CLEAR GUIDE MEDICAL

SCENERGY TP

USER MANUAL

P/N 30063R317

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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 TP User Manual is available for download at www.clearguidemedical.com/support.

710471 / Medical Electrical Equipment and Devices

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 TP 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.
R311	2018/02/06	3.11.8299	ECN 18-003: Minor changes to improve usability.
R312	2018/11/15	3.12.8755	ECN 18-004: PACS pull mode. GUI and text update.
R314	2020/05/09	3.14	ECN 19-006: VisiMARKER II and Interson.
R314.1	2020/08/20	3.14	Updated “Indications for Use” and added fiducial placement for small anatomical regions.
R315	2021/06/25	3.15	ECN 21-001: Mini Optical Head; hub-based needle tracking
R315.1	2022/10/21	3.15	Updated references and graphics for clarity per ECN 19-003: VisiMARKER II; ECN 20-001: CORE 13, CORE 24 MR; ECN 20-003: SteriMASK for Mini Optical Head; and ECN 21-003: SuperPROBE with Mini Optical Head.
R316	2023/07/14	3.16	Added TP planning support via ECN 22-002. Added statement indicating **CLEAR GUIDE** SteriGRIDis required for transperineal procedures. Replaced SuperPROBE with Optical Head in the “Indications for Use”.
R317	2025/07/10	3.17	Extended TP planning support via ECN 25-001. Added option to remove none TP material.

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1 Before Use

1.1 Intended Audience

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.

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 (page 2) before attempting to use the system.

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

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 (page 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 TP User Manual, the following symbols and terms have special meanings:

Table 2: 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.

Table 2: Symbols and Descriptions

Symbol or Term	Description
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

The device is a stereotaxic accessory intended to provide fusion of images from certain imaging modalities. 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.

2.2 Indications for Use

The **CLEAR GUIDE** SCENERGY is software that provides fusion of images from Computed Tomography (CT), Magnetic Resonance (MR), and Ultrasound (US) modalities. US images can be fused with either CT or MR.

The **CLEAR GUIDE** SCENERGY utilizes the **CLEAR GUIDE** CORE and **CLEAR GUIDE** Optical Head 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, in patients of sufficient size (at least 25 kg).

2.3 Functionality

2.4 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 (page 2).
- Verify presence of all components listed below under “Package Contents”.

Package Contents:

1x **CLEAR GUIDE** CORE

1x Power adapter (with AC power cord)

1x **CLEAR GUIDE** SCENERGY TP User Manual

1x **CLEAR GUIDE** TP Access tool which includes one box of **CLEAR GUIDE** SteriGRID

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 (page 2).

2.5 Components and Connections

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 **CLEAR GUIDE** TP Access is an MR-safe tool used in conjunction with **CLEAR GUIDE** SCENERGY TP to hold the **CLEAR GUIDE** SteriGRID next to perineum during procedure. Please refer to **CLEAR GUIDE** TP Access IFU for more information.

Table 3: Connectors and Cords

Name	Detailed Description
USB	This allows importing patient 3D imaging volumes onto the system (e.g. via USB flash drives).
Ethernet	The system can request 3D imaging volumes over a network directly from and upload screenshots to 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 power adapter provided with the **CLEAR GUIDE** CORE which is configured for your **CLEAR GUIDE** SCENERGY TP software.

CORE 13	`MANGO60S-USB-PDA`	*Shenzhen Megmeet Electrical Co., Ltd*
CORE 17	`MPU101-105`	*SINPRO Electronics Co Ltd*
CORE 24, CORE 24 MR	`FSP180-AHAM1`	*FSP Technology Inc. (Sparkle Power Inc.)*

For other compatible computers, refer to the manufacturer's manual provided with the **CLEAR GUIDE** SCENERGY TP software.

2.6 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:

2.6.1 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 (page 2) for information about suitable units.

2.6.2 Physical Connectivity

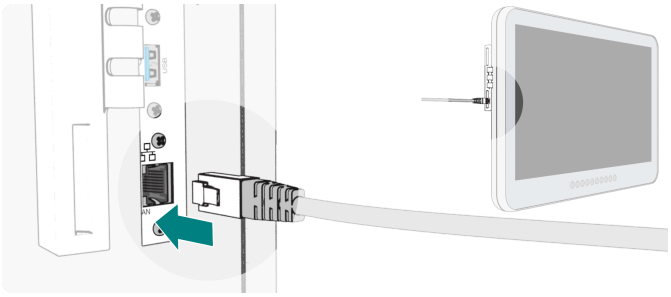


Figure 1: Ethernet connection (shown for CORE 24 model)

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 (page 2).

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.

2.6.3 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 3.1 “System Startup”.
2. Tap the gears icon at the bottom left of the user interface.
3. Choose the “SETTINGS” tab (Figure 2).
4. Enter the administrative password, or contact **CLEAR GUIDE** MEDICAL with the provided challenge-response code.

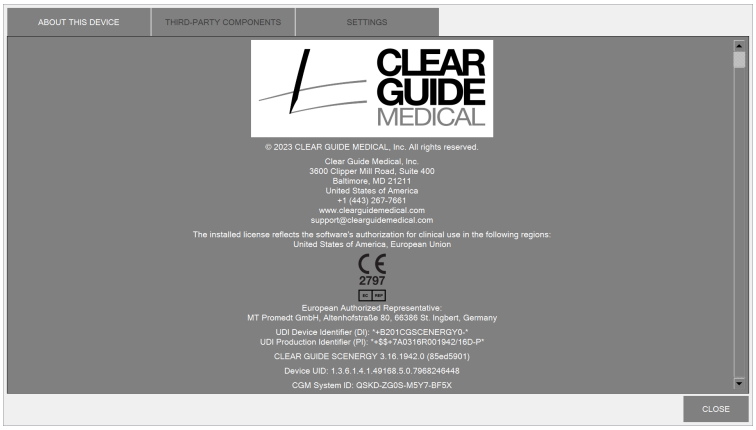


Figure 2: Settings window: System information

The following configuration steps then have to be performed (Figure 3):

1. Integrate into Hospital Network:
   (a) In the “NETWORK” section, select the desired network interface.
   (b) Assign static IP address (including subnet mask) or select DHCP.
   (c) The “TEST NETWORK” and “PING” buttons can be used for troubleshooting.

(d) In the “DICOM STATION DEFINITION” section, confirm AET (Application Entity Title). Change, if requested (default “SCENERGY”). Fill in any other details, as needed.

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)** In the “PACS SETUP” section, add one line to the table for each system the **CLEAR GUIDE** SCENERGY TP will communicate with and fill in all the details (Device Name, AET, IP/hostname, port). This is necessary for both incoming and outgoing communication. Use the “PING TEST” and “C-ECHO TEST” buttons to confirm functionality. Do not expect any of the following steps to work if these tests fail!

   (Optional) If desired, enable TLS and select the correct key and certificates. Tap “VALIDATE and APPLY”. This will affect all outgoing communication.

4. **(Optional, if licensed)** Check “ENABLE PACS SEARCH” to enable the PACS search feature. Select (by tapping) any DICOM system that should be usable for PACS searches.

5. **(Optional, if licensed)** Check “ENABLE WORKLIST CLIENT” to enable the modality worklist client. Select (by tapping) any DICOM system that should be used for modality worklist queries. Set up to four DICOM tags that should be included in the queries (for example: restrict query to a certain modality or station name).

6. **(Optional)** Configure **CLEAR GUIDE** SCENERGY TP to receive DICOM objects:

   (a) Switch to the “LOCAL C-STORE SCP” section.

   (b) **(Optional)** If desired, enable TLS and select the correct key and certificates. Tap “VALIDATE and APPLY”.

   (c) PORT: change if requested (default assigned listening port is 11112).

   (d) MODE: Choose from one of the following.

   - REJECT ALL: All incoming requests will be rejected.
   - ACCEPT ALL: All incoming requests will be accepted (“promiscuous mode”).
   - ACCEPT AET: Incoming requests will be filtered by the callers’ AET. Select by tapping systems that will send image data to **CLEAR GUIDE** SCENERGY TP . Note: the system will not accept image datasets if “ACCEPT AET” is selected but no AETs are specified.

   (e) Add **CLEAR GUIDE** SCENERGY TP to hospital network as DICOM Recipient (normally performed by hospital IT). Provide hospital IT staff with IP address (if neccessary), port, and AET.

7. **(Optional)** Configure **CLEAR GUIDE** SCENERGY TP to send DICOM Files to PACS:

   (a) Switch to the “SCREEN CAPTURES” section.

   (b) **(Optional)** If desired, activate the option to “auto-upload screen captures to PACS” option and select the correct system to enable auto-upload.

   (c) **(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.

   (d) Configuration steps on the **Storage Destination (e.g., PACS)** may be necessary. Provide Hospital IT with the following information: IP address, port, and AET.

   (e) **(Optional)** For manual upload, you may configure the system to auto-select all screenshots when the screenshots window is opened.

   (f) **(Optional)** For manual upload, you may configure the system to auto-delete screenshots after successful upload.

   (g) **(Optional)** For manual upload, you may configure the system to auto-delete the currently loaded CT/MRI volume from the device’s internal storage after successful upload of screenshots.

8. Test connections (both receiving and sending) as per the following sections.

2.6.4 Test: Receiving DICOM Files

1. Run **CLEAR GUIDE** SCENERGY TP on the CORE by rebooting it.
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 TP .
3. On **CLEAR GUIDE** SCENERGY TP , the Network Status should change to “RECEIVING IMAGES. . . ” (arrow should indicate “downloading”).
4. After data is transferred successfully, the dataset should show up in the STUDIES list.
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.

2.6.5 Test: Sending DICOM Files

1. Load a 3D imaging volume, or create an “Emergency Patient ID” 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.
2. Repeat these steps for each storage destination.

2.6.6 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 TP 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.
- You may want to try the “promiscuous mode” setting. 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 “promiscuous mode” configuration is only meant for troubleshooting and deactivates important security measures of the **CLEAR GUIDE** SCENERGY TP .

2.6.7 Dataset Download

The **CLEAR GUIDE** SCENERGY TP system supports a “push” mode. A desired 3D imaging can be “pushed” to the system by hospital personnel. 3D imaging machines provide direct push capability to any DICOM-compatible device, including **CLEAR GUIDE** SCENERGY TP . 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 TP .

The **CLEAR GUIDE** SCENERGY TP 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 TP .

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.

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.

If licensed and configured, **CLEAR GUIDE** SCENERGY TP allows “pulling” image data from PACS or other DICOM-compatible systems. For details, refer to the DICOM Conformance Statement. Open the “PATIENT” dialog and witch to the “PACS” tab. Select the PACS to query (or select “ALL”), the desired modality, restrict the study date, and enter any additional search criteria like patient ID, name, or study description.

After tapping “SEARCH”, wait for search results to show up. You may re-order the list by tapping on the table headings. Select the desired dataset and tap “LOAD” to initiate the download. The dataset will automatically be loaded and processed for use.

2.7 Patient Data Handling

The **CLEAR GUIDE** SCENERGY TP 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 2.6 “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.

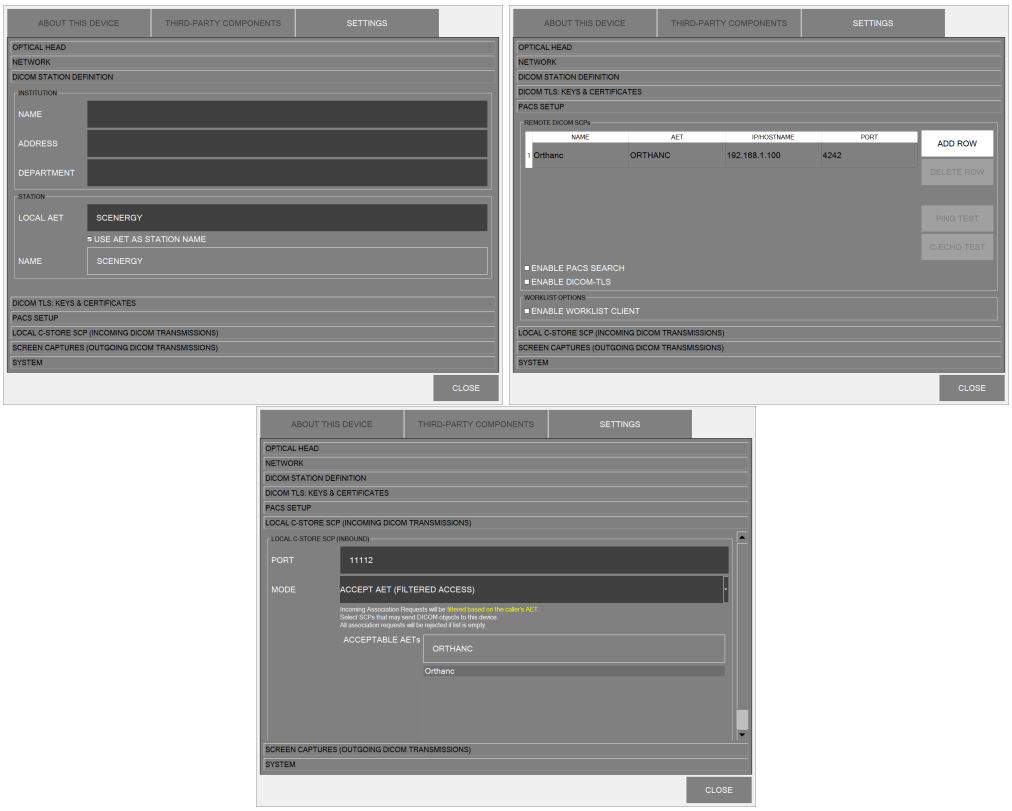


Figure 3: SETTINGS tab: DICOM station settings (top left); DICOM peer options (top right); Local C-STORE SCP options (bottom).

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 TP .

3 Using the System

3.1 System Startup

1. 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 4 left).

Figure 4: 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 4 right).

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

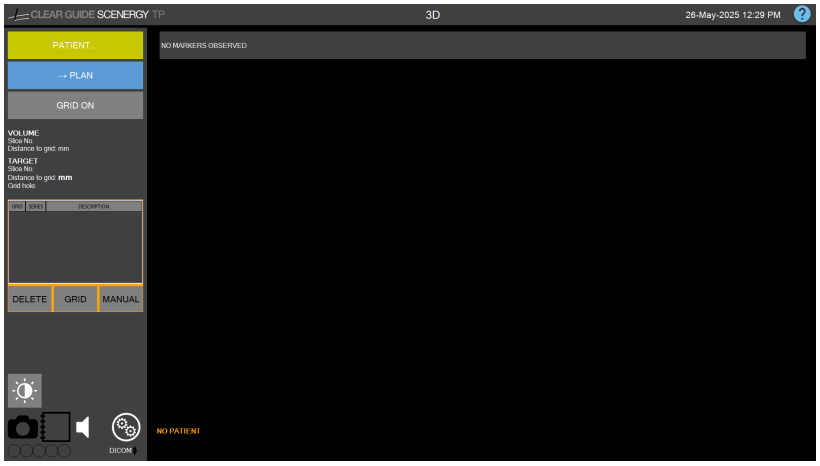


Figure 5: Transperineal Startup User Interface

3.1.1 Scanning Parameters

CT SCANNER SETTINGS:
Set the scanner to have in-plane **pixel spacing** not larger than 1x1 mm^2, and slice spacing of at most 2 mm. Do not acquire CT volumes with tilted gantry (i.e. only scan at 0° angle).

IMPORTANT

MR SCANNER SETTINGS:
Currently, **CLEAR GUIDE** SCENERGY TP supports T1 and T2 sequences. Markers may not be detected in other imaging sequences. Set the scanner to have slice spacing of at most 5 mm. If available, use a 3D protocol rather than a 2D one. Breath-hold is strongly recommended, unless impossible or clinically inappropriate.

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.

3.2 Loading 3D Volume Data

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

- network transmission initiated by a DICOM/PACS system (“push” mode)
- network transmission requested by the **CLEAR GUIDE** SCENERGY TP (“pull” mode)
- loading from USB drives
- loading a pre-imported scan that is already stored on the CORE.

3.2.1 PACS Search and Volume Download

If configured, a PACS can be searched for CT or MRI volumes, and the datasets can be downloaded from the PACS. Tap PATIENT... , then switch to the “PACS” tab. You can select the PACS to be searched (or query all available), restrict the search to studies of a certain modality or date, and add any additional search criteria, like patient ID, patient name, or study description.

After tapping SEARCH to initiate the query, results should be shown in a table. You can reorder the table by tapping the table headings. Select one dataset and then tap LOAD to request the dataset. It will be downloaded and then automatically processed for use.

3.2.2 3D Volume Transfer from PACS

If the **CLEAR GUIDE** SCENERGY TP 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.

3.2.3 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.

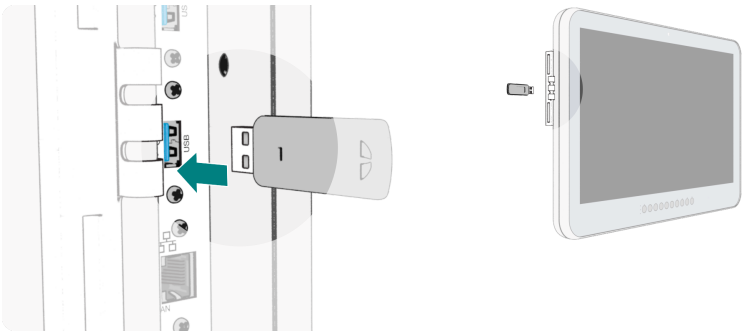


Figure 6: USB Port on **CLEAR GUIDE** CORE side panel of CORE 24 model

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.

3.2.4 Scan Loading

Choose a scan from the list of available studies (Figure 7 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 7 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.

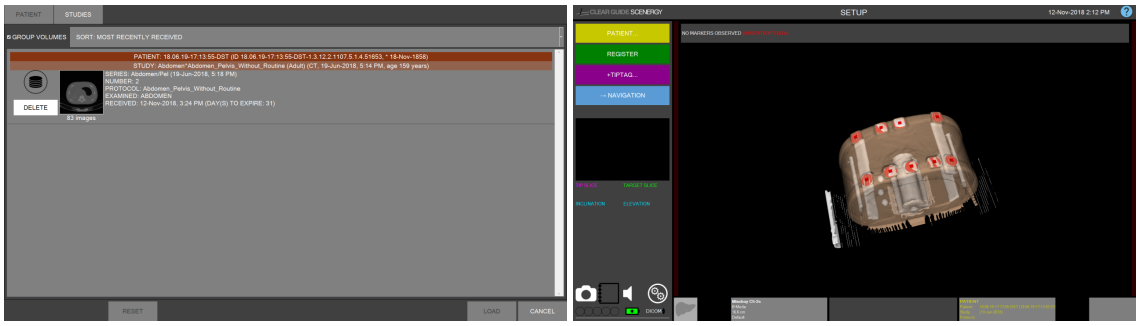


Figure 7: Patient Data List showing all available 3D volumes (left); 3D View displaying expected markers after loading (right)

3.3 PLAN Mode

IMPORTANT	The following section only applies if the system is configured for use in transperineal procedures such as transperineal prostate biopsy and ablation.

IMPORTANT	**CLEAR GUIDE** SteriGRID *Biopsy Needle Guide* is required for transperineal procedures. Other grids cannot be used for this purpose.

In this configuration, the system provides a planning functionality which can overlay a needle guide grid (**CLEAR GUIDE** SteriGRID) on slices of a 3D volume. The 3D volume shall contain both the imaging area and the grid. This allows the user to scroll through the slices and select a target, and view slices from multiple 3D volumes. The system finds the closest hole on the grid to the chosen target and displays that to the user in addition to other information such as depth of insertion. Figure 8 shows the workflow for transperineal access.

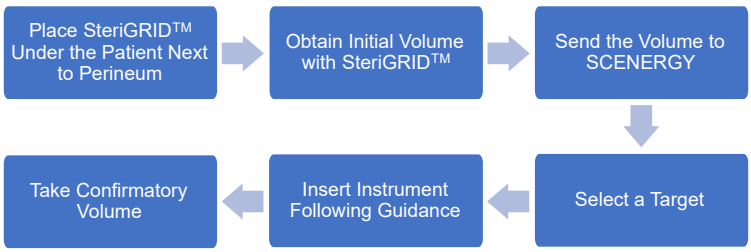


Figure 8: Workflow for transperineal access

3.3.1 Patient Scanning

To be able to use the Plan mode the following steps need to be performed.

- Place the base of the **CLEAR GUIDE** TP Access below the patient on the MR/CT scanning bed (see Figure 9).

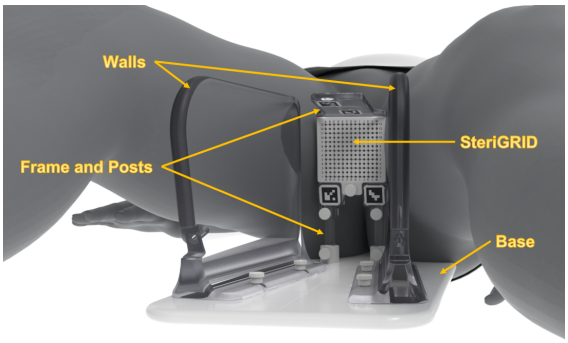


Figure 9: **CLEAR GUIDE** TP Access with **CLEAR GUIDE** SteriGRID. The base of **CLEAR GUIDE** TP Access is placed below the patient prior to MR/CT scan.

- Mount and secure the left and right walls with the provided fasteners. Raise the patients legs using soft materials such as pillows.
- Assemble and insert the posts together with the frame into the base and secure them with fasteners.
- Prepare the intervention area following clinical workflow.
- Insert **CLEAR GUIDE** SteriGRID inside the frame and secure it using the provided fastener.
- Perform the scan of the patient using the MR or CT settings mentioned in Section 3.1.1.
- Send the captured volume to the **CLEAR GUIDE** CORE.

WARNING: The grid and the patient shall not move with respect to each other after the volume is acquired. If repositioning is required, a new volume shall be obtained.

Once **CLEAR GUIDE** SCENERGY TP receives the volume, the user can select and load it (see section 3.2). The system processes the volume and displays a 3D representation of the volume and the grid as shown in Figure 10.

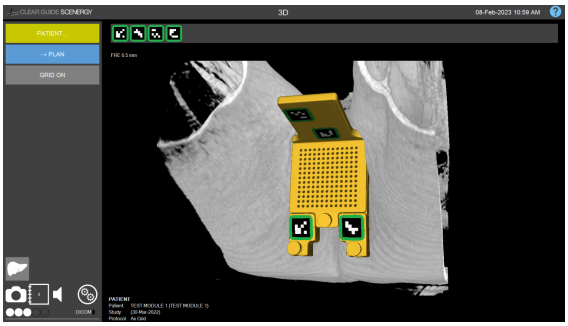


Figure 10: 3D view of the loaded volume with **CLEAR GUIDE** SteriGRID.

WARNING: Check the position of the grid with respect to the patient in the 3D view. Make sure that the grid is shown at the correct location.

To move to the planning mode and the individual slices, press → PLAN (see Figure 12). To return to the main screen, press 3D ←.

3.3.2 Loading Multiple Volumes

As of software version 3.17, the system has the ability to concurrently load multiple volumes. The system assumes that those volumes have a common coordinate system, and that the patient has not moved between acquisitions. This allows for one volume to be used for grid detection and another for planning. This is useful if the scanner settings required by the procedure are not compatible with those required for VisiMARKER detection.

1. Multiple 3D scans (volumes) may be acquired from the patient. At least one of the volumes needs to be scanned with the settings described in section 3.1.1, and needs to show the **CLEAR GUIDE** SteriGRID. The other volumes may be scanned using the settings required based on the clinical requirements.
2. Transfer all volumes to the system and load them on by one. Load the volume for the grid via tapping the LOAD - GRID button.
3. In the volumes list (figure 13), you can change the grid volume by selecting the volume and tapping GRID button.

Though it is not necessary for both volumes to overlap, we recommend having some overlapping area to allow visually confirming correct alignment.

WARNING: The volumes used for grid and planning should be from the same session with the same coordinate system. Patient should not move during acquisition of these volumes. Check the overlapping areas to ensure alignment.

3.3.3 Manual Registration

As of software version 3.17, the system allows the user to manually segment the grid from a loaded volume (any modality). This feature can be used if the automatic process fails to detect the **CLEAR GUIDE** SteriGRID, or misdetects it, for example because of scanner settings required by the procedure. The procedure is as follows:

1. Load a volume, start manual registration using the MANUAL button in the volumes list.
2. In the segmentation view (Figure 11, scroll through the slices to find the fiducials as shown on that screen. Adjust brightness or contrast as needed.
3. Mark the center of a fiducial by tapping. Tap again to correct if necessary.
4. Tap one of the four SAVE buttons to confirm the location.
5. Repeat for all four fiducials.
6. When at least three fiducials have been saved, tap ACCEPT to finalize the registration.
7. Back in the 3D view, verify that the **CLEAR GUIDE** SteriGRID is displayed in the correct, expected location and orientation.

CAUTION: Only accept the manual registration if the Fiducial Registration Error FRE is acceptably small (less than 3mm).

Figure 11: Manual segmentation of the **CLEAR GUIDE** SteriGRID

3.3.4 User Interface

The **Main View** shows a 2D axial slice of the imported volume. On first launch, this view starts at the middle of the volume. The user can browse though the slices with the slider at the bottom of the screen.

The system overlays a **Green** grid pattern with holes, letters and numbers on each slice. The grid is separated into evenly spaced holes corresponding to the **CLEAR GUIDE** SteriGRID.

The user selects a target by tapping or clicking on the slice. When a target is selected, a **yellow target circle** appears on the screen in that location. Once a target is selected, the nearest grid hole to the target as well as its corresponding grid number and letter are highlighted by changing color from **green** to **orange**.

Browsing away from the current slice causes the **yellow target circle** to disappear, and moving back to the target slice shows the circle again.

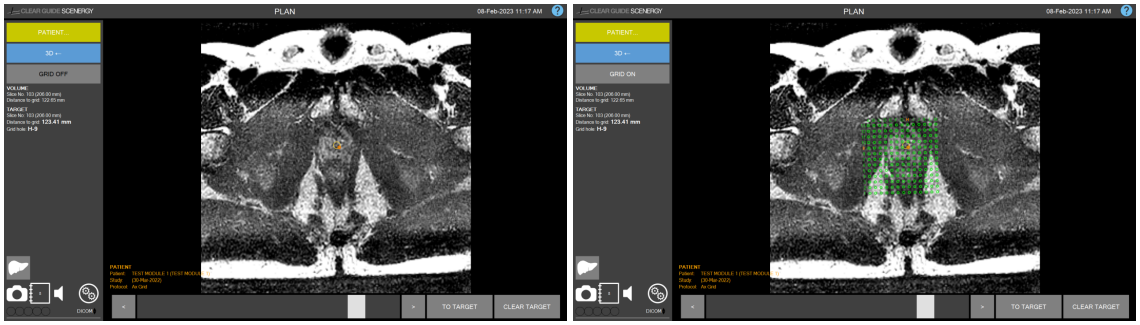


Figure 12: Plan Mode: Grid Off (left) and Grid On (Right)

The user can zoom into the image (two finger gesture) and move the zoomed image around (one finger drag). One method for easy target selection is to hide the grid and zoom into the image. After zooming, a reset button appears on the top right side of the image which can be used to reset the zoomed image.

3.3.5 User Interface: Left Side

1) User Interface Buttons:

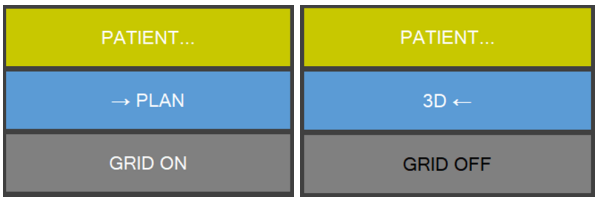
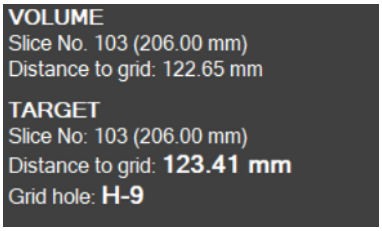


Table 5: PLAN Mode: User Interface Buttons

User Interface Button	Function
→ PLAN	Switches to PLAN mode.
3D ←	Switches back to 3D mode.
GRID ON GRID OFF	Toggles the green grid overlay ON or OFF.

2) Targeting and positional information



Targeting and positional information determines the current location of the slice within the volume and the selected target. The distance of the current slice and the target slice is with respect to the beginning of the volume. The “Distance to grid” is computed with respect to the face of the **CLEAR GUIDE** SteriGRID that is not touching the patient.

VOLUME shows the currently viewed slice number and the corresponding depth in Millimeter from slice 0. The distance of the current slice to slice 0 is also displayed in mm.

TARGET shows the slice number corresponding to the selected target. The distance of the target point to the grid is also displayed in mm. The Grid hole determines the labels of the closest hole to the target. The columns and rows of the **CLEAR GUIDE** SteriGRID are labeled in letters (From A - M) and numbers (From 1 - 13) respectively.

IMPORTANT	The distance to grid is always referring to the front face of the grid not the face touching the patient.

3) Volumes List

When the system if configured for transperineal procedures, up to four volumes may be loaded concurrently. The system will show all currently loaded volumes in a list in the left pane of the user interface (Figure 13):

- Tap on a volume to select this volume for display.

- Tap DELETE to unload a volume; this will not remove the volume from the source drive or the PACS.
- Tap GRID to use the **CLEAR GUIDE** SteriGRID detected in the selected volume for registration.
- Tap MANUAL to begin manual **CLEAR GUIDE** SteriGRID registration procedure (page 21).

IMPORTANT

When loading multiple volumes, the system assumes a consistent patient position and a common coordinate system across all datasets. To ensure this, avoid patient movement between scans and minimize table repositioning whenever possible. Changing the scan range or field of view is allowed, as long as the patient coordinate system remains unchanged.

CAUTION: While loading volumes from different sessions is possible, this may result in misalignment. Do not use datasets from different sessions for planning or navigation.

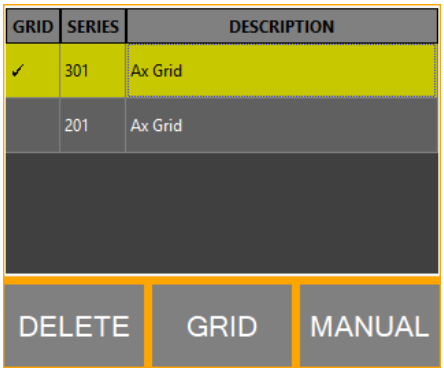


Figure 13: Volumes List showing all currently loaded 3D volumes

3.3.6 User Interface: Right Side

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

1) Reset Zoom button resets the zoom level back to the default if the image has been zoomed.

2) Slice Slider allows the User to move through the slices of the loaded patient image. The slider can be moved one slice at a time using the arrows shown on the left or right side, or by dragging the slider.

3) TO TARGET allows for the return to the target selection slice if the current view is different from the initially selected target. If there is no target selected this button is grayed out and cannot be selected.

4) CLEAR TARGET erases the selected target and clears all the information of that target provided on the left side of the screen. If there is no target to clear this button is grayed out and cannot be selected.

3.4 General UI controls

The following UI controls are used in every system configuration and perform the same task and function for Navigation Mode and Plan Mode.

1) Contrast and brightness of a loaded CT/MR can be adjusted in a dialog window by tapping the button showing one of the following icons:

As shown in Figure 14, two sliders appear which can be moved to set the upper and lower boundaries. In case of CT, several Hounsfield unit (HU) window presets are available (top to bottom: bone, intestines, kidney, liver, lung, water). The contrast presets should not overrule clinical judgment about optimal contrast settings. When an MRI is loaded, the presets will be hidden.

The color of the slice overlay during fusion can be changed by pressing the “COLOR” button, which will cycle through a palette of 16 pre-defined colors to suit clinical needs.

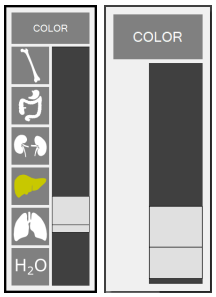


Figure 14: Contrast and brightness adjustment: CT (left) and MR (Right)

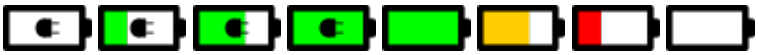
2) Screen Capture (camera) / **Screen Capture Management (logbook)** / **Audio Feedback (speaker)** / **Settings (gears)** buttons for taking and managing documentation screen captures, sound effects, and system settings.

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 3.5 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.

3) 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.

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



5) DICOM Network Indicator showing DICOM network status; respective arrows will light up when data is sent or received to indicate activity.

3.5 Screen Captures and Screen Capture Management

3.5.1 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 three 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 emergeny 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.
- If configured, patient information can be downloaded from a modality worklist server. Tap the PATIENT... button to open the patient information window. On the tab labelled "WORKLIST", you can select which modality worklist server to query and restrict the exam date, if needed. After tapping RELOAD WORKLIST, the worklist server will be queried and results should show up in the table below. Re-order the entries by tapping the table headings. Select one entry and tap LOAD to use the selected patient information.

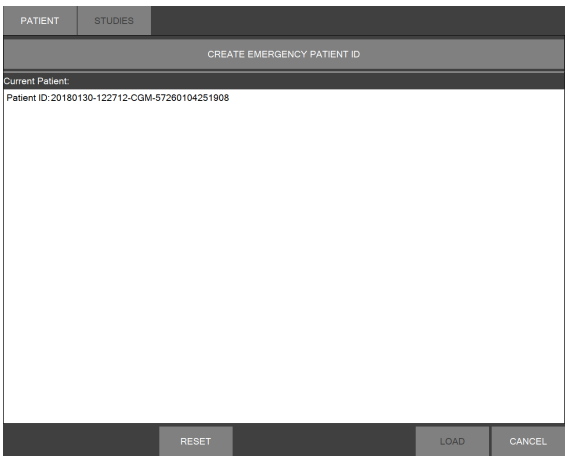


Figure 15: Creating an emergency patient ID.

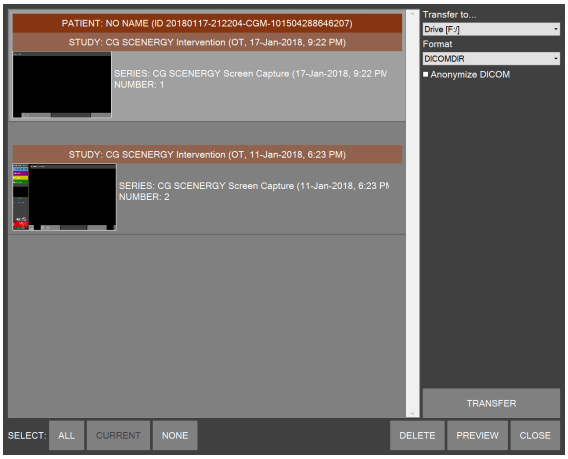


Figure 16: Screen Capture Management Window

3.5.2 Screen Capture Management

Tapping the logbook icon will open the Screen Capture Management Window (Figure 16).

- 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.
  - 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.

3.6 System Shutdown

1. After using the **CLEAR GUIDE** SCENERGY TP , 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.

3.7 Post-Use Care

3.7.1 Disconnecting and Storage

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

Refer to Section 3.1 for more information about turning the **CLEAR GUIDE** system ON or OFF.

Refer to Section 2.5 for information about reattaching connections prior to use.

3.7.2 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℃
- Relative Humidity: 10. . . 80% (non-condensing)
- Atmospheric Pressure: 70. . . 106kPa

3.8 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.

3.8.1 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, soft, low-lint 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.

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 6: Warning Pop-up Dialogs

Pop-up Dialog Message	Meaning	How to Resolve
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 TP .
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 TP .
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 TP 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 TP 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.
Loading study failed!	The DICOM data from the 3D volume has not been loaded successfully by SCENERGY TP .	Make sure the 3D volume is available in an appropriate DICOM format. Re-export the volume.
Maintenance overdue. Contact Customer Support (page 2). Contact **CLEAR GUIDE** MEDICAL for maintenance.	The Maintenance period has expired and needs to be renewed.	Contact Customer Support to schedule a SCENERGY TP maintenance appointment (page 2).
Maintenance required in [number] days. Contact Customer Support (page 2).	The Maintenance period is about to expire.	Contact Customer Support to schedule a SCENERGY TP maintenance appointment (page 2).
Maintenance period is about to expire. Contact **CLEAR GUIDE** MEDICAL for maintenance.	The maintenance period of the SCENERGY TP is about to expire.	Contact Customer Support to schedule a SCENERGY TP maintenance appointment (page 2).
No valid studies found on device X.	The file that SCENERGY TP expected to be 3D volume data is not in the correct DICOM format.	Re-import the 3D volume in an appropriate DICOM format.
Selected study not <a supported 3D volume modality>. Proceed with caution.	The file that SCENERGY TP 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.

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 (page 2). If the problem is related to the underlying 3D imaging system, ultrasound machine, or related accessories, please refer to those machines' user manuals.

Table 7: Troubleshooting Guide

Problem	Potential Solution
System will not power on.	Check all power connections. If secure, contact Customer Support (page 2).
CLEAR GUIDE CORE unexpectedly powers down.	Check all power connections. If secure, contact Customer Support (page 2).
Touchscreen appears inaccurate, does not work, or turns dark.	Restart system by power cycling the equipment. If problem persists, contact Customer Support (page 2).
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 (page 2).
System does not power off.	Unplug the system. If problem persists, contact Customer Support to schedule maintenance (page 2).
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 (page 2). Do not attempt to use **CLEAR GUIDE** guidance.
3D volume data is not received by the **CLEAR GUIDE** SCENERGY TP .	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 (page 2).

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 (page 2).

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

Keep the **CLEAR GUIDE** system clean. Follow the procedures described in Section 3.7 after each use.

5.1 Power Ratings and Precautions

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

Model #	Power Adaptor Input Rating	Computer Input Rating
CORE 13	100-240 VAC, 2.0-1.0A, 50-60 Hz	19Vdc, 3.31A
CORE 17	100-240 VAC, 1.25-0.5A, 47-63 Hz	12Vdc, 8.33A
CORE 24, CORE 24 MR	100-240 VAC, 2.3-0.8A, 50-60 Hz	12Vdc, 15A

ONLY use the power adapter provided with the **CLEAR GUIDE** system.

CORE 13	`MANG060S-USB-PDA`	*Shenzhen Megmeet Electrical Co., Ltd*
CORE 17	`MPU101-105`	*SINPRO Electronics Co Ltd*
CORE 24, CORE 24 MR	`FSP180-AHAM1`	*FSP Technology Inc. (Sparkle Power Inc.)*

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 adapter 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 2.5) 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: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Clear Guide Optical Head, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: The use of accessories, transducers and/or cables other than those specified or provided by the manufacturer of this equipment, 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 and result in improper operation.

WARNING: A risk of increased emissions or decreased immunity may result if any additional cables are attached.

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: Use of this equipment adjacent to or stacked with other equipment **should be avoided** because it could result in improper operation. If such use is necessary, this equipment and the other equipment **should be observed** to verify that they are operating normally.

The **CLEAR GUIDE** system is intended for use in the electromagnetic environment specified in the manufacturer's declarations "Table 10: Electromagnetic Emissions" and "Table 11: Electromagnetic Immunity". The customer or user of the **CLEAR GUIDE** system should ensure that it is used in such an environment.

Table 10: 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 A	The **CLEAR GUIDE** system is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **WARNING:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Clinical Station stimulator or shielding the location.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

Table 11: Electromagnetic Immunity

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Guidance on EM Environment**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
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.

Immunity Test	IEC 60601 Test Level	Compliance Level	Guidance on EM 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	30A/m	30A/m	Power frequency magnetic fields should be a levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF 61000-4-3 IMMUNITY to proximity fields from RF wireless communications equipment	3Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz MHz – Modulation – Field Strength: 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m	(**V1**)=3Vrms (**E1**)=3V/m MHz – Modulation – Field Strength: 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the **CLEAR GUIDE** system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=(3.5/V1)(\sqrt{P})$ 150kHz to 80MHz $d=(3.5/E1)(\sqrt{P})$ 80 to 800 MHz $d=(7/E1)(\sqrt{P})$ 800 MHz to 2.5 GHz $E=(6/d)(\sqrt{P})$ $d=(6/E)(\sqrt{P})$ Where P is the maximum output power rating in watts (W) and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level (V1 and E1) in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Clear Guide Optical Head Mini is used exceeds the applicable RF compliance level above, the **CLEAR GUIDE** system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **CLEAR GUIDE**.

The **CLEAR GUIDE** system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **CLEAR GUIDE** system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **CLEAR GUIDE** system as recommended below, according to the maximum output power of the communications equipment.

Table 12: Separation distance according to frequency of transmitter (m)

Max Output Power (Watts)	**Separation (m) 150kHz to 80MHz** $d=(3.5/V1)(\sqrt{P})$	**Separation (m) 80MHz to 800MHz** $d=(3.5/E1)(\sqrt{P})$	**Separation (m) 800MHz to 2.7GHz** $d=(7/E1)(\sqrt{P})$	**Separation (m) 710, 745, 780, 5240, 5500, 5785** $d=(6/9)(\sqrt{P})$	**Separation (m) 385, 450,810, 870, 930, 1720, 1845, 1970, 2450** $d=(6/28)(\sqrt{P})$
0.01	0.117	0.117	0.233	0.067	0.021
0.1	0.369	0.369	0.738	0.211	0.070
1	1.170	1.170	2.333	0.667	0.214
10	3.689	3.689	7.379	2.108	0.700
100	11.667	11.667	23.333	6.670	2.143

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

5.3 Operating Environmental Conditions

CLEAR GUIDE systems should be used in ambient conditions similar to the recommended storage conditions (see Section 3.7):

- Temperature: 5...40℃
- 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℃
- 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 13: 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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