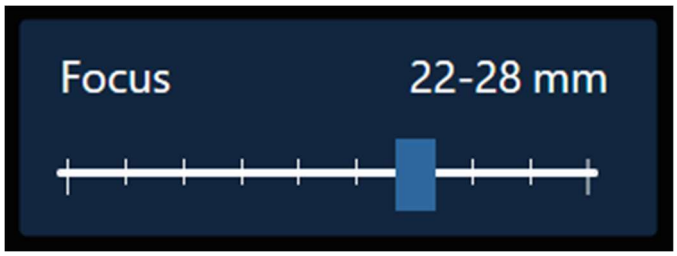


Figure 8.1.2: Focus control and on-screen focal depth display.

Notes.

- Position the focal zone at or just **below** the target anatomy for best sharpness.
- **Interaction with Depth:** The available **Focus** range and scale are determined by the currently selected **Depth**. When you change **Depth**, the **Focus** slider's range updates accordingly:
    - Reducing **Depth** reduces the imaging field and accordingly, the maximum focal zone ; the focal marker is repositioned within the shallower imaging field.
    - Increasing **Depth** expands the imaging field and accordingly, the maximum focal zone depth is increased; the focal marker is rescaled within the deeper field.
    - If the focal zone was set beyond the new **Depth** limit, it is automatically constrained to the deepest valid position within the updated depth range.

8.2.3 Gain

Purpose. Controls overall image brightness by amplifying received echoes (does **not** increase acoustic output).
How to adjust. Drag the **Gain** slider until tissue interfaces are clearly visible without saturation. The current value is shown on screen (e.g., as a percentage).

Figure 8.1.3: Gain control with current value display.

Notes. If the image is too dark, increase **Gain** before increasing **Power**.

8.2.4 Dynamic Range

Purpose. Adjusts grayscale contrast. Higher dynamic range (larger value) distributes gray levels across a wider range of amplitudes (lower contrast); distributes gray levels across a narrower range of amplitudes (increased contrast).
How to adjust. Drag the **Dynamic Range** slider to balance tissue differentiation and contrast. The current value is shown on screen (e.g., in dB).
Notes. If fine soft-tissue differences are needed to be visualized, try a **higher** dynamic range; for

crisper boundaries, try a **lower** dynamic range.

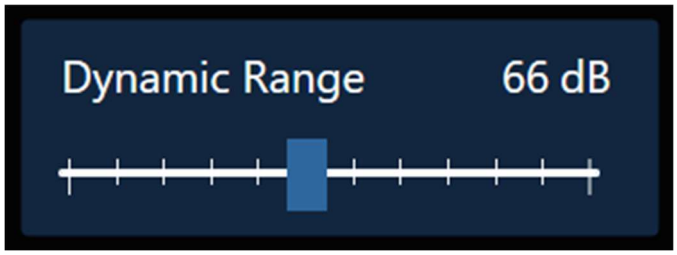


Figure 8.1.4: Dynamic Range control with current value display.

8.2.5 Depth

Purpose. Sets the imaging field in the axial direction so the anatomy of interest fills the image appropriately.
How to adjust. Drag the **Depth** slider to include the target region while minimizing space below the target anatomy. The current depth is shown on screen (e.g., in millimeters).
Notes. Reducing depth can improve visualization of **superficial** targets; increasing depth is required for **deeper** targets. Depth changes may influence the display of focal markers and on-screen scale.

Figure 8.1.5: Depth control.

8.2.6 Preset Name Display

The active preset is shown above the Image Settings panel as **Preset: *<name>***. The label updates when a preset is **loaded**, **renamed**, or **saved**.

- **Modified state.** If any Image Settings control (Power, Focus, Gain, Dynamic Range, Depth) is changed after a preset is loaded, the label appends **"(modified)"** → **Preset: *<name>* (modified)**.
- **Clearing "(modified)".** The "(modified)" tag is cleared when you:
    - **Save New Preset** (the new preset becomes active and is shown as **Preset: *<new name>***), or
    - **Update** the selected preset (the stored parameters match the on-screen values), or
    - **Load** any preset (reverts to that preset's saved parameters).
- The "(modified)" tag is informational only; scanning can continue normally while it is displayed.

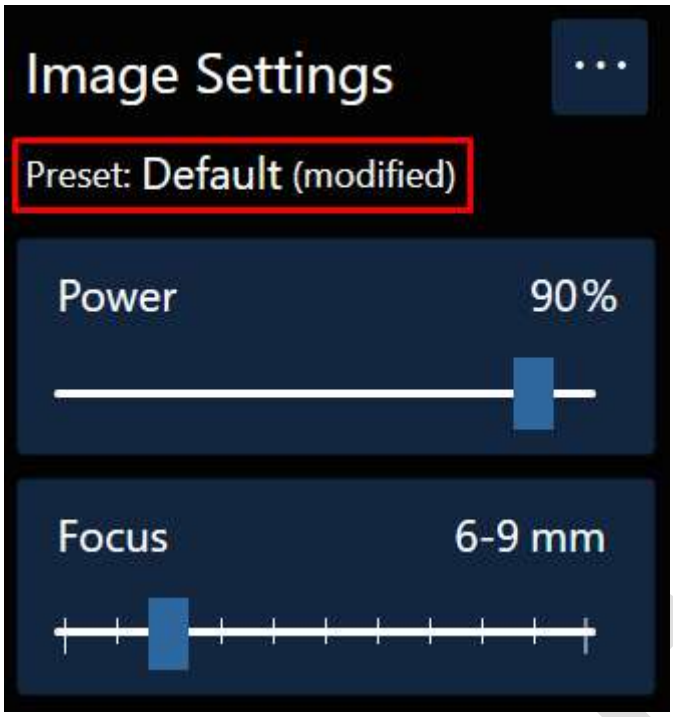


Figure 8.2.6: Active preset name shown above the Image Settings panel, including the "(modified)" indicator after an adjustment.

8.3 Indication of System Status

The IntraGuide Software GUI includes dedicated indicators that allow the operator to monitor the system's operational state at a glance. These on-screen indicators display critical information about the system's **Battery** level, available **Disk Space**, **Probe** connection status, and the status of the **ClipGuide** feature. **Figure 8.2** shows the system status area of the GUI where these indicators are located.

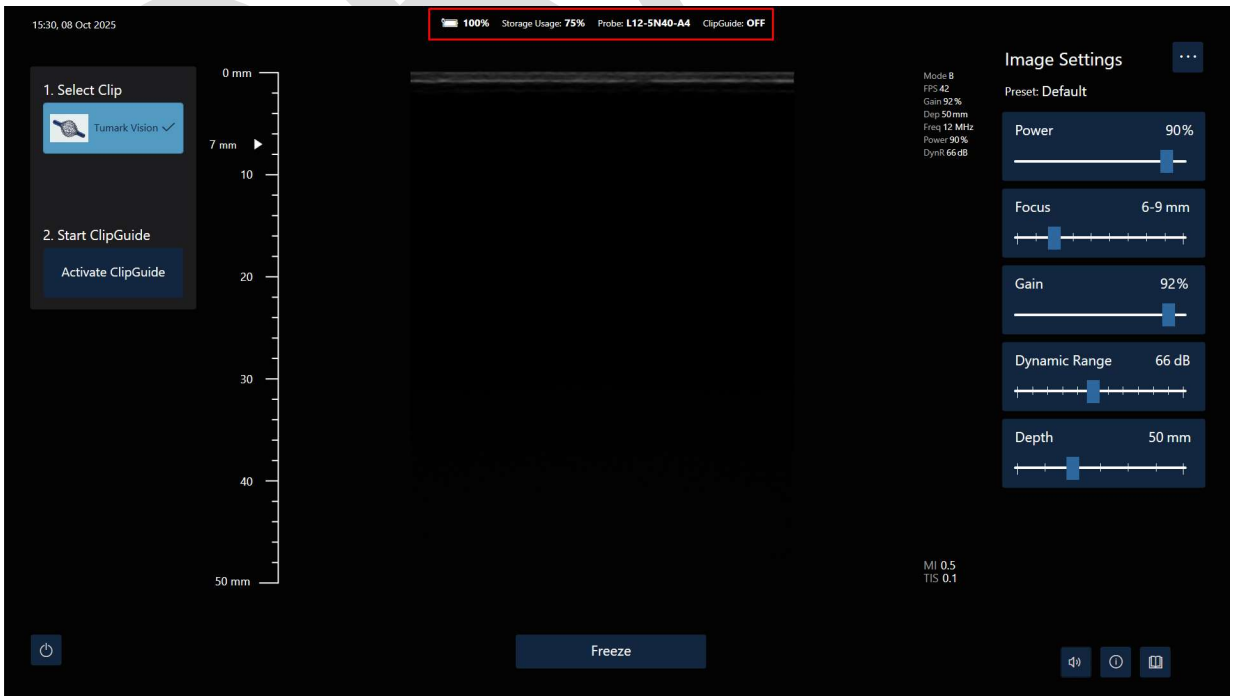


Figure 8.2. Location of System status indicators in the GUI

8.3.1 Battery

The **Battery** indicator displays the IntraGuide PC's current battery charge level (shown as a percentage, often alongside a battery icon). Under normal conditions, this indicator shows a high percentage (up to 100% when fully charged) and decreases gradually as the battery discharges. If the battery charge falls below a critical level, the GUI will display warning.

User Action: When a low battery warning appears, immediately connect the system to external AC power to recharge the battery and ensure continuous operation. No additional action is required as long as the battery indicator remains at a safe level (no warning).

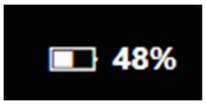


Figure 8.2.1: Battery Status Indicator

8.3.2 Disk Space

The **Disk Space** indicator shows the amount of storage capacity remaining on the system (for example, it may display the percentage of free disk space or a textual status). In normal operation, this indicator reflects sufficient free space and no warnings are shown. If the available disk storage falls below a predefined threshold (i.e., the disk is nearly full), the system will display a disk space **warning** on the GUI.

User Action: If a disk space warning appears, **do not** attempt to delete files or resolve the issue yourself – instead, contact AURA Technical Support for assistance. The appearance of a disk space warning indicates that the system may require maintenance or data management by authorized service personnel.

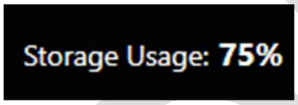


Figure 8.2.2: Disk Space Status Indicator

8.3.3 Probe Status

The **Probe** status indicator reflects the connection status of the ultrasound probe. When the supported probe is properly connected and recognized, the indicator displays the probe's name, confirming that the system is ready for scanning. If no probe is connected or the probe is not detected, the indicator will display **"No Probe"** in place of a probe name. A "No Probe" status means the system cannot detect an ultrasound probe and scanning cannot proceed.

User Action: If "No Probe" is shown, ensure that the probe is securely connected to the IntraGuide system, the IntraGuide Box (ultrasound unit) is powered on, and all cables are properly attached. After reconnecting, verify that the indicator changes to show the probe name. If the **"No Probe"** message remains after checking connections and power, contact AURA support for further assistance.

Figure 8.2.3: Probe Status Indicator

8.3.4 ClipGuide

The **ClipGuide** status indicator shows whether the ClipGuide feature is active or inactive. It displays **“ClipGuide: ON”** when the ClipGuide function is active, and **“ClipGuide: OFF”** when the function is turned off; no color coding is used for this. **“ClipGuide: ON”** indicates that the ClipGuide algorithm is currently running and will assist in locating compatible biopsy clips in the ultrasound image. Conversely, **“ClipGuide: OFF”** indicates that the feature is not active (no clip-finding assistance is running). There are no warning or error states for ClipGuide status – the indicator simply reflects the ON/OFF state.

User Note: The operator should verify that ClipGuide is set to **ON** if marker localization is required for the procedure. If ClipGuide is not needed, it is normal for the indicator to show **OFF**, and no action is required (the feature can remain off until its use is desired).

Figure 8.2.4: ClipGuide Status Indicator

8.4 Ultrasound Scanning Presets

The **Presets** panel in IntraGuide is the place to view, create, load, update, rename, and delete ultrasound presets that control the current imaging parameters.

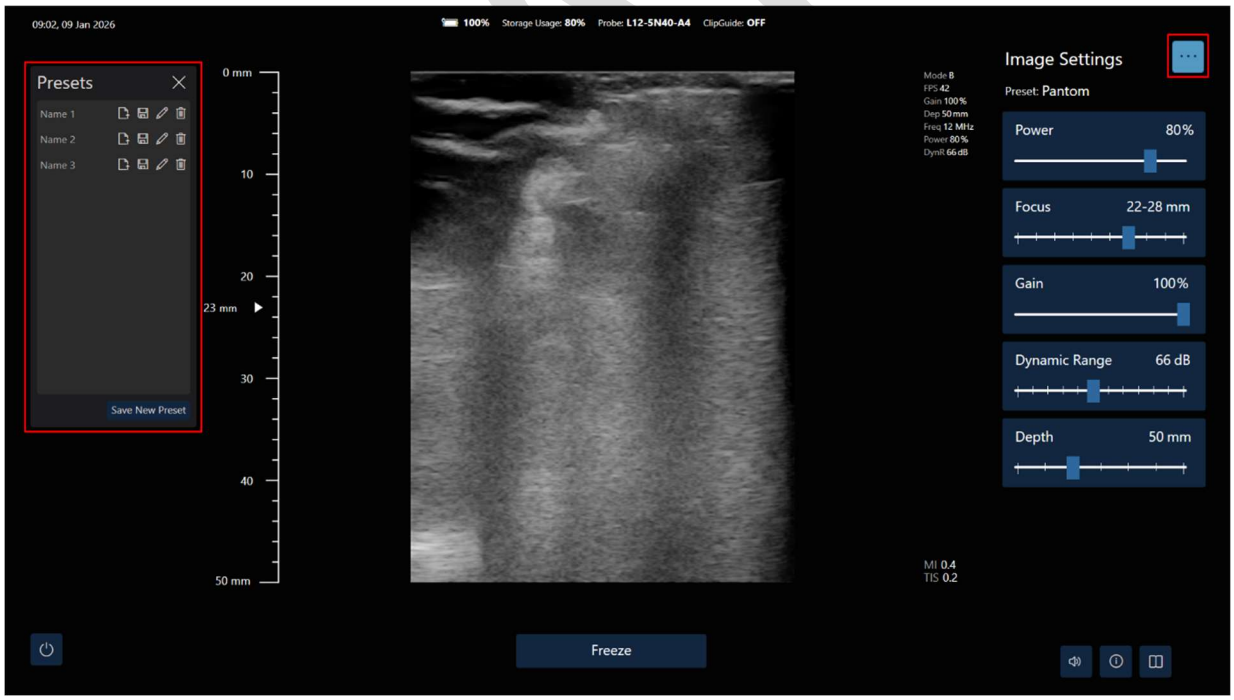


Figure 8.3.1: Preset Menu button (⋯) in the Image Settings header (right, small red box) and the Presets panel (left, big red box) once opened.

8.4.1 Opening & closing the Presets panel

8.4.1.1 Opening

The Presets panel is opened from the Image Settings area. When the **three-dot (⋯) button** in the Image Settings header (top-right of the control panel) is tapped, the system displays the **Presets** panel

on the **left** side of the screen. The ultrasound image and Image Settings remain visible while the panel is open. The panel stays open after any action (e.g., Load or Update) until it is explicitly closed by the user.

Prerequisite: To open the preset panel **ClipGuide must be OFF.** While ClipGuide is **ON**, the Presets button is **disabled** and the panel cannot be opened. To open Presets, deactivate ClipGuide, tap the **three-dot (⋯) button** in the Image Settings header. The Presets panel then opens on the left.

Figure 8.3.X: The three-dot (⋯) button (preset menu button) opens the presets panel.

8.4.1.2 Closing

The Presets panel is closed from its own header. When the **X** button in the top-right of the Presets panel is tapped, the system hides the panel and returns to the standard layout. Tapping outside the panel does not guarantee closure; the **X** button should be used to reliably dismiss the panel. The currently active imaging settings and the selected preset remain unchanged when the panel is closed.

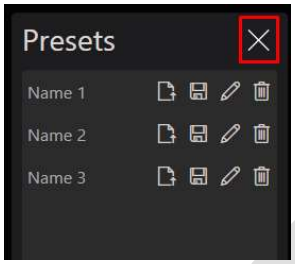


Figure 8.3.Y: Closing the Presets panel using the X button.

8.4.2 Save a New Preset

The **Save New Preset** function allows the creation of a new preset from the current ultrasound settings. When this icon is selected, the system prompts the operator to enter a name for the new preset. The new preset name must be unique – if a name is already in use, the software will alert the user to choose a different name. Once a valid name is entered and confirmed, the system saves the current imaging parameters as a new preset and adds it to the presets list for future use.

Safety Note: To avoid accidentally overwriting an important preset, create a new preset rather than updating an existing preset unless you intend to replace it.

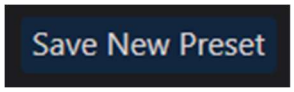


Figure 8.3.1: Save New Preset button

8.4.3 Load Preset

The **Load Preset** function is used to apply a saved preset's settings to the system. The Load option is typically represented by an "open folder" icon or similar symbol. Selecting a preset from the list and then pressing the **Load** icon immediately loads all ultrasound imaging parameters stored in that preset. This allows the operator to quickly switch the system to a predefined configuration (e.g., specific depth, gain, and other imaging settings) optimized for a particular exam. No confirmation dialog is required for loading a preset since it is a non-destructive action; however, any unsaved adjustments made to settings

will be overridden when the preset is applied. Operators should ensure that any important current settings are saved (as a new preset, if needed) before loading another preset.

Figure 8.3.2: Load Preset icon

8.4.4 Update Preset

The **Update Preset** overwrites the currently selected preset with the current imaging settings. This option is used to save adjustments made to a preset back into that preset profile (for example, if you fine-tuned the gain and want to make those changes permanent for the preset in use). After selecting Update Preset, a confirmation message will appear, such as "Overwrite the preset '<preset name>' with current settings? Yes/No." If you confirm, the preset is overwritten with the new parameters immediately. The next time you load this preset, it will reflect the updated settings. Safety consideration: Use this feature with caution to avoid unintentionally erasing a well-tuned preset. Once overwritten, the previous settings cannot be recovered. If you are not absolutely sure you want to replace the old settings, choose New Preset instead to save your changes under a different name. This preserves the original preset and prevents accidental loss of an optimized configuration.

Figure 8.4.4: Update preset icon.

8.4.5 Rename preset

The **Rename Preset** option (indicated by a pencil icon) allows you to change the name of an existing preset. When this function is selected, a dialog box will appear, prompting you to enter a new name for the currently highlighted preset. The new name must not duplicate any existing preset name; if a duplicate name is entered, the system will prompt the user to choose a different, unique name. After the operator enters an acceptable new name and confirms, the preset's label is updated in the list to the new name. Renaming a preset does **not** alter any of the stored ultrasound parameters associated with that preset – it only changes the identifier under which the preset is listed for easier recognition. This function helps keep preset names descriptive and up to date (for instance, reflecting a new protocol or user preference).

Figure 8.4.4: Rename preset icon.

8.4.6 Delete preset

Permanently removes the currently selected preset from the system's preset list. When this option is chosen, a confirmation dialog (for example, "Are you sure you want to delete preset '<preset name>'?" with Yes/No options) will appear. If you confirm deletion, the preset is deleted immediately and will no longer be available for selection. The current ultrasound image settings will remain as they were momentarily – deleting a preset does not freeze or change the image – but since the preset file is gone, you cannot revert to those exact saved settings later via a preset.

Safety consideration: Deletion is irreversible, so only remove presets that you are certain you no longer need. The confirmation step is designed to prevent accidental loss of a preset. If a preset was deleted in error, you would have to manually recreate those settings, so always double-check the preset name in the prompt before confirming.

Figure 8.4.5: Delete preset icon.

8.5 Sound Control

Location and appearance. The control is a square button with a speaker icon positioned at the bottom-right of the screen.

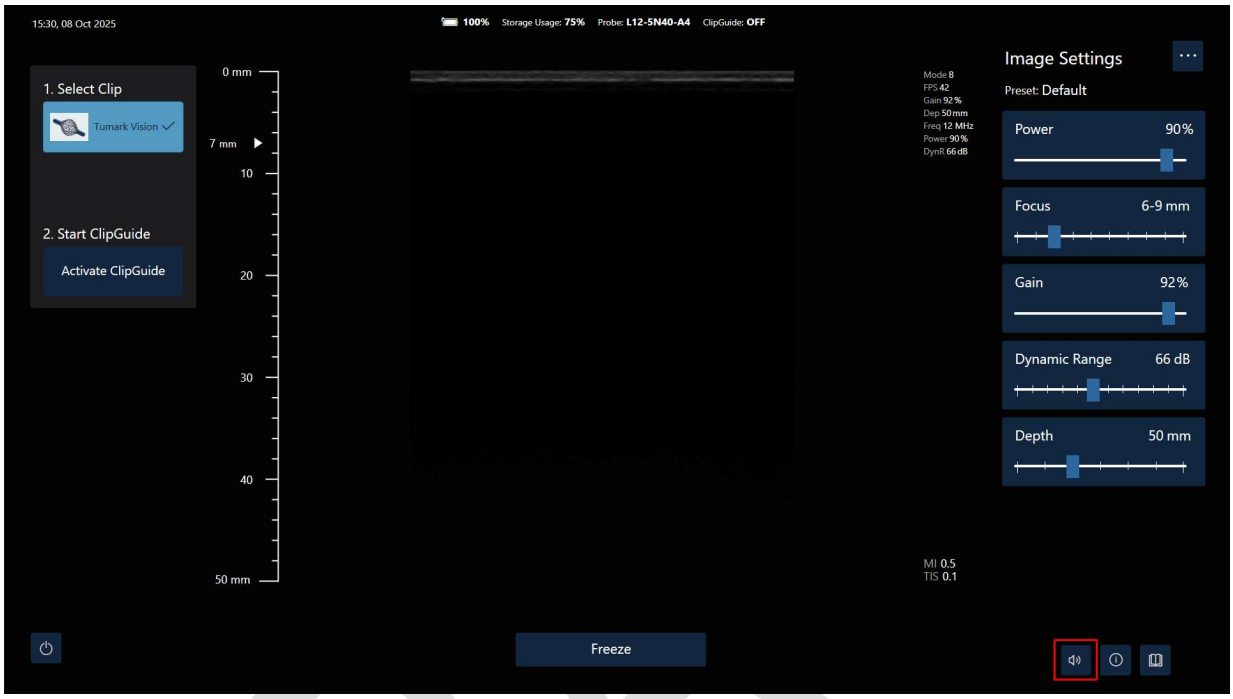


Figure 8.5 — Sound control (speaker icon) highlighted in the bottom-right corner of the Full Screen view]

The Sound control adjusts the tablet's system/OS output volume used for ClipGuide. When this icon is selected, the system displays a volume slider; dragging the slider left decreases the level and dragging right increases it. Changes take effect immediately and apply to all audio produced by the application. To silence audio, reduce the slider to its minimum position.

Range: The Sound slider adjusts the volume in percentage units (1–100%).

9 ClipGuide

9.1 Purpose and Scope

ClipGuide is an assistive software feature that analyzes the **live** B-mode stream to help the operator locate a **previously implanted biopsy clip**. Note that ClipGuide is validated **only for Tumark® Vision (SOMATEX® / HOLOGIC®)**biopsy markers; other marker types are not supported.

Note: ClipGuide operates only while **live scanning** is running. If the image is **Frozen**, ClipGuide analysis is **suspended** and resumes automatically after **Unfreeze**. (See Freeze/Unfreeze.)

9.2 ClipGuide Panel Layout

The **ClipGuide panel** is on the **left** side of the screen, it presents two steps:

1. **Select Clip** – choose the supported marker type.

2. **Start ClipGuide** – tap **Activate ClipGuide** to start real-time detection.

The system **status bar** at the top shows ClipGuide state as **ClipGuide: ON/OFF**. When ClipGuide is activated, this text changes to **ON**; when deactivated, it shows **OFF**.

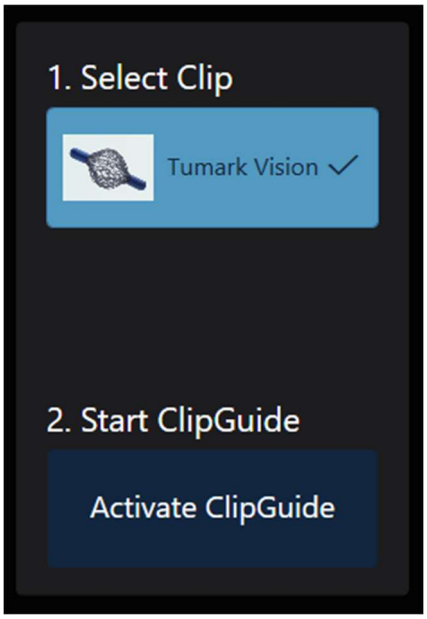


*Figure 9.2: ClipGuide panel showing **Step 1: Select Clip** and **Step 2: Activate ClipGuide**.*

Note: When the **Presets** panel is opened (available only when ClipGuide is OFF), it **temporarily covers** the ClipGuide panel. Closing Presets Menu (tap **X** on the Presets header) displayed the ClipGuide panel automatically.

9.3 Activate / Deactivate ClipGuide

Tap **Activate ClipGuide**. The top bar changes to **ClipGuide: ON** and the software starts running on the live ultrasound image. To stop ClipGuide, tap Deactivate ClipeGuide (the same control). The top bar changes to **ClipGuide: OFF**.

- **While ON:** the system may overlay a **circular marker** at candidate clip locations in the ultrasound image.
- **While Frozen:** ClipGuide is paused; overlays stop updating. Unfreeze to resume.

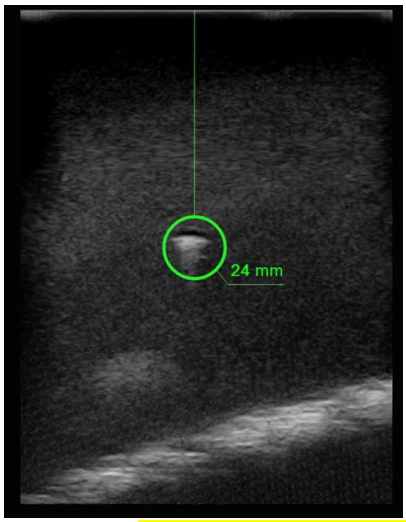
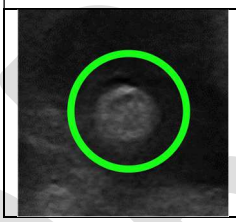
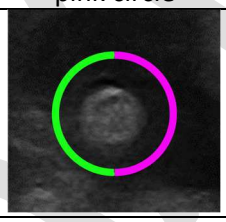
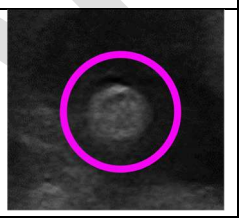


Figure 9.3: ***Activate ClipGuide*** *and "ClipGuide: ON" shown in the status bar. (Add a better image of the whole screen?)*

9.4 Interpreting the On-Screen ClipGuide Indicator

When ClipGuide identifies a clip, it draws a **circle overlay** at that location.

The ClipGuide visualization has three distinct patterns:

Full green circle	Half-green/half-pink circle	Full pink circle
		

The assignment of the categories has been calibrated on all frames of the testing dataset which is representative for the intended use cases of ClipGuide.

Full green circle will be shown on the upper 33% of frames when frames are sorted by probability of the ML-model.

Full pink circle will be shown on the lower 33% of frames when frames are sorted by probability of the ML-model.

Half-green/half-pink circle is an intermediate visualization which will be shown for frames where the probability of the ML-model is between the green (higher probability) and pink (lower probability).

9.5 Sound ClipGuide Indicator

A short tone is played **for visualizations with green and half-green/half-pink circle. No tone is played with pink circle.**The volume of the tone follows the tablet's current volume setting.

The overlay and tone are **assistive cues**—they do not replace clinical judgment. Always verify the target visually in the ultrasound image before acting.

10 Maintenance

The IntraGuide ultrasound system is designed for an **expected service life of 7 years** under normal operating conditions, provided that:

- The system is used according to the Instructions for Use.
- Preventive maintenance and calibration are performed as recommended.
- Only accessories and parts approved by AURA Health Technologies are used.

This period reflects the time during which the manufacturer guarantees essential performance and compliance with applicable safety standards (IEC 60601-1, IEC 60601-2-37). After this period, continued use should involve a risk assessment and may require refurbishment or replacement.

10.1 Inspecting the System

Before each use, briefly examine the system for **cleanliness and intact condition**. Make sure the tablet and ultrasound unit housings are not cracked or deformed, all screws and covers are secure, and all **labels and symbols are legible**. Check the **probe** and **connectors** for chips, cracks, residue, bent pins, or signs of liquid ingress. Run your hand along the **cables**—especially the **power cable**—and look for **peeling, splitting, or cracking** of the outer insulation. If any damage is found, **power down**, **carefully disconnect**, and **replace the cable** before use.

After the visual check, power on the tablet to confirm the screen responds to touch and the system starts normally. If you notice abnormal odors, unusual heat, error messages, consistent "**No Probe**" status, or any other irregularity, **do not use the system**—shut it down and contact **AURA** support.

	**WARNING:** Do not use the IntraGuide system if any component is damaged.

10.2 Software Update

Updates to the software are only performed on-site by AURA field service personnel.

10.3 General Cleaning

This section describes **routine surface cleaning** of the IntraGuide system components that do **not** contact the patient:

- **IntraGuide PC** (15.6" Rugged Medical Grade Windows Tablet, "MD-150")
- **IntraGuide Box** (beamformer enclosure)
- **External cables** and **trolley** surfaces

Important: Cleaning of the **ultrasound probe (transducer)** is covered separately in 10.4 Ultrasound Probe Maintenance and Disinfection

Shut the system down from the on-screen **Shutdown** button and unplug the system from mains (wall outlet) before cleaning. Wipe only the **external surfaces** of the equipment; do not open housings or allow liquid to enter vents, seams, ports, or connectors. Apply solution to a **soft, lint-free cloth** or other appropriate wipe—**do not spray or pour** liquids directly onto the device.

Use facility-approved, **electronics-compatible** cleaning wipes/solutions, such as screen cleaner, 70% isopropyl alcohol, alcohol prep pads, 10% ammonium chloride, 6% sodium hypochlorite. Some disinfectants or cleaning solutions may leave residual film or require additional efforts to remove completely. We recommend testing the solution on a discreet area of the system.

Do not use:

- Do not use bleach (NaClO) or ammonia (NH3)
- abrasive powders, abrasive cloths, scouring pads, polishes, towels and paper towels and similar abrasive items.
- window cleaners, household cleaners, solvents
- cleaners containing nitric acid (HNO3), hydrogen peroxide (H2O2) or sodium hydroxide (NaOH)
- compressed air, aerosol sprays

	**CAUTION:** The use of inappropriate cleaning or disinfecting chemicals may permanently damage the IntraGuide system or its components.

Clean the IntraGuide PC screen and exterior, the IntraGuide Box exterior, cables, and trolley surfaces with light, even pressure. If the product label requires a **wet contact (dwell) time**, keep surfaces visibly wet for that period; rinse with a water-damp cloth only if the product IFU instructs, then dry thoroughly. Do not reconnect the system to mains (wall outlet) until all parts are **completely dry**.

Perform a quick wipe-down **between patients** for high-touch areas and whenever visibly soiled; do a more thorough wipe of all external surfaces **daily** or per facility policy. If any liquid ingress, damage, or persistent residue is observed during cleaning, stop use and contact **AURA** support.

10.3.1 Recommended materials

- **Soft, lint-free** microfiber cloths or single-use, non-abrasive wipes.
- Facility-approved **electronics-compatible** cleaning/disinfecting wipes/solutions.
- Cotton swabs for narrow recesses (lightly moistened, not dripping).

10.3.2 Note: Avoid paper towels and rough textiles that can scratch glass or plastics. If a residue remains after disinfection, finish with a wipe lightly moistened with clean water, then dry with a lint-free cloth.Frequency and triggers

- **Between patients:** Wipe high-touch surfaces (tablet screen and bezel, handles, probe cable jacket near the grip—not the probe head; see 10.3).
- **Daily:** Wipe beamformer exterior and cable runs.
- **As needed:** When visibly soiled or after exposure to contamination (follow facility infection-control policy).

10.3.3 Post-cleaning check

- Verify that the **screen responds to touch** normally and that **ports** are clean/dry.
- Confirm all cables are fully seated and not kinked.

- Power on the system and confirm normal operation; if abnormal behavior appears, **disconnect the system from mains (wall outlet)** and contact **AURA** support

10.4 Ultrasound Probe Maintenance and Disinfection

This section describes **routine care, cleaning, and disinfection** of the ultrasound transducer used with the IntraGuide system. Follow your facility's infection-control policy in addition to these instructions.

Scope. The steps below apply to the **probe head** and **probe cable jacket**.

Safety prerequisites.

- Keep liquids away from the **electrical connector**; **do not immerse** the connector; clean only externally.
- If you observe cuts, cracks, swelling, discoloration, delamination, or exposed wires, **remove from service** and contact AURA.

10.4.1 Ultrasound Probe Used in Non-Invasive Procedures (intact skin)

The following disinfectants are approved for **wiping of the transducer:**

Cidex Plus, Cidex OPA, Anioxyde 1000, 75% IPA, Sani-cloth bleach, Metricide OPA plus, Rely+On PeraSafe, Cydezyme XTRA, Cleansept Wipes, Nu-Cidex, Alkazyme, Steranios 2%, Salvanios PH10, Cidex 2%, Klenzyme, Revital-Ox Resert

	**CAUTION:** Some of chemicals, such as phenol, benzethonium chloride, hexachlorophene (Phisohex), benzoyl peroxide, hydrogen peroxide, are commonly found in clinics or hospital settings while others are often found in antibacterial skin cleaners or lotions. Use of these chemicals will cause damage to the ultrasound probe. This damage is not covered by the warranty.

Point-of-use pre-clean (immediately after the exam)

1. Wipe ultrasound gel from the **transducer head** with a soft, lint-free cloth or a wipe from the above list of approved disinfectants.
2. If soil remains, wipe again with a cloth lightly moistened with clean water. Keep fluids away from the probe connector.

Routine desinfection and cleaning Use a soft cloth lightly moistened with an above listed **approved disinfectant.**

1. Wipe all external surfaces (head, body, cable jacket) using **minimal moisture** near strain reliefs/connector.
2. Maintain the disinfectant's **wet-contact (dwell) time**.
3. If the disinfectant requires **rinsing**, wipe with a clean-water cloth to remove residue.
4. Dry thoroughly with a lint-free cloth.

11 Transportation, Storage, and Utilization

11.1 Operating & Storage Conditions

Operate & store the system in **10–**35°C (50-95°F), 10%-85% **RH (non-condensing)**, **80–106 kPa (600-795 mmHg)**.

Hot environments affect the charging of the battery of the IntraGuide PC. If the internal temperature of the battery rises above 45°C (113°F) the battery will not charge.

	**WARNING:** Do not expose the IntraGuide PC to temperatures above 60°C (140°F). These conditions may cause the battery to malfunction, ignite or explode.

11.2 Transportation and Storage

Disconnect AC power cables from the mains (wall outlet) before moving the system.

Move and store the IntraGuide system and accessories in a **clean, dry, and secure** manner that protects against **shock, vibration, dust, and moisture**, and in compliance with your facility policy and **local regulations**.

	**CAUTION:** Special regulations apply to shipping devices containing Li-ion Polymer batteries. If dropped, crushed, or short-circuited, these batteries may release dangerous amounts of heat, may ignite or explode.

11.3 Disposal

Disposal and recycling of the IntraGuide system and its accessories must be performed by a **qualified, licensed waste handler** in accordance with **local laws and regulations** (including e-waste/WEEE, battery, and medical-waste rules). Before hand-off, **power off** the system, remove accessories and consumables, and **decontaminate** any surfaces per your facility policy. Where available, use your facility's approved **e-waste recycling** channel or a manufacturer/distributor **take-back** program. If you are unsure how to proceed, **contact AURA** for guidance to an authorized recycler.

	**WARNING:** Do **not** dispose of equipment in household waste, do **not** incinerate, and do **not** open housings to remove internal components yourself.

11.4 Warranty

AURA guarantees that the IntraGuide system is free from defects regarding materials and workmanship at the original purchaser's location for 18 months. Items not included in warranty are misuse, negligence or accidental damage. AURA points out that the loss of data is not included in this warranty.

The foregoing warranty is exclusive of and in place of all other warranties and representations, expressed or implied, including but not limited to any warranty of merchantability or fitness for any

particular trade usage. This warranty is also in place of any other obligations, liabilities, rights, or claims, whether included in the contract or not, including any rights arising from negligence on the part of AURA for any direct, incidental, consequential, or any other damages.

A warranty claim must be made without delay and must be received during the applicable warranty (guarantee) period by AURA.

If it is necessary to return a product for repair and/or adjustment, authorization from AURA must be obtained first. Instructions as to how and where these products should be shipped will be provided by AURA.

Any product or component returned for examination and/or warranty repair shall be sent insured and prepaid via the means of transportation specified by AURA. Shipping charges for all products or components replaced or repaired under warranty should be defined separately.

In all cases, AURA has sole responsibility for determining the cause and nature of failure, and AUR decisions about this shall be final.

12 Troubleshooting

Use this section to resolve common issues quickly. If a step fails or a warning persists, **stop use and contact AURA support**.

Symptom	Likely cause	Action (touch-only unless noted)
— STARTUP & SHUTDOWN —		
App does not appear after power on	System not fully booted	Wait for Windows to finish booting; the app launches **full screen** automatically.
“Shutdown” does nothing	Confirmation dialog awaiting input System not responding	Tap **Shut down** in the dialog; wait for system power-off Hold power button for 10s to force shut down of the system
Unexpected power-off	Low battery, AC power not connected	Connect system to mains (wall outlet), then restart. If repeated, contact **AURA**.
— STATUS BAR —		
Battery very low	Not charging / low charge	Connect system to mains (wall outlet); resume use when battery % is adequate.
Storage Usage warning	Disk nearly full	Follow the warning; **contact AURA** for service.
App shows No Probe	Probe not detected	Reseat the connector; check cable/strain relief; restart the system if needed.
ClipGuide: OFF and won’t change	Not activated or image is **Frozen**	Tap **Activate ClipGuide**; ensure image is **Unfrozen**.
— FREEZE / UNFREEZE —		
Freeze button seems unresponsive	App completing a prior action	Wait 1–2 seconds and try again.

Image froze by itself	**Auto-freeze** after inactivity (~15 min)	Tap **Unfreeze** to resume live imaging.
— IMAGE SETTINGS —		
Image too dark/bright	Gain/Power not optimal	Adjust **Gain** first; then adjust **Power** (follow ALARA).
Target not sharp	Focus not at ROI	Move **Focus** to the target depth; adjust **Depth** if needed (Focus range follows Depth).
Anatomy not fully visible	Depth too shallow/deep	Change **Depth** so the target fits on screen.
— PRESETS —		
Can't open the Presets panel	**ClipGuide is ON** (button disabled)	Tap **Deactivate ClipGuide**, then tap the **⋯** button to open Presets.
Can't find Save New Preset	Button location not noticed	The **Save New Preset** button is at the **bottom** of the Presets panel.
Name won't save (error shown)	Invalid input (e.g., special characters or name too short/long)	Follow the on-screen validation; use letters/numbers/spaces and a short **unique** name. Tap outside the field to trigger validation if needed.
"This name already exists…" appears	Duplicate name	Enter a **unique** name and confirm.
Update didn't change the preset	**Tapped "No"** in the Update dialog	In the Update dialog, tap **Update** to save; **No** cancels.
Rename didn't apply	Invalid/duplicate name or tapped **No**	Enter a valid, unique name and tap **Rename**; **No** cancels.
Delete didn't work	Tapped **No** in Delete dialog	In the Delete dialog, tap **Delete** to confirm; **No** cancels.
Error when loading a preset	File **corrupted** or contains **invalid values**	Choose another preset or **contact AURA**.
"(modified)" won't clear	Current settings differ from last saved	**Save New Preset** or **Update** the preset; **Loading** any preset also clears "(modified)".
— CLIPGUIDE (UI) —		
No overlays while scanning	**ClipGuide is OFF**	Tap **Activate ClipGuide**; verify **ClipGuide: ON** in the top bar.
	Clip not in frame (too shallow/deep or off-screen)	Reposition the probe; adjust **Depth/Focus** so the suspected region is in view.
	Image is **Frozen**	Tap **Unfreeze**; detection runs only in live imaging.
ClipGuide panel "missing"	**Presets** panel is open (left dock)	Close **Presets** (tap **X**). The **ClipGuide panel** is visible by default.
— SOUND (CLIPGUIDE TONE) —		
No tone on detection	Detection score ≤ **DS2**	Tone plays **only** for detections **above DS2**; rely on overlay for DS2 or below.
No tone even for strong detections	System volume too low / muted	Tap **Sound** (speaker) and move the **volume slider** right; you can also press the tablet **Volume +** hardware button.

Tone too loud/quiet	System volume level	Adjust via **Sound** slider or tablet **Volume ±** buttons; changes apply immediately.
— TABLET & HARDWARE —		
Touchscreen unresponsive	Moisture/residue on screen	Clean the screen (see **10.2 General Cleaning**); dry fully, then retry.
Cable warm, cracked, or peeling	Cable damage	**Shut down**, disconnect, and **contact AURA**.
Unusual odor/heat	Hardware fault	**Stop use**, power down, and **contact AURA**.

13 FAQs

Content for this section is under development and will be addressed in detail.