

CLEAR
GUIDE
MEDICAL

SCENERGY
USER MANUAL

P/N 30063R310



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System functionality is based upon the purchased license. Questions related to licensing or specific system functionality can be directed to **CLEAR GUIDE MEDICAL**.

Depending on the actual system variant and software revision, the screen captures provided herein may differ slightly from the actual **CLEAR GUIDE** system screen. The current **CLEAR GUIDE SCENERGY** User Manual is available for download at www.clearguidemedical.com/support.



710471 / Medical Electrical Equipment and Devices



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VERSION HISTORY

Document Version	Document Date	Software Release	Notes
R00			Initial release
R01			
R02	2016/05/03	3.2.4814	Updated per ECN 16-010 and 15-026
R03	2016/09/28	3.4.5653	ECN 16-018: TipTAG instruments; multiple instruments; encryption; UPS; multiple SuperPROBE orientations; screen captures; I18N; startup HW recovery; legal; performance improvements; logging; VM CT/video detection improvements; deformation improvements; 3D view; US error messaging
R04	2016/11/08	3.5.59xx	ECN 16-020 "Halloween": merged SCENERGY and ONE (UM version P30005R08.draft); TipTAG updated; help screens; GUI layout; administrative settings page; WML troubleshooting; deformation modeling consolidated; CG_STARTUP; ...
R36	2017/03/23	3.6.6581	ECN 17-002 "Spring SCONE": network adapters management; various UI changes; registration refinement; snapshots push-to-PACS; enforce two-sided TipTAG calibration (only changes to UM listed; see ECN for full change list). Document revision jump to consolidate with software version.
R36.1	2017/04/07	3.6.6581	Minor text updates; replaced ETL with Q-Mark
R36.2	2017/05/XX	3.7.7031	Updated with MR Text
R36.3	2017/07/XX	3.7.7031	Updated with Latest Indications for Use
R38	2017/10/04	3.8.7294	ECN 17-005 "Late Summer ECN": Removed references to ONE; Added: Centralized Optical Head, Licensing scheme; incl. MT Promedt changes.
R310	2018/02/06	3.10.8024	Removed the mention of animal and human dataset for MRI evaluation. Minor fixes to the document. ECN 18-001 changes.

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1 Before Use

1.1 Intended Audience

This **CLEAR GUIDE SCENERGY** User Manual is a reference document for operators to be used during procedures based on ultrasound fused with another modality – specifically, computed tomography (CT), magnetic resonance (MR), or similar 3D imaging modalities, depending on system version, feature license, and regulatory availability ¹. As such, this document is written for someone familiar with 3D volume and ultrasound imaging techniques. This User Manual does not provide guidelines for clinical aspects of 3D-volume- or ultrasound-based procedures or for interpreting the respective imaging. Prior to using the **CLEAR GUIDE** system, operators must have respective 3D volume imaging and ultrasound training.

The intended audience for this User Manual consists of end users. These include interventionalists as well as technicians operating under the direction of a physician. To ensure correct and reliable system operation, it is crucial for end users to be trained in using the **CLEAR GUIDE** system and for them to be aware of the capabilities and limitations of the system, and of the visual tracking approach in particular.

CLEAR GUIDE systems are intended for prescription use only.

Other manuals – such as the Field Service Manual – are available for qualified individuals. Please contact **CLEAR GUIDE MEDICAL** directly.



WARNING: Do not operate the **CLEAR GUIDE** system without having read this User Manual. Further questions regarding its safe operation should be referred to **CLEAR GUIDE MEDICAL** Customer Support before attempting to use the system.



CAUTION: U.S. federal law restricts this device to sale by, or on the order of a physician.

¹As of software version 3.10.8024, CT imaging is supported in the United States, Canada, and Europe, while MRI is only available in the United States. Please contact **CLEAR GUIDE MEDICAL** for up-to-date information (see p. 2).

1.2 Getting Help





CLEAR GUIDE MEDICAL offers help with questions or issues relating to CLEAR GUIDE systems:

- Option 1: Consult this User Manual, including Section 3 “Using the System” and Section 4.2 “General Troubleshooting”.
- Option 2: Contact CLEAR GUIDE MEDICAL directly (see p. 2).

1.3 Symbols and Terms

For instructions with a particular order, steps in this User Manual are *numbered*. **Bulleted** lists do not imply an order. Throughout this **CLEAR GUIDE SCENERGY** User Manual, the following symbols and terms have special meanings:

Table 1: Symbols and Descriptions

Symbol or Term	Description
 WARNING	A hazardous situation that – if not avoided – could result in death or serious injury to the patient, or substantial damage to the equipment.
 CAUTION	A potentially hazardous situation that – if not avoided – could result in minor or moderate injury to the patient, or damage to the equipment.
IMPORTANT	A non-hazardous situation (both in terms of patient safety and equipment safety) that must be understood for proper functioning of the CLEAR GUIDE system.
 TIPS	A useful tip for operating the CLEAR GUIDE system.
 RESOURCE	References where more information can be found.

- **MUST / REQUIRED / SHALL:** an absolute requirement.
- **MUST NOT / SHALL NOT:** an absolute prohibition.
- **SHOULD / RECOMMENDED:** there may be valid reasons to ignore the described action, but the full implications must be carefully weighed before choosing a different course.
- **SHOULD NOT / NOT RECOMMENDED:** there may be valid reasons when the particular action is acceptable, but the full implications must be carefully weighed before choosing that course.

2 About the System

2.1 Intended Use/Indications for Use

The **CLEAR GUIDE SCENERGY** is software that provides image fusion for 3D volume modalities (such as computed tomography (CT) and magnetic resonance (MR), depending on system version, feature license, and regulatory availability) and ultrasound (US) (Figure 1).

The **CLEAR GUIDE SCENERGY** utilizes the **CLEAR GUIDE CORE** and **CLEAR GUIDE SuperPROBE** platform to display images of the target regions and the projected path of the interventional instrument, while taking into account patient movement and deformation. Instrumentation used with the **CLEAR GUIDE SCENERGY** might include an interventional needle or needle-like rigid device, such as a biopsy needle, an aspiration needle, or an ablation needle. The device is intended to be used in any interventional or diagnostic procedure where the combination of these modalities is used for visualization, except for procedures on the brain. The device is intended for use in a clinical setting.

The **CLEAR GUIDE SCENERGY** is intended for prescription use only.

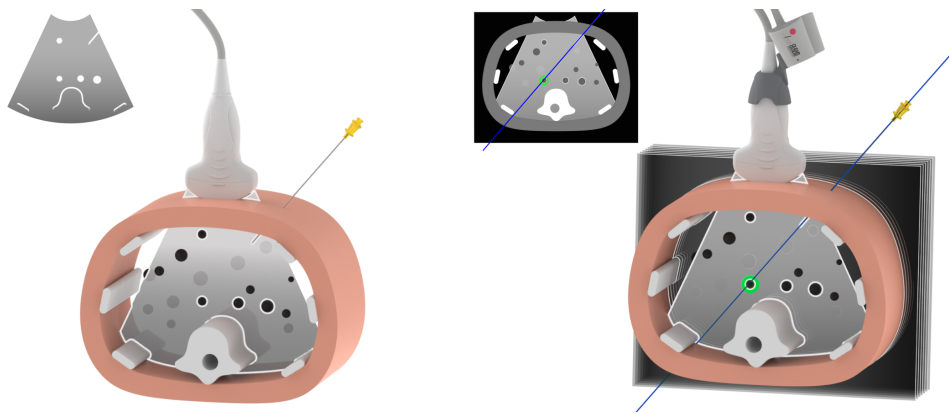


Figure 1: US-guided intervention (left); **CLEAR GUIDE SCENERGY**-guided intervention with fused 3D imaging (right)

2.2 Product Functionality

2.2.1 What does the system do?

The **CLEAR GUIDE SCENERGY** fuses pre-procedural 3D imaging data (e.g. magnetic resonance (MR) or computed tomography (CT), depending on system version, feature license, and regulatory availability) and live ultrasound (US), and provides instrument guidance towards targets visible in the 3D imaging, live ultrasound, or both. Using multi-modality **CLEAR GUIDE** VisiMARKER skin fiducials, the **CLEAR GUIDE SCENERGY** correlates in real time each ultrasound image with corresponding 3D imaging slices and targets, and thus indicates transducer drift.

2.2.2 How does it work?

The **CLEAR GUIDE CORE** interfaces with an ultrasound machine and optionally a PACS or other DICOM-compatible 3D imaging system. It receives live ultrasound images and tracks instruments and the current ultrasound slice relative to the patient (and to 3D imaging present on the **CLEAR GUIDE SCENERGY**).

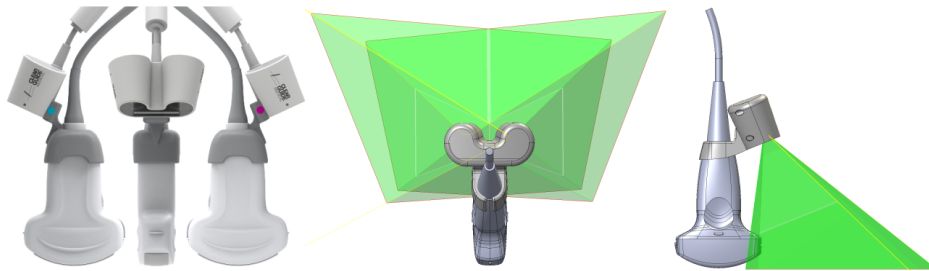


Figure 2: **CLEAR GUIDE** SuperPROBE – approximate Field of View

The Optical Head is attached rigidly and permanently to a standard ultrasound transducer, together called the **CLEAR GUIDE** SuperPROBE. Stereo cameras in the Optical Head observe the **field of view** (see Figure 2) around the SuperPROBE, and detect instruments as well as markers applied to instruments and the patient. VisiMARKERS on the patient and/or TipTAG markers on the instruments enable their tracking. On-board infrared lighting supports operation in dark environments.

3D imaging volumes can be overlaid onto live ultrasound imaging, and displayed on the **CLEAR GUIDE CORE** (Figure 3).

2.2.3 What is required for correct function?

Instrument guidance and fusion rely on several prerequisites: a compatible ultrasound machine, correct calibration of the SuperPROBE, and clearly visible VisiMARKERS/TipTAGs and interventional instruments. In addition, for MR fusion, supported and approved MR-compatible fiducial markers are required. More details regarding these fiducials are provided in section 3.8.4. **CLEAR GUIDE** systems come pre-configured for a specific combination of ultrasound machine and transducer. During registration with the patient, the Optical Head must observe sets of VisiMARKERS. Instruments need to be sufficiently long and straight to be tracked.

2.2.4 How is it set up?

The **CLEAR GUIDE** system is set up next to the user's ultrasound machine. The **CLEAR GUIDE CORE** is placed close to the existing ultrasound screen. The **CLEAR GUIDE** SuperPROBE is the handheld imaging

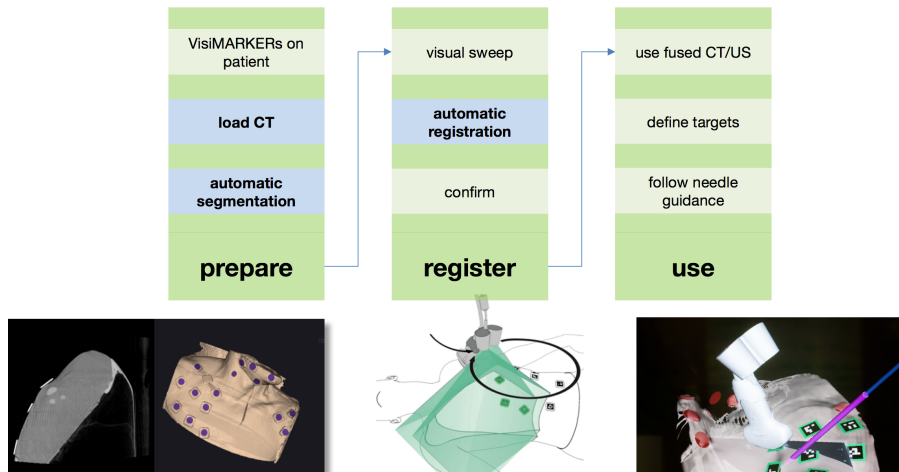


Figure 3: Workflow (here e.g. CT/US) of **CLEAR GUIDE SCENERGY**

and tracking part, and is used the same way as a standard ultrasound transducer. This manual explains successful and safe operation of **CLEAR GUIDE** systems.

2.3 Unpacking and Inspecting Contents

Upon receiving the **CLEAR GUIDE** system, carefully inspect all equipment. Repeat this inspection prior to subsequent system uses.

- Examine shipping packages and each component for damage. In the event of damage, please contact **CLEAR GUIDE MEDICAL** Customer Support immediately.
- Verify presence of all components listed below under “Package Contents”.

Package Contents:

- 1x **CLEAR GUIDE CORE**
(video cable to be attached by installation technician)
- 1x **CLEAR GUIDE SuperPROBE**
(Optical Head installed on ultrasound transducer; *may be shipped separately*)
- 1x Power adapter (with AC power cord)
- 1x **CLEAR GUIDE SCENERGY** User Manual



Check the **CLEAR GUIDE MEDICAL** website for software or User Manual updates:

www.clearguidemedical.com/support

If newer versions are available, download them directly, or contact **CLEAR GUIDE MEDICAL** Customer Support to schedule a software update.

2.4 Components and Connections

CLEAR GUIDE systems work with existing 3D imaging and ultrasound systems. **CLEAR GUIDE** systems do not provide 3D imaging or ultrasound functionality themselves. Instead, **CLEAR GUIDE** systems are comprised of the following main components (instructions on how to correctly detach components are in Section 3.15.1 “Disconnecting and Storage”):

- **CLEAR GUIDE** CORE;
- **CLEAR GUIDE** SuperPROBE (**CLEAR GUIDE** Optical Head installed on ultrasound transducer); and
- detachable power adapter and cord.

The **CLEAR GUIDE** CORE is a medical-grade touchscreen computer. Some versions of the system feature a built-in UPS (uninterruptible power supply) for short periods of time without AC power (e.g. for moving from room to room) without shutting down. (Such systems show a battery status icon at the bottom of the user interface.) Note that **off-grid operation (not plugged into AC power) is not supported**.

The Optical Head is installed onto the user’s existing ultrasound transducer during initialization, and both together form the **CLEAR GUIDE** SuperPROBE. The SuperPROBE contains stereo cameras and its own infrared light source for operation in dark environments.

CLEAR GUIDE systems may be used with existing **instrumentation and/or sterile drapes**. These are not included, and should be used in accordance with their respective instructions for use (see Sections 3.4 “Supported Instruments” and 2.8 “Sterility Solutions” for recommendations).

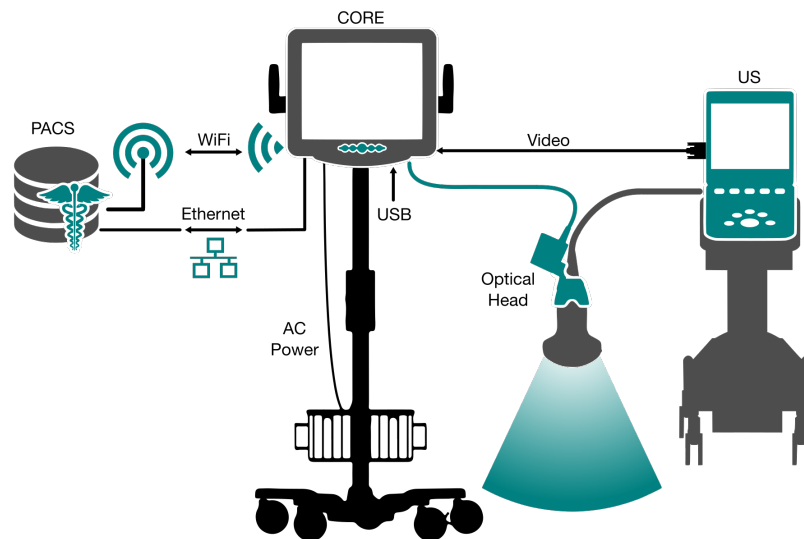


Figure 4: Illustration of integrated ultrasound and **CLEAR GUIDE** systems

Table 2: Connectors and Cords

Name	Detailed Description
Video	This connects the ultrasound video (monitor) output to the CLEAR GUIDE CORE.

Name	Detailed Description
Optical Head	This connects the SuperPROBE Optical Head to the CLEAR GUIDE CORE (via USB or proprietary port, depending on model).
USB	This allows importing patient 3D imaging volumes onto the system (e.g. via USB flash drives).
Ethernet / Wi-Fi	The system can import 3D imaging volumes over a network directly from a picture archiving and communication system (PACS) or other DICOM-compatible system.
AC Power	This adapter provides power to the CLEAR GUIDE CORE , with an AC/DC transformer between mains and the CORE.



WARNING: USB ports and Ethernet connections are intended to be connected only to host-powered devices and cabling that are rated at maximum 5 VDC (total differential).



WARNING: Any product connected to the **CLEAR GUIDE CORE** must meet the minimum safety and essential performance requirements of IEC 60950 or IEC 60101-1, as tested by an NRTL-approved facility.



WARNING: ONLY use the SINPRO Electronics Co Ltd. Type MPU101-105 power adapter provided with the **CLEAR GUIDE CORE**.



WARNING: DO NOT attempt to use a **CLEAR GUIDE** system with a different ultrasound machine than the one for which it is configured. Doing so can result in incorrect guidance information and injury to the patient.



WARNING: NEVER attempt to separate the Optical Head from the ultrasound transducer. Attempting this could cause significant damage to the equipment or its calibration.

2.5 System Installation and Network Setup

IMPORTANT

The following steps will be performed by a qualified **CLEAR GUIDE MEDICAL** technician during the initial installation visit. However, technical staff may need to repeat some steps if the system has been put into storage or moved. Contact **CLEAR GUIDE MEDICAL** for service if needed.

Correct system installation comprises the following steps:

2.5.1 CORE Mechanical Installation

Have the **CLEAR GUIDE CORE** installed by a professional technician on a suitable medical-grade cart, monitor stand, or similar with VESA 75/100 mounting. Only use mounting hardware recommended by the manufacturer of the mounting solution. **Ensure stability** by pushing/moving the screen or pulling the cables. Verify tightness of all screws.

If suspending the unit, make sure the equipment is sturdy and stable. If not properly suspended, the **CLEAR GUIDE CORE** may fall and cause serious injury to people standing nearby as well as to the unit itself. Two or more people are required for installing the unit by suspension.

Exercise caution when moving a cart-mounted **CLEAR GUIDE** system. Quick stops, excessive forces, and uneven surfaces may cause the unit to tip over.

If the **CLEAR GUIDE CORE** does collide or fall to the ground, immediately turn off power and disconnect cords. Contact a service technician for repairs. Continued use of the unit may cause a fire or electric shock. Do not attempt to repair the unit.

When positioning the **CLEAR GUIDE CORE**, allow for easy disconnection. Do not block the power cord mains plug.



CAUTION: Ensure the mounting of the **CLEAR GUIDE CORE** complies with applicable safety standards, in particular mechanical stability. If in doubt, contact **CLEAR GUIDE MEDICAL** Customer Support for information about suitable units.

2.5.2 Physical Connectivity

1. Ensure correct ultrasound transducer cable connection.
2. Plug the Video Cable into the ultrasound machine's video output.
3. Plug the SuperPROBE Connector into the **CLEAR GUIDE CORE**.
4. If configured for wired network connectivity, make sure Ethernet is connected (Figure 5).
5. Ensure that the Power Adapter is the correct model (compare labels on the Power Adapter itself and on the back of the **CLEAR GUIDE CORE**).
6. Plug the DC end of the Power Adapter into the **CLEAR GUIDE CORE**.
7. Plug the AC end of the Power Adapter cord into a hospital-grade, 3-wire grounded utility outlet.

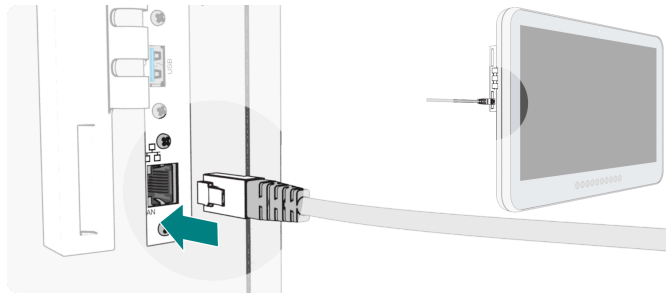


Figure 5: Ethernet connection (shown for CORE 24 model)

WARNING: Before use, inspect the Power Adapter for any damage, signs of electricity, sparks, excessive heat, or other unusual signs. If these are observed, do not use the system and contact **CLEAR GUIDE MEDICAL** Customer Support.



The Power Adapter is not serviceable and can only be replaced through **CLEAR GUIDE MEDICAL** Customer Support. Only use the Power Adapter provided with the system, or replacements provided through service personnel. Always ensure the Power Adapter model (on its label) matches the required model as described on the back of the **CLEAR GUIDE CORE** before connecting both. To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.



CAUTION: Ensure that the SuperPROBE is clean and damage-free before every use. The Optical Head should be rigidly attached to the ultrasound transducer. There should be no ultrasound gel, debris, damage, or unusual odors.

If any of these problems are observed, perform a thorough cleaning of the SuperPROBE. If they persist, do not use the system and contact **CLEAR GUIDE MEDICAL** Customer Support.

2.5.3 DICOM/PACS Networking

To communicate over an existing network with a picture archiving and communication system (PACS) or any DICOM compatible system, the appropriate settings must be set and verified during installation as follows:

1. Start up the system by following Sections 3.5 “System Startup” and 3.6 “Initial SuperPROBE Check”.
2. Tap the gears icon at the bottom left of the user interface.
3. Choose the “SETTINGS” tab (Figure 6).
4. Enter the administrative password, or contact **CLEAR GUIDE MEDICAL** with the provided challenge-response code.

The following configuration steps then have to be performed (Figure 7):

1. Integrate into Hospital Network:

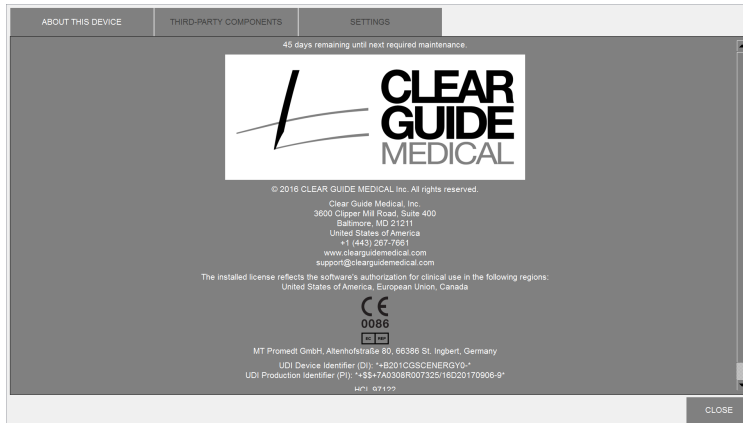


Figure 6: Settings window: System information

- (a) Connect to network (wired or wireless). For wireless networking, enter network details or install a network profile XML file from a USB drive.
 - (b) Assign static IP address (including subnet mask) or select DHCP.
 - (c) Confirm AET (Application Entity Title). Change, if requested (default **CLEAR GUIDE SCENERGY**).
2. **(Optional)** For DICOM-TLS, switch to the “Keys and Certificates” section and install all necessary TLS keys and certificates. These will have to be provided on a USB drive in PEM format.
 3. **(Optional)** Configure **CLEAR GUIDE SCENERGY** to receive DICOM Files:
 - (a) **(Optional)** If desired, enable TLS and select the correct key and certificates. Tap “VALIDATE and APPLY”.
 - (b) PORT: change if requested (default assigned listening port is 11112).
 - (c) Remote AETs: Choose from one of the following.
 - REJECT ALL: All incoming requests will be rejected.
 - ACCEPT ALL: All incoming requests will be accepted.
 - ACCEPT AET: Incoming requests will be filtered by the callers’ AET. Add/edit AETs of systems that will send image data to **CLEAR GUIDE SCENERGY**; AETs to be provided by IT staff. Enter AETs in a space-separated list.
 - i. For example: if the IT staff provides “Station_3564” and “CT2” as the sending AETs, enter “Station_3564 CT2” in this field.
 - ii. Note: the system will not accept image datasets if “ACCEPT AET” is selected but no AETs are specified.
 - (d) Add **CLEAR GUIDE SCENERGY** to hospital network as DICOM Recipient (normally performed by hospital IT). Provide hospital IT staff with IP address (if necessary), port, and AET.
 4. **(Optional)** Configure **CLEAR GUIDE SCENERGY** to send DICOM Files to PACS:
 - (a) **(Optional)** If desired, enable TLS and select the correct key and certificates. Tap “VALIDATE and APPLY”.
 - (b) If needed, set **STATION NAME**.
 - (c) If needed, fill in institution details.
 - (d) For each possible **Storage Destination (e.g. PACS)**, create a line in the table under “C-STORE SCU” and provide name, AET, IP or hostname and port of that host.

- (e) Configuration steps on the **Storage Destination (e.g., PACS)** may be necessary. Provide Hospital IT with the following information: IP address, port, and AET.
 - (f) **(Optional)** If desired, select one Storage Destination as default by clicking the appropriate button. Once a Default Storage Destination has been defined, you can activate the option to “auto-upload screen captures to the default PACS”.
 - (g) **(Optional)** When auto-uploading of screen captures is enabled, you may also configure the system to always retain a local copy of the screen captures.
5. Test connections (both receiving and sending) as per the following sections.

2.5.4 Test: Receiving DICOM Files

1. Run **CLEAR GUIDE SCENERGY** on the CORE by rebooting it. The Network Status at the bottom left of the screen should show IDLE (green light) after system startup.
2. With the help of IT staff, select a sample 3D volume from the 3D imaging machine or PACS and export/send/copy it to **CLEAR GUIDE SCENERGY**.
3. On **CLEAR GUIDE SCENERGY**, the Network Status should change to “RECEIVING IMAGES...” (blinking green light).
4. After data is transferred successfully, the status changes back to IDLE (green light) and, after a few seconds, the STUDIES button becomes active. Tap STUDIES to bring up a list of available studies.
5. Compare the patient name, the study date, number of images, and the preview image shown on the screen with those provided by the 3D imaging machine or PACS.
6. Select a study and press LOAD. After some processing, and if a complete volume has been sent to the system, its surface and any markers (if included) should appear on screen.
7. Repeat these steps for each sending host.

2.5.5 Test: Sending DICOM Files

1. In the configuration window, select the line of **Storage Destination (e.g., PACS)** and click TEST to initiate a **C-ECHO Request**. It should succeed.
2. Load a 3D imaging volume and create a screenshot. Open the screenshots list, select the newly created screenshot, and send it to the **Storage Destination (e.g., PACS)**. If this succeeds, the configuration is complete. If this fails (but the **C-ECHO Request** succeeded), the **Storage Destination (e.g., PACS)** may not support the image format. Refer to the **DICOM Conformance Statement** for details.
3. Repeat these steps for each storage destination.

2.5.6 DICOM/PACS: Troubleshooting

It is important that the correct numbers/names etc., including CALLING_AET values, are set in the configuration as well as on the hospital 3D imaging system or PACS. Should data transmission still not work, the following may help to locate the problem. You will need the assistance of a local network administrator for some of those steps.

- Ping the **CLEAR GUIDE CORE** from the sending devices, and vice versa. A test failure indicates a basic network connectivity problem. Check the network configuration and cabling.

- Next, initiate a DICOM echo request on the sending devices. If this succeeds, the configuration is correct and DICOM connections can be established. However, if the echo request fails, something is misconfigured. Check configurations.
- Next, if both pings and echo requests succeed, but still no DICOM data transmission is possible, this indicates that **CLEAR GUIDE SCENERGY** does not support the data format that has been transmitted. Note that only 3D imaging volumes in DICOM format are supported. Refer to the **DICOM Conformance Statement** for details on supported modalities and formats.
- Finally, try to change the CALLING_AET field to a single asterisk (*), which allows any connection request to be accepted. Reboot the **CLEAR GUIDE CORE** and initiate a DICOM echo request on one of the sending devices. Should the echo request succeed now, this indicates a problem in the AET configuration; review the configuration.

IMPORTANT

The Single Asterisk Method for CALLING_AET is only meant for troubleshooting and deactivates important security measures of the **CLEAR GUIDE SCENERGY**. Always replace the asterisk with the actual AET names after troubleshooting!

2.5.7 DICOM/PACS: Special Notes

CLEAR GUIDE SCENERGY does not support “pulling” image data from PACS or other DICOM-compatible systems. Instead, any desired 3D imaging needs to be “pushed” to the system by hospital personnel. 3D imaging machines provide direct push capability to any DICOM-compatible device, including **CLEAR GUIDE SCENERGY**. If integration with the 3D imaging machine directly is not possible, image data can be sent first to the hospital PACS and then to **CLEAR GUIDE SCENERGY**.

The **CLEAR GUIDE SCENERGY** can be configured to accept image data from multiple sources, so both the 3D imaging machine and the central PACS can be configured to send data to the system, as well as any other DICOM-compatible image acquisition system within the hospital network that is desired to work with **CLEAR GUIDE SCENERGY**.



WARNING: DICOM/PACS connectivity must be configured by a qualified technician during the initial installation together with appropriate IT personnel.



To be able to receive 3D imaging over network, the **CLEAR GUIDE CORE** must be connected to the institution’s network and switched on.

WiFi transfer of 3D imaging data may be slow and subject to electromagnetic interference. **CLEAR GUIDE MEDICAL** recommends using a wired Ethernet connection.



CAUTION: Operate **CLEAR GUIDE** systems only on secure medical-grade computer networks! Otherwise, there is an increased risk of compromising the security of confidential patient information.

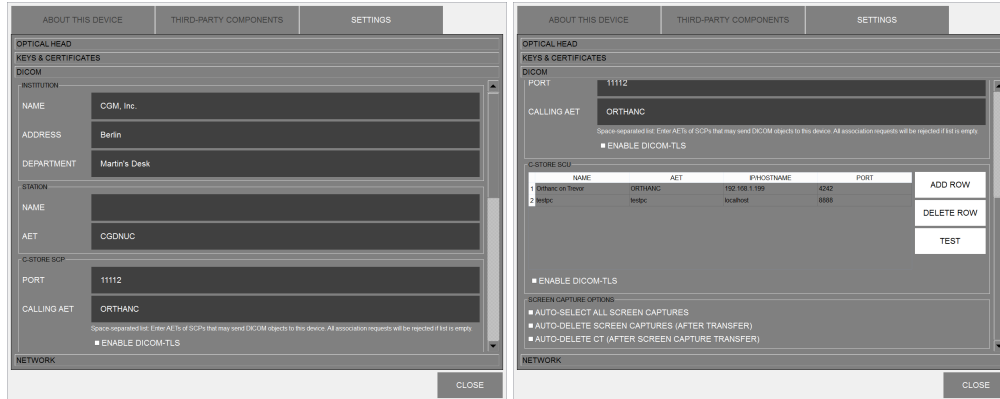


Figure 7: SETTINGS tab: DICOM settings (left); Screen Capture options (right)

2.6 Patient Data Handling

The **CLEAR GUIDE SCENERGY** may be connected to an existing network, and can be configured to receive 3D imaging directly from PACS or other DICOM-compatible systems.

This is configured by a qualified technician familiar with the institution's network infrastructure (see Section 2.5 "System Installation").

3D imaging volumes that were received over network are stored on the system for later use. Volumes older than 31 days are automatically removed from the system. Also, if the stored volumes on the system exceed 16 GB of disk space, the oldest volumes are automatically removed. Furthermore, volumes stored on USB drives can be either loaded for immediate use, or stored (imported) onto the system for later use.

Volumes already on the system can also be manually deleted by an operator. All volumes are secured and cannot be exported.

IMPORTANT

All personally identifiable information (PII) / protected health information (PHI) stored on USB devices must be appropriately managed by the user to be in compliance with HIPAA Privacy Rules, which protect the privacy of individually identifiable health information, and with any other applicable privacy regulations. Within the system, personally identifiable information is displayed only during the procedure, and hidden as soon as a new 3D imaging volume is loaded. No patient information can be exported from or transmitted by the **CLEAR GUIDE SCENERGY**.

2.7 Lighting

CLEAR GUIDE systems have been validated in different lighting environments, including complete darkness and very bright light. As such, there is no minimum or maximum lighting requirement. However, users should consider the following prior to use of **CLEAR GUIDE** systems:

- In rare cases, strong directional lights (e.g. overhead OR lights) may cause transient tracking dropouts due to shadows. These should resolve quickly (<1 second). It is recommended to reposition the lights if the problem persists.
- Changing lighting conditions (e.g., changing overhead light levels or moving head lamp light) are not expected to impact use of **CLEAR GUIDE** systems.
- **CLEAR GUIDE** systems have been validated with blue sterile drapes in the background.



CAUTION: Avoid excessive lighting in the interventional area. Light reflections or overexposure of the cameras can cause tracking to fail or become unreliable.

2.8 Sterility Solutions

Ultrasound gel and the **CLEAR GUIDE** SteriMASK sterile sleeve should be used per clinical practice and as directed by the physician. Only **CLEAR GUIDE** SteriMASK units should be used for full sterility to accommodate the Optical Head cameras.

Always ensure that the SteriMASK does **not obstruct the Optical Head field of view** to avoid tracking failure. If ultrasound gel gets on the Optical Head window, gently clean with a damp cloth or tissue.

Consult the SteriMASK orientation video available at www.clearguidemedical.com/sterimask to learn how to appropriately use the SteriMASK (Figure 8).

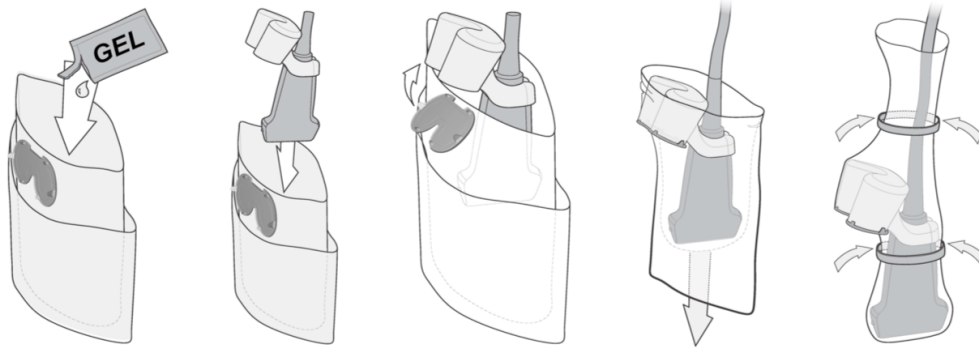


Figure 8: **CLEAR GUIDE** SteriMASK application



CAUTION: Ensure the Optical Head is clean (no ultrasound gel, liquids, dust, smudges, or other contaminants) and scratch-free. Otherwise, **clean** the Super-PROBE and the front window before use.



Refer to Section 3.16 for **CLEAR GUIDE** system cleaning procedures.

3 Using the System

The following section describes instrument guidance and fusion (Figure 9), once the **CLEAR GUIDE** system has been started and set up (per Section 2 “About the System”).



WARNING: Improper use of a **CLEAR GUIDE** system (i.e. failing to follow the instructions for use) could result in death or serious injury to the patient, or substantial damage to the equipment.

These instructions **are not** clinical guidelines for 3D-imaging- or ultrasound-based interventions. Any 3D imaging system, ultrasound machine, transducer, and other imaging accessories should be used in accordance with their respective instructions for use.

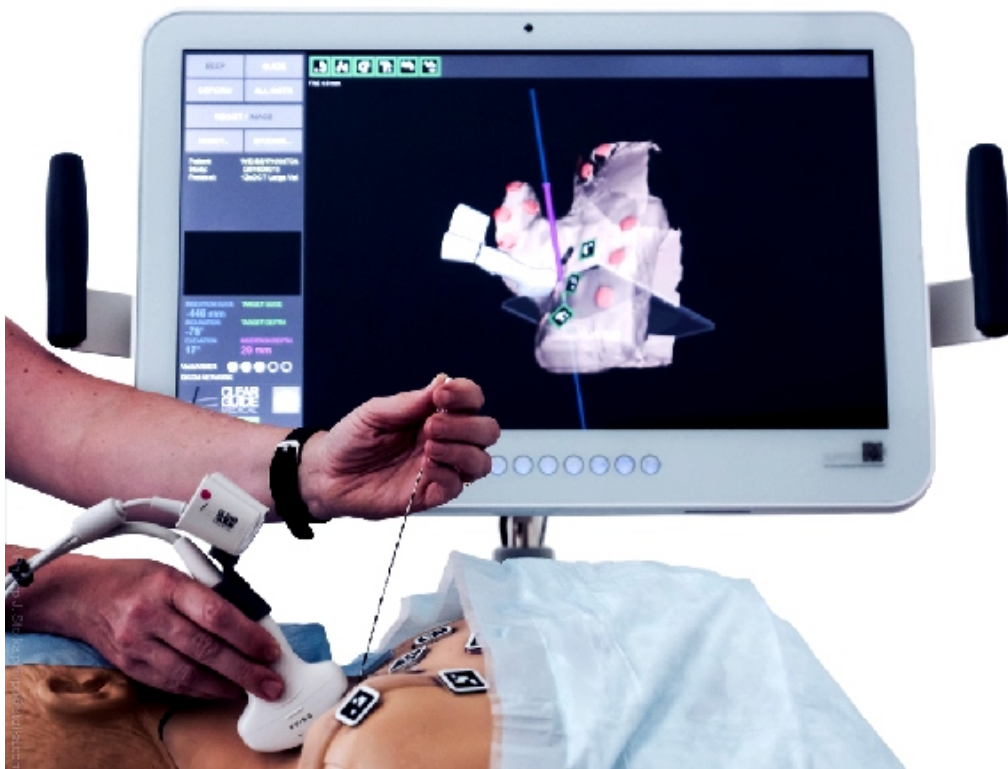


Figure 9: **CLEAR GUIDE** SCENERGY with SuperPROBE and instrument tracking relative to patient 3D imaging

3.1 SuperPROBE Handling

The SuperPROBE must be handled correctly to avoid damage or failure. **Do not obstruct the Optical Head field of view.**



CORRECT

Hold the SuperPROBE by the ultrasound transducer



WRONG!

Do not face Optical Head away from the intervention area



WRONG!

Do not obstruct or bend the Optical Head

Figure 10: SuperPROBE handling instructions

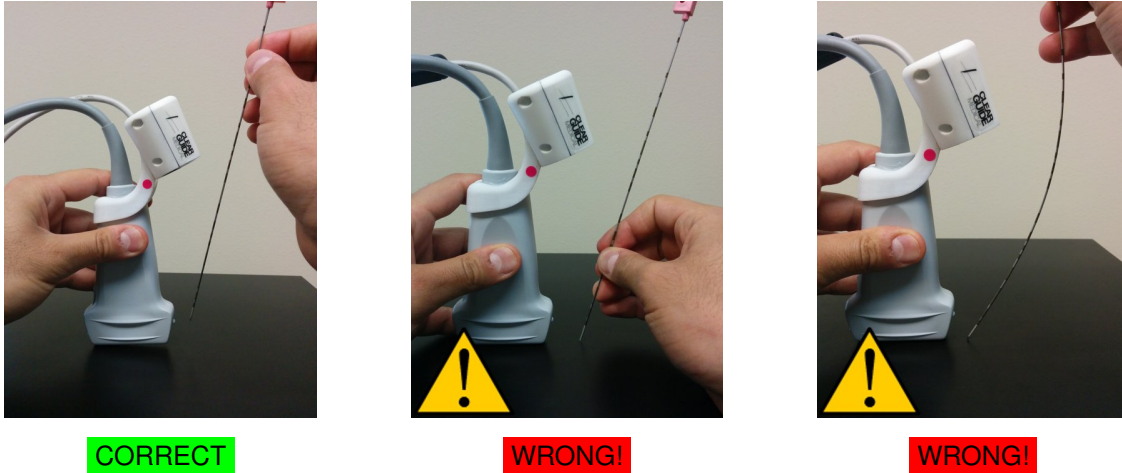
WARNING: NEVER twist, bend, or disassemble the SuperPROBE.



Applying excessive force or torque to the **CLEAR GUIDE** SuperPROBE or any of its components (Optical Head, bracket, cable, and ultrasound transducer) will cause loss of calibration, require maintenance, and may cause significant equipment damage.

3.2 Instrument Handling

Interventional instruments must be handled correctly to ensure correct tracking. The Optical Head field of view must be kept clear of clutter, especially of other needle-like straight objects. Instruments are tracked within approx. $\pm 30^\circ$ to either side of the SuperPROBE. Instruments may be tilted between vertical (“downwards/towards the patient”) and nearly horizontal (“parallel to the patient skin”).



<p>CORRECT</p> <p>Hold instrument near distal end; keep at correct distance in field of view</p>	<p>WRONG!</p> <p>Do not cover the instrument in the field of view</p>	<p>WRONG!</p> <p>Do not bend the instrument</p>
---	--	--

Figure 11: Instrument handling instructions



WARNING: Do not twist or bend instruments. This makes tracking inaccurate.



Hold instruments **near the distal end** (i.e., far away from the patient). Leaving the proximal and central sections free permits unobstructed instrument observations.



Keep the intervention area **clear of clutter** – e.g. other instruments, wires, sharp edges, corners, boxes, packaging materials, patient covers, and other objects.

3.3 Supported Ultrasound Settings

CLEAR GUIDE systems support 2D single-full-image ultrasound settings, where a single 2D ultrasound image is displayed at standard zoom level on the ultrasound machine’s screen. This usually includes at least B-mode imaging. Typically, all depth settings are supported, as well as mirrored and inverse images. **Supported settings vary depending on ultrasound machine and transducer**, and can be displayed by tapping the Ultrasound Information Box (Figure 12).

A continuously evolving list of compatible and incompatible ultrasound systems and transducers is available at www.clearguidemedical.com/faq-cg. If a certain ultrasound or transducer is not listed, contact **CLEAR GUIDE MEDICAL** Customer Support directly. An assessment visit may be required prior to installation to confirm compatibility.

3.3.1 Ultrasound Settings Detection

The **Ultrasound Information Box** at the bottom of the screen displays the current detected ultrasound image settings. If the indicated settings in the Ultrasound Information Box differ from actual ultrasound machine settings, **immediately stop using the CLEAR GUIDE system and call CLEAR GUIDE MEDICAL Customer Support**.

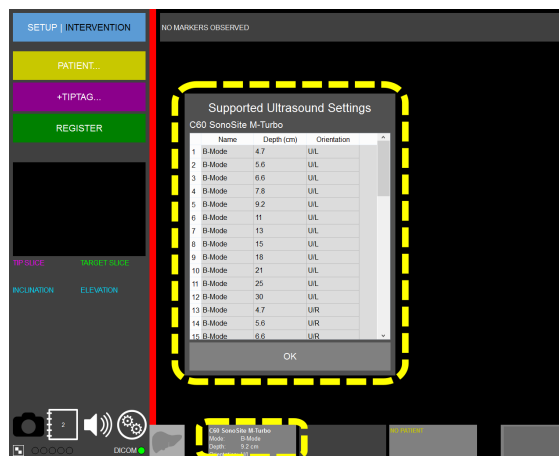


Figure 12: User Interface showing Supported Ultrasound Settings

3.3.2 Frozen Ultrasound

If the **CLEAR GUIDE** system detects a “frozen” image on the ultrasound machine (i.e. when the machine is not generating new live images), **blue indicator bars** will appear on all views. No guidance is available when the ultrasound image is frozen.

3.3.3 Unsupported Ultrasound Settings

If the **CLEAR GUIDE** system cannot identify current settings, no guidance will be displayed on the **CLEAR GUIDE CORE**. One of several error messages will be shown instead (Figure 13):

- “No valid ultrasound settings detected”: The system received an ultrasound video signal, but could not identify known settings. Set the ultrasound machine to a setting listed in Supported Ultrasound Settings.

- “Ultrasound input not available”: The system did not receive an ultrasound video signal. Check and re-seat the video cable connecting the CORE to the ultrasound machine.
- “Invalid ultrasound image”: The system received an ultrasound video signal, but could not identify known settings. Set the ultrasound machine to a setting listed in Ultrasound Supported Settings.

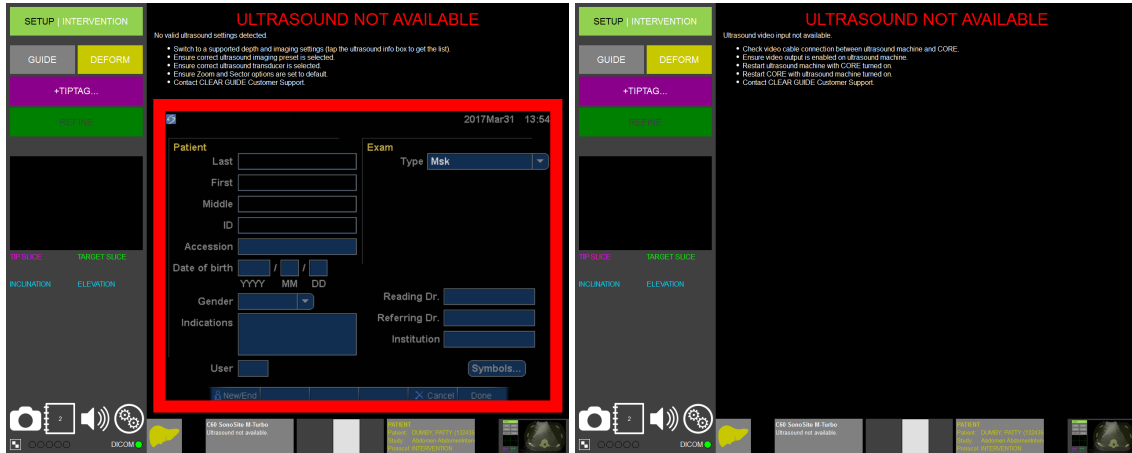


Figure 13: Example views with no valid ultrasound stream detected

CLEAR GUIDE systems should never be used with unsupported settings. They may show inaccurate navigation under the assumption of a supported setting.



WARNING: STOP using the **CLEAR GUIDE** system if the User Interface indicates different settings than the underlying ultrasound machine. Failure to observe this warning could lead to inaccurate instrument tracking, image guidance, and potentially to patient harm. If the two displays are different, proceed with the existing ultrasound guidance only, and **ignore** system guidance.



CAUTION: The **CLEAR GUIDE** system cannot assess or improve ultrasound image quality. To ensure safe and successful guidance, familiarize yourself with the operation of the underlying ultrasound system, and optimize imaging parameters for the relevant anatomy.

3.4 Supported Instruments

CLEAR GUIDE systems support the following three types of instruments, looking for TipTAG instruments first, followed by PercepTIP instruments, and finally regular instruments.

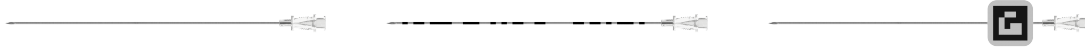


Figure 14: Supported instrument types: regular, PercepTIP, TipTAG (left to right)

3.4.1 TipTAG Instruments

Instruments can be combined with CLEAR GUIDE TipTAG markers for improved tracking. These single-use markers can be attached firmly to the instrument and calibrated to the instrument tip (also see Section 3.7 “TipTAG Instruments”). CLEAR GUIDE systems can **track up to five such instruments** at a time:

- **Length of Instrument Shaft:** ≥ 4 cm visible during calibration
- **Diameter:** between 14G and 20G

3.4.2 PercepTIP Instruments

CLEAR GUIDE PercepTIP instruments exhibit a non-repeating pattern that allows the system to track the instrument tip. Contact CLEAR GUIDE MEDICAL Customer Support for a catalog of available PercepTIP-enabled instruments. CLEAR GUIDE systems can **track up to five such instruments** at a time:

- **Length of Instrument Shaft:** ≥ 4 cm visible at all times

3.4.3 Regular Instruments

Regular instruments are straight, rigid, needle-like tools such as needles, biopsy guns, and ablation tools. CLEAR GUIDE systems track one regular instrument at a time:

- **Length of Instrument Shaft:** ≥ 4 cm visible at all times
- **Diameter:** between 14G and 20G

3.4.4 “No Instrument Detected”

If the CLEAR GUIDE system does not detect a supported instrument, **red indicator bars** will appear on all navigation views (Figure 15). No instrument guidance information will be provided.



CAUTION: Do not use CLEAR GUIDE instrument guidance if system tracking is not reliable. For more information, see Section 4 “Troubleshooting”.



CAUTION: Always ensure the CLEAR GUIDE system can track all instruments reliably before starting the intervention. Guidance may be unreliable for instruments that are too short, thin, or thick, or with occluded or dirty patterns or markings.

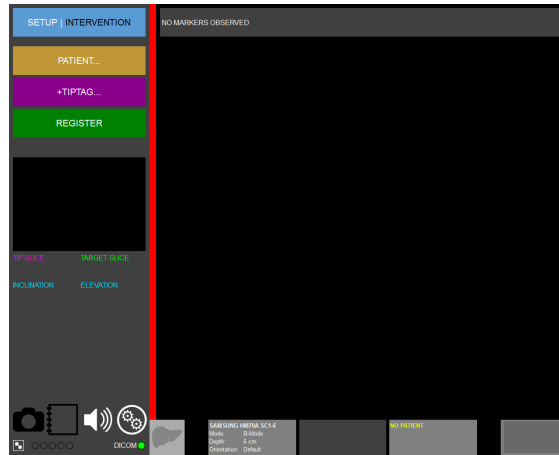


Figure 15: User Interface (no instrument detected: red indicator bars)



CAUTION: Do not use **CLEAR GUIDE** instrument guidance for procedures that require more simultaneous instruments than the instrument type maximum.

3.5 System Startup

1. Turn the existing ultrasound machine ON.
2. Turn on the AC Power Adapter of the **CLEAR GUIDE CORE**, if applicable.
3. Turn on the **CLEAR GUIDE CORE** by pressing the front power button. The startup sequence may take several minutes. The system automatically starts the system software (Figure 16 left).

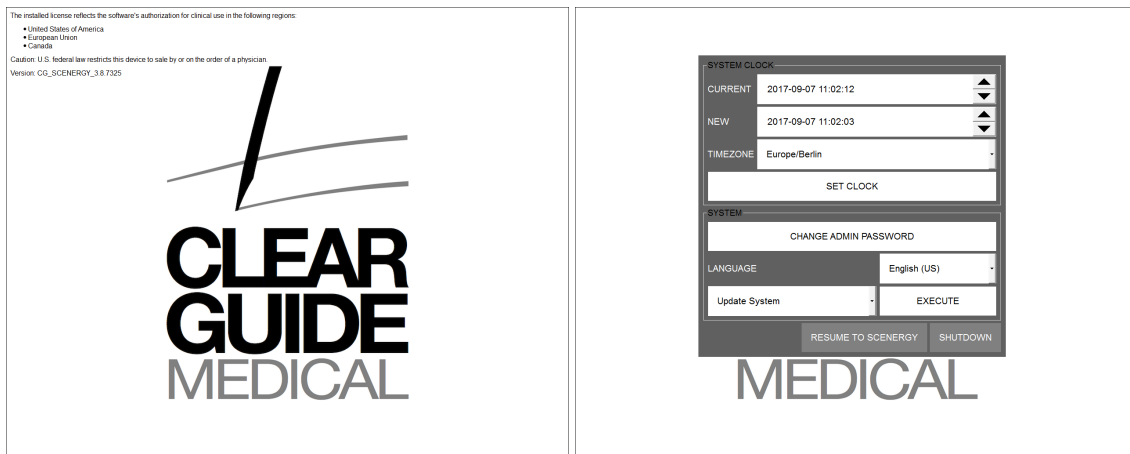


Figure 16: Startup screen (left); Startup Administrative Dialog (right)



To access the **Startup Administrative Dialog** (password-protected), keep tapping the screen during startup or press the LeftShift+RightShift+Ctrl keys on a keyboard until the dialog appears (Figure 16 right).

Language and time/date settings can be changed from this dialog.

4. If a **SuperPROBE** is attached to the system, the system will establish a connection. In case of a connection problem, reconnect the SuperPROBE (Figure 17).

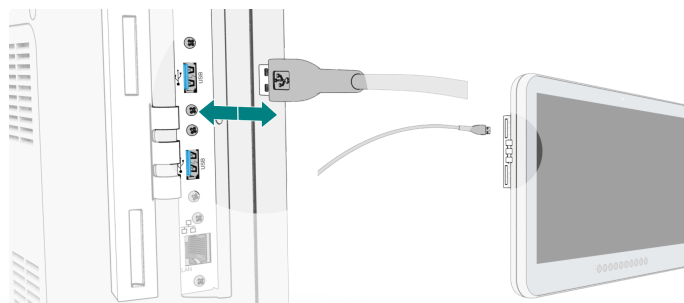


Figure 17: SuperPROBE connection shown for CORE 24 model

5. A **system maintenance check** is run whenever an Optical Head is detected.
 - (a) **Within two weeks of the next maintenance date**, the system will require an operator acknowledgment (Figure 18 left). During subsequent uses of the system, the user interface will show a persistent reminder message (the background color of the warning will be **orange**).

- (b) **If the maintenance date has passed**, the user will be asked to contact **CLEAR GUIDE MEDICAL** to schedule maintenance (Figure 18 right). The system must not be used clinically after the current maintenance date has passed. Instead, schedule a maintenance visit as soon as possible to ensure continued correct operation. During subsequent use of the system, the user interface will show a persistent warning message (red).

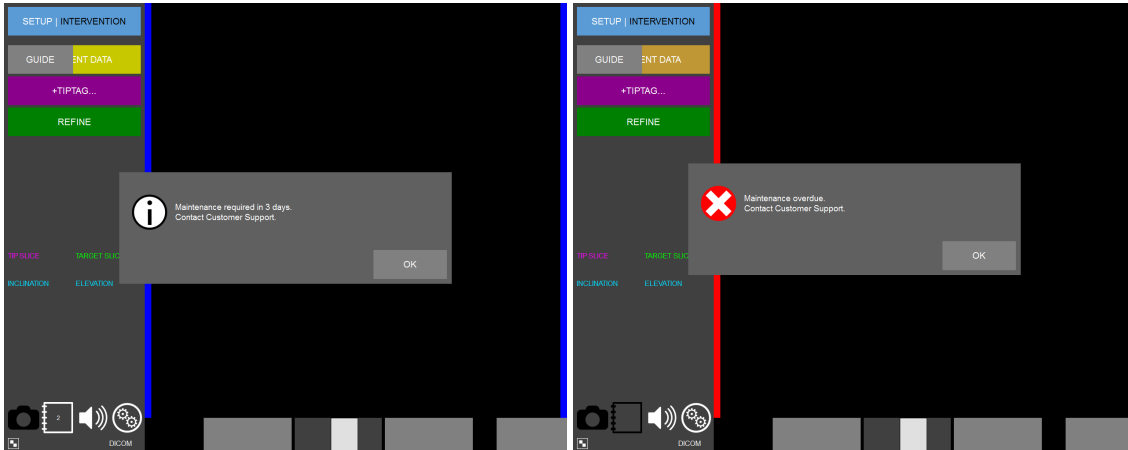


Figure 18: Maintenance expiration warning (left); overdue warning (right)

6. After a successful maintenance check, the **CLEAR GUIDE CORE** will next launch the SuperPROBE check.

3.6 Initial SuperPROBE Check

Whenever an Optical Head is detected, the **CLEAR GUIDE** system verifies the SuperPROBE calibration. During this process, the SuperPROBE has to be pointed at the on-screen checkerboard pattern:

1. Point the SuperPROBE toward the **CLEAR GUIDE** CORE screen (Figure 19).
2. Align the SuperPROBE so the moving boundary lines surround the checkerboard.
3. When the displayed lines turn **green** and “Hold steady” is displayed on the screen, hold the SuperPROBE still for a few seconds until the check is complete.

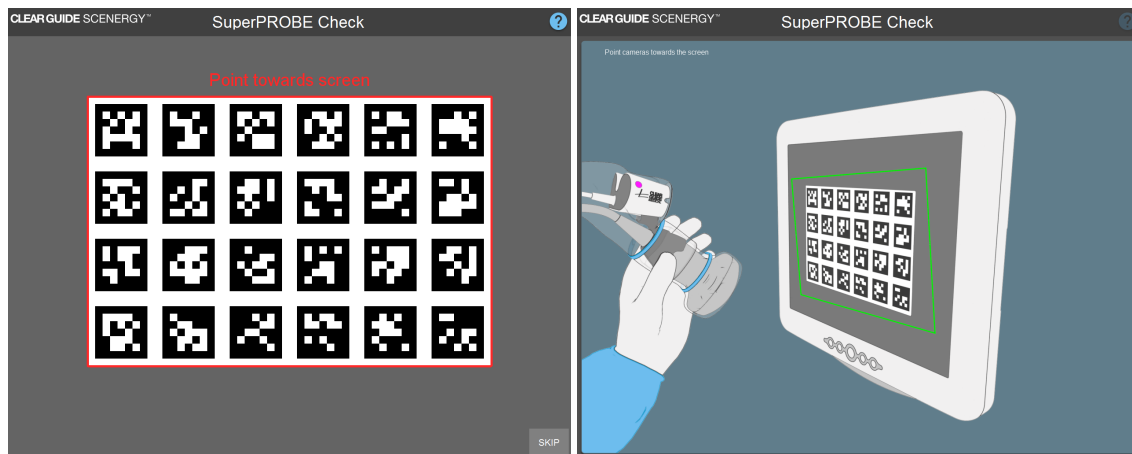


Figure 19: Point the SuperPROBE towards the **CLEAR GUIDE** CORE screen

If the initial check fails, an **error message** indicates the failure (Figure 20 left). The system can then:

- be used at the operator’s own risk (by pressing **ACCEPT**), or
- be turned off (by pressing **SHUT DOWN**).



WARNING: Do not use a SuperPROBE that failed this check. Contact **CLEAR GUIDE MEDICAL** Customer Support for maintenance.

If needed, a **CLEAR GUIDE** SuperPROBE that failed the initial check can still be used (e.g. for testing or training purposes, in a situation where an overriding clinical need exists after careful consideration of the risks, etc.). However, if check failures persist, **maintenance is required for that SuperPROBE and it should not be used clinically.**

The most probable reason for such check failures is damage of the SuperPROBE, e.g. from a drop. If the SuperPROBE is *dropped* during a procedure, it is recommended to reconnect the SuperPROBE and perform this check.

The initial check may be skipped by pressing **SKIP** on the check screen, e.g. if conditions preclude clear visibility of the screen. This is **not recommended**, and the check should be completed as soon as possible. When skipping the initial check, the system will ask to confirm use at the operator’s own risk by pressing **ACCEPT** (Figure 20 right).

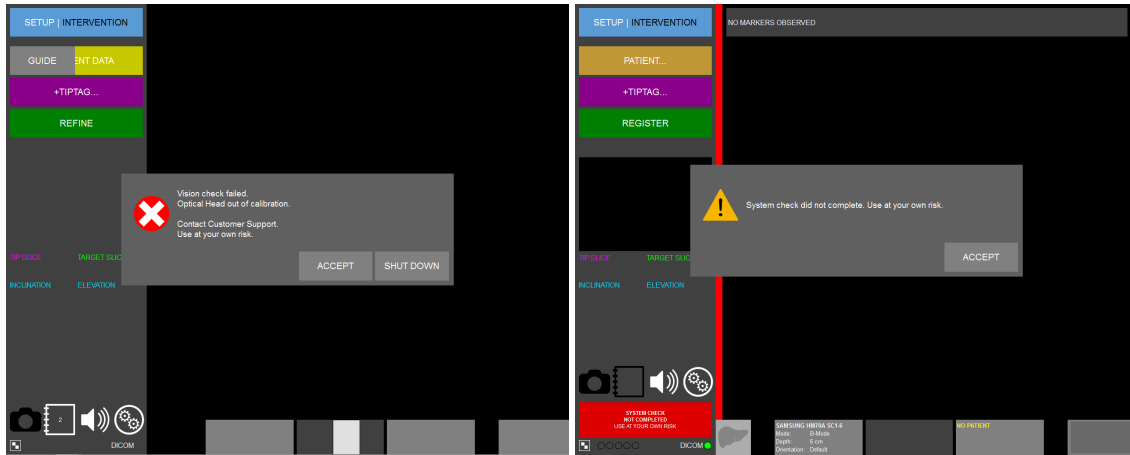


Figure 20: Initial SuperPROBE check failure message (left); check skip message (right)

If the initial SuperPROBE check was not completed successfully, a **red warning** label will be displayed (Figure 20). Pressing the **red warning label** will bring up the initial check screen to repeat the check. **The system will then continue into SETUP mode.**

3.7 TipTAG Instruments

Supported instruments (Section 3.4) can be combined with **CLEAR GUIDE** TipTAG markers. These can be calibrated to instrument shaft and tip, and permit tip tracking (similar to PerceptTIP instruments) if an attached TipTAG is visible.

TipTAG instruments can be added or removed at any time, in either SETUP or INTERVENTION modes.

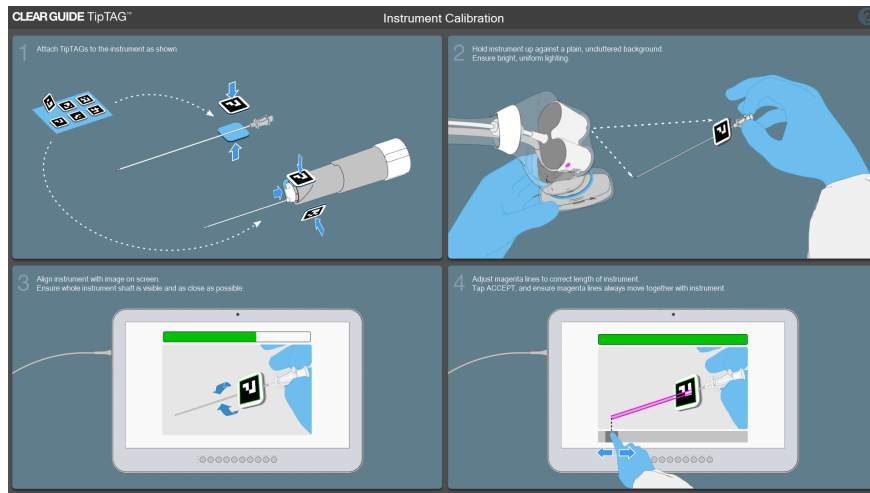


Figure 21: Application of TipTAG markers to interventional instruments (1) and calibration (2, 3, 4)

3.7.1 TipTAG Calibration

1) **Attach TipTAG markers** (available in sterile packaging) to the instrument shaft or body.

- Choose TipTAG markers placement type: instrument shaft or body (see Figure 22).
- Consider the minimum instrument shaft length necessary for introduction and other usage when **choosing tag attachment locations** on the instrument.
- Attach markers. To allow for instrument rotation, and to avoid marker adhesion to gloves, drapes etc., it is recommended to attach TipTAGs **back-to-back**. It is possible to attach more than just one or two markers to an instrument to improve visibility from different angles.

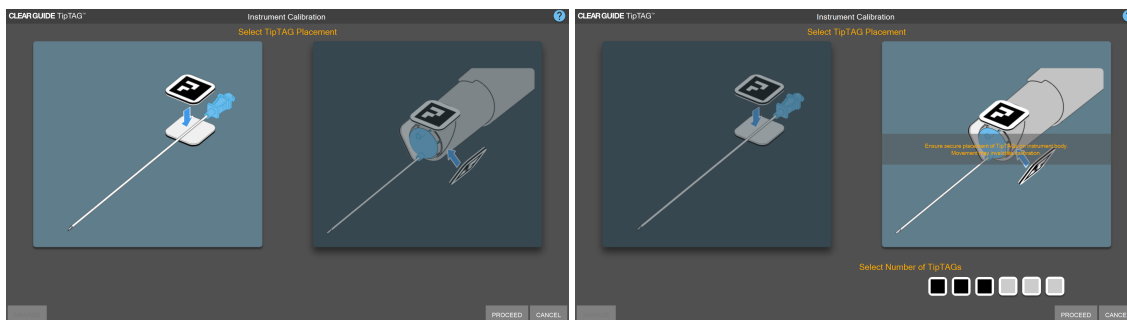


Figure 22: Selection of TipTAG placement: double-sided on shaft (left); multiple markers on body (right)

2) **Calibrate** the new TipTAG instrument by pressing **+TIPTAG...** on the left side of the screen. This opens the TipTAG calibration screen.

- Select the desired/chosen TipTAG placement (Figure 22). For TipTAG markers attached to the instrument body, indicate the number of markers attached.
- Hold the instrument against an uncluttered background, and **aim the SuperPROBE at the instrument** such that the **whole instrument shaft and exactly one attached marker** are visible in the real-time preview window. Rotate the TipTAG about the shaft back and forth keeping the tag in view. A progress bar shows the progress of calibration. When calibration is completed, magenta confirmation lines are displayed along the instrument shaft.
- **Adjust the detected shaft length** manually with the length slider to line up the magenta lines with the actual tip position, and press **ACCEPT** to confirm the new TipTAG instrument or **REJECT** to collect new shaft observations. The newly confirmed marker will be added to the list of calibrated markers on the top of the screen (Figure 23 left).
- To **completely remove** a previously calibrated instrument, tap on the respective marker list.
- **Repeat** this calibration for each attached TipTAG marker. When all possible TipTAGs have been calibrated, the system will display **CALIBRATION COMPLETED**.
- **Finish** calibrations by pressing **FINISH**.
- If not all TipTAG markers were calibrated, the system will ask for confirmation (Figure 23 center, right).

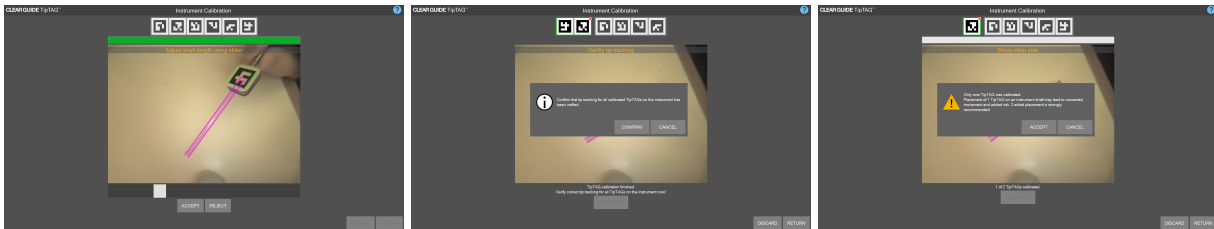


Figure 23: Adjust shaft length (left); confirming number of calibrated TipTAG markers (all)

3.8 SETUP Mode

This operational mode contains preparation steps performed prior to an intervention. These functions may be optional or required.

Table 3: SETUP Mode functions

Function	Optional/Required
Loading Patient Data	Required for image fusion
TipTAG Instrument Preparation	Optional
Patient Registration	Required for image fusion

3.8.1 Initial “Early Markers”: CT Scanning with CLEAR GUIDE VisiMARKERS

The **CLEAR GUIDE SCENERGY** system can perform real-time image fusion between ultrasound images and 3D imaging volumes. For CT, the patient needs to be prepared with skin-attached **CLEAR GUIDE VisiMARKER** fiducials placed around the intervention site before performing the interventional scan (Figure 24). These VisiMARKERS will then allow registration. The markers visible in the 3D imaging volume are called “early markers”.

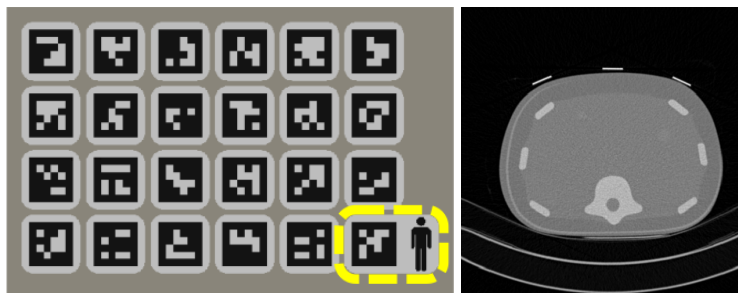


Figure 24: VisiMARKER sheet (Orientation Marker highlighted in yellow) (left); “early markers” appearance in high-quality CT slice (right)

IMPORTANT CT SCANNER SETTINGS:
 Set the scanner to have in-plane **pixel spacing** not larger than 1x1 mm², and slice spacing of at most 2 mm.

Do not acquire CT volumes with tilted gantry (i.e. only scan at 0° angle).

If after loading the CT volume some markers cannot be seen on the 3D patient representation, reconstruct the volume again using “soft tissue” (or a different) reconstruction settings before loading.



Avoid using “bone window” in CT reconstruction. **Soft tissue reconstruction** is preferred for better system performance. Use beam hardening correction in the CT scanner whenever possible; this reduces potential metal artifacts during CT scanning.

3.8.2 CLEAR GUIDE VisiMARKER Application

1. Open the package aseptically.
2. *Optionally:* Align the Orientation Marker (with patient icon; Figure 24) with the patient as shown in Figure 25, with the head on the icon towards the patient’s head. Markers should only be applied on clean, dry, and shaved skin.
3. Peel off markers one at a time and place them >10 cm around the intervention site. **Apply 5... 12 or more markers**, ideally irregularly placed (Figure 25 A). The more markers applied, the more robustly the system will register to the patient.
4. **CLEAR GUIDE** VisiMARKERS are provided sterile. However, the patient may require preparation (e.g. Betadine) after VisiMARKER placement. Wipe any excess preparation off the markers with a standard gauze pad.

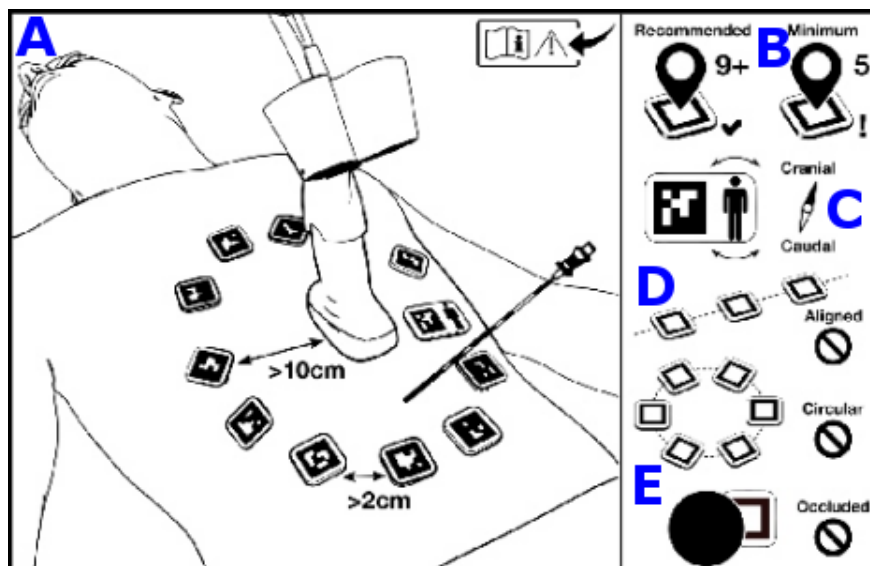


Figure 25: VisiMARKER Instructional Drawings. A: Correct VisiMARKER placement. B: Recommended and minimum number of markers to use. C: Correct alignment of orientation marker with patient. D, E: Incorrect VisiMARKER placement (in a line, in a circle).

3.8.3 Optimal VisiMARKER Placement

The key to good patient tracking is **good marker placement** – ensuring that some markers will always remain in the Optical Head’s field of view during the procedure, i.e. not under a drape, on the side of the

patient, or obscured by other instruments. Registration will be better if marker spacing and distance is irregular.



Place the markers in a **circle (>20 cm in diameter)** around the intervention area. They should be close enough to the area to be seen by the SuperPROBE while using the ultrasound, yet far enough away to not interfere with the procedure.



Ensure each marker is placed **2 – 10 cm from its neighboring markers**. **DO NOT place the markers in a regular pattern**. An irregular quasi-circular pattern is preferred for marker placement. Place markers so the Optical Head can **always see at least two markers** simultaneously during Visual Sweep registration.

The SCENERGY system **warns if less than four markers** (not including the Orientation Marker) are present in the 3D imaging volume, and will **not work with less than three markers**.

3D imaging must be repeated with new markers if too few markers remain on the patient by the time the procedure is performed.



WARNING: Use only one package of VisiMARKERS per patient. Never place duplicate VisiMARKERS from another package on the patient!



WARNING: Do not move fiducial markers between 3D imaging and the procedure. If a marker falls off, **DO NOT re-apply the marker**.

3.8.4 Initial “Early Markers”: MR Scanning with Approved Fiducial Markers

The CLEAR GUIDE SCENERGY system can perform real-time image fusion between ultrasound images and MRI volumes. The patient needs to be prepared with skin-attached fiducial markers (not provided; see below). The markers visible in the MR scan are called “early markers”.

Ensure that the positions of these markers are clearly identified (outlined or marked) on the patient skin. Scan the patient.

MRI functionality of the CLEAR GUIDE SCENERGY has been tested and validated to work with the following commercially available MRI-compatible fiducial markers (Figure 26):

- Beekley “PinPoint” Markers (PN REF 128)
- IZI Multi-Modality Radiology Markers (PN MM3005)

IMPORTANT

With IZI fiducials, ensure you use the design with the opening at the center, and not the full disk shaped fiducial markers. The correct part number is MM3005.



Figure 26: Currently supported MRI-compatible fiducial markers: IZI Multi-Modality Radiology (left) and Beekley Pinpoint (right) fiducial markers

MR SCANNER SETTINGS:

Currently, **CLEAR GUIDE SCENERGY** supports T1 and T2 modalities.

For T1 sequence, use slice thickness of no more than 3mm with no gap between the slices (0% gap). If available, use a 3D protocol rather than a 2D one. Ensure the scan can be completed via one breath-hold.

For T2 sequence, use slice thickness of no more than 5mm with no gap between the slices (0% gap). Ensure the protocol used can be completed via one breath-hold. Protocols that require multiple reconstructions to create the volume may result in marker deformation and unsuccessful processing by **CLEAR GUIDE SCENERGY**. If available, use a 3D protocol instead of a 2D one.

IMPORTANT

For either T1 or T2 sequence, breath-hold is strongly recommended, unless impossible or clinically inappropriate.

Currently, only T1 and T2 sequences have been validated. Other unique sequences done at the direction of a physician must be done with care. Specifically, segmentation results must be confirmed by matching **CLEAR GUIDE SCENERGY** segmentation outputs with actual fiducial marker placement, and fusion must be confirmed.

Following imaging of the patient, fiducial markers can be removed, and the patient can be prepped for the intervention. After prep, apply sterile **CLEAR GUIDE** VisiMARKER to the previously identified locations. See Figure 27 for a depiction of the MR workflow.

3.8.5 Additional “Late Markers”

Additional VisiMARKERS (from the original package) may be added before registration to **improve visual tracking**. These new VisiMARKERS are called “late markers”, since they are not present in earlier imaging. Late markers can also **enable registration** if early markers have been placed too distant from each other, if early markers are obscured (e.g. by draping), or if early markers are otherwise too distant from the Optical Head.



CAUTION: Do not add late markers to locations where (removed) early markers had previously been applied. Use the same VisiMARKER package as before.

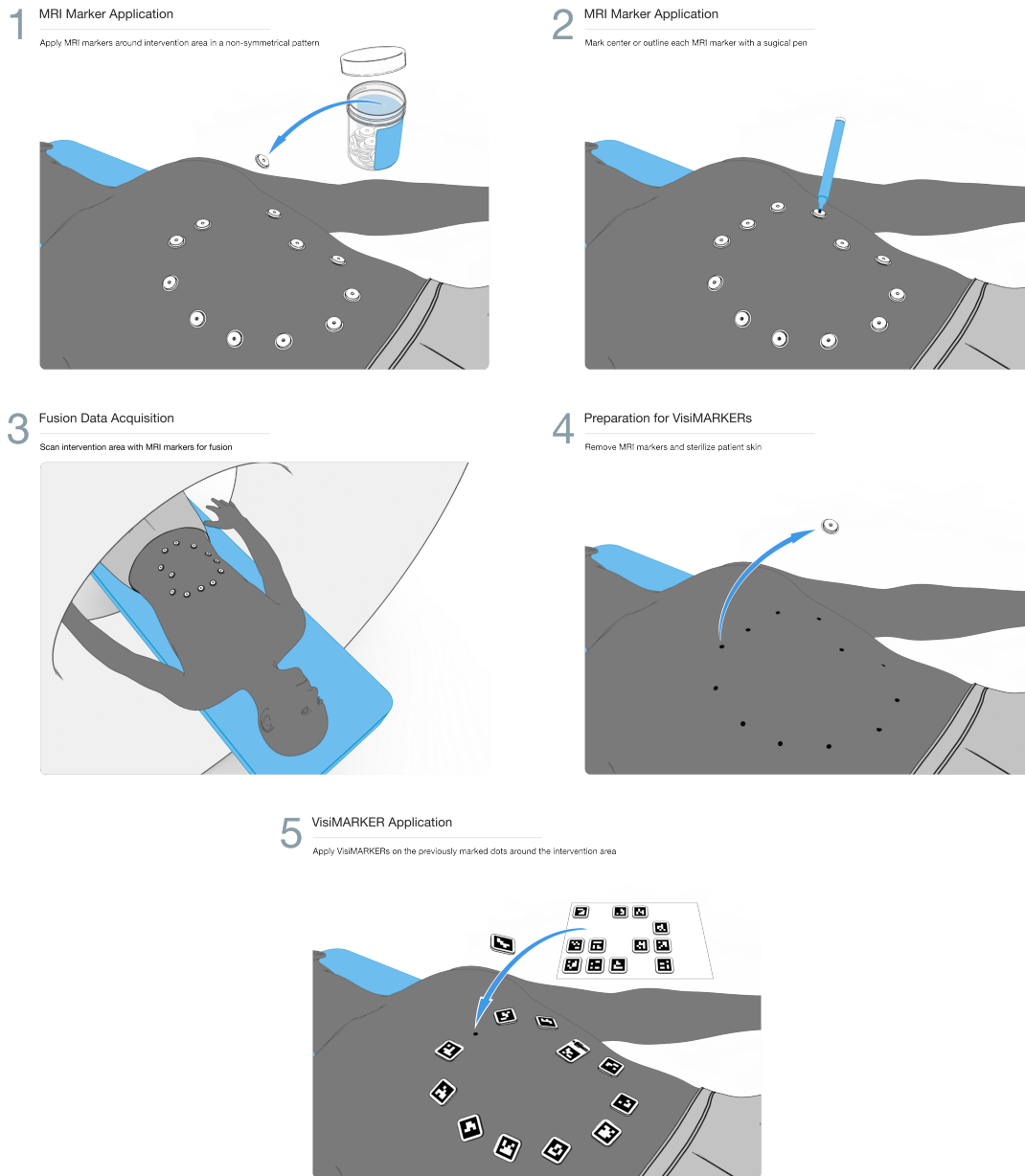


Figure 27: MR Workflow: Apply MRI markers; outline their locations on the skin; perform MRI scan; replace all MRI markers with **CLEAR GUIDE** VisiMARKERS.

3.9 Loading 3D Volume Data

There are several ways to load 3D volumes (in DICOM format) for use with the **CLEAR GUIDE** SCENERGY:

- network transmission from a DICOM/PACS system
- loading from USB drives
- loading a pre-imported scan that is already stored on the CORE.

3.9.1 3D Volume Transfer from PACS

If the **CLEAR GUIDE SCENERGY** is properly configured, it can receive 3D volumes directly from the institution's PACS (*Picture Archiving and Communication System*), or any other system capable of sending DICOM-format imaging volumes over network.

They can be sent at any time while the **CLEAR GUIDE** system is on, and will be stored until use. The DICOM networking status is shown in the screen's lower left corner.

3.9.2 3D Volume Transfer via USB Drive

On the 3D imaging system or PACS workstation, store the 3D volume on a Microsoft Windows-compatible USB storage device. Insert the USB storage device into a USB port of the **CLEAR GUIDE CORE**. The USB drive is then automatically searched for compatible content.

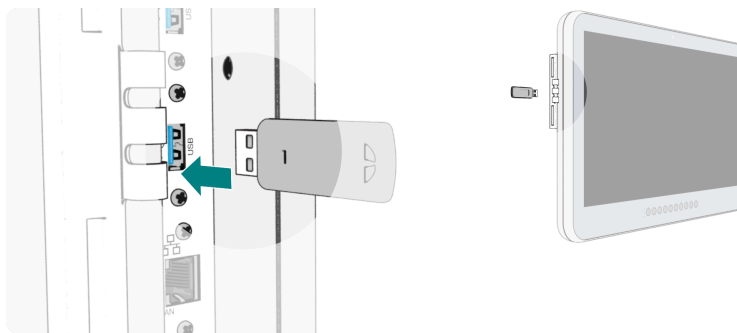




Figure 28: USB Port on **CLEAR GUIDE CORE** side panel of CORE 24 model

Once this search is finished, the list of all available studies can be opened when in SETUP Mode by tapping the **PATIENT...** button and then switching to the studies tab. Studies from the USB drive are identified by the USB icon.

Storing for Later Use: 3D volumes from USB drives can be stored on the system for later use by pressing **IMPORT** next to the respective volume. It will then show up twice in the list: once with a USB icon , and also with the internal storage icon ("Stack of Disks" ). The USB drive can then be removed.

3.9.3 Scan Loading

Choose a scan from the list of available studies (Figure 29 left) via **PATIENT...** > switch to studies tab > select study > **LOAD**.

A progress bar will indicate the current status ("Requesting Volume", "Loading Dataset", "Segmenting Patient", "Initializing Deformable Model", "Detecting Markers" etc.). The system then automatically displays the patient skin surface in a 3D View, **with red symbols where the system expects to find markers** according to the 3D volume (Figure 29 right). The surface can be rotated to find the optimal view.

The **segmentation is automatic** and cannot be modified. To change the segmentation, another 3D volume with a different marker placement must be loaded. Reloading the same 3D volume will result in the same segmentation.

If an incorrect 3D volume has been loaded, press **PATIENT...** > **RESET**, or load the correct volume directly via **PATIENT...** > switch to studies tab > select correct study > **LOAD**.

3D volumes stored on the system can be **deleted** via **PATIENT...** > switch to studies tab > select study > **DELETE**.

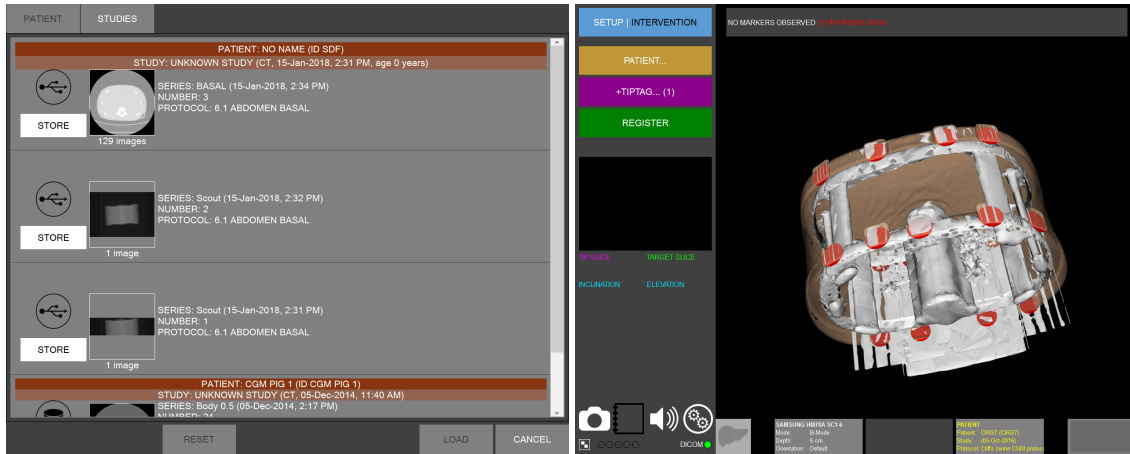


Figure 29: Patient Data List showing all available 3D volumes (left); 3D View displaying expected markers after loading (right)

3.10 Visual Sweep Registration

The system learns the patient position by observing VisiMARKERs on the patient. This enables both dynamic target tracking as well as image fusion.

3.10.1 Perform Visual Sweep Registration

Pressing **REGISTER** in SETUP mode starts registration. Actual registration is performed by **sweeping the SuperPROBE over the VisiMARKERs approximately 15–20 cm above the patient**, so that the cameras observe all markers one by one (Figure 30 left).

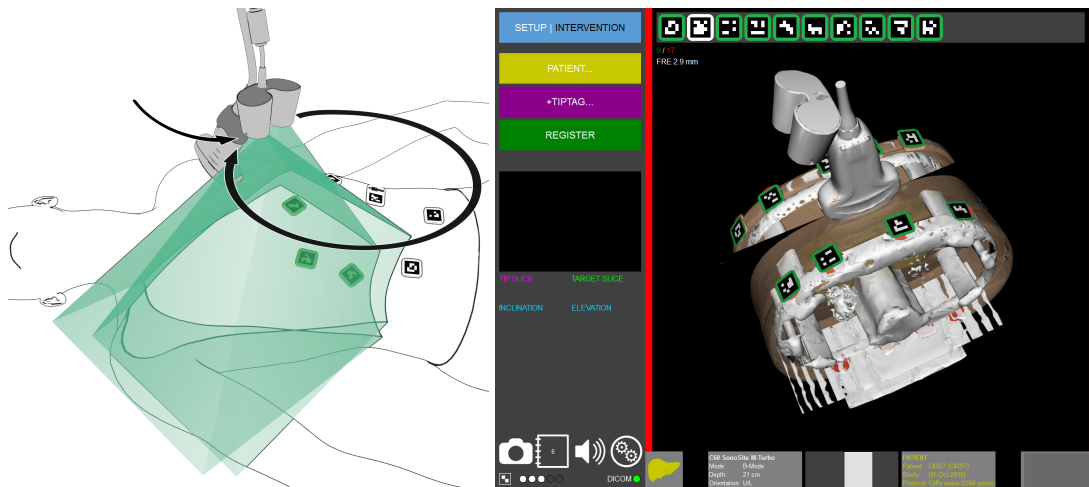


Figure 30: SETUP Mode: Visual Sweep over VisiMARKERs on Patient

For the SCENERGY with a loaded 3D volume, observed markers are automatically registered to red symbols (Figure 30 right) with an acoustic signal. VisiMARKERs successfully registered will be outlined in **GREEN** (after **at least three observed markers**). The real-time **Fiducial Registration Error (FRE)** helps to assess registration accuracy. (A warning will be displayed if the final FRE is >3 mm.) This allows the user to continue with the current registration, or retry to achieve a better registration. However, keep in mind that the FRE is not a direct indicator of fusion accuracy.

Sometimes markers may fail to register even after several sweeps. It is **essential to check that all registered GREEN markers are matched correctly** to the patient. This is especially important when the system warns about **some markers not registered**, or about a possible **ambiguous registration**.

If all other VisiMARKERs are correctly registered, the procedure can continue. If they are not correct, repeat the registration by pressing **REGISTER** > **RESET...**

- **Jumpy, non-contiguous motion** may not be integrated successfully.
- VisiMARKER localization improves with more observations, especially **longer looping sweeps**.
- Breathing may affect VisiMARKER localization. Perform the **Visual Sweep under breath hold at the same stage as during 3D imaging**.

Pressing **END REGIST** ends the registration. The 3D View then shows all tracked instruments, targets, ultrasound (and fused 3D imaging if applicable), and all detected VisiMARKERs.

3.11 INTERVENTION Mode

After registration, press **INTERVENTION** to continue to INTERVENTION mode (Figure 31). To return to SETUP mode later, press **SETUP** again.

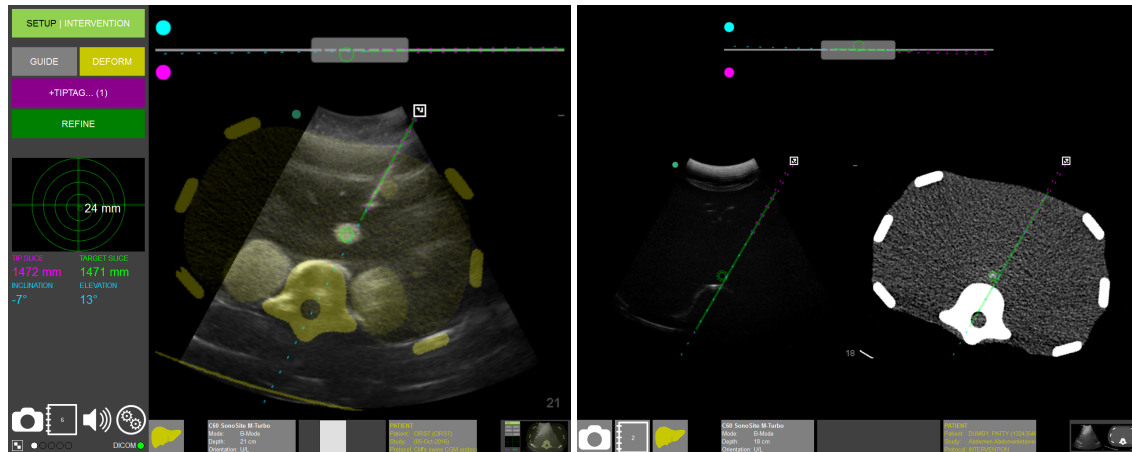


Figure 31: INTERVENTION Mode: Fusion (left) and Side-by-Side (right) views

3.11.1 User Interface: Navigation Views

The **Main View** of the display is the primary, in-plane (lateral/axial) 2D imaging view (Figure 31).

Blue dotted guidance lines show the trajectory of the instrument.

Green guidance bars are shown within 5 mm of the image plane. (An in-plane insertion will thus have longer green lines than an out-of-plane insertion, with more of the trajectory close to the image plane.)

Magenta dotted guidance lines indicate the instrument shaft and tip when using **CLEAR GUIDE** Percep-TIP or TipTAG instruments.

A **yellow** intersect mark indicates where the instrument trajectory intersects the image plane. This mark shrinks when the instrument is in-plane to minimize distraction.

The **Top View** is an out-of-plane guidance view (lateral/elevational) showing the instrument trajectory from above, with the imaging plane shown as a **gray line** (a “Bird’s Eye View” of the interventional field). Same as in the Main View, **blue/green guidance lines** show the trajectory of the instrument, here relative to the imaging plane.

Additionally, the **gray transducer face** is shown at scale for reference.

The **cyan** and **magenta orientation circles** next to the image plane correspond to the colored dots on the SuperPROBE. Moving the instrument towards either side of the SuperPROBE corresponds to the same motions in the Top View.



WARNING: Always align the instrument in both the Main View (in-plane) and the Top View (out-of-plane). Misalignment is likely if only one of the two views is used.

When a target is selected, a **green target square** (for static targets) or a **green target circle** (for dynamic tracked targets) will appear on all views. When all **Blue dotted** guidance lines are aligned with in-plane

green target symbols, the instrument is pointing towards the target. Failure to line these up could result in missing the intended target.

Note: Guidance lines and target symbols are shrunk by 50% for imaging depths \leq 6cm.

3.11.2 User Interface: Left Side

From top-to-bottom, the left of the screen contains the following components:

1) User Interface Buttons:

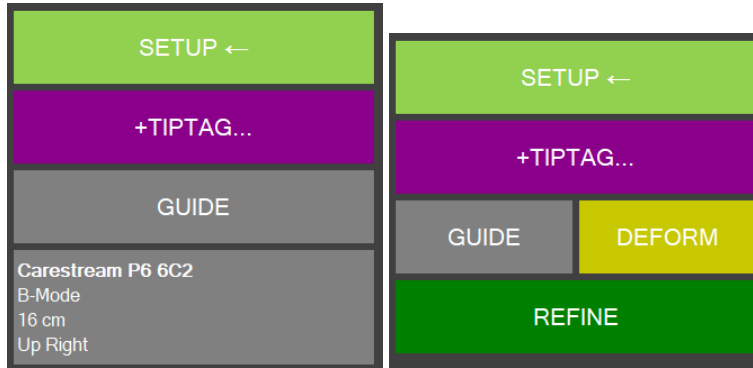
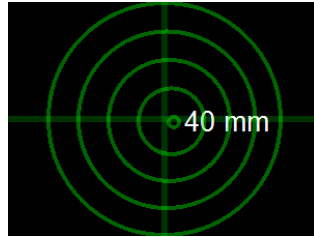


Table 4: INTERVENTION Mode: User Interface Buttons

User Interface Button	Function
→ INTERVENTION	Switches to INTERVENTION modes.
SETUP ←	Switches back to SETUP modes.
GUIDE	Toggles instrument guidance and target display on/off.
DEFORM	Toggles Deformation Correction on/off.
+TIPTAG...	Opens TipTAG instrument management.
REFINE	Starts manual Registration Refinement.

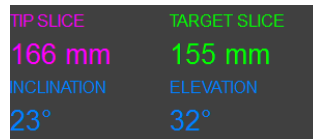
2) Targeting Crosshair to visually assist with instrument/target alignment (only available when tracking a single instrument). Centering all outlines points the instrument directly at the target (also see Section 3.12 “Interventional Guidance and Targeting”).



3) Numerical Instrument Alignment to assist with instrument/target alignment (only available when tracking a single instrument with SCENERGY).

Tip Slice and **Target Slice** indicate the 3D volume slice (Z coordinate) at which the instrument tip and the current target are detected, respectively.

Inclination and **Elevation** values show instrument angulation relative to a 3D volume slice and relative to “up” direction. This helps relating intra-procedural guidance to pre-procedural planning.



4) Screen Capture (camera) / Screen Capture Management (logbook) / Audio Feedback (speaker) / Settings (gears) buttons for taking and managing documentation screen captures, sound effects, and system settings.

Tapping the **Screen Capture** button stores an image of the current screen, and updates the displayed image count. These screen captures can be selected, viewed, deleted, or exported onto DICOM/PACS systems or USB drives by tapping the **Screen Capture Management** button. See Section 3.13 for details.

Only a limited number of images can be stored. Before reaching that threshold, the system will display a warning, asking to export and/or delete stored screen captures.



5) Tracking Quality Indicator showing robustness of the VisiMARKER tracking. White symbols indicate the amount of visible markers. 3D imaging fusion navigation is available only when VisiMARKERS are visible.



6) Battery Indicator showing current AC/battery power status and battery charge level (only available on certain CORE models).



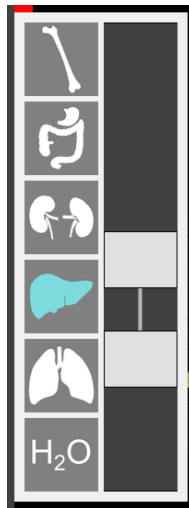
7) DICOM Network Indicator showing DICOM network status (initializing: yellow; connecting: flashing yellow; idle: green, receiving data: flashing green).



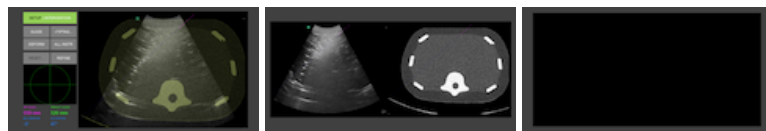
3.11.3 User Interface: Right Side

Top-to-bottom, the right of the screen contains the following components:

- **Top View** helps with in-plane instrument and target alignment.
- **Main View** shows the current imaging data. For supported instruments in the field of view, guidance lines are overlaid to help with targeting.
- **Contrast/brightness slider and CT Hounsfield unit (HU) window presets (if applicable)** based on the organ scanned, with icons showing representative organs (top to bottom: bone, intestines, kidney, liver, lung, water). Pressing the preset icon brings up a menu which allows for free adjustment of upper and lower window boundaries. The contrast preset icons should not overrule clinical judgment about optimal contrast settings.



- **Fusion Slider** for blending between the imaging modalities in the Main View.
- **Fusion / Side-by-Side toggle** to select different viewing modes (Figure 31) – fused ultrasound and 3D volume overlay, or side-by-side separate modality views. All instrument and target overlays are available on all views. Without registration of a 3D volume, only ultrasound will be shown.



3.12 Interventional Guidance and Targeting

Before starting an intervention, it is important to **first verify proper image fusion and tracking of instruments** at the lighting levels in the intended environment.

3.12.1 Verify Instrument Guidance

To **verify instrument guidance**, move the instrument within the cameras' field of view. Trajectory overlays should move along with the instrument movements.

If no movement occurs, or if movements are disjointed ("jumpy"), clear the surrounding environment of clutter, other instruments etc. and repeat testing. If this does not solve the problem, **STOP** using the **CLEAR GUIDE** system and proceed without instrument guidance. Contact **CLEAR GUIDE MEDICAL** Customer Support for troubleshooting.

Otherwise, follow the procedures in the following section to successfully and reliably align interventional instruments with anatomical targets.

3.12.2 Using CAIG™: CLEAR GUIDE Computer-Assisted Instrument Guidance

CLEAR GUIDE system provides targeting to use with the guidance system.

1. Use the ultrasound transducer until the **desired target anatomy is visible** on the Main View (in accordance with its instructions for use and best clinical practice).
2. Once the target anatomy is visible, tap the desired location on the **CLEAR GUIDE CORE** touchscreen. **Green target symbols** will appear to mark the selected location, in both Main and Top Views. If the system observed VisiMARKERS at that time, the **target will be dynamically tracked** (shown as a green target circle, moving together with the underlying anatomy); otherwise the **target will be static and not tracked** (shown as a green target square, staying in place).



CAUTION: If the patient moves, or if the operator moves the ultrasound transducer after target selection, a **dynamic green target circle** may move out of plane and become smaller or disappear entirely. Move the ultrasound transducer back and forth until the circle reappears in plane.

A **static green target square** will not move, but the underlying anatomy may move out of place – in that case, move the ultrasound transducer back and forth until the anatomy lines up with the target square again.



CAUTION: If the target seems to appear in the wrong location after a tap, re-select that target. If the problem persists, stop using the targeting feature, and contact **CLEAR GUIDE MEDICAL** Customer Support.



To **remove a defined target**, simply tap the screen again to remove the green target symbol. Tapping the screen again selects a new target (per Step 2 above).

3. **Bring the instrument into the field of view** of the Optical Head cameras. If no instrument is detected, "No Instrument Detected" **red** bars will appear on the sides of all views.



Placing the instrument tip lightly on the patient skin (without insertion) allows positioning the instrument for the optimal trajectory without losing a chosen entry point. This “grounding” concept makes the following alignment movements easier.



CAUTION: If the instrument guidance or the image suffers delays or is jittery, restart the **CLEAR GUIDE** system. If the problem persists, contact **CLEAR GUIDE MEDICAL** Customer Support.

4. **Move the instrument to align the green guidance bars with green target symbols:**

- (a) **In the Main View**, align the green guidance bars to intersect the in-plane green target symbol (by tilting the distal end of the instrument **in-plane up (+) or down (-)**, towards or away from the Optical Head) (Figure 32).
- (b) **In the Top View**, align the green guidance bars to intersect the green target symbol (by shifting the distal end of the instrument **out-of-plane to cyan and magenta**, through the imaging plane).

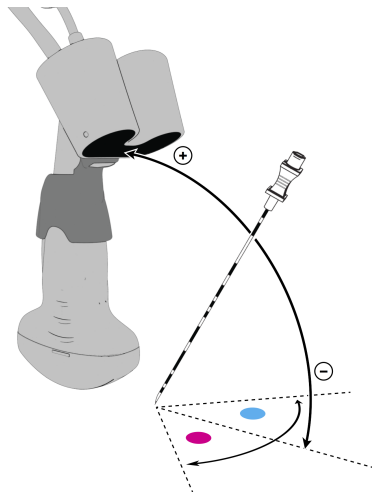


Figure 32: Alignment of transducer, instrument, and target

5. **Insert** the instrument towards the target.



WARNING: When using **CLEAR GUIDE** systems to target lesions located near the diaphragm, particular care must be taken to **account for respiratory motion and the risk of puncturing the lung**. Stage-gating (e.g. breath holds) will limit the risks associated with using the system – specifically, (1) fusion error introduced by respiration and (2) lung puncture.



WARNING: Correctly following the **CLEAR GUIDE** guidance does not ensure that the instrument trajectory is free of anatomically critical regions. Always use medical judgment to decide on the correct instrument insertion path.

WARNING: CLEAR GUIDE systems do not detect or correct for bent instruments. Therefore, **do not twist or bend the instrument.**



A bent instrument may cause the CLEAR GUIDE tracking mechanism to display an inaccurate instrument path. Ensure that the trajectory aligns with its intended target prior to insertion.

Rigid and large-diameter instruments reduce bending (and thus the chance of inaccurate instrument guidance). See Section 3.4 “Supported Instruments” for more information on supported instruments.



CAUTION: Do not insert the instrument prior to ensuring that the CLEAR GUIDE system can detect the instrument under current lighting and background conditions.



CAUTION: If target input stops working, or if touch input becomes erratic, stop using the target guidance system. Call CLEAR GUIDE MEDICAL Customer Support to schedule maintenance (see Section 4.3).

IMPORTANT

For regular instruments, CLEAR GUIDE systems cannot monitor the instrument’s insertion depth. Even for CLEAR GUIDE PerceptTIP and TipTAG instruments, insertion depth monitoring may fail. Always visually confirm the instrument’s tip location through standard medical practice techniques (e.g. visualization on the ultrasound image, needle depth markings, etc.).

3.12.3 Targeting Feedback

CLEAR GUIDE systems provide **targeting feedback** through audio and visual cues if:

- A **target** is selected; and
- One (1) **instrument** is present in the field of view.

Audio feedback is a qualitative indicator of instrument/target alignment: a higher rate of clicks indicates a closer projected path than a lower rate.

The **Targeting Crosshair** shows alignment visually (Figure 33). Centering the outlines on the green crosshair results in a projected path that is closer to the target. Outlines are circles for dynamic (tracked) targets, and rounded boxes for static (fixed) targets. Displayed numbers indicate the **distance-to-target** for tip-enabled instruments. Negative distances indicate overshoot, where the instrument has been inserted deeper than the intended target.

Instrument and target overlays can also be toggled on and off by pressing **GUIDE**, e.g. for non-guidance phases of the intervention.



CAUTION: For PerceptTIP and TipTAG instruments, the targeting feedback indicates the distance from actual instrument tip to target. Otherwise, the information relates to the **projected path** towards the target.

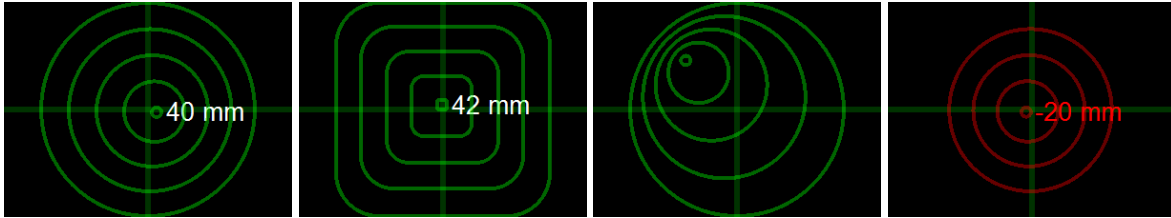


Figure 33: Targeting Crosshair (left to right: aligned with dynamic target; aligned with static target; not aligned; overshoot)

3.12.4 Verifying Image Fusion, and Registration Refinement

To **verify image fusion** after completed registration, check for proper alignment of anatomy and targets in ultrasound and 3D imaging in INTERVENTION mode, with the blending slider approximately centered.

If case of major misalignment, repeat the registration in SETUP Mode and then re-verify fusion. For smaller misalignments (Figure 34 left), the imaging modalities can be **manually re-aligned**.

First, find a **suitable fusion image** with sufficiently detailed anatomy, then tap the **REFINE** button. This **unlocks the rigid relationship** between the images, fixing the CT image in place. The ultrasound transducer can now be moved so that **features in both images line up**. **Do not freeze** the ultrasound image. Once this is achieved, press **END REFINE** to memorize this updated registration (Figure 34 right). The **REFINE** button changes to show **REFINED** to indicate a modified registration.

This process can be repeated to approximate an optimal registration. The changes accumulate with each new refinement.

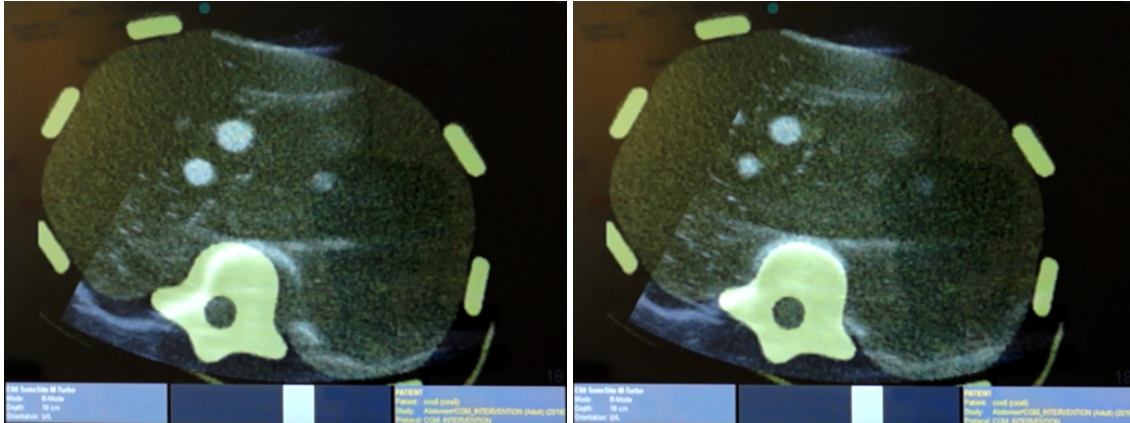


Figure 34: Fusion alignment example before (left) and after (right) manual registration refinement

Successive **refinements should be performed from different imaging orientations** of the SuperPROBE, to ensure good alignment both in- and out-of-plane of the image (Figure 35). Also, after each refinement, **fusion alignment should be verified from different imaging orientations**. (Deviations or “slippage” from the current image plane, which are difficult to observe visually while performing a refinement, are indicated by the SHORT AXIS indicator).

IMPORTANT

The SHORT AXIS indicator tracks whether the transducer moves out-of-plane during registration refinement. Because the 3D volume image is frozen, this type of movement could lead to misalignment if not checked.

A refined registration can be reset back to the original automatic registration (from the Visual Sweep) by tapping **REFINED** followed by **RESET**.

If fusion is still not correct after repeated refinements, **STOP** using the system and proceed without fusion image guidance. Contact **CLEAR GUIDE MEDICAL** Customer Support for troubleshooting.

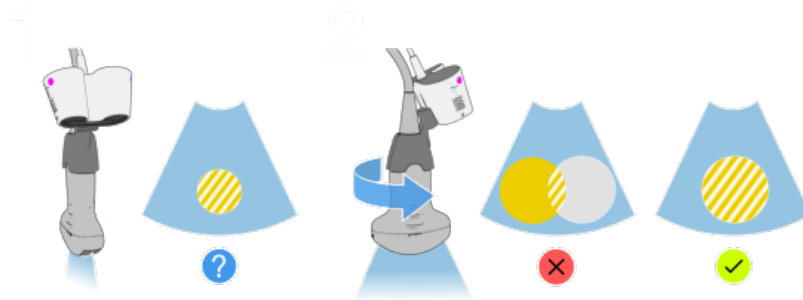


Figure 35: Rotate SuperPROBE and verify fusion alignment from other directions

3.12.5 CT Deformation Correction

When the ultrasound transducer is applied to the patient, the force on the skin deforms underlying organs. The **CLEAR GUIDE SCENERGY** estimates this deformation in real time and shows in CT how different layers of tissue change with the motion of the ultrasound transducer (Figure 36).

This improves the navigation accuracy of the system, since the CT then exhibits the same deformation as the ultrasound image. Press **DEFORM** to enable/disable this automatic correction of the CT scan.

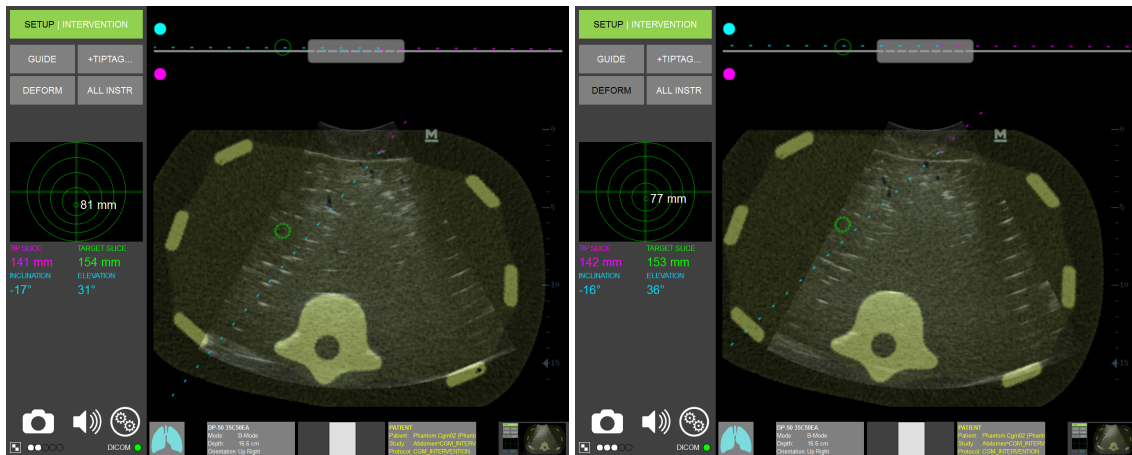


Figure 36: CT Deformation Correction on (left) or off (right)

3.13 Screen Captures and Screen Capture Management

3.13.1 Screen Captures

Screen capture are taken by tapping the Screen Capture button (camera icon). This button is enabled only when patient information is available. There are two ways to achieve this.

- When loading a CT or MRI volume, this volume's patient information will be used when creating screen captures. Hence, loading a CT or MRI volume will enable the Screen Capture button; resetting the volume will disable the button.
- An emergency patient ID can be created to enable the Screen Capture button. Tap the **PATIENT...** button to open the patient information window. On the tab labelled "PATIENT", you can create an emergency patient ID by tapping the button **CREATE EMERGENCY PATIENT ID**. Once an emergency patient ID has been created, the Screen Capture button will be enabled.

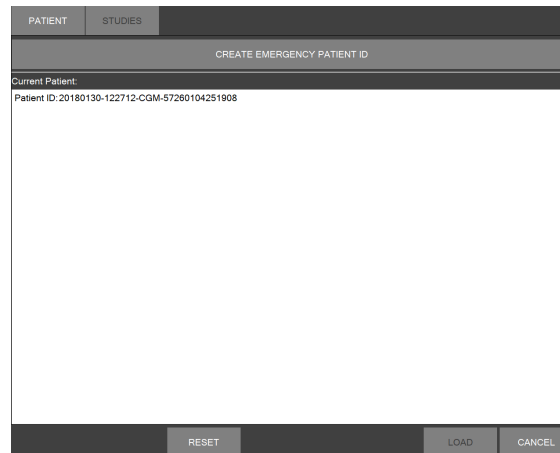


Figure 37: Creating an emergency patient ID.

3.13.2 Screen Capture Management

Tapping the logbook icon will open the Screen Capture Management Window (Figure 38).

- Tap any item to select it; tap it again to unselect it. You can also use the button labelled "ALL" to select all items; the button labelled "NONE" will unselect all items, and the button labelled "CURRENT" will select those items that were made using the currently loaded 3D volume.
- When only one item is selected, tap "PREVIEW" to display the image and patient information related to it.
- Tap "DELETE" to permanently erase all selected items from the device.
- To export screen captures, first select a destination. If configured, the PACS can be selected as a destination. If a USB drive is attached, that USB drive can be selected as a destination. For a USB drive, you also need to choose the format:
 - "DICOMDIR" will create a DICOMDIR data structure, or update it if one is found.
 - "COPY FILES" will copy the files to the drive's root folder.

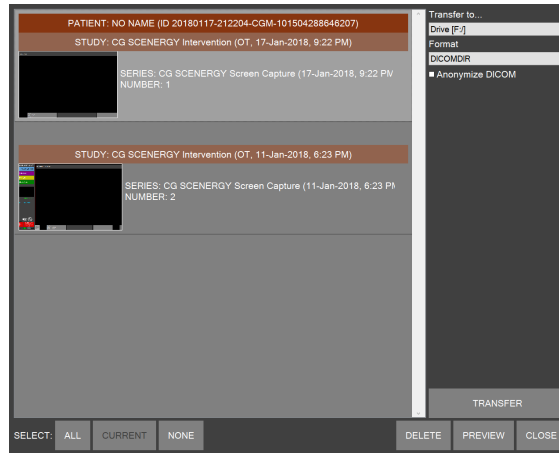


Figure 38: Screen Capture Management Window

- If desired, check “Anonymize DICOM” (and optionally “Retain Full Dates”) to export fully or partially anonymized versions of the screen captures.

Finally, tap “EXPORT” to initiate the export to the selected destination.

3.14 System Shutdown

1. After using the **CLEAR GUIDE SCENERGY**, press the power button on the **CLEAR GUIDE CORE** to turn off the system.
2. Wait for complete system shutdown. The system is completely shut down when the screen goes blank and the blue power button light turns off.
3. Turn OFF the power adapter of the **CLEAR GUIDE CORE**, if applicable.



CAUTION: Do not first unplug or turn off the power adapter. This sudden loss of power could damage the equipment, and/or result in a lengthy self-check process upon next startup.

3.15 Post-Use Care

3.15.1 Disconnecting and Storage

To avoid electrical hazard, the **CLEAR GUIDE** CORE should be unplugged from AC power after use.

The **CLEAR GUIDE** SuperPROBE should be disconnected from the existing ultrasound machine for cleaning and disinfection, but it can remain attached during storage (i.e., after reattachment following cleaning, disinfection, and drying – per Section 3.16). The **CLEAR GUIDE** SuperPROBE cable features a locking connector that can be unlocked by pulling back on the outer metal ring.



Refer to Section 3.5 for more information about turning the **CLEAR GUIDE** system ON or OFF.



Refer to Section 2.4 for information about reattaching connections prior to use.

3.15.2 Storage Environmental Conditions

After use, the **CLEAR GUIDE** system should be appropriately stored to avoid mechanical shocks and other stresses (e.g. vibrations, drops, temperature or humidity extremes), and away from dust or water. Storage conditions should be consistent with ultrasound machine storage.

- Temperature: 5...40°C
- Relative Humidity: 10...80% (non-condensing)
- Atmospheric Pressure: 70...106kPa

3.16 Cleaning and Disinfection

Prior to each use, ensure that the SuperPROBE is clean – free of ultrasound gel from previous imaging, debris, films, or unusual odors. Also, inspect the SuperPROBE for damage (e.g. cracks).



WARNING: Do not sterilize the SuperPROBE with techniques including autoclaving, ultraviolet or gamma radiation, gas, steam, or heat sterilization. This will result in severe equipment damage.

Instead, in sterile environments, use the **CLEAR GUIDE** SteriMASK ultrasound transducer drape. Do not obstruct the Optical Head window with the sterile sleeve.



WARNING: NEVER submerge or rinse the SuperPROBE or other **CLEAR GUIDE** system components. This could result in serious electrical hazard to the operator, and it could damage the equipment.



WARNING: To avoid electrical shock, disconnect both SuperPROBE and power adapter from the **CLEAR GUIDE** CORE prior to any cleaning or disinfection.



WARNING: Follow the ultrasound transducer manufacturers' instructions for cleaning or disinfecting existing ultrasound transducers. Failure to follow cleaning and disinfecting instructions could lead to contamination hazards.

3.16.1 CLEAR GUIDE CORE Cleaning Procedure

Follow these steps to clean the **CLEAR GUIDE** CORE touchscreen:

1. Turn off the **CLEAR GUIDE** system, and disconnect it from the power adapter.
2. Moisturize a clean, non-abrasive, cotton cloth with an ammonia-based window cleaner (apply the cleaner to the cloth rather than to the touchscreen surface).
3. Wipe the touchscreen with the damp cloth.
4. Let the touchscreen dry completely before starting the **CLEAR GUIDE** system.

3.16.2 CLEAR GUIDE SuperPROBE Cleaning Procedure

Follow these steps to clean the SuperPROBE:

1. Wear protective gloves during the cleaning and disinfection process.
2. Turn off the **CLEAR GUIDE** system, and disconnect the SuperPROBE from the system and from the ultrasound machine.
3. Carefully remove SteriMASK from the SuperPROBE.

4. Wipe ultrasound gel or other fluids from the SuperPROBE with a damp cloth moistened with a mild soap or cleaning solution. Apply the solution to the cloth instead of applying it directly to the SuperPROBE surface.
5. If necessary, wipe SuperPROBE with a water-dampened cloth to remove any lingering soap residue. Then wipe SuperPROBE with a dry cloth.
6. Ensure that the SuperPROBE is dry (air drying) before storing.
7. Examine the SuperPROBE and other components for damage (e.g. cracks, fluid leaks etc.). If damage is observed, stop using the SuperPROBE and contact **CLEAR GUIDE MEDICAL** Customer Support.



CAUTION: Use only medical-grade cleaning solutions that are approved for cleaning the ultrasound transducer that is part of the SuperPROBE. Refer to the respective transducer manual for information.



CAUTION: Do not use abrasive cleaners, cloths, or other materials or tools that may scratch the front window of the Optical Head. This may affect tracking quality negatively.



CAUTION: NEVER separate or disassemble the SuperPROBE (i.e. the existing ultrasound transducer and Optical Head). Do not use excessive force while cleaning the SuperPROBE. Do not force objects, tissues, or cleaning agents into the SuperPROBE or between its components. This could result in internal calibration loss, requiring maintenance prior to next use.

4 Troubleshooting and Maintenance

4.1 Warning Pop-up Dialogs

CLEAR GUIDE systems rely on the user to be aware of how the system works and how to get the best performance out of the system by following instructions carefully. The systems include some safeguards to warn the user about certain problems.

Table 5: Warning Pop-up Dialogs

Pop-up Dialog Message	Meaning	How to Resolve
Error E1000 has occurred while starting up the system: Could not load the translation file. Contact Customer Support. The system will shut down.	An unrecoverable error has occurred during system startup and so the system has shut down to ensure patient safety.	Contact Customer Support. Have error code, error message, and software version or serial number of your system available.
WARNING: Duplicate VisiMARKERS observed. VisiMARKER observations automatically reset. Please try again.	It appears that two identical VisiMARKERS (e.g. from two separate packages) have been placed on a patient.	Visually inspect the markers on the patient, and remove one of the duplicates. Re-register the patient. If the problem persists, contact Customer Support.
No VisiMARKERS detected in study. Three or more required for registration.	The system has not found any VisiMARKERS in the patient 3D volume.	Apply fiducial markers to the patient and perform another scan. Load that scan onto the SCENERGY.
Only two VisiMARKERS detected in study. Three or more required for registration.	The system has found too few VisiMARKERS in the patient CT or scan.	Apply additional fiducial markers to the patient and perform another scan. Load that scan onto the SCENERGY.
Only three VisiMARKERS detected in study. Fusion quality may be low. Proceed with caution.	Only three of the VisiMARKERS applied to the patient were registered between ultrasound and 3D volume. This is the minimum number of markers to enable the SCENERGY to work. However, it is not a very robust registration.	Adding additional VisiMARKERS after the 3D volume scan can help to make the registration better. Even though these additional markers are not contained in the 3D volume, they will make SCENERGY tracking more robust.
Fiducial registration error is large: FRE = [number]. Refine registration or proceed with caution.	The match between the markers visible in 3D imaging and ultrasound is not very good. Markers may have moved around or fallen off.	Perform the registration again, making sure to scan all markers and removing any markers that were moved or reapplied after coming off. If the message persists, remove all markers, reapply new fiducial markers and perform a new 3D volume scan.
CAUTION: Ambiguous registration. Confirm correct VisiMARKERS matching before proceeding.	The VisiMARKERS were applied in such a regular way in the 3D volume as to have more than one way the cameras can interpret the spatial layout.	Double-check that the checkerboard patterns on a couple of the VisiMARKERS on the patient are shown correctly on the 3D volume/ultrasound, i.e. the orientation is as expected.
Loading study failed!	The DICOM data from the 3D volume has not been loaded successfully by SCENERGY.	Make sure the 3D volume is available in an appropriate DICOM format.
Maintenance overdue. Contact Customer Support. Contact CLEAR GUIDE MEDICAL for maintenance.	The Maintenance period has expired and needs to be renewed.	Contact Customer Support to schedule a SCENERGY maintenance appointment.
Maintenance required in [number] days. Contact Customer Support.	The Maintenance period is about to expire.	Contact Customer Support to schedule a SCENERGY maintenance appointment.
Maintenance period is about to expire. Contact CLEAR GUIDE MEDICAL for maintenance.	The maintenance period of the SCENERGY is about to expire.	Contact Customer Support to schedule a SCENERGY maintenance appointment.

Pop-up Dialog Message	Meaning	How to Resolve
VisiMARKERs placement may cause wrong registration.	The VisiMARKERs were applied in a symmetrical way that can lead to multiple, different registrations rather than one unique registration.	Double check that the checkerboard pattern on a couple of the VisiMARKERs on the patient are shown correctly on the CT/Ultrasound, i.e. the orientation is as expected.
No valid studies found on device X.	The file that SCENERGY expected to be 3D volume data is not in the correct DICOM format.	Re-import the 3D volume in an appropriate DICOM format.
Patient data not registered. For fusion, complete the registration.	The registration process has not been performed.	Follow the registration process described in Section 3.10.
WARNING: Registration error too large. VisiMARKER observations automatically reset. Please try again. ATTENTION: Do not move VisiMARKERs or use duplicate ones!	The match between the markers visible in 3D imaging and ultrasound is insufficient to register the 3D volume to Ultrasound. Markers may have moved around or fallen off.	Perform the registration again, making sure to scan all markers and removing any markers that were moved or reapplied after coming off. If the message persists, remove all markers, reapply new fiducial markers and perform a new scan.
CAUTION: Only X out of Y VisiMARKERs registered. For best guidance, register all VisiMARKERs.	Not all of the applied VisiMARKERs have been used to register the 3D volume to the ultrasound. This may be because they have not been scanned by the cameras or because they have moved since the 3D volume scan.	Look at the 3D volume where the red circles are that have not been registered. Sweep them again with the SuperPROBE cameras. If they do not register, it may mean that some markers have moved since the 3D volume scan. Double check that all the other successfully registered markers have the correct checkerboard pattern on the correct VisiMARKER before using the system.
Selected study not <a supported 3D volume modality>. Proceed with caution.	The file that SCENERGY expected to be supported 3D volume data is not in a correct DICOM format and therefore should not be used.	Re-import the 3D volume data in an appropriate DICOM format.
System check did not complete. Use device at your own risk. PRESS TO RETRY	The calibration check described in Section 3.6 was not completed because the camera did not check the calibration.	Retry the calibration setup, holding the transducer steady and making sure the cameras have the opportunity to check their internal calibration.
Vision check failed! Optical Head out of calibration. Contact customer support. Use system at your own risk.	The calibration check described in Section 3.6 failed because the cameras are definitely out of calibration.	The SCENERGY should not be used. Contact Customer Support for maintenance.
Vision check skipped! Optical Head not checked. Use system at your own risk.	The calibration check described in Section 3.6 was skipped by the operator for some reason. The status of the camera calibration is unknown.	The SCENERGY camera calibration may or may not be working properly. It is recommended to return to the camera calibration screen and complete the check. Using the SCENERGY without checking the camera calibration has risks to the patient and should be avoided.

4.2 General Troubleshooting

The information in this section is intended to help correct problems a user may encounter with the system. If the encountered problem is not listed here, please contact **CLEAR GUIDE MEDICAL** Customer Support. If the problem is related to the underlying 3D imaging system, ultrasound machine, or related accessories, please refer to those machines' user manuals.

Table 6: Troubleshooting Guide

Problem	Potential Solution
System will not power on.	Check all power connections. If secure, contact Customer Support.
CLEAR GUIDE CORE unexpectedly powers down.	Check all power connections. If secure, contact Customer Support.
System image quality is poor.	Check video connection (per Table 2). If problem persists, refer to user manual of existing ultrasound machine for problem solutions.
Touchscreen appears inaccurate, does not work, or turns dark.	Restart system by power cycling the equipment. If problem persists, contact Customer Support.
Ultrasound and/or 3D volume does not move.	Check for "Frozen Ultrasound" blue bars. If present, unfreeze image on the existing ultrasound machine, in accordance with its instructions for use. If problem persists, contact Customer Support.
Ultrasound image appears jittery, or exhibits latency.	Check the video connection by reseating the video plug and re-orienting the video cable. If problem persists, contact Customer Support.
Ultrasound image on CLEAR GUIDE system is not consistent with underlying ultrasound machine.	Stop using the CLEAR GUIDE system. Maintenance may be required. If problem persists, contact Customer Support.
Guidance is not displayed.	Ensure field of view is clear and uncluttered, and then bring an instrument into the field of view. If problem persists, contact Customer Support.
An interface other than the CLEAR GUIDE system is displayed (i.e., the system does not boot directly into CLEAR GUIDE User Interface).	Restart system by power cycling the equipment. If problem persists, contact Customer Support.
CLEAR GUIDE tracking does not seem to work in low light conditions.	Internal illumination may have malfunctioned. If problem persists, contact Customer Support.
System does not power off.	Unplug the system. If problem persists, contact Customer Support to schedule maintenance.
Audio Feedback is inaudible.	Check mute button, ensure that instrument is in the field of view. If problem persists, attempt to increase volume using the CORE front volume buttons. If problem persists, contact Customer Support.
System display is fuzzy or erratic, appears corrupted, or displays the Windows bluescreen.	The touchscreen or CORE may have failed, requiring maintenance. Contact Customer Support. Do not attempt to use CLEAR GUIDE guidance.
3D volume data is not received by the CLEAR GUIDE SCENERGY .	Verify physical network connection. Verify network settings in the Settings Dialog (gears UI symbol). Verify study in DICOM format is sent to correct receiving system. If problem persists, contact CLEAR GUIDE MEDICAL Customer Support.
3D volume data does not register, or has wrong orientation.	Verify markers are present on 3D volume and in valid locations. Repeat Visual Sweep via REGISTER > RESET. If problem persists, contact CLEAR GUIDE MEDICAL Customer Support.

Problem	Potential Solution
Instrument tracking is erratic.	Ensure instruments are visible to the Optical Head (do not obstruct view with hands, drapes, or covers). Ensure instruments are clean (free of visible contaminants). Ensure TipTAG instruments have been calibrated correctly.
Fused 3D volume and ultrasound seem not aligned.	Verify markers are present on 3D volume, and verify that VisiMARKERS are in valid locations. Repeat Visual Sweep via REGISTER > RESET . Perform manual registration refinement via REFINE . If problem persists, contact CLEAR GUIDE MEDICAL Customer Support.
Ultrasound appears to be in the wrong orientation.	Change ultrasound orientation on the ultrasound machine. CLEAR GUIDE systems have checks at start-up to prevent mis-oriented ultrasound from appearing on the screen. However, if a wrong orientation is suspected, STOP using the CLEAR GUIDE system. Contact Customer Support to schedule maintenance.

4.3 Maintenance

Maintenance will be scheduled on an ongoing basis from the time of the previous service date. Depending on system environment (harsh use, number of different operators, type of use, etc.) and system performance (based on assessment by the service personnel during servicing) the **scheduled intervals will generally range between three (3) to six (6) months**, but may differ.

Self-servicing the system can cause decalibration, severe component damage, expose the operator or patient to danger, or impair the system's resistance to environmental influences, among other problems.

Contact **CLEAR GUIDE MEDICAL** Customer Support for any maintenance questions.



WARNING: Failure to have maintenance performed by **CLEAR GUIDE MEDICAL** on an as-scheduled basis could result in decalibration of the SuperPROBE and subsequent guidance malfunction.



WARNING: Self-servicing the **CLEAR GUIDE** system will void the product warranty. Only **CLEAR GUIDE MEDICAL** personnel are authorized to perform maintenance or service on the **CLEAR GUIDE** system.

4.4 Software Licensing

All **CLEAR GUIDE** computer programs are protected by copyright and/or patents of **CLEAR GUIDE MEDICAL** (“CGM”). Such programs are licensed under the following software license agreement:

CGM, or its suppliers, retain(s) ownership of, and title to, any computer program supplied with the Equipment and to the trade secrets embodied in such computer programs. Subject to the Buyer's acceptance and fulfillment of the obligations in this paragraph, CGM grants the Buyer a personal, non-transferable, perpetual, non-exclusive license to use any computer program supplied with the Equipment that is necessary to operate the Equipment solely on the medium in which such program is delivered for the purpose of operating the Equipment in accordance with the instructions set forth in the operator's manuals supplied with the Equipment and for no other purpose whatsoever. Buyer may not reverse-assemble, reverse-compile or otherwise reverse-engineer such computer programs nor may Buyer make a copy of such program or apply any techniques to derive the trade secrets embodied therein. In the event of a failure by Buyer to comply with the terms of this license, the license granted by this paragraph shall terminate. Further, because unauthorized use of such computer programs will leave CGM without an adequate remedy at law, Buyer agrees that injunctive or other equitable relief will be appropriate to restrain such use, threatened or actual. Buyer further agrees that (i) any of the CGM suppliers of software is a direct and intended beneficiary of this end-user sublicense and may enforce it directly against Buyer with respect to software supplied by such supplier, and (ii) NO SUPPLIER OF CGM SHALL BE LIABLE TO BUYER FOR ANY GENERAL, SPECIAL, DIRECT, INDIRECT, CONSEQUENTIAL INCIDENTAL OR OTHER DAMAGES ARISING OUT OF THE SUBLICENSE OF THE COMPUTER PROGRAMS SUPPLIED WITH THE EQUIPMENT.

5 Safety



WARNING: Do not operate the **CLEAR GUIDE** system in the presence of flammable anesthetics.



WARNING: Do not disassemble or open the **CLEAR GUIDE** CORE, the SuperPROBE, or cables. None of the product components are user-serviceable.



WARNING: No modifications to the **CLEAR GUIDE** system are allowed.



WARNING: Improper handling of the SuperPROBE – e.g. dropping the transducer or striking it against a hard surface – could result in possible loss of calibration and in damaged equipment, including housing and other electrical safety features. Handle with care! In the event of dropping the SuperPROBE, inspect for exterior damage to the equipment. If the SuperPROBE appears damaged, contact **CLEAR GUIDE** MEDICAL Customer Support.



CAUTION:

Do not point the SuperPROBE towards unprotected, open eyes of the patient or other humans. It emits invisible **infrared light**, which may cause complications when applied continuously directly to the eye from very short distances.



CAUTION: Overheating could cause **CLEAR GUIDE** system failure. To minimize the chance of overheating, turn the **CLEAR GUIDE** system off between uses; otherwise damage to the equipment is possible.



CAUTION: The SuperPROBE cables are bound together by cable ties. If these loosen or move, this could impact usability of the SuperPROBE. Always inspect cabling before use.



Inspect the **CLEAR GUIDE** system prior to use. If any component appears damaged (CORE, SuperPROBE, or cables), DO NOT proceed with using the **CLEAR GUIDE** system. Contact **CLEAR GUIDE** MEDICAL Customer Support (see Section 1.2).



Keep the **CLEAR GUIDE** system clean. Follow the procedures described in Section 3.15 after each use.

5.1 Power Ratings and Precautions

Model: **CLEAR GUIDE** CORE for
CLEAR GUIDE SCENERGY

Power Adaptor Input Rating: 100–240 VAC, 1.25–0.5 A, 47–63 Hz.

Medical Panel PC Module Input Rating: 12 VDC, 8.33 A

Only use Power Adaptor SINPRO Electronics Co Ltd. Type MPU101-105 with the **CLEAR GUIDE** system.



WARNING: Always power the **CLEAR GUIDE** system from a grounded mains outlet.



WARNING: To avoid the risk of electric shock, never touch any metal parts of the system (such as the SuperPROBE plug, or the panel PC near the power adaptor plug) while touching the patient.

5.2 Electromagnetic Compatibility

As medical electrical equipment, the **CLEAR GUIDE** system may encounter or cause electromagnetic phenomena. Users of the system should understand the following:

- Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Accompanying Documents. For the **CLEAR GUIDE** system, Accompanying Documents include this User Manual, along with any labels, product inserts, or other product information.
- Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.

The system has been evaluated according to IEC 60601-1, Clause 17, as well as the collateral standard IEC 60601-1-2. The **CLEAR GUIDE** system has been found to comply with these electromagnetic compatibility limits for medical devices, which are designed to protect against harmful interference. All cables and accessories (see Section 2.4) come with the system and are within compliance of these standards. The maximum length of the power cord is 2m. No other cable in the system is exchangeable.



WARNING: The use of accessories, transducers and/or cables other than those specified, with the exception of those sold by the manufacturer as replacement parts for internal components, may result in increased electromagnetic emissions or decreased immunity of the equipment or system.

The following tables describe these electromagnetic phenomena, and suggestions for managing these phenomena (through use in a specified electromagnetic environment) are provided, as well.



WARNING: The equipment or system **should not** be used adjacent to or stacked with other equipment, and that if adjacent or stacked use is necessary, the equipment or system **should be** observed to verify normal operation in the configuration in which it will be used.

The **CLEAR GUIDE** system is intended for use in the electromagnetic environment specified in the manufacturer's declarations "Table 7: Electromagnetic Emissions" and "Table 8: Electromagnetic Immunity". The customer or user of the **CLEAR GUIDE** system should ensure that it is used in such an environment.

Table 7: Electromagnetic Emissions

Emissions Test	Compliance	Guidance on Electromagnetic Environment
RF Emissions CISPR 11	Group 1	The CLEAR GUIDE 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	Class B	The CLEAR GUIDE system is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

Table 8: Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Guidance on Electromagnetic Environment
ESD IEC 61000-4-2	±6kV Contact ±8kV Air	±86kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
EFT IEC 61000-4-4	±2kV Mains ±1kV I/Os	±2kV Mains ±1kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CLEAR GUIDE system requires continued operation during power mains interruptions, it is recommended that the CLEAR GUIDE system be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF 61000-4-3	3Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	(V1)=3Vrms (E1)=3V/m	Portable and mobile communications equipment should be separated from the CLEAR GUIDE system by no less than the distances calculated/listed below: $D=(3.5/V1)(\text{Sqrt } P)$ 150kHz to 80MHz $D=(3.5/E1)(\text{Sqrt } P)$ 80 to 800 MHz $D=(7/E1)(\text{Sqrt } P)$ 800 MHz to 2.5 GHz Where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.

The **CLEAR GUIDE** system is intended for use in electromagnetic environments in which radiated disturbances are controlled. The operator of the **CLEAR GUIDE** system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the **CLEAR GUIDE** system, according to the maximum output power of the communications equipment.

Table 9: Recommended Separation Distances

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz $D=(3.5/V1)(\text{Sqrt } P)$	Separation (m) 80MHz to 800MHz $D=(3.5/E1)(\text{Sqrt } P)$	Separation (m) 800MHz to 2.5GHz $D=(7/E1)(\text{Sqrt } P)$
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.333

5.3 Operating Environmental Conditions

CLEAR GUIDE systems should be used in ambient conditions similar to the recommended storage conditions (see Section 3.15):

- Temperature: 5...40°C
- Relative Humidity: 10...80%
- Atmospheric Pressure: 70...106kPa



WARNING: If the operation environment contains multiple needle-like instruments or other straight-edged objects, or if environmental conditions affect observable brightness or contrast, this could impact **CLEAR GUIDE** system functionality.

For shipping the **CLEAR GUIDE** system:

- Temperature: -20...60°C
- Relative Humidity: 10...80% (non-condensing)
- Atmospheric Pressure: 18.6...106kPa

5.4 Disposal of Unit

See European Commission Directive 93/86/EEC and the Waste Electrical and Electronic Equipment Directive (WEEE2 2012/19/EU) for disposal guidance. When seeking to dispose of the electrical products – at the user's request or at product end of life – please refer to local regulations for guidance.

IMPORTANT















Do not dispose of **CLEAR GUIDE** systems with other household waste. Refer to local regulations for guidance.

6 Labeling Symbols

The symbols below are found on the product, packaging, or other labeling.

Table 10: Labeling Symbols

Symbol	Definition
	Alternating current (AC)
	Direct current (DC)
	Do not dispose with household waste
	Fragile
	Handle with care
	Infrared radiation
	“OFF” (power)
	“ON” (power)
	Protect from weather
	Read instructions for use
	Stand-by
	This side up

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