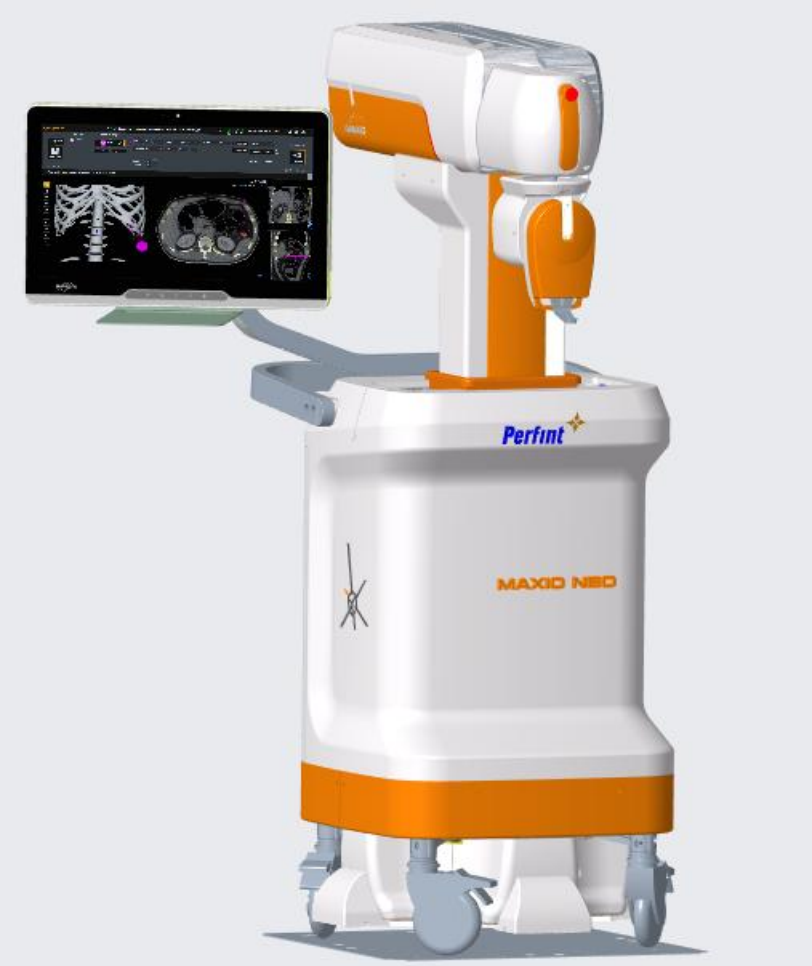
MAXIO NEO

User Manual



GENERIC NAME: ROBOTIC GUIDANCE SYSTEM FOR IMAGE GUIDED PROCEDURES (MULTIPLE PROBE)

PRODUCT: MAXIO

MODEL: NEO

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Software version V2.5.16

Note: CE certification of MAXIO NEO under EU MDR 2017/745 is in progress with the Notified Body. The CE marking with the Notified Body identification number and the Authorized Representative details shown in the labels, User Manual, GUI and packaging are prepared for the purpose of the conformity assessment submission only. These shall be formally released and applied to the device only after the EU certificate is issued.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Disclaimer of liability

- MAXIO® has to be installed and calibrated by Perfint Authorized Service and Support personnel, who shall also perform a field verification procedure prior to its “first” use. Customers should use MAXIO® only after being trained and certified by Perfint Authorized Application Specialist.
- This manual is originally drafted in English. It shall be made available in the local national language whenever the product is to be marketed in the member states, as applicable and permitted by the national regulation requirements and only by authorized dealers.
- Do not use MAXIO® for purposes other than those indicated. Perfint shall not be responsible for any damage arising out of any unspecified usage not in accordance with the guidelines and procedures specified in this manual.
- Device must be used under sterile conditions, following all warnings and cautions. Perfint shall not be held responsible for any damage caused due to deviation from the above-mentioned cautions and warnings.
- Any claims of product performance and indications for use contained within this document relate only to data submitted to and reviewed by regulatory authorities in those jurisdictions in which clearance(s) and/or approval(s) have been obtained.
- No product performance claims or indications for use are made for jurisdictions in which such clearance(s) and/or approval(s) have not been obtained.
- Any claim is restricted to terms of limited warranty as in Appendix F: Warranty Information
- Considering the general maintenance requirements, the equipment has an expected service life of 7 years. Attempting do-it-yourself repairs invalidate warranty and are an infringement to regulations and are inadmissible acc. to IEC 60601-1. Only authorized personnel may perform service and repairs.

General Warnings and Precautions:

- Rx Only: Federal (U.S.A) law restricts this device sale by or on the order of a physician, if sold in U.S.A. No modification of the equipment is allowed.
- Avoid spilling of liquids. Leakage of liquids inside may cause fire or electrical shock.
- When not in use, keep the device switched OFF to avoid misuse/damage due to high voltage.
- Do not open up the device or remove device panels. There are no serviceable parts inside. There is a danger of shock if incorrectly used, handled or serviced and a danger of explosion if the battery is incorrectly replaced.
- Do not use the device if the power cord is damaged.
- To avoid the risk of electric shock, the device must be connected using a 3-pin plug to a 3-pin socket with a protective earth connection.
- To avoid product damage, do not repair or replace power supply and USB cable. Refer servicing to authorized service personnel.
- The device is shipped under EMI/EMC standards. Any major changes at site are to be avoided.
- Prior to first use, the MAXIO® must be installed, calibrated and tested by Perfint Authorized Service and Support personnel to ensure proper functioning of MAXIO®.
- Only clinicians qualified to perform CT-guided interventions shall use the MAXIO® for the procedure planning and execution. MAXIO® shall be used only by such clinicians trained and certified by Perfint Authorized Application Specialist.
- MAXIO® is intended for the guidance of straight needles/ablators only.
- MAXIO® is intended for use in conjunction with a CT system only.
- MAXIO®requires the clinician to comply with the guidelines for patient movement management. This includes the clinical determination of the appropriate level of patient breath hold management including the potential use of local anesthesia.
- Applicable clinical guidelines for explaining procedures to the patients must be followed.
- Patient movement during procedures may lead to incorrect positioning of the Probe/tools. The clinician must ensure that the patient movement is managed throughout the entire procedure.

Residual Risk Summary

Use conditions: ■ Foreseeable Misuse by the User ■ Fault Condition by the Device ■ Normal Use of the Device

S.No	Use Condition	Group	Residual Risk	RR table reference	Section reference
1	Foreseeable Misuse by the User	Wrong Needle Positioning	Device Usage Contrary to Intended Use (Off-Label Use)	1a.1	Disclaimer of Liability
2			Incorrect Selection of Bush or Needle	1a.2	1.5.6.1, 8.1.1
3			Needle Bending During Insertion	1a.3	1.5.6.1, 8.1.1
4			Patient Positioned Outside MAXIO Range	1a.4	4.1
5			Incorrect Cradle Position Setting	1a.5	8.1.1
6			Accidental CT Table Movement After Needle Placement	1a.6	8.1.1
7			Improper Docking of the Device	1a.7	3.2.1
8			Incorrect Image Selection, Image Orientation, or Use of Gantry-Tilted Image Data	1a.8	5.1, 5.3, 5.4, 6.1
9		Patient Infection – Unsterile Environment	Use of Non-Sterile Needle Bush / Needle Guide	1b.9	1.5.6.1 to 1.5.6.6
10		Transit / Handling Damage	Device Damage During Transit or Handling on Inclined Surfaces	1c.10	10.1, Appendix B.2
11			Device Damage During Transit or Handling Over Obstacles	1c.11	10.1, Appendix B.2
12		Needle Collision with the Device	Device Arm Collision with Previously Placed Needle During Multi-Needle Procedures	1d.12	6.3.4, 8.1.1
13		Disposal / End-of-Life of Device	Improper Disposal or Unauthorised Reuse of Decommissioned Device and Batteries	1e.13	12.5.5
14	Fault Condition by the Device	Wrong Needle Positioning	End Effector Damage Due to Accidental Impact (Mechanical Play in End Effector)	2a.14	10.1
15			BHM Functionality Failure	2a.15	4.1.1
16			Incorrect Guidance Trajectory or Loss of Emergency Stop / Control	2a.16	Appendix J.1.4
17			Axis Position Change Due to Accidental Impact or Transport	2a.17	3.2.2
18		Device Instability	Loss of Device Stability During Movement Due to Castor Wheel Damage or Loosened Fasteners	2b.18	10.1
19		Uncontrolled Motion Hits the Patient	Uncontrolled or Unexpected Arm / Axis Movement	2c.19	8.1.1
20		Electrical Shock – Line Voltage	Electric Shock Due to Line Voltage on Accessible Surfaces in Case of Damaged Power Cord or Loss of Protective Earth	2d.20	General Warnings and Precautions, Appendix J, 12.5
21	Normal Use of the Device	Wrong Needle Positioning	Patient or Organ Movement	3a.21	4.1.1, 4.1.2, 8.1.1

LIST OF RESIDUAL RISKS AND ASSOCIATED CAUTIONS AND WARNINGS:

S.No	Residual Risk	Cautions and Warnings Provided in User Manual
1. Foreseeable Misuse by the User		
1a. Wrong Needle Positioning		
1	Device Usage Contrary to Intended Use (Off-Label Use)	**Section: Disclaimer of Liability** Do not use MAXIO® for purposes other than those indicated. Perfint shall not be responsible for any damage arising out of any unspecified usage not in accordance with the guidelines and procedures specified in the user manual
2	Incorrect Selection of Bush or Needle	**Section: 1.5.6.1 - Needle Bushe/Needle Guide** Ensure that Needle bush/ Needle guide is chosen such that they have same gauge marking on both sides. Incorrect use of Needle bush/ Needle guide would result in inaccurate results. Needles of different brand vary in the needle outer diameter. While choosing the Needle bush/ Needle guide for a gauge needle, ensure the Needle bush/ Needle guide is not too tight or too loose. Needles thinner than 18G may necessarily be not rigid. Ensure that needles do not bend during insertion. Also, where possible use shorter and thicker needles. **Section: 8.1.1 - Positioning for Probe Placement** Long needles and those thinner than 18G are noted to bend during insertion. Where possible use short and thicker needles. Needles that are held too tight or too loose may result in inaccurate placement of needles. Using needle of length other than the selected needle length will result in inaccurate placement and may result in harm to patient.
3	Needle Bending During Insertion	**Section: 1.5.6.1 - Needle Bush/Needle Guide** Needles thinner than 18G may necessarily be not rigid. Ensure that needles do not bend during insertion. Also, where possible use shorter and thicker needles. **Section: 8.1.1 - Positioning for Probe Placement** Long needles and those thinner than 18G are noted to bend during insertion. Where possible use short and thicker needles. Bending the needle during insertion will result in inaccurate placement of the needle. Insert needle carefully to prevent bending.
4	Patient Positioned Outside MAXIO Range	**Section: 4.1 - Patient Positioning** Do not position the patient's region of interest above the arrow indicated on the MAXIO device range sticker placed on the CT table.
5	Incorrect Cradle Position Setting	**Section: 8.1.1 - Positioning for Probe Placement** Accidental touching of gantry controls or any change in the table position may lead to inaccurate cradle positioning. Inaccurate cradle positioning will lead to inaccurate positioning of the needle. Cradle should be moved to the precise value displayed in the application every time the CT table is positioned.
6	Accidental CT Table Movement After Needle Placement	**Section: 8.1.1 - Positioning for Probe Placement** Moving the cradle before disengaging the End Effector from the needle guide may result in harm to the patient. Do not move the cradle before disengaging end effector from the needle guide.

S.No	Residual Risk	Cautions and Warnings Provided in User Manual
7	Improper Docking of the Device	**Section: 3.2.1 MAXIO ® DOCKING** Loose or improper docking of MAXIO® to the InstaReg mat may result in inaccuracies in the procedure. User cannot perform the procedure if, the Docking or Trackerstatus icons on the Main Screen do not display green. Additionally, Do not perform the procedure if the table marker verification is not successful. Contact Perfint Customer Support.
8	Incorrect Image Selection, Image Orientation, or Use of Gantry-Tilted Image Data	**Section: 5.3 Imaging Considerations** MAXIO provides a user-configurable time limit for generating a warning message to the clinician on the age of loaded scan data. Clinician confirmation is required to proceed with data created prior to the configurable time limit. Clinician confirmation also includes a check of patient name and patient ID for the scan data. **Section: 6.1 - Load Patient Image** Series cannot be loaded as the current patient orientation is HFDR/HFDL; only HFS, HFP, FFS, FFP orientations are supported **Section: 5.1 - Recommended CT scan protocol** Field of View: No re-centering of patient image. Reconstruction Offset: 1. Always scan and reconstruct the patient series with zero offset throughout the procedure. 2. Do not change the patient position in the gantry (x-y-z coordinates) once you have started the scan **Section: 5.4 - CT Image Transfer** A cross-check of the patient ID embedded in the CT scan data is provided to the user during image loading and in procedure summary screen for confirmation. Check the patient physical orientation with what is displayed on the screen. Always set CT view to radiology view
1b. Patient Infection – Unsterile Environment		
9	Use of Non-Sterile Needle Bush / Needle Guide	**Section: 1.5.6.1 - Needle Bush/Needle Guide** Always use only sterilized Needle bush/ Needle guide for procedures **Section: 1.5.6.2 - Needle Stabilizers** Always use sterile needle stabilizers for procedures **Section: 1.5.6.3 - Needle Holder** Always use sterile holder for procedures. **Section: 1.5.6.4 - MAXIO Drape** Always use sterile drape for procedures **Section: 1.5.6.5 - Touchpad Drape** Always use sterile drape for procedures. **Section: 1.5.6.6 - Grippers** Always use only sterile grippers for procedures

S.No	Residual Risk	Cautions and Warnings Provided in User Manual
1c. Transit/Handling Damage		
10	Device Damage During Transit or Handling on Inclined Surfaces	**Section: 10.1 - Moving the Device** MAXIO has to be parked and transported in the Home Position. Two people are needed to move the unit in inclined plane. Attempts by one person could result in injury or damage. Maximum allowable floor inclination is restricted to 5 degree. **Section: Appendix B.2 - MAXIO Device Labeling Details** Movement Restriction Label sticked on the top cover to provide warning to the user - "DO NOT MOVE THE DEVICE ON INCLINED SURFACE"
11	Device Damage During Transit or Handling Over Obstacles	**Section: 10.1 - Moving the Device** The maximum allowable height of obstacles over which the device may be moved shall not exceed 20 mm. **Section: Appendix B.2 - MAXIO Device Labeling Details** Step-Down Height Limitation Label sticked on the top cover to provide warning to the user - "DO NOT MOVE THE DEVICE OVER OBATACLES"
1d. Needle Collision with the Device		
12	Device Arm Collision with Previously Placed Needle During Multi-Needle Procedures	**Section: 6.3.4 - Parallel Probe Plan** When potential needle to needle intersections are identified, a message is displayed in the Information Bar in the image window. Re plan to eliminate potential intersections. **Section: 8.1.1 - Positioning for Probe Placement** Under sequential placement continuing to next probe placement without removing placed needles will result in collision and may result in harm to patient.
1e. Disposal / End-of-Life of Device		
13	Improper Disposal or Unauthorised Reuse of Decommissioned Device and Batteries	**Section: 12.5.5 Disposal** Do not dispose the device, accessories and disposables as general waste. Do not reintroduce a decommissioned or refurbished device into clinical use without inspection, requalification, and written authorization from Perfint.
2. Fault Condition by the Device		
2a. Wrong Needle Positioning		

S.No	Residual Risk	Cautions and Warnings Provided in User Manual
14	End Effector Damage Due to Accidental Impact (Mechanical Play in End Effector)	**Section: 10.1 - Moving the Device** Special attention must be given to the Grippers/ Holder arm during device movement or transport. Grippers/ Holder arm may get damaged due to accidental hits.
15	BHM Functionality Failure	**Section: 4.1.1 Breath Hold Monitoring** Do not use the breath hold device if the LED indicator does not display correctly, for example if the LED does not change with the patient's breathing or does not match the patient's actual breathing phase. Contact Perfint Customer Support
16	Incorrect Guidance Trajectory or Loss of Emergency Stop/Control	**Section: Appendix J.1.4 - EMI/EMC related Warnings** The essential performance of the MAXIO system is its ability to accurately and guide the physician to insert a needle into the planned target location within the patient's body, as determined by the treatment or procedure plan. Loss or degradation of this performance could result in: • Incorrect needle placement, leading to inaccurate targeting of the lesion, • Potential injury to adjacent critical structures. Remedial Actions in Case of Loss or Degradation: • Pull the needle out of the patient. • Press the Clamp/Release button on the Control Panel to release needle bush from the End Effector. • Press the Emergency Switch to release Needle Bush from End Effector.
17	Axis Position Change Due to Accidental Impact or Transport	**Section: 3.2.2 Table Marker Verification** Do not proceed with the procedure if the laser crosshair does not fall on the table marker during table marker verification. A mismatch indicates that the device positioning has been disturbed. Contact Perfint Customer Support. NOTE: Device positioning may be disturbed by an accidental impact, a change in axis range, or a change in laser arm position
2b. Device Instability		
18	Loss of Device Stability During Movement Due to Castor Wheel Damage or Loosened Fasteners	**Section: 10.1 - Moving the Device** Do not use the device if a castor does not rotate freely, the device drags or pulls to one side, or the device wobbles during movement. This may indicate damaged castor wheels or loosened screws. Contact Perfint Customer Support
2c. Uncontrolled Motion hit the Patient		
19	Uncontrolled or Unexpected Arm/Axis Movement	**Section: 8.1.1 - Positioning for Probe Placement** Press the Emergency Stop key immediately to stop all axes if any unexpected or uncontrolled axis movement is observed
2d. Electrical Shock – Line Voltage		

S.No	Residual Risk	Cautions and Warnings Provided in User Manual
20	Electric Shock Due to Line Voltage on Accessible Surfaces in Case of Damaged Power Cord or Loss of Protective Earth	**Section: General Warnings and Precautions** Do not open up the device or remove device panels. There are no serviceable parts inside. There is a danger of shock if incorrectly used, handled or serviced and a danger of explosion if the battery is incorrectly replaced. Do not use the device if the power cord is damaged. To avoid the risk of electric shock, the device must be connected using a 3-pin plug to a 3-pin socket with a protective earth connection. **Section: Appendix J- Safety & EMI/EMC Details** To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth. **Section: 12.5 Servicing** To avoid electrical shock hazards, do not remove panels or covers from the machine.
3. Normal Use of the Device		
3a. Wrong Needle Positioning		
21	Patient or Organ Movement	**Section: 4.1.2 Patient Immobilization** Patient movement during procedures may lead to incorrect positioning of the needle. Ensure patient movement is managed by patient immobilization throughout the entire procedure. **Section: 4.1.1 Breath Hold Monitoring** Breath Hold Monitor is used to ensure that the patient breath level during CT scan and during needle/probe insertion is maintained at the same level. This is critical to ensure accuracy of needle placement based on the plan. Alternate methods, including General Anesthesia, are used to maintain same breath level during CT scan and during needle/probe insertion based on clinical practice used during ablation procedures performed manually as well as based on clinical situation specific to the patient. However, MAXIO® has been verified only with the use of Breath Hold Monitor that is provided as an accessory. It is the responsibility of the user to ensure that the patient breath level during CT scan and during needle/probe insertion is maintained at the same level. **Section: 8.1.1 Positioning for Probe Placement** Abnormal patient movement during needle insertion may result in harm to the patient. In case of abnormal patient movement during or after needle insertion, Pull the needle out from the patient immediately. Press the Clamp/Release button on the Control Panel to release needle guide from the End Effector, or Press the Emergency Switch to release Needle guide from End Effector.

Table 1 Residual Risk (RR)

Conventions Used in This Manual:

The reader should be familiar with the following symbols used throughout this manual intended to direct the reader's attention to a particular issue or feature in the system:

Symbol	Meaning and Use
	Caution: Describes precautions necessary to protect the equipment.
	Warning: Describes precautions necessary to prevent injury or loss of life.
	Do Not Reuse: Describes preventing reuse.
	Note: Is intended to alert user to related or useful information.
	Ramp: Is intended to alert user to the requirement for an inclined plane to move the equipment.
	Obstacle Height: Is intended to alert the user that the equipment shall not be moved over obstacles exceeding the specified height.
	Laser Warning: Describes precautions to prevent injuries due to exposure to Laser.
	Residual Risk: A risk that remains after all the risk control measures have been implemented.

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1. INTRODUCTION

This user manual describes the MAXIO® system including the MAXIO® suite from Perfint Healthcare and presents the information needed to operate the same. The user manual has to be read entirely before operating the system and has to be operated only by trained clinicians.

MAXIO® has several unique features designed to deliver the following to clinicians:

- Reconstructed 3D images of patient tumor volume and organs from received CT data for better visualization.
- Visual representation of the targeted path and position(s) of manually advanced instruments such as biopsy needles, aspiration needles, anesthesia needles, or ablation applicators for procedure planning.
- Visual indication of the pseudo ablation volume as per data published by the ablation manufacturer.
- Registration of images for better pre-procedure planning and intra-procedure and post procedure visual comparison of the images with the planned images.
- Point-based landmark registration matches CT and MRI by mapping corresponding anatomical landmarks.
- MAXIO supports segmentation of Tumor and No-Go regions in Biopsy, Pain Management and other workflows
- Calculates needle placement deviation in the Check Scan using the 3D distance (X, Y, and Z) between the planned target point and the actual needle tip location.
- Rendering quality in the 3D view, providing clearer, more detailed, and realistic visualization of anatomical structures and instrument trajectories
- Visualizes and quantifies ablation margins by calculating the distance between the tumor boundary and the ablation volume, displaying the results in both 2D and 3D view and a tabular format across the Planning and Post-Verify screens that lists unablated tumor sections per slice for each tumor.
- Continuation of ablation procedure from post verification if any residual tumor exists

1.1 Scope of this Manual

This manual provides information on the operation of the MAXIO®. This guide does not provide clinical guidance or provide information regarding the operation of instruments used in conjunction with MAXIO® such as ablation tools.

1.2 MAXIO® Intended Use, Indications of Use, Intended Users, Patient Population, Clinical Benefits

1.2.1 Intended Use and Indications of Use

MAXIO is a user controlled, stereotactic accessory intended to assist in the planning and manual advancement of one or more instruments during Computed Tomography (CT) image guided procedures.

MAXIO permits physician verification of patient position prior to needle advancement and monitoring of respiratory levels during the procedure. Image registration and overlay tools available in MAXIO are intended to provide guidance to the user during planning and instrument placement.

MAXIO is indicated for use with rigid straight instruments such as needles and probes used in Computed Tomography (CT) guided percutaneous interventional procedures performed by physicians trained for CT procedures on organs and anatomical structures in the thorax, abdomen

and pelvis.

Current CT images can be registered with CECT, PET, MRI or other images using MAXIO for additional anatomical or functional information during interventional procedures.

	Do not use MAXIO® outside the scope of the indications of use. MAXIO® is intended to be used only by qualified clinician trained by Perfint Certified Application Specialist. Perfint shall not be responsible for any damage arising out of MAXIO® misuse or "Off-label" use.

1.2.2 Intended Users

The MAXIO system is intended to be used by trained physicians in image guided procedures, including:

- Interventional radiologists
- Radiologists trained in CT-guided procedures
- Physicians trained in percutaneous interventional techniques

Users must also receive training on the operation and workflow of the MAXIO system prior to clinical use

1.2.3 Patient Population

The MAXIO system is intended to be used for patients requiring CT-guided percutaneous diagnostic or therapeutic interventions involving anatomical structures in the thorax, abdomen, or pelvis.

The system may be used in adult patients and other patient populations when clinically appropriate, as determined by the treating physician.

1.2.4 Clinical Benefits

- MAXIO provides accurate position to more complex location and can help to take sample from smaller lesions.
- Reaching smaller lesions gives opportunity for early diagnosis and can improve the life expectancy of the patient.
- This also gives better planning and visualizing the planned path before performing the puncture. This will reduce the risk of planning on vital organs on the trajectory compare to manual procedure. Non visualization of the trajectory causes more insertion and checkscan by the manual procedure.
- MAXIO process takes less time and less radiation to the patient.
- Delivering anesthesia in planned trajectory reduces the pain associated with needle insertion and reduces the patient movement. This was not possible in the manual procedure.
- The growing number cancer patients need more clinicians who can perform safe needle positioning.

1.3 Contraindications

MAXIO® is not recommended for use on patients and organs that are not clinically recommended for CT guided interventions.

Patients and subjects who may not be able to follow instructions appropriately for this kind of procedures such as infants, children and patients affected by conditions like Creutzfeldt-Jacob disease, may have to be as curtained by the hospital for such procedures.

1.4 Principles of MAXIO® Operation

- MAXIO is a user-controlled, CT image-guided stereotactic accessory. It assists the physician in planning and in the manual advancement of, rigid straight instruments (needles and ablation probes) during CT-guided percutaneous procedures such as biopsy, ablation and pain management, on organs and anatomical structures of the thorax, abdomen and pelvis.
- The system consists of an integrated planning station (an all-in-one PC that runs the planning software) and a floor-standing, multi-axis robotic arm. The arm's end effector holds the needle guide and includes a laser cross-hair unit. MAXIO is used only with a CT or PET-CT system. Patient images are imported from the CT/PET-CT console over Ethernet using DICOM 3.0. They can also be registered with contrast-enhanced CT, PET or MRI images to help identify lesions.
- Registration: MAXIO is docked on the InstaReg (Instantaneous Registration) mat fixed to the floor beside the CT table. A camera reads the pattern on the mat, and a tilt sensor measures device tilt; both are compared with the calibration values stored at installation, which establishes the relationship between the robot coordinate frame and the CT image coordinate frame. The registration is confirmed by aligning the laser cross-hair with a reference marker fixed on the CT table. Planning and robot motion are not enabled until the power-on self-test, axis initialization, docking and this verification have been completed.
- Planning: the patient is positioned and immobilized on the CT table, with breath-hold monitoring, and at least three skin markers are placed near the region of interest. A planned CT scan is acquired, transferred to MAXIO and displayed as multiplanar and 3D reconstructions. The physician identifies the target and defines the needle trajectory by setting the entry and target points, which determine the orbital and cranio-caudal angles; the software prevents a trajectory through a segmented NO-GO (critical structure) region. For ablation, the probe manufacturer's published ablation volume is displayed to assess tumor coverage. Multiple and parallel probe trajectories can be planned.
- Patient-position verification: before positioning, the arm points the laser cross-hair at the planned location of each skin marker. If the laser coincides with all markers, positioning is enabled; if any marker does not align, the patient is re-scanned and the procedure re-planned.
- Positioning: When the physician confirms the plan, the software converts the trajectory into axis positions for the arm. Robot motion is initiated only by deliberate user action on the Position key of the control panel or the foot switch and can be stopped at any time with the emergency switch. The arm aligns the needle guide with the planned entry point and trajectory, at a distance set by the needle length selected in the plan and holds it rigidly in position.
- Needle insertion and verification: the physician clamps the needle guide and, with the patient at the same breath-hold level as in the planning scan, manually inserts the selected needle through the guide to its full length, which places the needle tip at the planned target. The guide is then released and the arm retracted. A verification CT scan is acquired and registered with the planning images so that any deviation between the planned and actual needle position can be assessed; for ablation, post-procedure images can be compared with the plan to assess the ablation margin.
- Limits of the mode of action: the system provides planning, visualization and mechanical guidance of the needle guide only. It does not insert needles, deliver therapy or energy, connect to or control the ablation generator, or track patient movement in real time. All clinical actions are performed by the physician, who is responsible for managing patient movement (immobilization and breath-hold), supported by the skin-marker verification described above.

The following are key features of The MAXIO® System:

- Enables transfer of medical images from the CT console to the system for procedure planning and analysis.
- Automatically generates volumetric reconstruction from the acquired image stack and provides visualization using volumetric rendering and multiplanar reconstruction (MPR) views to support procedural planning and navigation.
- Provides semi-automated segmentation of the liver and visualization of the segmented anatomy to assist in procedure planning.
- Provides an image registration module supporting registration between CECT and CT, CT and CT datasets using liver contour–based and mutual information–based registration algorithms, and CT–MR landmark-based registration to improve anatomical alignment and treatment planning.

- Supports fusion of PET and CT images to assist clinicians in identifying metabolically active lesions and improving targeting accuracy.
- Provides tools for interactive segmentation and high-quality visualization of anatomical structures and lesions to support accurate procedure planning.
- Enables planning of trajectories for both single-probe and multiple-probe procedures, allowing clinicians to determine optimal probe placements based on the target anatomy and procedural requirements.
- Provides graphical visualization of manufacturer-published ablation volume data, with the capability to modify or adjust the representation to assist clinicians in planning ablation coverage.
- Enables simulation and comparison of ablation volumes from different manufacturers to support assessment of tumor coverage during procedure planning.
- Provides visualization and quantitative assessment of expected ablation margins by comparing the tumor volume with the planned ablation zone during procedure planning.
- Provides a patient positioning verification module using skin marker verification to confirm patient alignment prior to procedure execution.
- Includes an automated sequencing module to guide the procedural workflow and enhance procedural safety.
- Incorporates an electromechanical arm that assists in guiding probe insertion to support accurate and stable placement during procedures.
- Supports intraoperative image registration and plan porting, enabling transfer and alignment of pre-procedure planning data with intraoperative imaging.
- Provides tools to measure deviation between the planned needle trajectory and the actual needle placement using intraoperative verification imaging (Check Scan).
- Provides visualization of registered post-procedure images to assist clinicians in evaluating treatment outcomes.
- Provides visualization and quantitative assessment of ablation margins after the procedure by comparing ablated tissue regions with residual tumor regions, enabling the clinician to determine whether additional ablation is required.
- Sterile and disposable gripper arms.

1.4.1 System Architecture

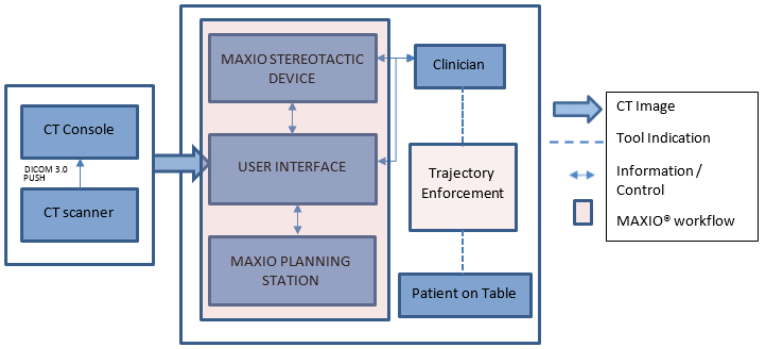


Figure 1.1. MAXIO® *System Architecture*

1.5 Device Description

MAXIO is a computer-controlled, image-guided electromechanical multi-axis arm, intended to be used in a CT scanning room for the stereotactic spatial positioning and orientation of an instrument holder or tool guide. The purpose of MAXIO is to assist a surgeon to manually advance straight needles for percutaneous image guided interventional oncology procedures through an instrument guide, by providing a reconstructed image of imported computer tomography data and visual representations of the targeted manually-guided instrument paths and instrument positions. It also is able to provide graphical representations of published data provided by instrument manufacturers / or specified by users relative to the targeted instrument position(s) on the reconstructed CT image and to provide visual comparison of pre-procedure and post procedure images.

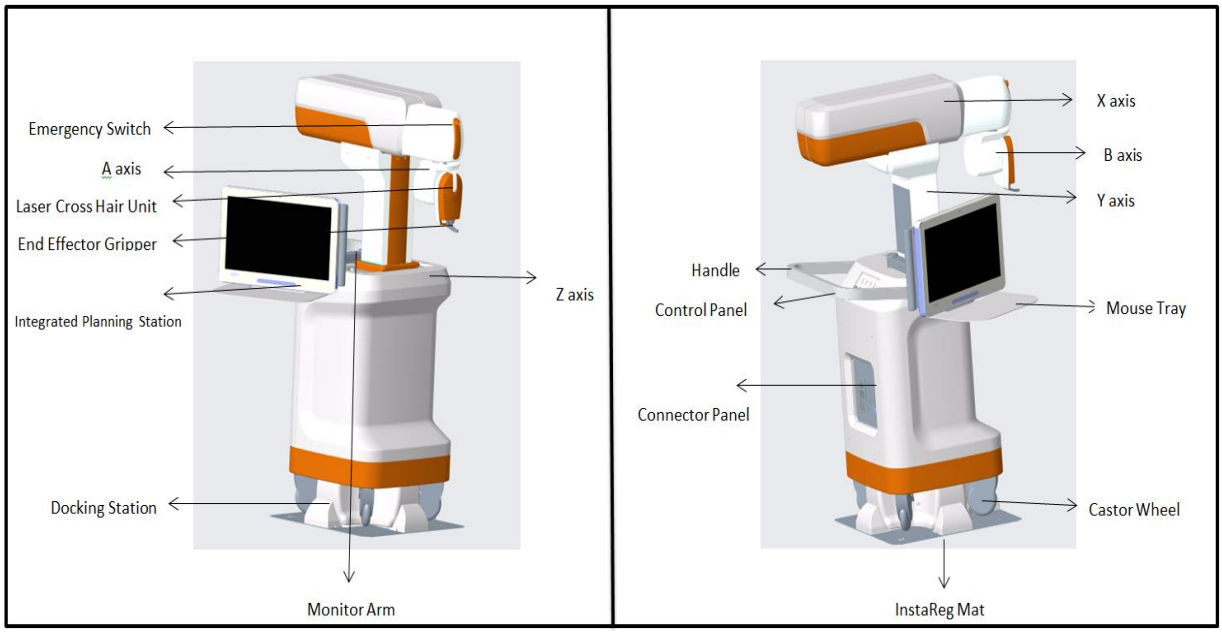


Figure 1.2. MAXIO System - Front and Rear Views

1.5.1 Control Panel

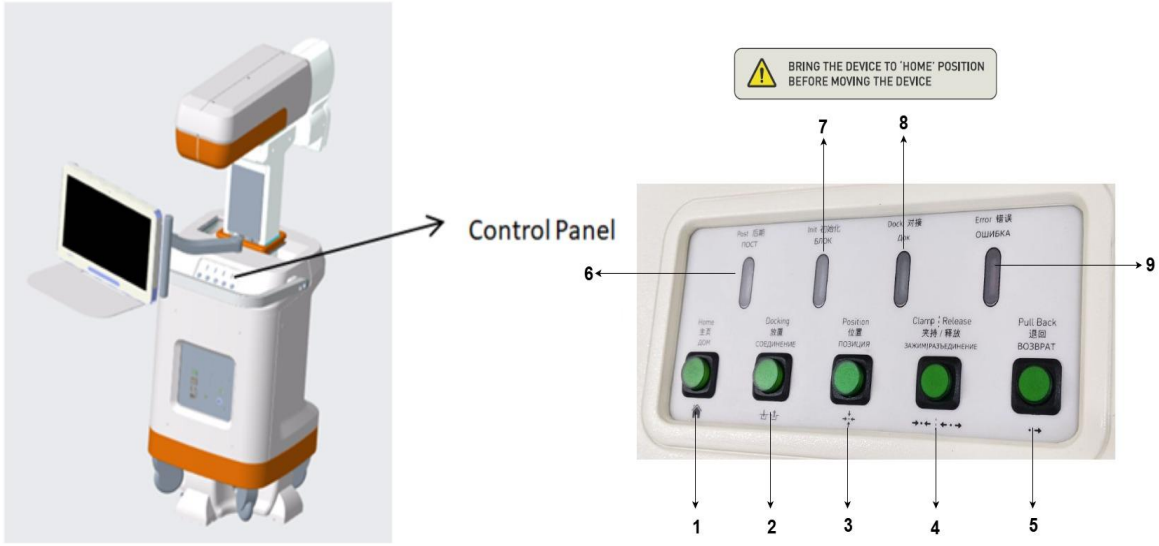


Figure 1.3. *Control Panel*

The MAXIO® control panel provides buttons and indicator lights to guide the user through the workflow:

1. Home - is used to get the device ready for operation (Half initialization) or move the electromechanical arm to a compact parking position.
2. Docking - allows the user to dock/undock the electromechanical arm to the InstaReg mat.
3. Position (same as yellow key in foot switch) - positions the electromechanical arm over the patient as per clinician plan.
4. Clamp/Release (same as blue key in foot switch) - allows the Gripper to Clamp/Release the Needle Guide (Bush).
5. Pullback (same as black key in foot switch) - takes the electromechanical arm away from the patient after successful positioning.
6. POST LED - glows green on successful POST completion.
7. HI LED - glows green on successful half initialization.
8. Dock LED - glows green on successful device docking.
9. Error indication LED - indicates a device error. In case of any device error, the LED glows red.

	MAXIO® prompts the user to the next key press activity by lighting the respective LED lights during the procedure workflow, in the control panel.
	When pressing the keys, wait for a response and avoid pressing the key multiple times.

1.5.2 Connector Panel

The MAXIO® device connector panel provides the following as shown in the figure 1-4:

1. Device Power ON/OFF switch - Controls the device (electromechanical arm).
2. Main Switch - Controls and monitors the input power-supply. The Main Switch should be left ON for battery charging.
3. Service port - is used for Service-related functioning. The port is to be used only by Perfint Authorized Service personnel.
4. Power On LED - glows green whenever the device is connected to the AC mains.
5. Ethernet port - is used as Connection slot for Ethernet cable for data communication between CT console and MAXIO®.
6. PE - is used for Grounding (Potential Equalization point)
7. Foot Switch connector - is used for connecting the foot switch.

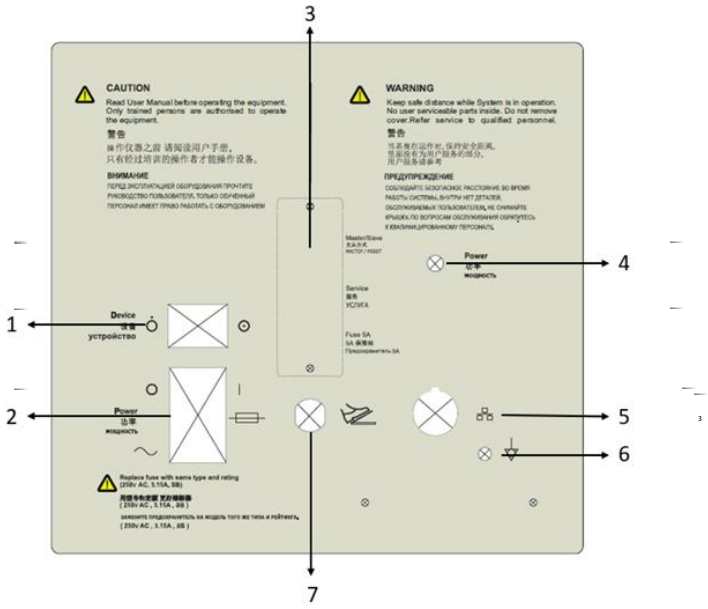


Figure 1.4. *Connector Panel*

1.5.3 Foot Switch

Footswitch enables the user to perform device operation like arm positioning, EE clamp and arm pullback by foot. See figure 1.5 below for positions and functions of the individual pedals in the foot switch.

The foot switch is connected to the foot switch connector provided at the connector panel for the device.

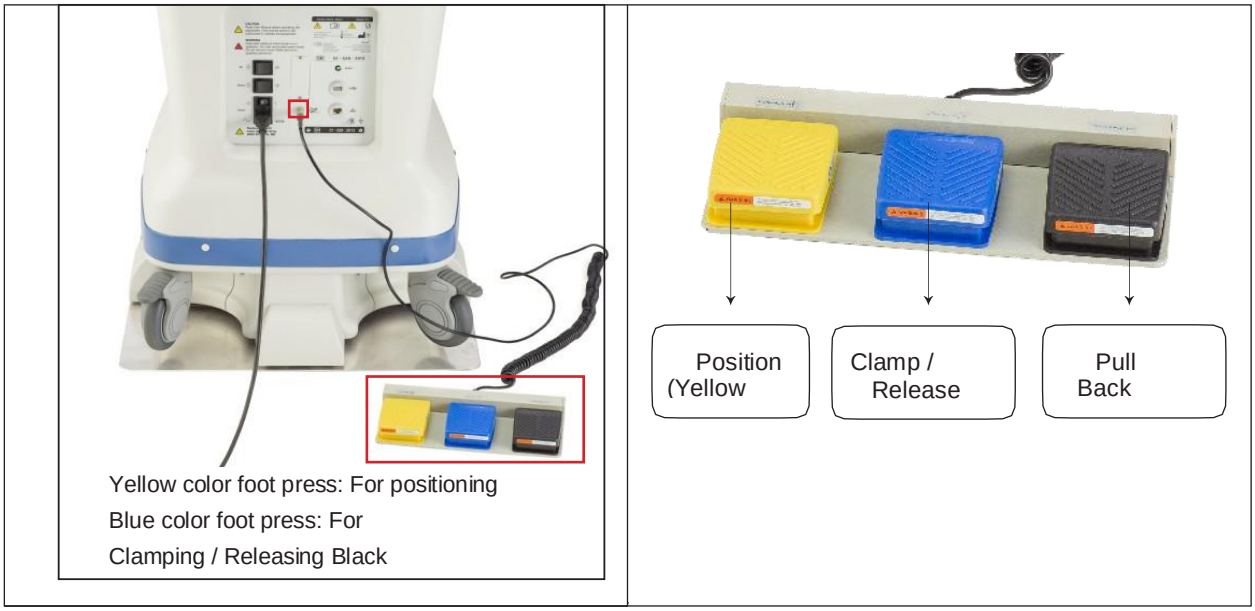


Figure 1.5. *Foot Switch*

1.5.4 Emergency Switch

The emergency switch located on the top of X-axis can be used to stop all the axes movements and release the gripper in case of an emergency situation. See figure 1.6 below. Activation of emergency switch leads to complete lockdown of the MAXIO® device axes and requires user to perform the emergency recovery procedure as mentioned below:



Figure 1.6. *Emergency Key*

For activating the emergency switch:

- Press to activate the emergency switch (Note: The Clinician has to withdraw the needle completely before the activation). For emergency recovery:
- Rotate clockwise to release the emergency switch.
- Undock MAXIO® from InstaReg mat.
- Turn the main power OFF and then ON.
- Press "Home" key to initialize and use the equipment.

1.5.5 End Effector (EE) Axis

The End effector is the last and most important arm of the MAXIO® system. The electromechanical arm moves in coordination to finally position the EE over the patient body at the desired angle and depth as planned by the clinician. The EE carries a pair of sterile grippers (left and right grippers as shown in the figure1.7below) to clamp the Needle Guide firmly, through which clinician can insert the probe/tool in to the patient body manually. The closing (clamping) and opening (unclamping) of EE are triggered by the clinician by means of control keys on the control panel or the blue pedal of the foot switch.

The EE also includes a laser cross-hair unit used for patient positioning confirmation (see section 8.1 for workflow details).



Figure 1.7. *(a) Disposable Sterile Grippers* *(b)Fixed Metal Grippers* *(NOT APPLICABLE FOR U.S)

Figure 1.7. *(a) Disposable Sterile Grippers (b) Fixed Metal Grippers* *(NOT APPLICABLE FOR U.S)

1.5.6 Disposables

1.5.6.1 Needle bush/ Needle guide

Description:

Needle bush/ Needle guide is a disposable accessory designed to lead a needle into its proper course when performing a Clinical procedure. The needle bushes and bushes are plastic split bushes that can be selected based on the size of the needle being used for the procedure. The needle bush & bush facilitates the doctor to use needles of different gauges and types. It ensures that the needle is tightly held by the gripper. The needle bush/ needle guides are supplied sterile and are designed for single use only. Each sterile pack contains single unit of needle guide.

Instruction for use:



Figure 1.10. *Needle bush/ Needle Guide Sterile Pack*

Refer to the technical specification sheet for gauge size of needle bush/ needle guides supplied by Perfint.

The usage of Needle bush/ Needle guide is shown in the figure 1-11(A-D) below. Dispose the Needle bush/ Needle guide appropriately after the first use.



A B C D

Figure 1.11. *Instructions for Sterile Needle bush/ Needle guide*

a. Needle bush/ Needle guide gauge marking
b. Needle bush/ Needle guide getting clamped by the EE Grippers
c. Needle inserted through Needle bush/ Needle guide
d. Splitting of Needle bush/ Needle guide (If required)

Warnings and Precautions:

	Always use only sterilized Needle bush/ Needle guide for procedures
	Ensure that Needle bush/ Needle guide is chosen such that they have same gauge marking on both sides. Incorrect use of Needle bush/ Needle guide would result in inaccurate results.
	Needles of different brand vary in the needle outer diameter. While choosing the Needle bush/ Needle guide for a gauge needle, ensure the Needle bush/ Needle guide is not too tight or too loose.
	Needles thinner than 18G may necessarily be not rigid. Ensure that needles do not bend during insertion. Also, where possible use short and thicker needles.

Contraindications:

- Do not reuse or re-sterilization.
- Do not use if sterile packaging is compromised.
- Do not use with incompatible needle gauges.
- Do not use if cracked or improperly seated.

Combination Information:

Intended for use with Disposable Grippers (US) or Fixed Metal Grippers (Non-US) integrated in MAXIO® End Effector. Interfaces directly with the clinical needle and indirectly with the patient via the needle pathway.

1.5.6.2 Needle Stabilizers

Description:

Needle Stabilizer is a rigid type disposable accessory used to guide/stabilize the needle at a chosen angle during clinical procedures. These help in holding the needle in place inside the patient body at the desired angle and depth. The Needle stabilizer is very useful for soft tissue procedures where the chances of needle sag are very high. This will hold the needles in place even after release from End Effector. The needle stabilizers are recommended for single use only.

These are fixed over the skin contacting material 3MTM Two-In-One Double Coated Tape 1577. These consumables do not have direct contact with the patient. The contacting material 3M™ Two In-One Double Coated Tape 1577 is 510k approved. The product has been tested for biocompatibility by the Manufacturer and the clinical data summary is attached along with this summary report.

Instruction for use:



Figure 1.13. *Needle Stabilizer*

To insert the Needle Stabilizer

1. Wear sterile gloves to insert the needle stabilizer.
2. Remove the adhesive paper from below the needle stabilizer base.
3. Press the needle stabilizer to open the clip as shown in the Figure 1.14.
4. Clamp the needle already inserted in the patient.
5. Push the needle stabilizer down the needle so that it is touching the patient's body.
6. Press the base of the needle stabilizer so that it adheres to the patient's skin surface.



A B C D

Figure 1.14. *Instructions for Sterile Needle Stabilizer*

To remove the Needle Stabilizer

1. Wear sterile gloves to remove the needle stabilizer.

2. Pull the base of needle stabilizer gently from the patient's skin surface.
3. Open the clip to disengage the stabilizer from the needle.
4. Dispose the used stabilizer in biohazard containers.

Warnings and Precautions:

☞	◆ NOTE: Always use sterile needle stabilizers for procedures.
⊘	DO NOT REUSE: Reusing needle stabilizers can result in infection and may cause serious illness to patient due to contaminants from previous usage. Do not reuse needle stabilizers. All used stabilizers must be disposed in biohazard containers.

Contraindications:

- Do not reuse.
- Do not use if adhesive backing is compromised.
- Do not apply on damaged, infected, or hypersensitive skin.
- Contraindicated in patients with adhesive hypersensitivity.
- Not intended to replace primary fixation during insertion.

Combination Information:

Intended for use with clinical needle after insertion. Does not mechanically interface with MAXIO® device or other disposables. Adhesive contacts skin; device body does not contact patient.

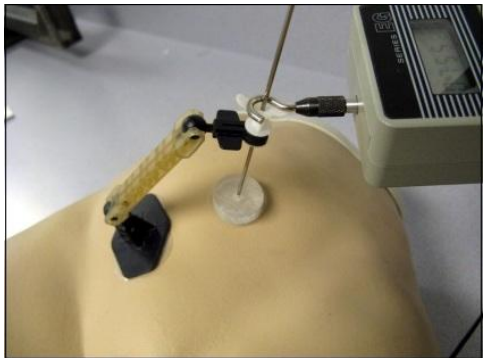
1.5.6.3 Needle Holder

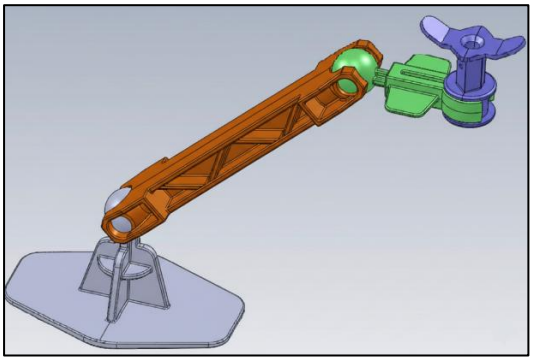
Description:

Needle Holder is a flexible type disposable accessory used to guide/stabilize the needle at a chosen angle during clinical procedures. These help in holding the needle in place inside the patient body at the desired angle and depth. The Needle Holder is very useful for soft tissue procedures where the chances of needle sag are very high. This will hold the needles in place even after release from End Effector. The needle holders are supplied Non-Sterile as per user requirement by Perfint and are recommended for single use only.

These are fixed over the skin contacting material 3MTM Two-In-One Double Coated Tape 1577. These consumables do not have direct contact with the patient. The contacting material 3M™ Two-In-One Double Coated Tape 1577 is 510k approved. The product has been tested for biocompatibility by the Manufacturer and the clinical data summary is attached along with this summary report

Instruction for use:





Needle Holder is supplied Sterile or Non-Sterile as per user requirement and are recommended for single use only. Non-Sterile Needle Holder is cleaned and packaged in sterilizable pouch

Warnings and Precautions:

	Always use sterile holder for procedures.
	Reusing the Needle Holder can result in infection and may cause serious illness to patient due to contaminants from previous usage

Contraindications:

- Do not reuse.
- Do not use if adhesive backing is compromised.
- Do not apply on damaged, infected, or hypersensitive skin.
- Contraindicated in patients with adhesive hypersensitivity.
- Not intended to replace primary fixation during insertion.

Combination Information:

Intended for use with clinical needle post insertion. Does not interface mechanically or functionally with MAXIO® device or other disposables. Adhesive contacts skin only.

1.5.6.4 MAXIO Drape

Description:

MAXIO Drape is used to cover the EE, A and B axis to prevent contact by physician during the procedure. The MAXIO Drape intentionally does not make contact with the patient or the needle The MAXIO Drape is intended for single use and hence should be disposed appropriately after every use. The drapes are recommended for single use only. This MAXIO Drape is used in the MAXIO System

Instruction for use:



A B C D

Figure 1.12. *Instructions for MAXIO Drape*

To use the sterile drape:

1. Sterile drapes must be placed on the system prior to securing the grippers.
2. Remove the drapes from the sterile pack. Align the holes on the drape (as shown in figure 1-12) to the left and right EE grove.
3. Remove the adhesive sticker (blue color) and paste the drape aligning on the laser cross hair unit as shown in figure 1.12 (c).
4. Pull the drape to cover the exposed electromechanical arm including the emergency switch and the entire AB axis.

5. Secure grippers as indicated in section above on Sterile Grippers.

Instructions to remove drape:

1. First remove grippers.
2. Remove drape.
3. Dispose used drape in biohazard containers.

Warnings and Precautions:

	Always use sterile drape for procedures.
	Reusing the drape can result in infection and may cause serious illness to patient due to contaminants from previous usage. Do not reuse drape. Dispose used drapes in biohazard containers.
	Handling the drape without sterile gloves may result in infection or other injury to the physician. Always use sterile gloves when inserting the sterile drape and always insert the sterile drape cover on the electromechanical arm before gripper assembly.

Contraindications:

- Do not reuse.
- Do not use if torn, punctured, or contaminated.
- Not intended to provide sterile barrier, It is only a contamination-reduction cover

Combination Information:

Intended for use with MAXIO® End Effector and robotic axes. No functional interaction with needle bush, needle, or stabilizers.

1.5.6.5 Touchpad Drape

Description:

Touchpad Drape is used to cover the Touch pad (mouse tray) to prevent contact by physician during the procedure. The Touchpad Drape intentionally does not make contact with the patient. The Touchpad Drape is intended for single use and hence should be disposed appropriately after every use. They are supplied Non-Sterile as per user requirement by Perfint and are recommended for single use only. This Touchpad Drape is used in the MAXIO System

Instruction for use:





Touchpad Drape is supplied Sterile or Non-Sterile as per user requirement and are recommended for single use only. Non-Sterile Touchpad Drape is cleaned and packaged in sterilizable pouch and is supplied as ready for ETO sterilization

Warnings and Precautions:

	Always use sterile drape for procedures.
	Reusing the Touchpad Drape can result in infection and may cause serious illness to patient due to contaminants from previous usage

Contraindications:

- Do not reuse.
- Do not use if torn, punctured, or contaminated.
- Not intended to provide sterile barrier, It is only a contamination-reduction cover (to prevent physician contact contamination of the touchpad)

Combination Information:

Intended exclusively for use with MAXIO® System touchpad. No interaction with needle, needle bush, grippers, or stabilizers.

1.5.6.6 Grippers

Description:

The grippers are part of the EE and are supplied sterile (as shown in the figure 1-8 below) along with the MAXIO®. Every pair of grippers contains a left and a right gripper part is used to clamp the needle bush firmly through which the clinician can insert the needle/tool into the patient body manually. The grippers are intended for single use and hence should be disposed appropriately after every use. The grippers are supplied Sterile or Non-Sterile as per user requirement by Perfint and are recommended for single use only.

Instruction for use:



Figure 1.8. *Left and Right Grippers*

To secure the grippers prior to a procedure (Refer Figure 1.9):

1. Wear sterile gloves to secure grippers.
2. Place a sterile drape on the system (see section 1.6.8 on sterile drape).
3. Insert the sterile left gripper in the left EE groove and rotate left (clockwise).
4. Insert the sterile right gripper in the right EE groove and rotate right (counter-clockwise).
5. When the grippers are placed properly the switch behind the grippers will become activated.



Figure 1.9

To remove the grippers following each procedure:

1. Wear sterile gloves to removegrippers.
2. Remove the left gripper by rotating right (counter-clockwise).
3. Remove the right gripper by rotating left (clockwise).
4. Dispose used grippers in biohazard containers.

Warnings and Precautions:

	Always use only sterile grippers for procedures.
	Each gripper sterile pack contains a pair of left and right grippers.
	Do not reuse grippers. Dispose used grippers in biohazard containers. Reusing grippers can result in infection and may cause serious illness to patient due to contaminants from previous usage.
	Do not reuse Needle Guide. Dispose used Needle guide in biohazard containers. Reusing the Needle Guide can result in infection and may cause serious illness to patient due to contaminants from previous usage.
	Use sterile gloves for the gripper assembly. Always insert the sterile drape cover supplied with the MAXIO®, on the electromechanical arm, before gripper assembly.
	Always clean the metal grippers with regular hospital disinfectant solution before procedure and after the procedure is completed

Contraindications:

- Do not reuse or re-sterilization.
- Do not use if sterile barrier is compromised.
- Do not use if damaged, cracked, or deformed.
- Do not use with incompatible needle bush sizes. (Not intended for direct patient contact)

Combination Information:
Intended for use with compatible Needle Bush / Needle Guide and MAXIO® End Effector. Provides mechanical clamping of the needle bush. No direct patient interface. For US markets, disposable sterile grippers are used instead.

1.5.7 QA/Skin Marker module for patient movement management

This module is provided for QA/skin marker verification for any change in device and/or patient position, just before executing the procedure. The module comprises of QA/skin marker, a laser cross-hair unit mounted on the EE and QA/skin marker module software. Place a minimum of 3QA/skin marker in irregular fashion near to the area of interest on the patient before taking the first scan. Before positioning the device for needle placement, verify the patient position by selecting a QA/skin marker in the image series and position the device laser on the corresponding QA/skin marker. Refer section 4.1.3 and chapter 7 for details. Laser cross-hair unit can be pulled down to actuate the laser pointer. When there is absolutely no patient movement, the laser cross hair will point exactly on the QA/skin marker chosen. In case of any deviation seen on the QA/skin marker, re-scan the patient and plan on the new images

⚠	Do not look into the laser beam. The laser unit is defined as a Class II laser product. Care should be taken such that neither the patient nor the clinician directly looks into the laser beam.

1.5.8 Integrated Planning Station

The Planning Station is the main user interface of the MAXIO®. The planning station is connected to the CT console and receives CT images. The images are displayed on the planning station where the clinician can plan for the procedure with the help of MAXIO®planning tools. Once confirmed, the plan is communicated internally to the electromechanical arm for execution. The user can use a track pad to plan and provide input to the MAXIO®through the planning station.



Figure 1.15. *Integrated Planning Station*

1.5.9 InstaReg Mat, Docking and Undocking

The InstaReg mat (Instantaneous Registration mat) is a pattern plate installed on the floor on either side of the CT table. The InstaReg mat becomes the calibration point which registers the MAXIO® system to the CT system. In preparation for a procedure, MAXIO® is wheeled in and docked on the InstaReg mat. At the end of the procedure, MAXIO® is undocked from the mat and wheeled out of the way as needed.

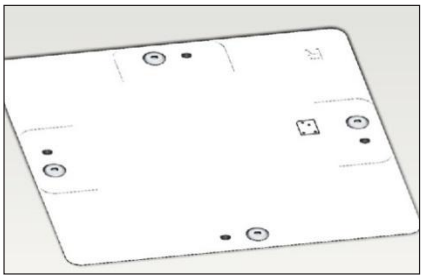


Figure 1.16. *InstaReg Mat*

1.5.10 Electromechanical Arm

The MAXIO® robotic device has 5 axes - 3 linear and 2 angular. The linear axes (X, Y and Z) span the patient width, height and cranio-caudal distance respectively, while the angular axes (A and B) allow the probe/tool to be positioned in any 3D angle.

2. PREPARING FOR SYSTEM USE

2.1 Site Requirements

Unless otherwise specified, the customer is responsible for site preparation, which may include, but not limited to the following:

- Evaluating the CT room size.
- Relative positioning of system components within the CT room.
- Accessibility for the equipment - doors, corridors and elevators (space and loading limitations).
- Floor loading, floor leveling and any building modification (if necessary).
- Installing the electrical conduit, junction boxes, ducts and earth reference terminal (ERT).
- Check for network port available inside the gantry room.
- Network configuration.
- Storage of the system, if necessary, prior to installation.

☞	Note: Ensure a unique IP address is assigned to the MAXIO system. The same IP address should not be used for any other device within the network.

2.2 Room Layout

MAXIO® Room Layout depends on the CT room layout and hence may vary accordingly.

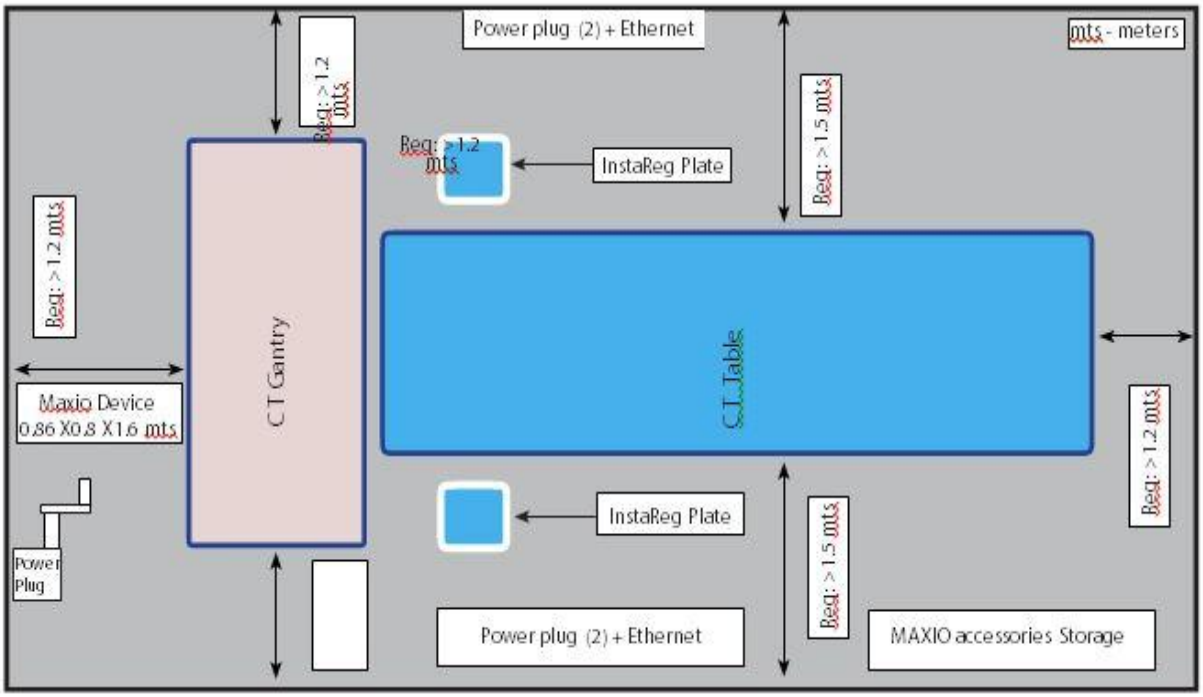


Figure 2.1. *Possible CT Room Layouts*

✋	The choice of parking area is dependent on the customer, but has to be defined in the pre installation site documentation. MAXIO® movement are depends on where the parking area is and the route from the parking area to the docking location.

3. STARTING THE MAXIO SYSTEM

3.1 MAXIO Device Preparation

This section describes the preparatory steps needed to get the MAXIO ready for use.

3.1.1 Move MAXIO from Parking Area

- Unlock the castor wheels and move MAXIO® from the parking area to the docking area on the left or right of the CT table. Disconnect the AC power supply if MAXIO® battery was charging at parking area.

☞	Do Not rotate the PC more than 90° (±).

✋	CAUTION: Using incorrect power supply cords could result in damage to the system. Use power supply cords meeting national requirements of the respective country in which the equipment is used.
⚠	WARNING: Accidental damage to MAXIO® may result in an electrical hazard which could cause harm to a patient or an operator. In case of accidental damage to MAXIO®, immediately detach the power cord to isolate MAXIO® from the power supply.

3.1.2 Turn MAXIO® Power On

On the Connector Panel:

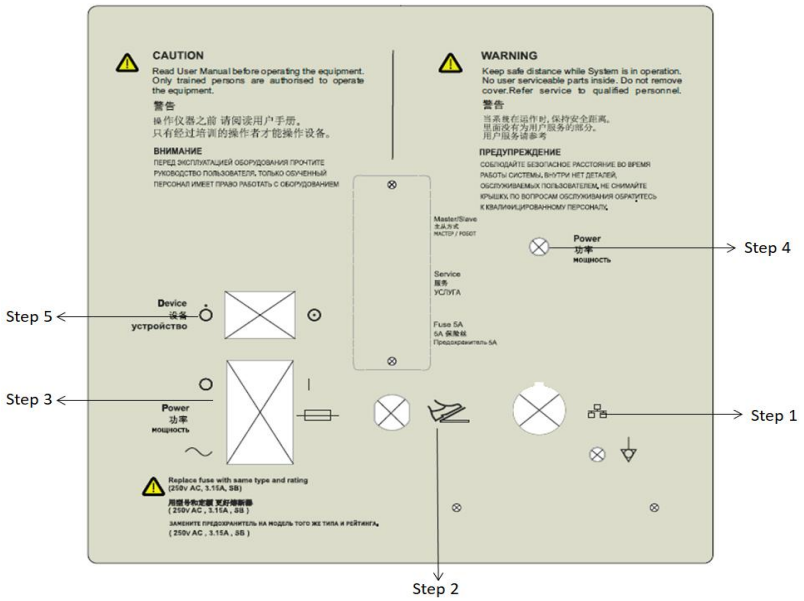


Figure 3.1. *Connector Panel*

1. Connect the Ethernet cable connected to the CT system or hospital network to the Ethernet port - to import CT images
2. Connect the Foot Switch - align the connector and rotate to lock

✋	CAUTION: Connecting devices not supplied with MAXIO® may result in unexpected behaviors. Do not connect devices that are not supplied with MAXIO®.

3. Connect the power supply cable and turn the Main power switch to On.
4. Green Power LED indicates availability of power.
5. Turn the Device power switch to On.

Up on powering On, MAXIO® runs a series of Power On Self Tests (POST) to ensure that the system is working properly. The POST LED on the control panel will display a green light upon successful completion of Power On Self Tests, which indicates that MAXIO® is ready for use.

If POST tests are not successful, the LED marked error turns RED, which indicates that MAXIO® will not be enabled for use

✋	NOTE: MAXIO® will not operate without successful completion of Power On Self-Test (POST). If first try is unsuccessful, repeat steps and try again. If still unsuccessful contact Perfint Customer Support (if POST LED on the Control Panel does not display green).

3.1.3 Electromechanical Arm Initialization

After successful POST, initialize the MAXIO® by pressing the INITIALIZE button on the control panel. The device initialization will position all the axes to its zero or base position.

On successful initialization, insert the sterile drape cover to cover the electromechanical arm and follow gripper assembly instructions provided in section1.6.6 to fix the grippers.

☞	MAXIO® cannot be used without successful initialization of each axis to the zero position
☞	Always use sterile gloves before opening the sterile pack. Always use sterile drape covers on the machine before use.
✋	Call Perfint Service in the event of an unsuccessful electromechanical arm initialization.

3.1.4 Turn the Planning Station Power On

Power the Planning Station ON by pressing the PC ON switch located on the connector panel to the ON position.

Turn the PC switch to ON. (Figure 3.1 Connector panel)

☞	The planning station may be powered ON separately from the main device being powered ON in order to conduct procedure planning activities independent of the main device.

On successful switch ON the MAXIO® application will load automatically leading to the login screen.

3.1.5 Planning Station Onstartup

The **On-Startup** application functions as a kiosk interface to ensure secure and controlled access to the MAXIO software.

- On system startup, the **On-Startup** application runs automatically and displays an **indeterminate progress bar**, indicating that the system is initializing and preparing to launch the MAXIO application.



Figure 3.24 *Onstartup loading screen*

- Once the MAXIO application is ready to load, the **On-Startup** application shall automatically initiate the launch of MAXIO.

3.1.6 Planning Station Login

MAXIO® restricts unauthorized user access through password protected login. By default, MAXIO® offers two logins - User, Admin.

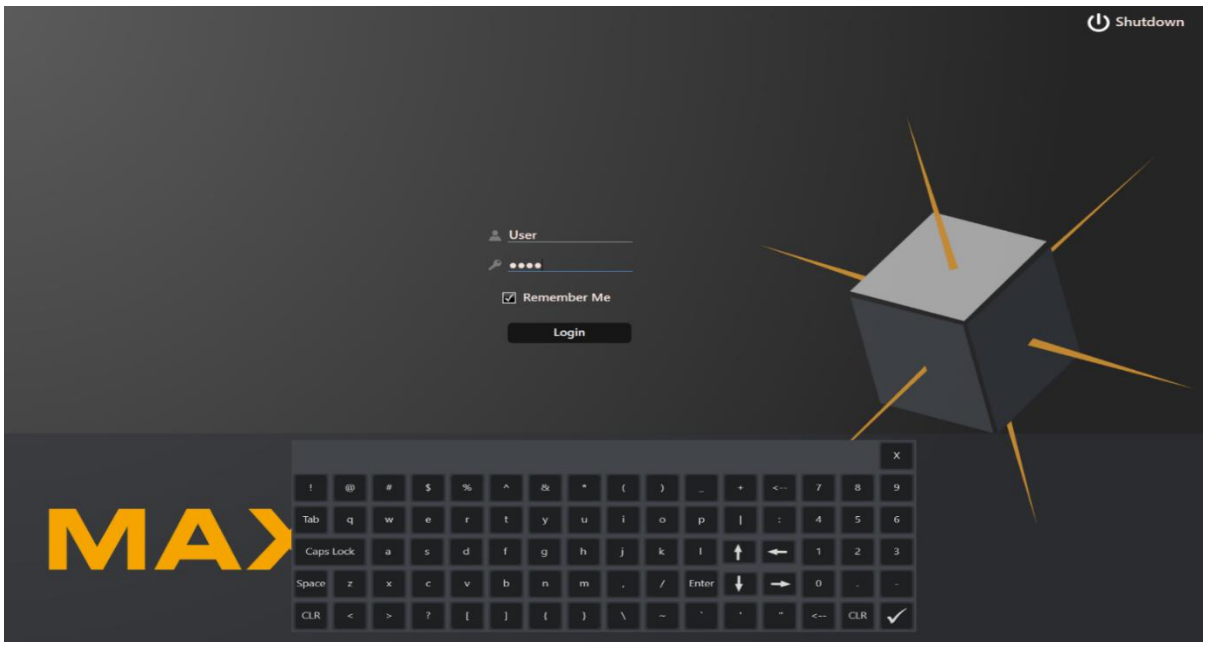


Figure 3.2. MAXIO® *Application Landing/Login Screen*

The virtual keyboard is displayed for the user to enter the login details (as shown in the figure 3.2).

ADMIN login

The admin users will have access to the setting option as shown in the figure 3.4 below.



Figure 3.3 *Settings Toolbox*

Select the setting option to select one of the options from the drop-down list as shown below:

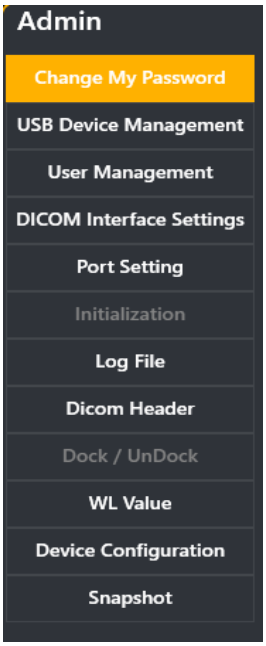


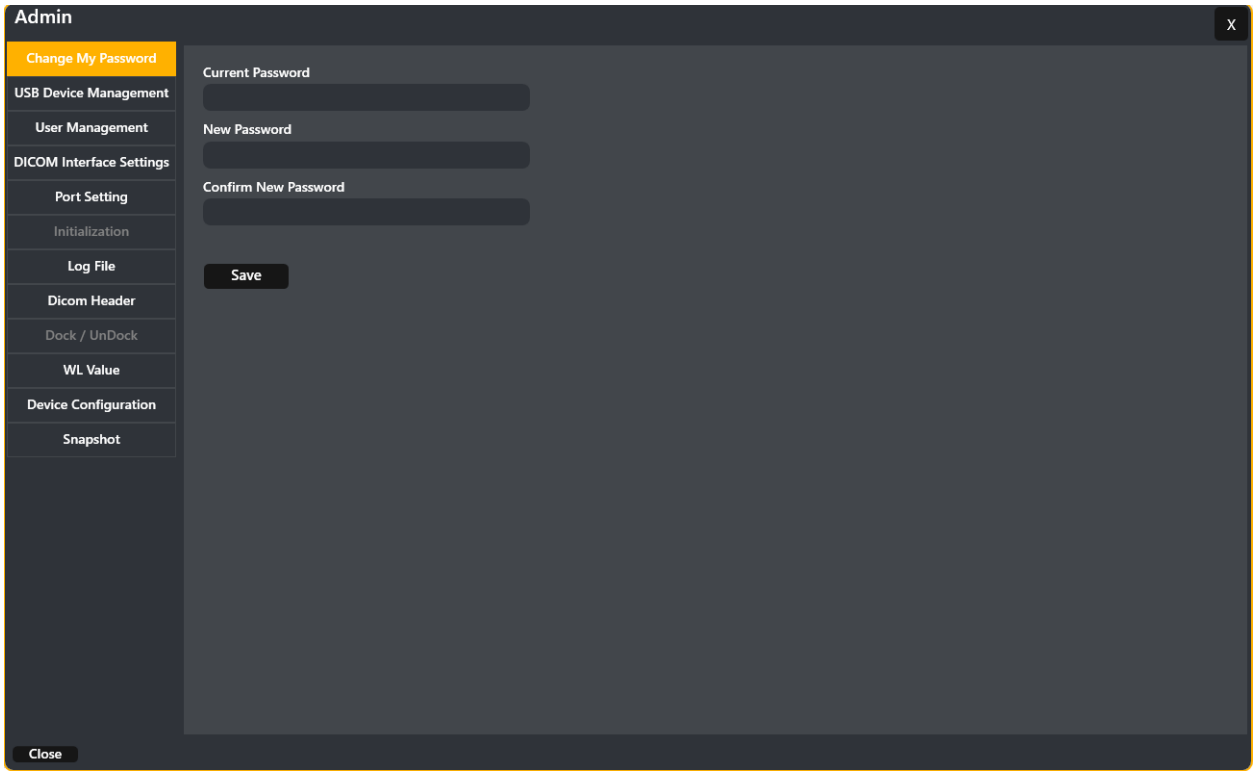
Figure 3.4 *Admin configuration Settings*

1. Change My Password: The admin has the option to change their password.

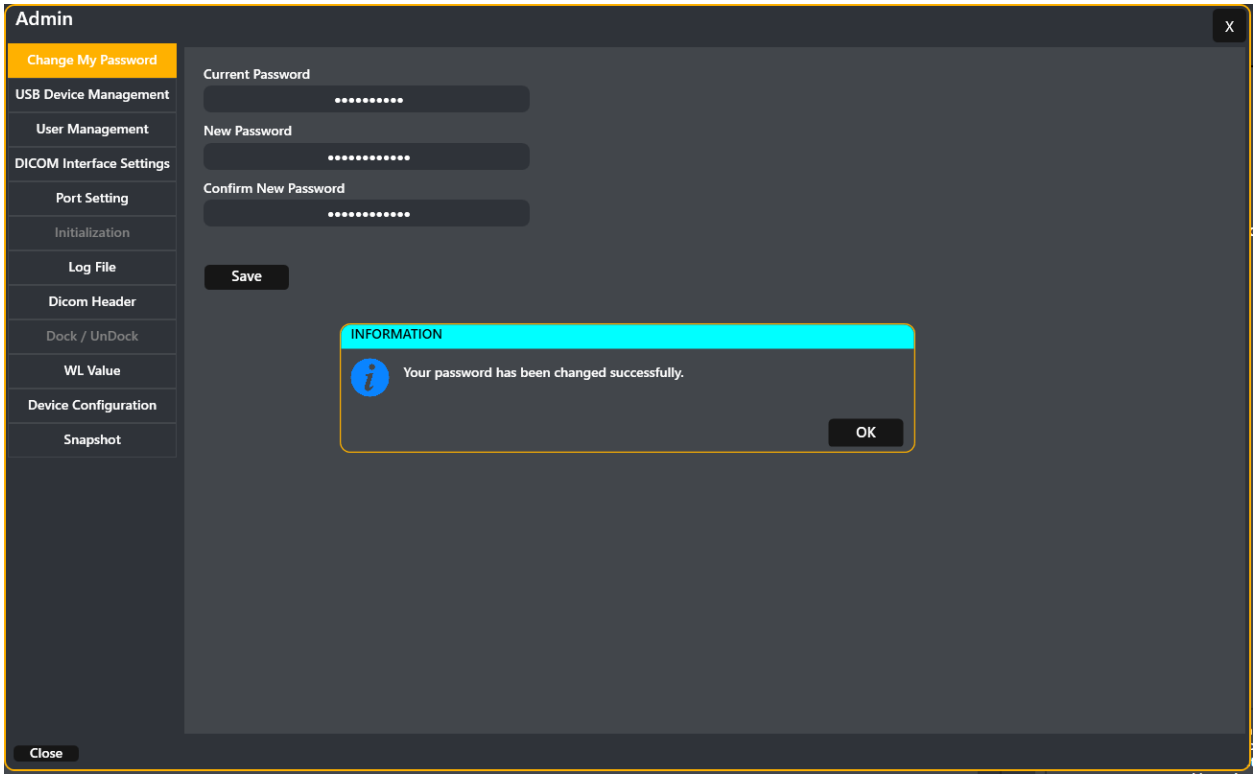
   Change admin Password

   - Click Change My Password tab

☞	Ensure that the new password meets the following password requirements: ○ Minimum length: 8 characters ○ Maximum length: 15 characters ○ At least one uppercase letter (A–Z) ○ At least one lowercase letter (a–z) ○ At least one numeric character (0–9) ○ At least one special character (e.g., @, #, $, %)



- Enter Current Password, New password and Confirm New Password to change the password.



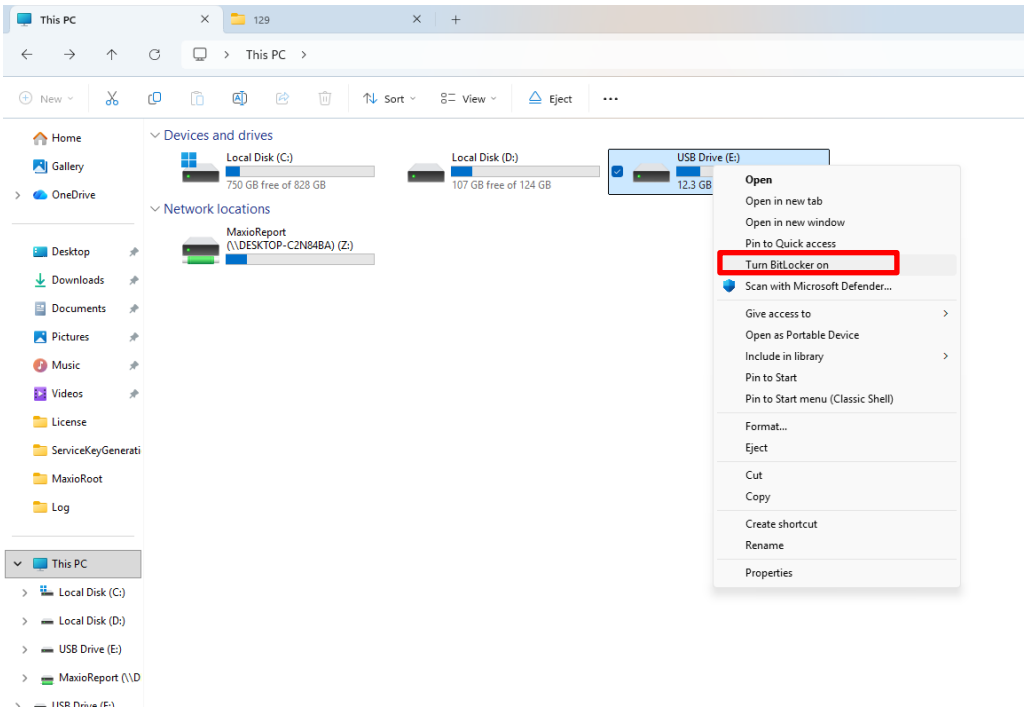
2. USB Device Management: The USB Device Management allows the admin user to enroll a connected removable drive as an authorized device.

To authorize a USB drive, follow the steps below:

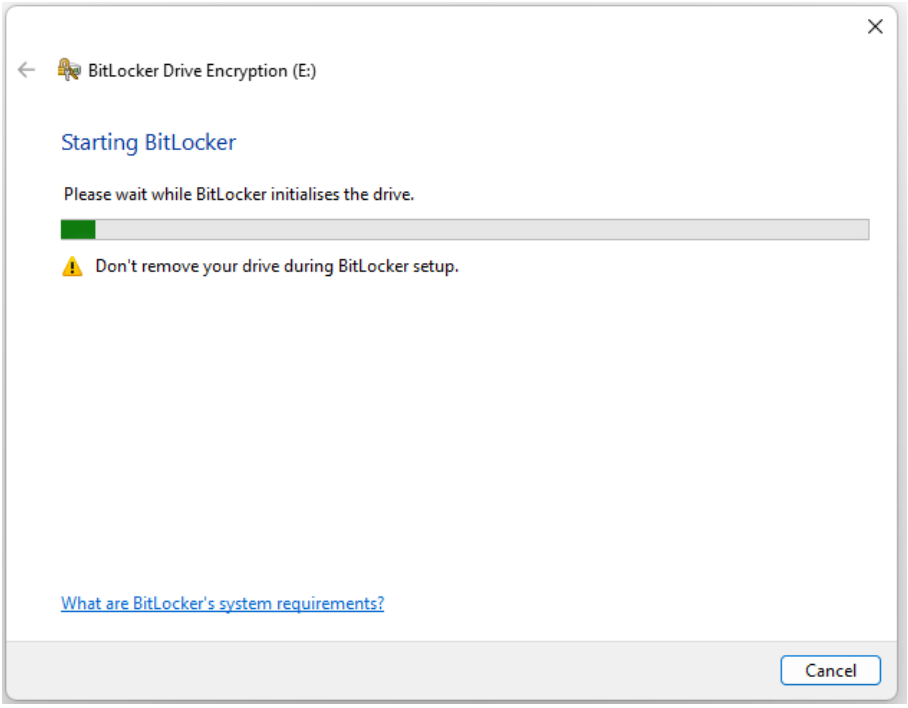
3.1.6.1 Pen drive Bitlocker (Only Applicable for Windows 11 pro)

Note: An external PC must be used to enable BitLocker encryption on the USB pen drive.

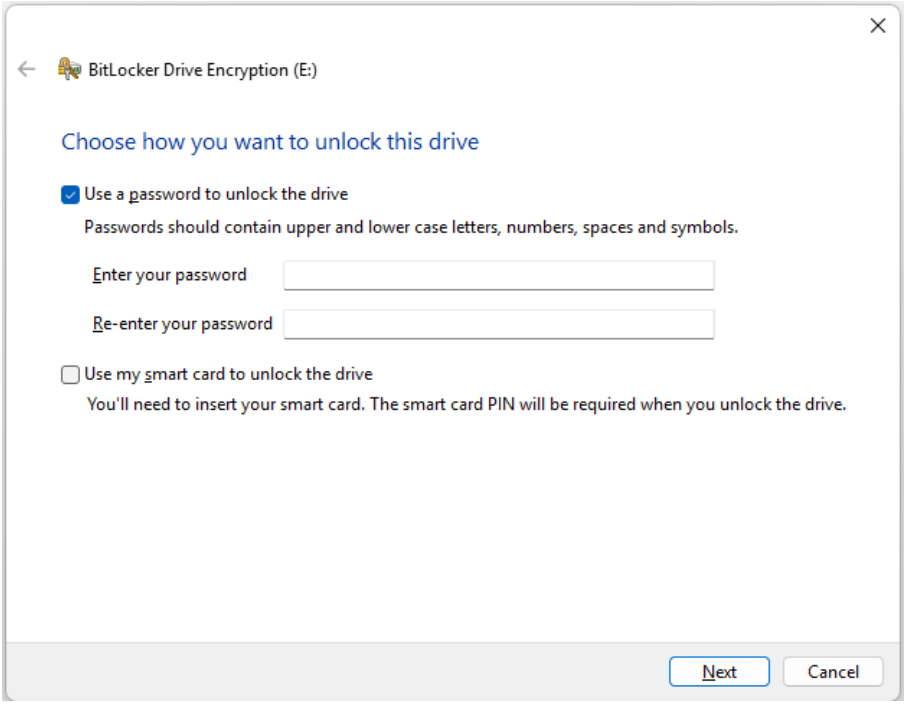
- Connect USB Pen drive
- Right click the USB Drive and click Turn BitLocker on



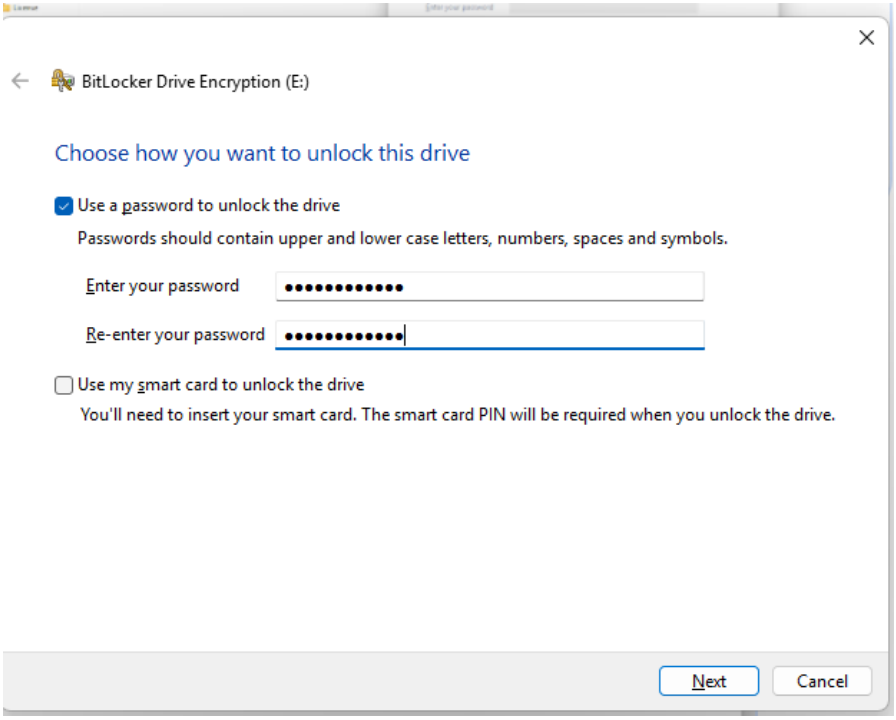
- Pen drive starting BitLocker



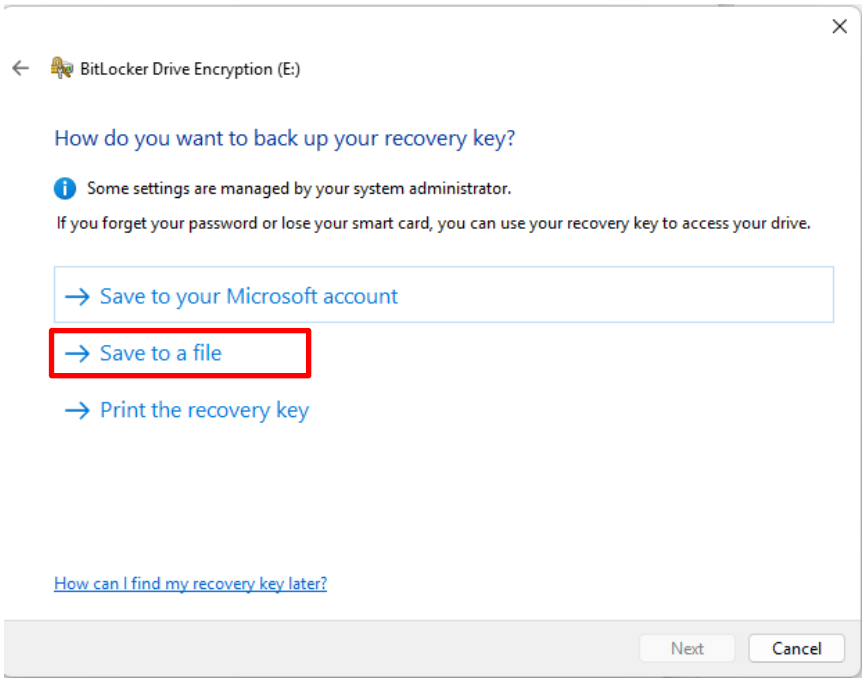
- Check Use a password to unlock the pen drive



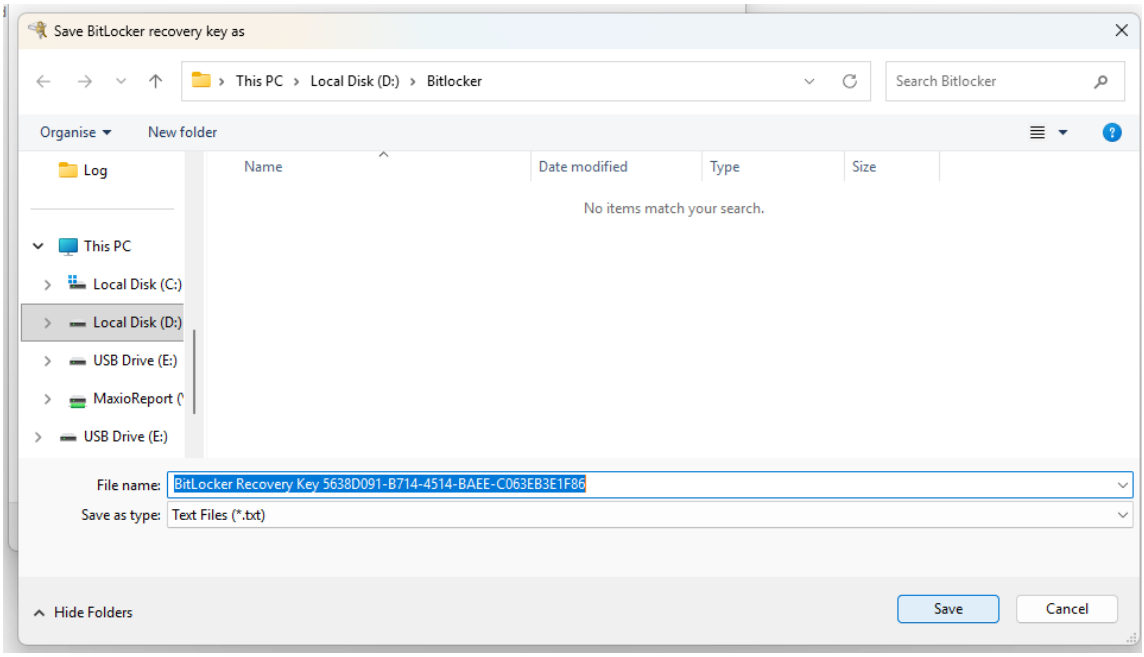
- Enter your password and re-enter your password



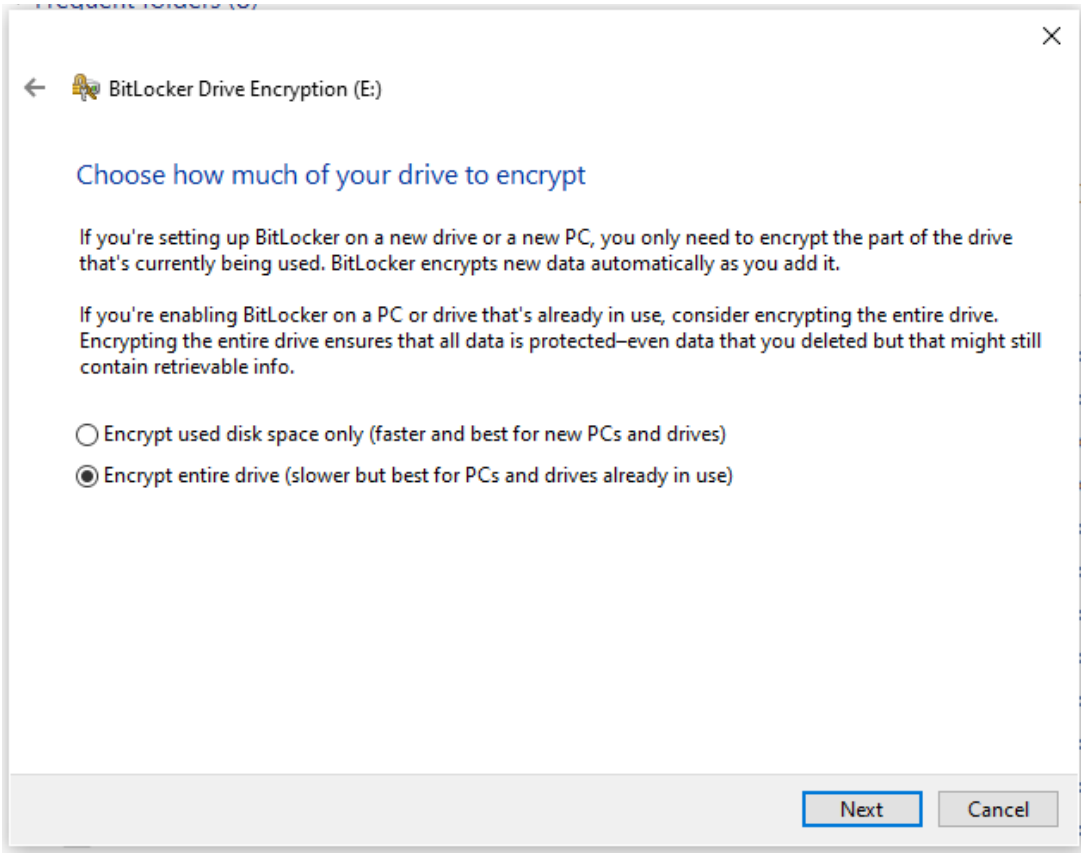
- Click Save to file to save the .txt file



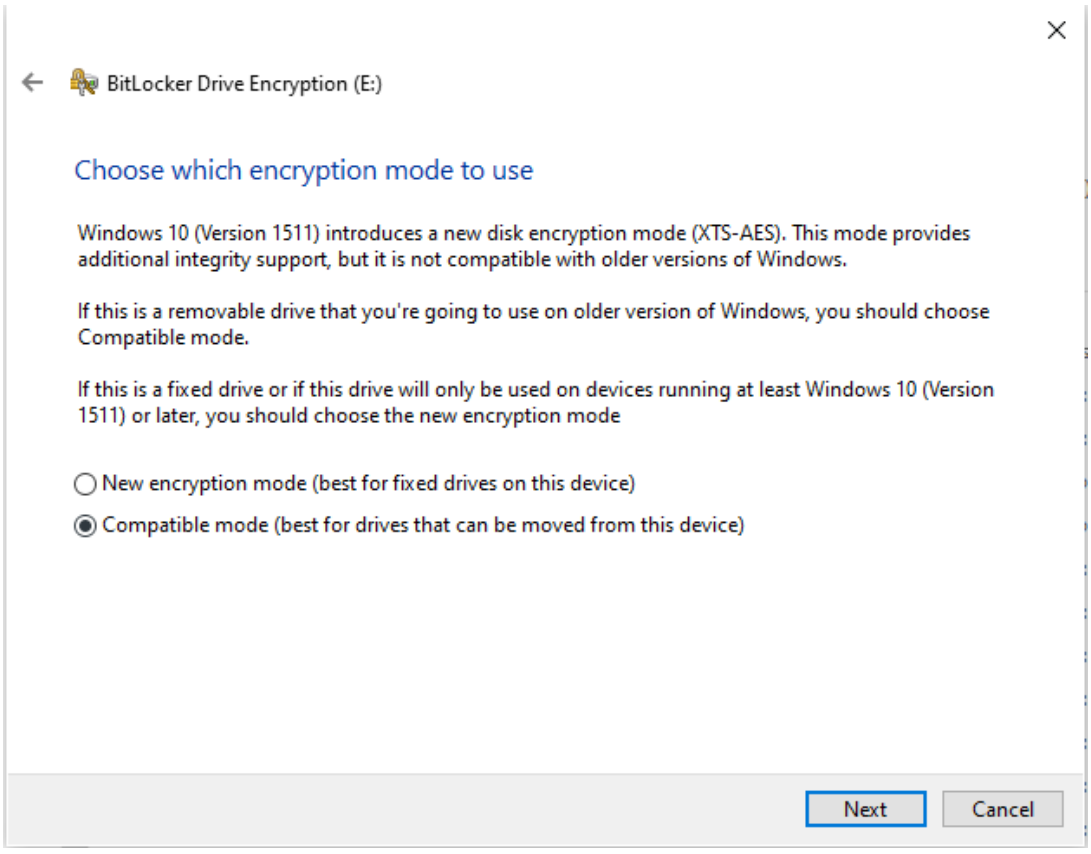
- Choose the location to save the file and click Save.



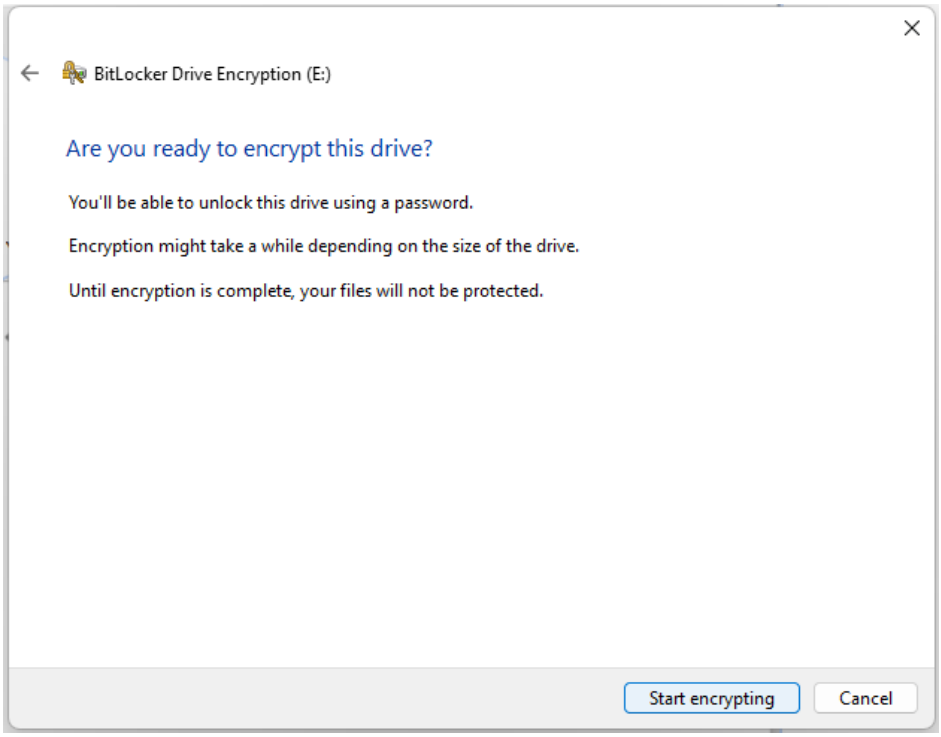
- Choose Encrypt entire drive (slower but best for PCs and drives already in use) and click Next



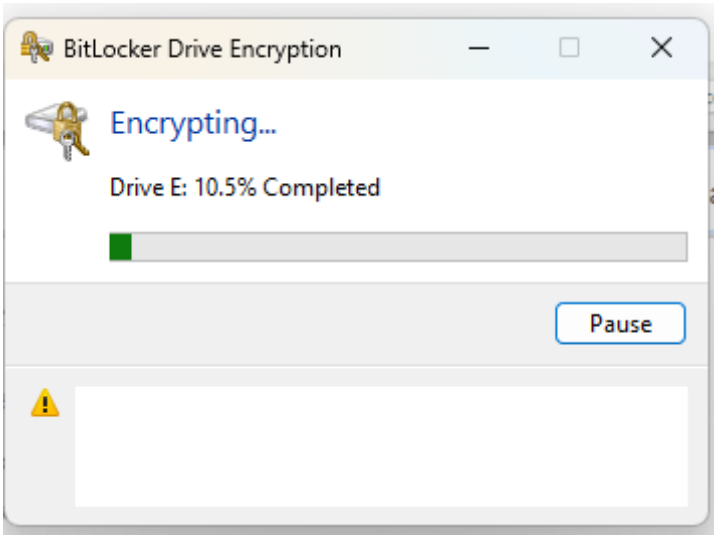
- Choose Compatible mode (best for drives that can be moved from the device) and Click Next



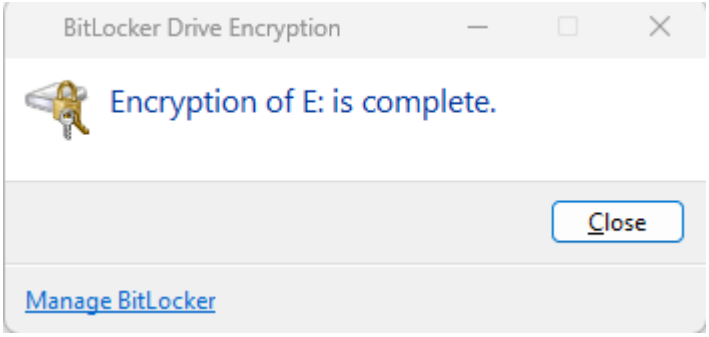
- Click Start encrypting button



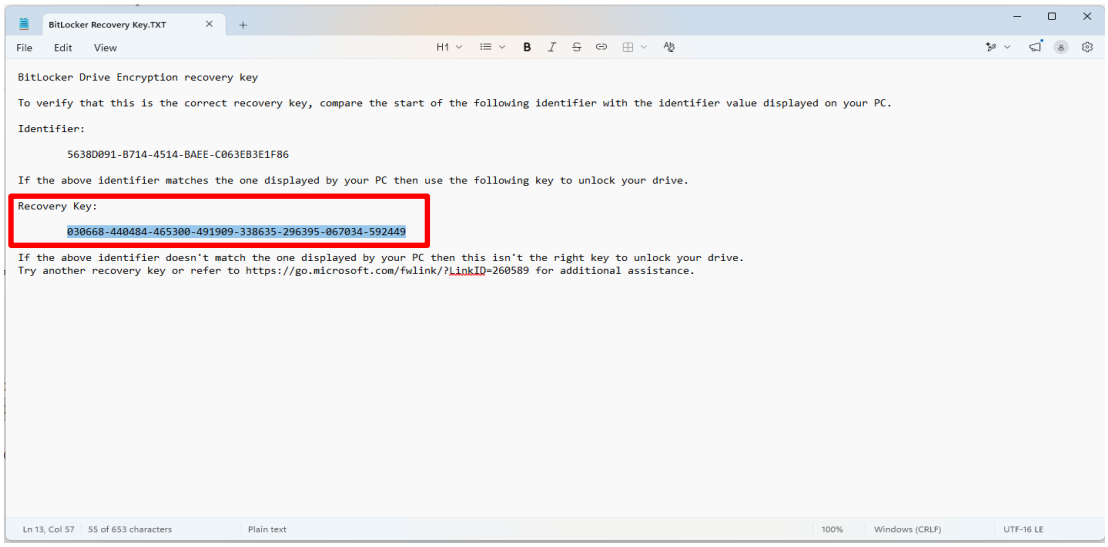
- Pen drive get start Encrypting



- Click Close

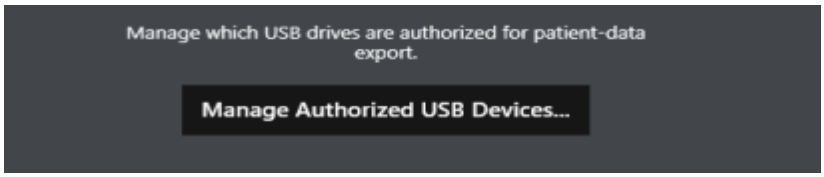


- Open the saved .txt file and **copy the Recovery Key**

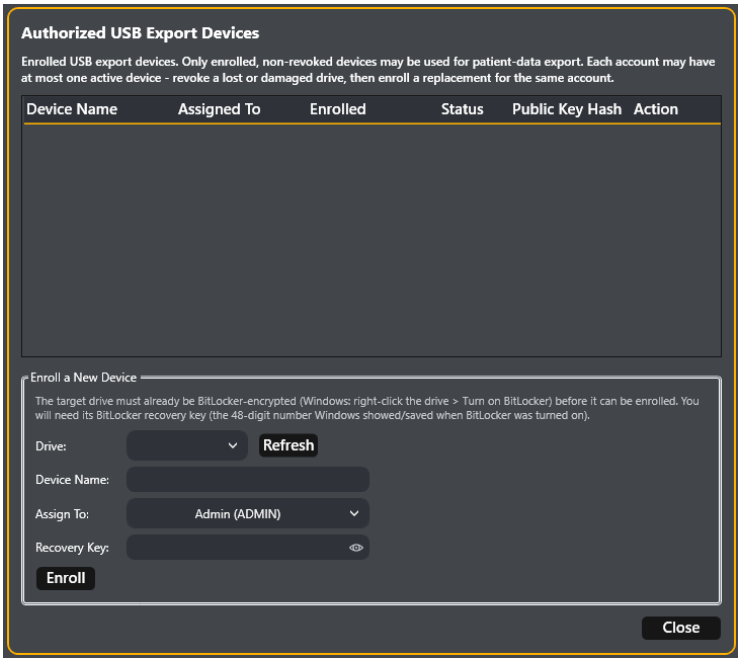


3.1.6.2 Authorized USB drives for Patient data export

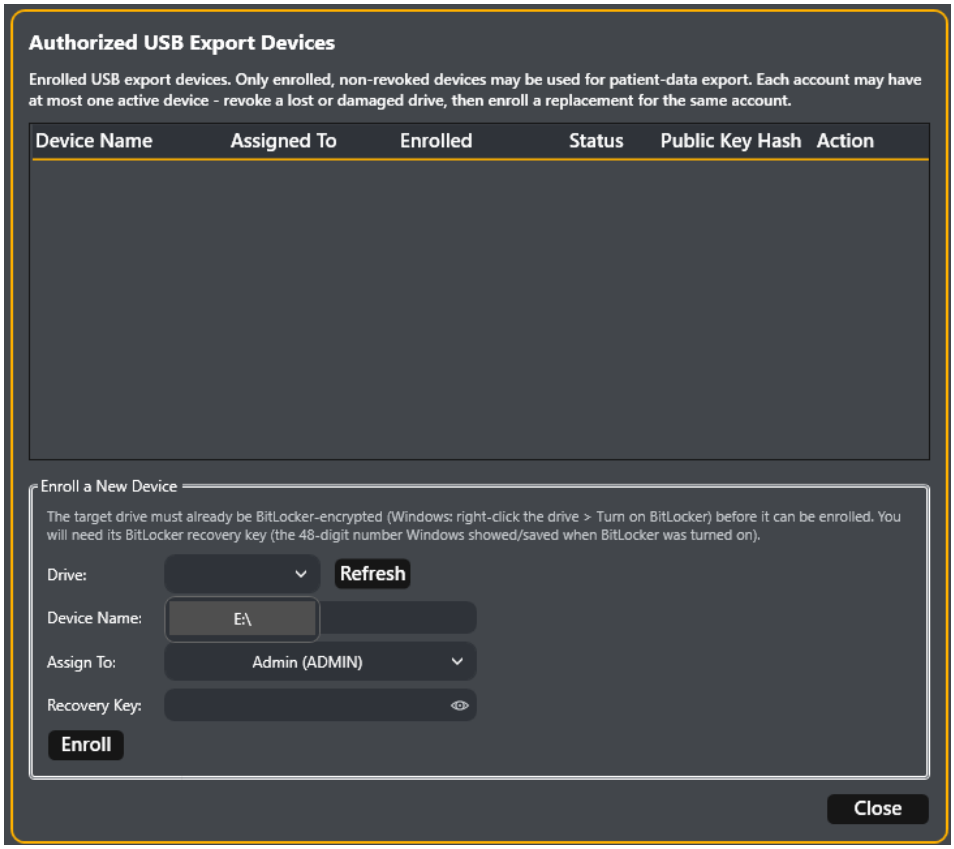
- Login the application as Service and navigate to Setting->USB Device Management



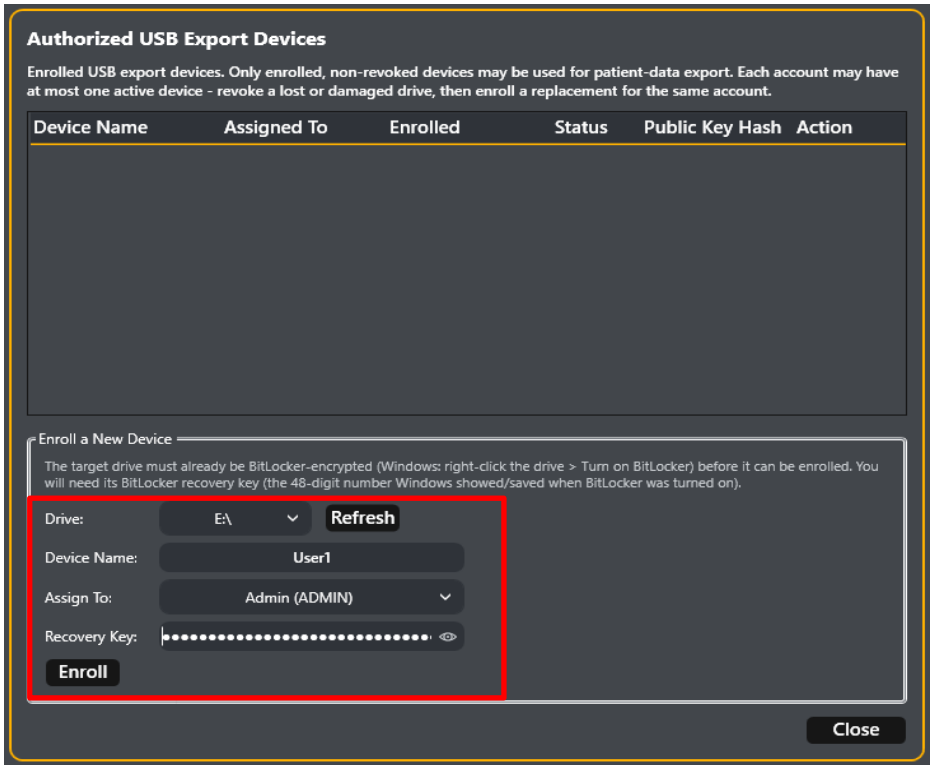
- Click "Manage Authorized USB Devices..." button



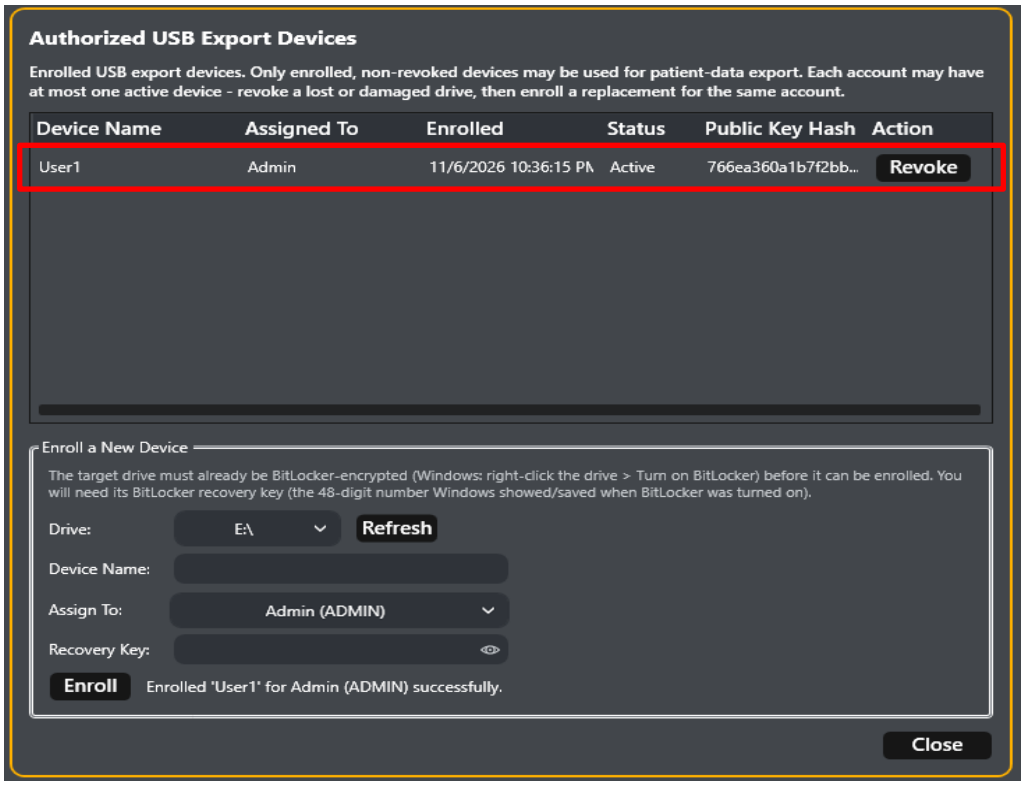
- Connect the Pen drive to enroll in the MAXIO application.
- Click Refresh button.
- Click dropdown and Select the Device Path



- Enter the Device Name.
- Select Assign To enter the Recovery Key (copied from section 3.1.6.1), and click the Enroll button.



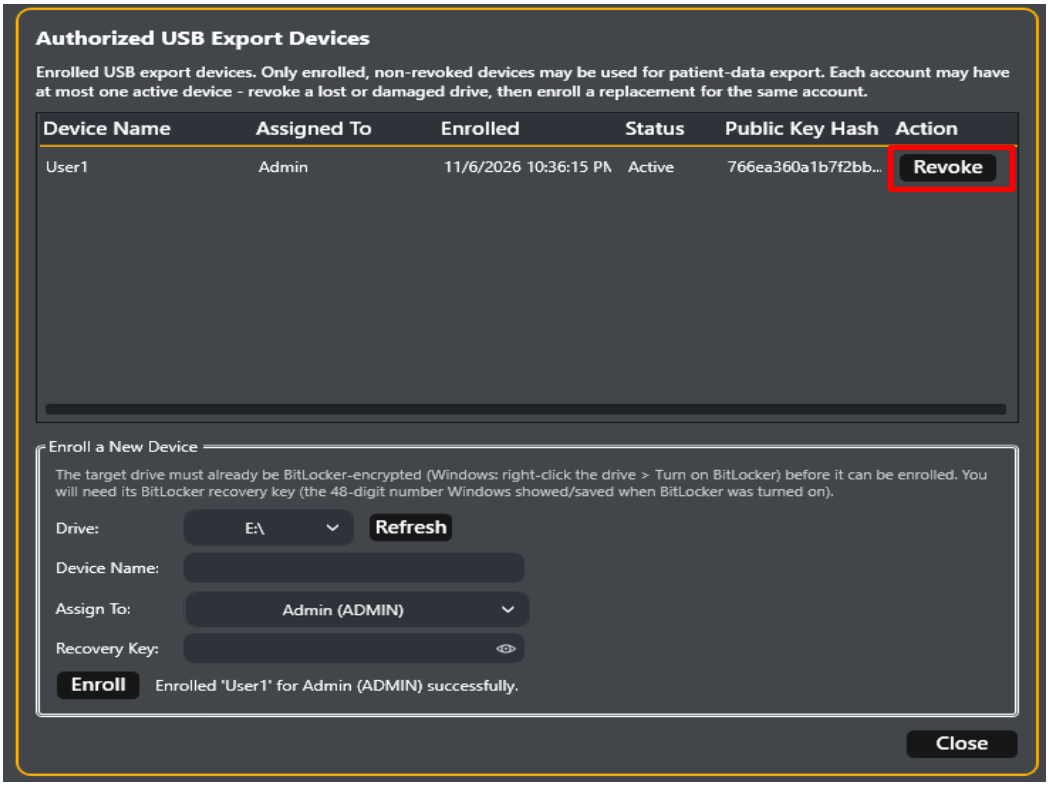
- The application shall list the details of the enrolled pen drives



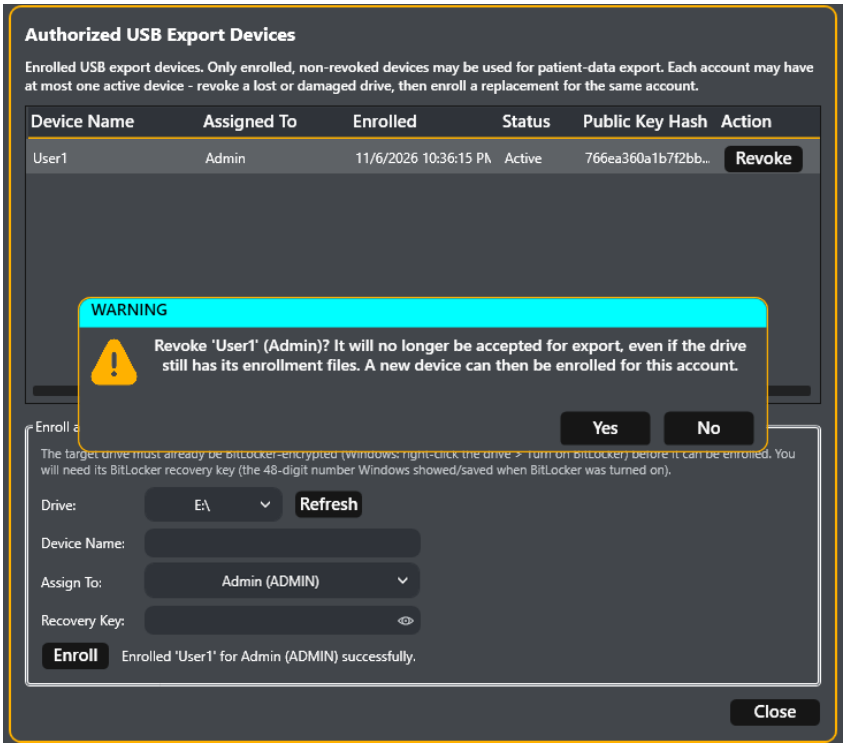
Revoke Pen drive

Note: If you want Unenroll the Pen drive then follow the below steps

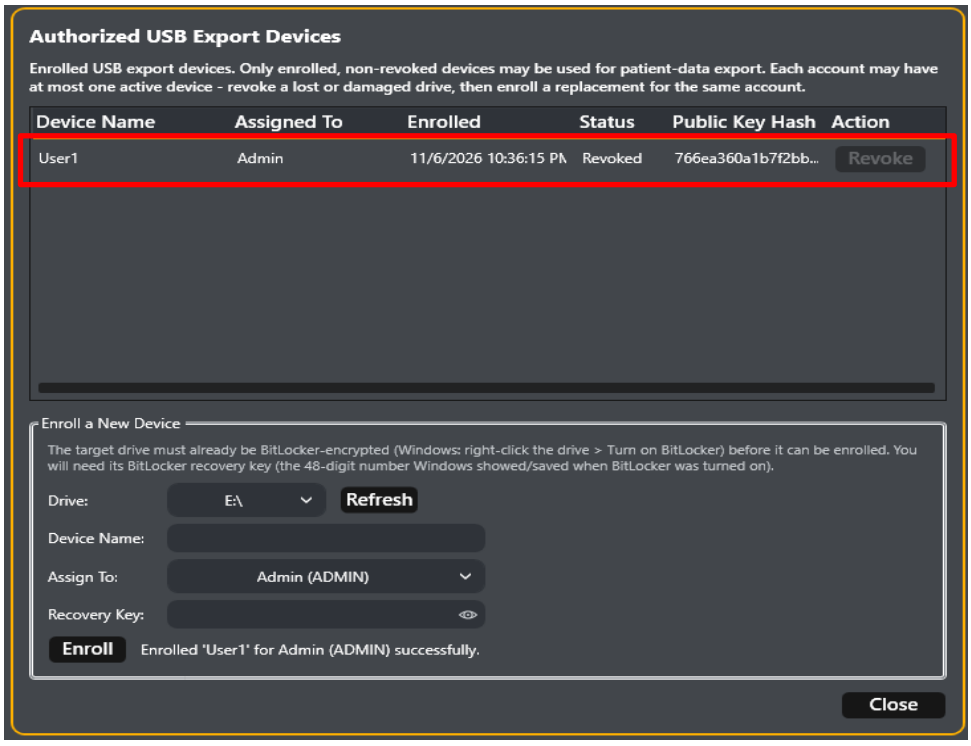
- Click Revoke button



- Click Yes

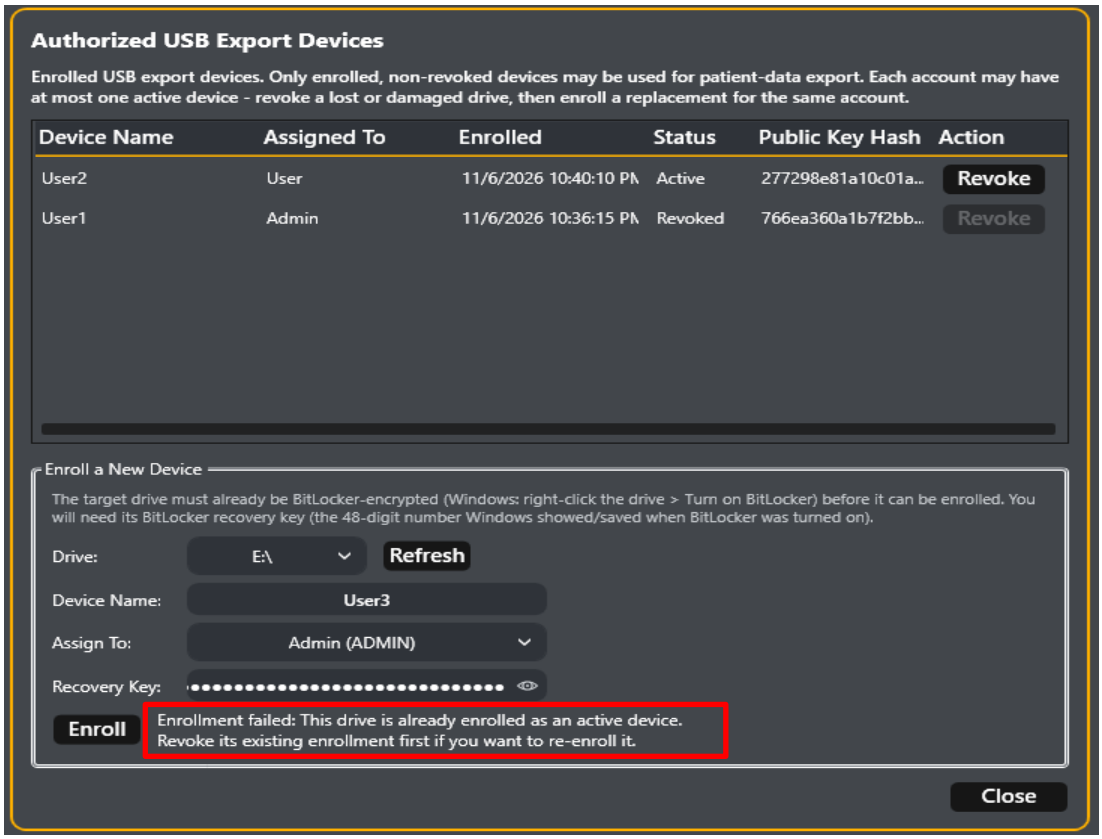


- Application successfully Revoke the USB Drive



The USB drive is already registered to another user account and cannot be registered again under a different user account while the existing registration is active.

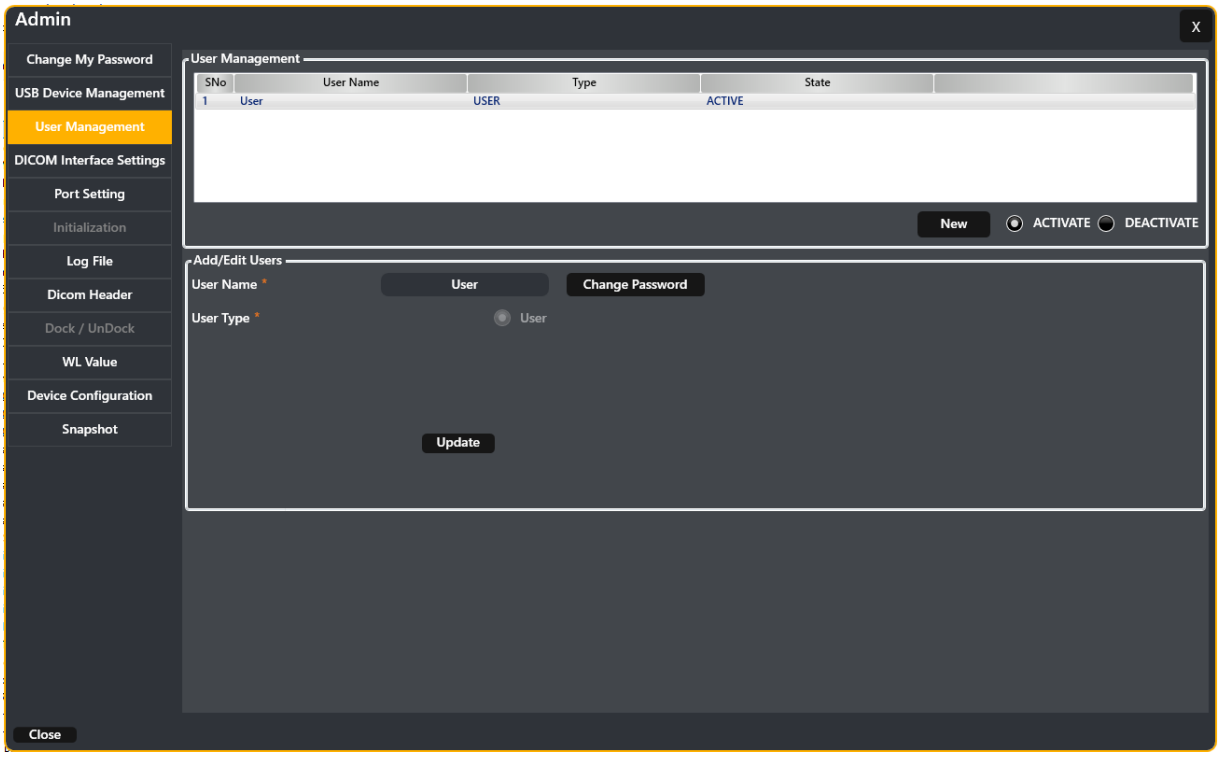
If a user attempts to register the same USB drive, the application shall display the following image:



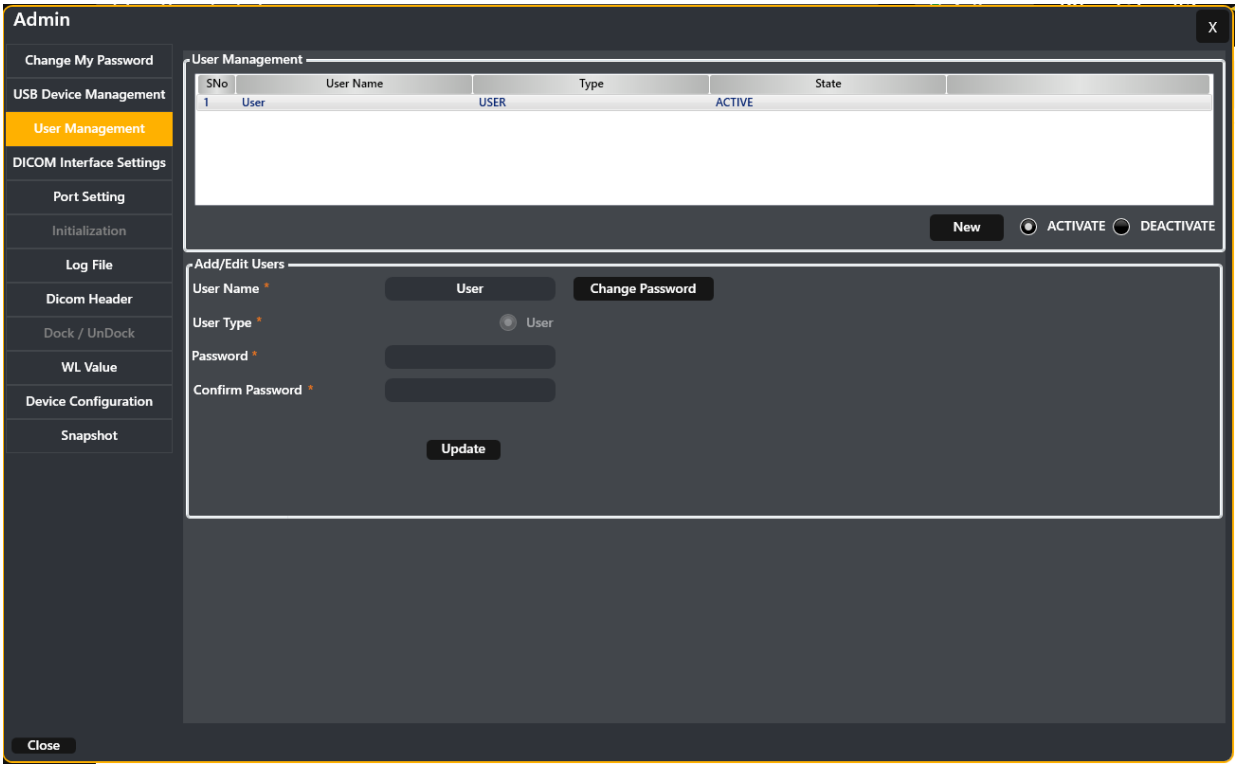
3. User Management: User logins can be created. The admin also has the facility to update the passwords of existing users.

To change an existing user's password, follow the steps below:

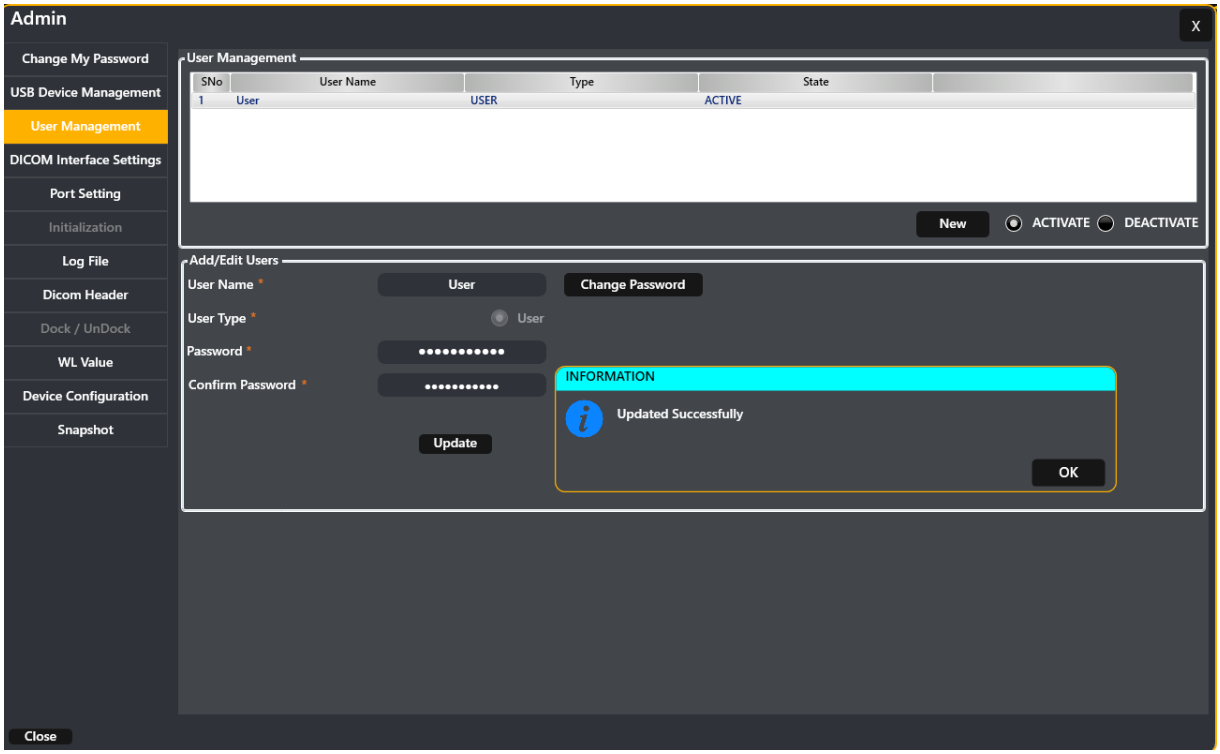
- Select the required user from the listed users



- Click Change Password.

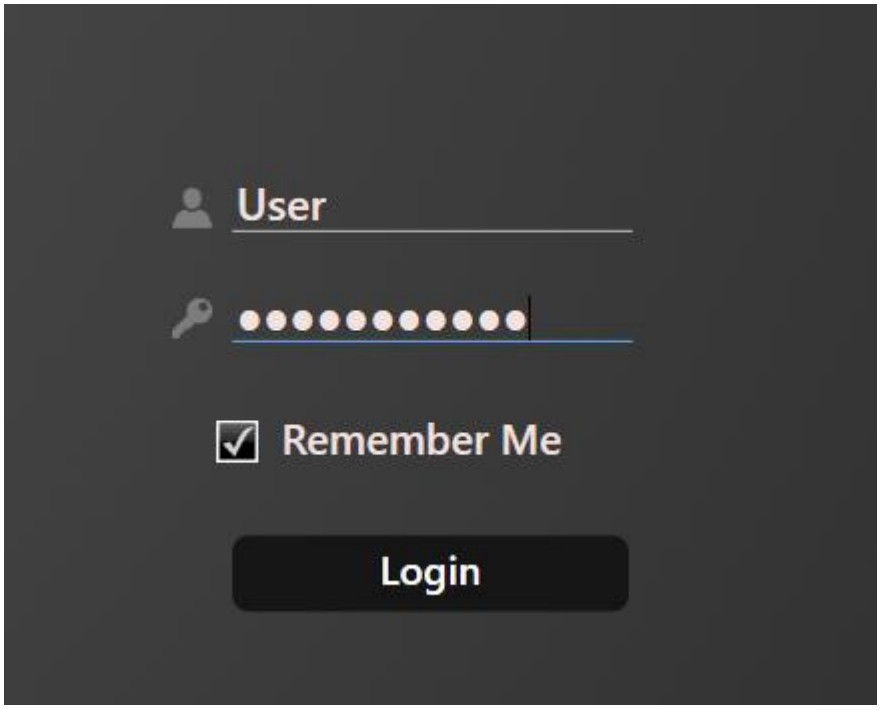


- Enter the new password in the Password field.
- Re-enter the new password in the Confirm Password field.
- Click Update.
- A success message shall be displayed confirming that the user's password has been changed successfully

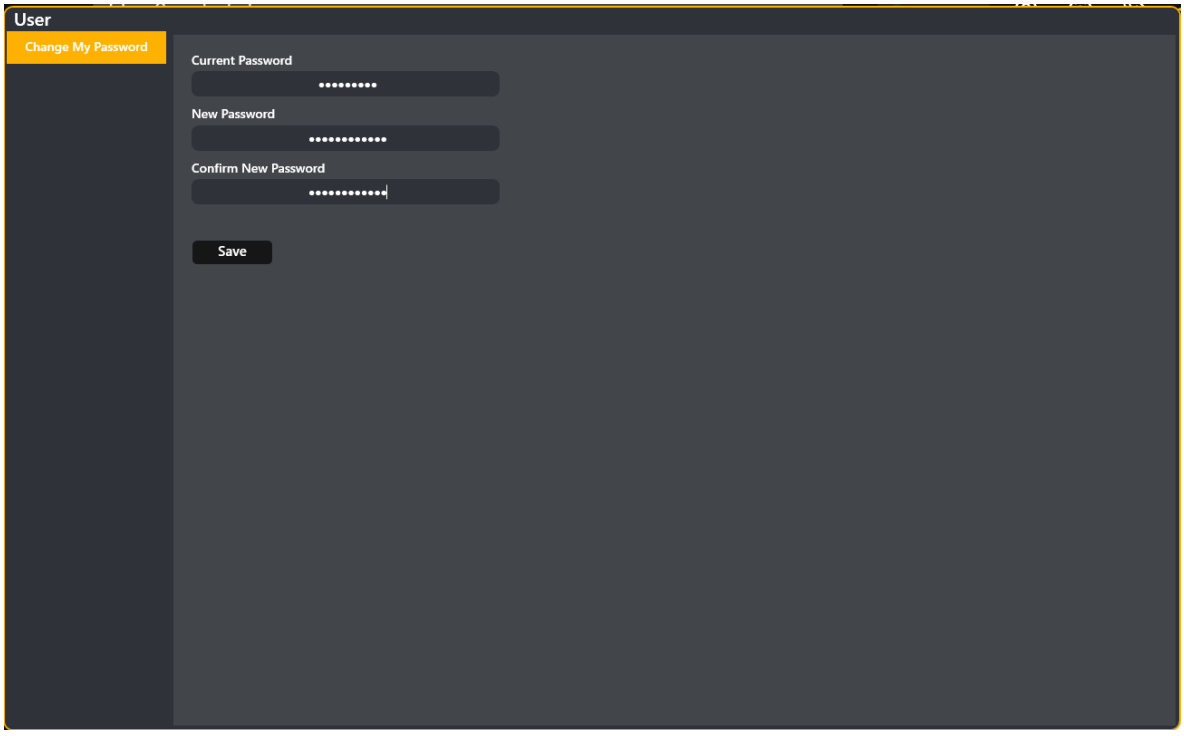


If the admin changes a user's password, the user must change the password again when logging in with the password provided by the admin.

Log in as a user using the password provided by the admin.

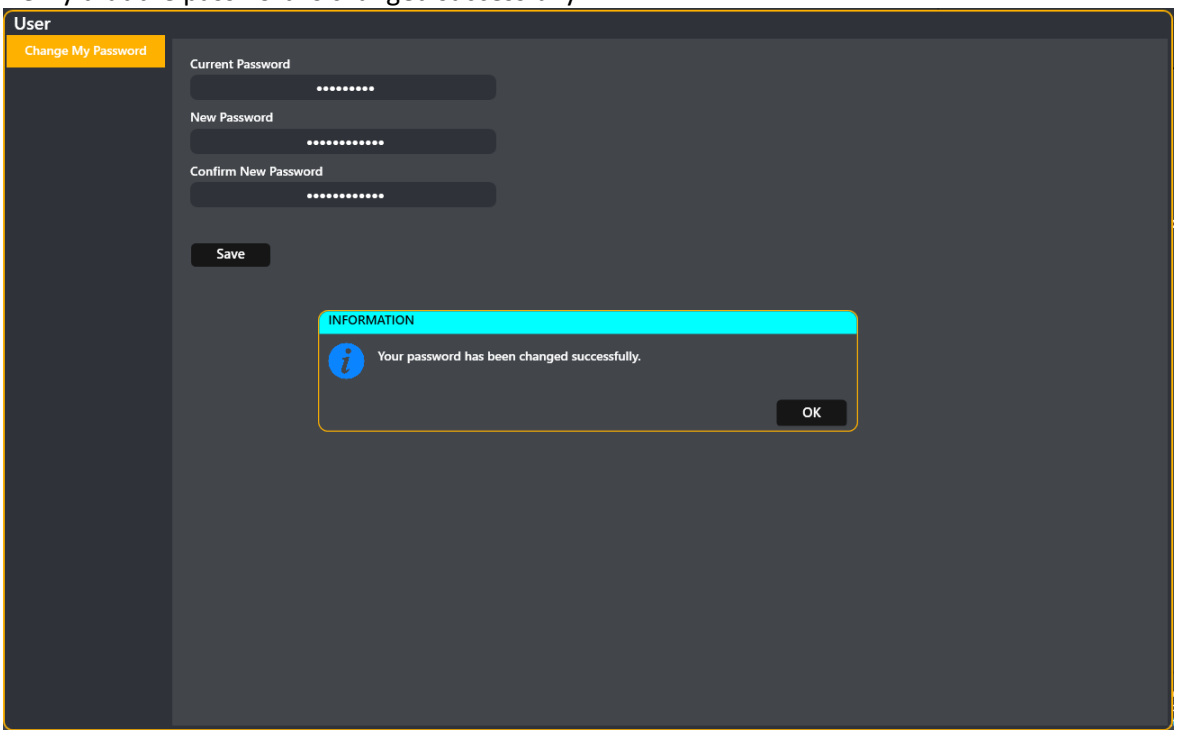


- Enter the Current Password
- Enter New Password
- Enter Confirm New Password



- Click Save button

- Verify that the password is changed successfully.



4. DICOM Interface Settings: Allows the configuration of the MAXIO® as host to the CT console for CT image transfer. This option allows the user to enter the AE title, port address and check for connectivity.
5. Port Setting: Allows the administrator to select the communication port of the MAXIO® PC through which data will be communicated to the MAXIO® and also to select tilt sensor port to allow tilt sensor to communicate with the MAXIO®.
6. Initialization: After a successful Power-On Self-Test, MAXIO is initialized either by pressing the Home key on the control panel or by selecting Initialization in the application; the axes are homed to their reference positions and communication with the application is established. The device reports 'Ready' by showing all status indicators in green and becomes available for use only after initialization is successful.
7. Dock/Undock: Allows the user to Dock/Undock the device.
8. Log File: Allows the user to browse and export log data related to their own previously performed procedures. The user can export only their own data and cannot access or export data belong to other users.
9. Device Configuration: Gives device configured values, calibration values in admin login for users reference. Restart the DICOM interface if images are missing during transfer.
10. Snapshot: Allows users to view and export their own procedure snapshots and generate procedure reports for a specified date range (DDMMMYYYY), including patient and procedure details, tumor segmentation, and needle planning and positioning details. Users cannot access other users' snapshots.

	Ensure right level of access is provided to MAXIO® operators. For non admin operators users of MAXIO®, provide only user level access.
	Ensure that the IP address for MAXIO® planning station is provided and managed by the hospital IP administrator. With such IP address, MAXIO® shall communicate with the CT console within the local PACS and shall not be used to connect to the external Internet.

	Ensure that the computers/servers connected to MAXIO® Planning station are protected with Anti- Virus and Anti-Malware software.

3.2 Procedure Setup Screen

The setup screen of the application gives information to the user to choose the MAXIO® Docking side, perform table marker check and select the respective procedure details. Below image is the representation of the setup screen.

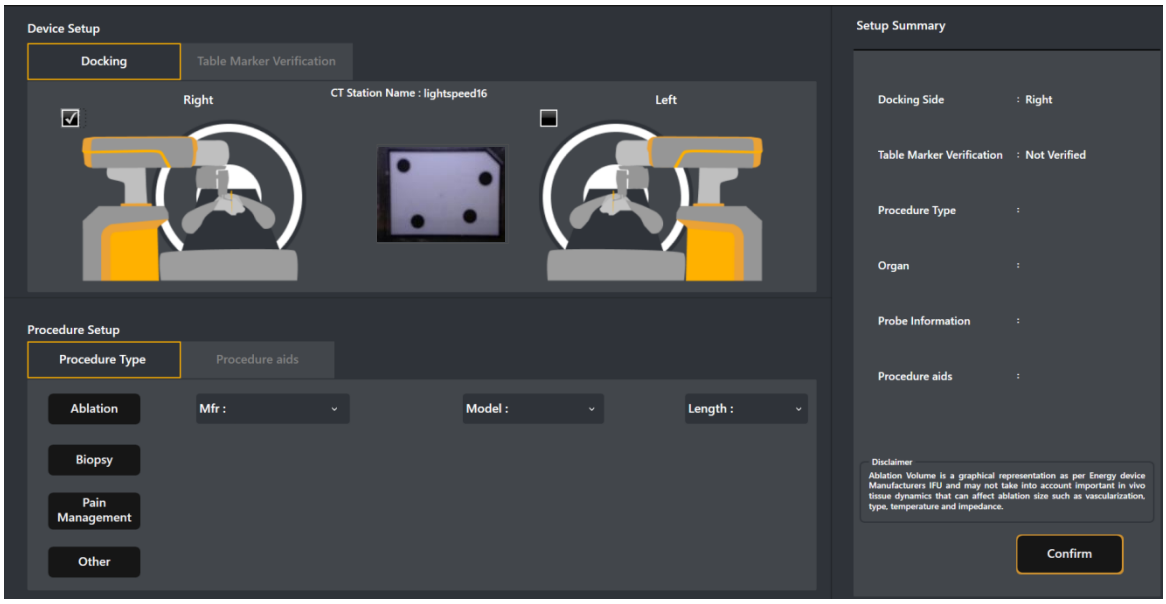


Figure 3.5 a) *Procedure setup screen* *(NOT APPLICABLE FOR U.S)

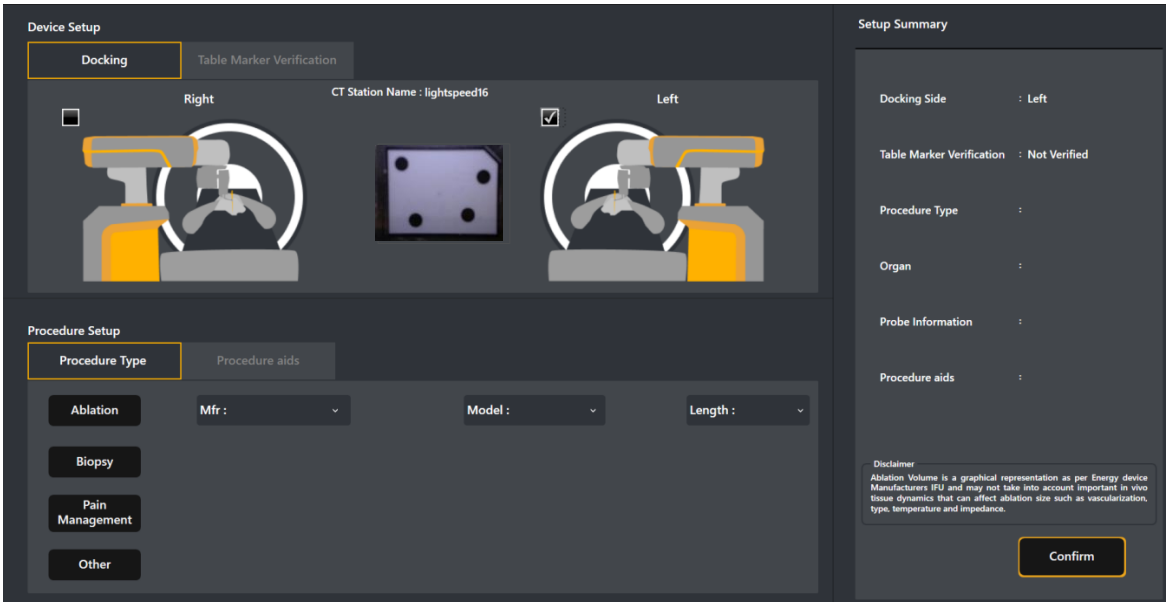


Figure 3.5 b) *Procedure setup screen * (APPLICABLE ONLY FOR U.S)*

3.2.1 MAXIO ® DOCKING

Dock MAXIO® on the InstaReg mat to register it to the CT system.

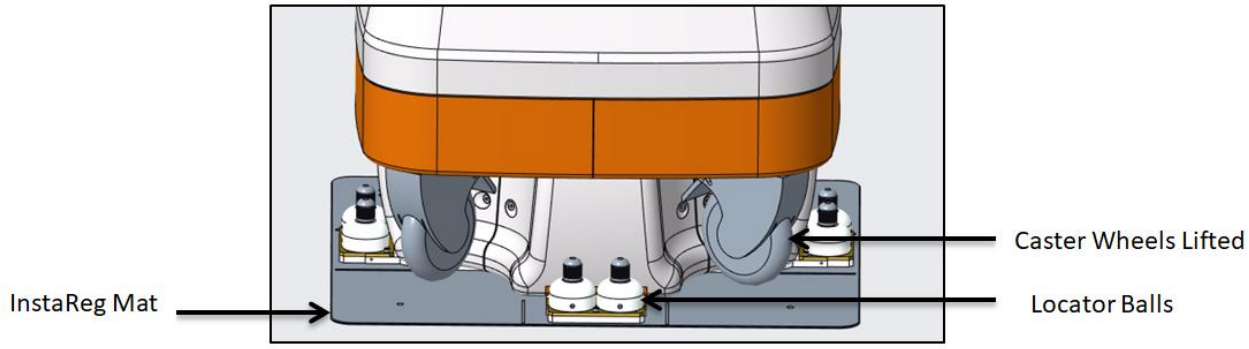


Figure 3.6 *Docking*

To dock MAXIO®:

1. Before docking, ensure that the rubber plug is removed from that InstaReg Mat.
2. Docking side should be selected based on the tumor location with reference to the gantry side.
3. Select the docking side; match the reference pattern in the planning station and pattern in the docking plate.
4. Press the Docking button, after blue light glows press dock key again. After first step of docking check if the pattern displayed in the planning station and the pattern on the docking plate is matching and press dock key on the Control Panel. The locator balls will rest on the locator holes and MAXIO® wheels will be lifted. The pattern on the InstaReg mat will be displayed on the main planning station screen.
5. As the docking progresses gently guide MAXIO® to more closely align with the pattern. If MAXIO® is positioned and guided correctly it will dock smoothly on the InstaReg mat.
6. The Docking and Tracker status icon will turn green when MAXIO® is correctly aligned with the InstaReg mat pattern. The base of the MAXIO® docking module has a camera that detects the pattern and a tilt sensor that detects the device tilt values. These are compared with calibration values set during installation
7. On the Main Planning Station screen, the InstaReg tracker and tilt sensor status icon will turn green if the pattern and tilt values match
8. If either of the device status icons displays red, or if MAXIO® docks with a jerk, press the Docking button again to undock the device and dock again.

	WARNING: Loose or improper docking of MAXIO® to the InstaReg mat may result in inaccuracies in the procedure. User cannot perform the procedure if, the Docking or Tracker status icons on the Main Screen do not display green. Additionally, do not perform the procedure if the table marker verification is not successful. Contact Perfint Customer Support for MAXIO® servicing
	WARNING: MAXIO® docking procedure cannot be completed successfully in the event of damage to the InstaReg mat and hence MAXIO® stereotactic arm cannot be activated for instrument placement. Contact Perfint Customer Support for InstaReg mat servicing.

	WARNING: MAXIO® docking procedure cannot be completed successfully if dust, dirt, liquid or any other material is present on the pattern or in the locating holes in the mat. Hence MAXIO® stereotactic arm cannot be activated for instrument placement. Carefully follow cleaning instructions (see chapter 12) to keep the holes in the plate clean.
	WARNING: Wrong selection of docking side could result in device registration failure; user should take care while choosing docking side to continue the procedure
	WARNING: Wrong selection of CT station could result in device registration failure; user should take care while choosing CT station to continue the procedure.

Choose the respective Docking side based on the actual device docked location, as shown in the Figure 3.7 below.



Figure 3.7 *Docking side selection*

3.2.2 Table Marker Verification

The Table Marker is a fixed reference point between the CT table and MAXIO®. The marker is adhered to the table during system installation and calibration. Table Marker Verification is the process of using the laser light to check the alignment of MAXIO® to the reference point on the CT table prior to each procedure. After successful device docking, application shows information to the user to proceed to Table Marker Verification.

To verify the Table Marker:

1. Click on the Table Marker button on the task pane as shown below:



Figure 3.8 *Table Marker button/ Table marker verification*

2. MAXIO® axes values for table marker verification will be sending to the device and the following pop up is displayed.

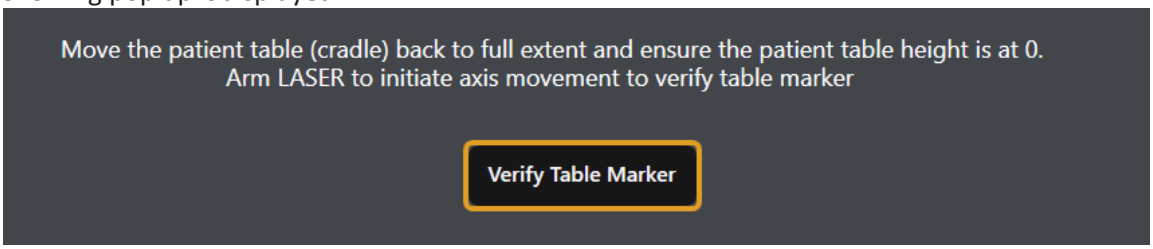


Figure 3.9 *Table Marker Verification POPUP*

3. Move the CT cradle and adjust the table height to the values displayed in the pop up.

4. Pull down the laser cross-hair unit to turn on the laser pointer.
5. If the laser cross-hair aligns with the table marker, proceed with the procedure, click 'yes'.

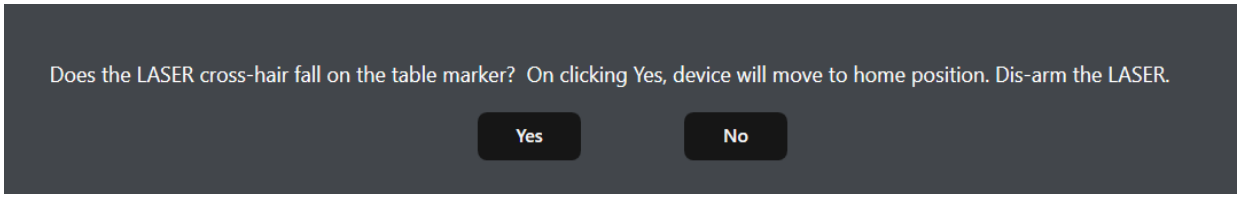


Figure 3.10 *Table Marker Confirmation POPUP*

6. If the laser cross-hair does not align with the table marker abort the procedure, click 'No' and contact Perfint Customer Support.

⚠	WARNING: Do not proceed with the procedure if the laser crosshair does not fall on the table marker during table marker verification. A mismatch indicates that the device positioning has been disturbed. Contact Perfint Customer Support. NOTE: Device positioning may be disturbed by an accidental impact, a change in axis range, or a change in laser arm position

3.2.3 Procedure Type

MAXIO® provides the user with a set of procedures to choose, based on the respective type of procedure to be performed. U.S users can select procedure type with segmentation or without segmentation and for other countries procedure types such as, Ablation, Biopsy, Pain Management and Other types of procedures and the option to select the Organ of Interest for which the procedure is being performed. Based on the type of procedure chosen by the user, MAXIO displays the Probe/Needle manufacturer with corresponding Probe/Needle model and length. The below figure is a representation of the procedure type selection.

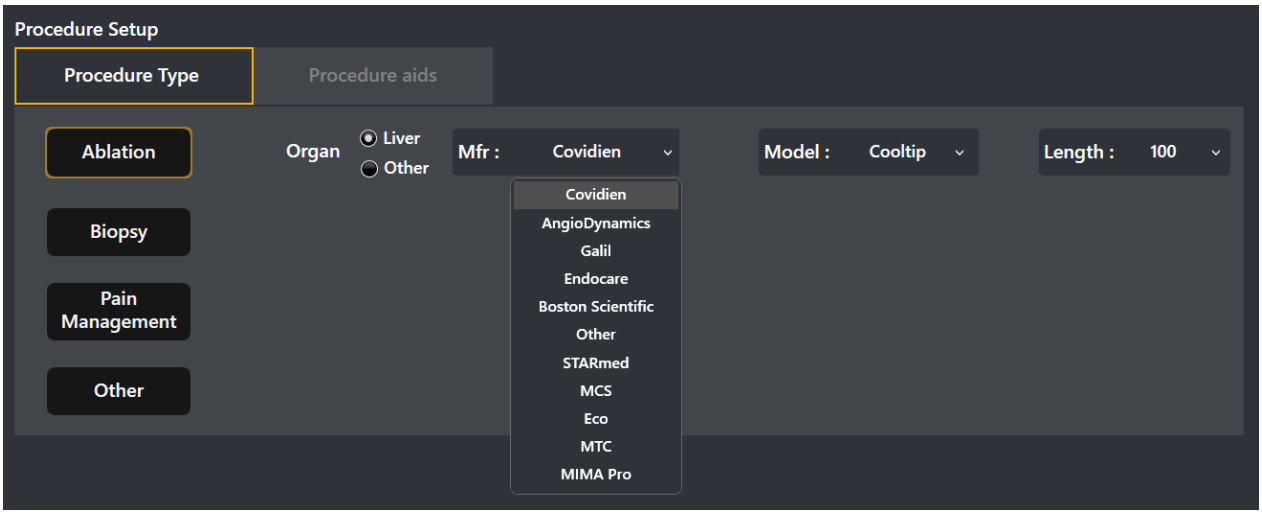


Figure 3.11 a*) Procedure Type Selection *(NOT APPLICABLE FOR U.S)*

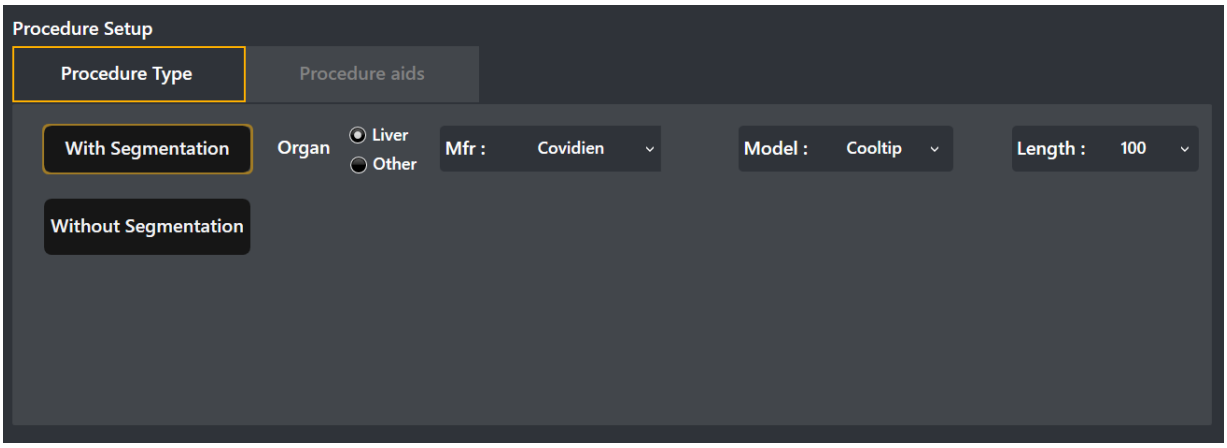


Figure 3.11 b) *Procedure Type Selection* *(APPLICABLE ONLY FOR U.S)

3.2.4 Procedure aids

MAXIO provides the ability to choose different procedure aids for performing the procedure. The procedure aids include Skin marker, Immobilizer bed and Breath hold monitor, for U.S users all procedure aids are mandatory.

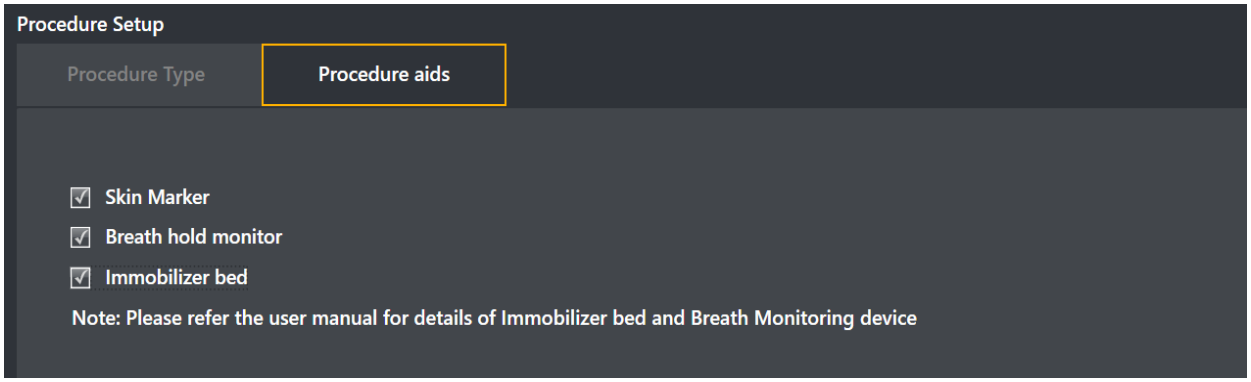


Figure 3.12 *Procedure Aids Selection*

Refer Section 4.1.3 for Skin marker placement on the patient.

Refer Section 4.1.2 for Patient Immobilizer bed

Refer Section 4.1.1 for Breath Hold Monitor

Once selecting all the required details for the Procedure setup, Setup summary is displayed on the right side which provides details on the procedure selected. Select 'Confirm' to proceed to load patient image.

⚠	NOTE: The ablation volume displayed represents published manufacturer data created on a homogeneous mathematical liver tissue model that does not consider factors like saline perfusion, vasculature or any other real clinical condition. This may be used only as a starting point for user to estimate ablation volumes and under no condition be assumed to represent the expected ablation volume.

3.3 Base Screen

The base screen of the application is the principle interface for all subsequent actions performed through the application during the image loading, planning, implementation and report generation phases of the procedure. The base screen structure remains the same throughout the procedure. Changes in procedural steps are accompanied by changes in functionality and functional elements shown in the base screen.

The base screen of the application interface may be divided into 8 sections as shown in the figure 3.13 below:

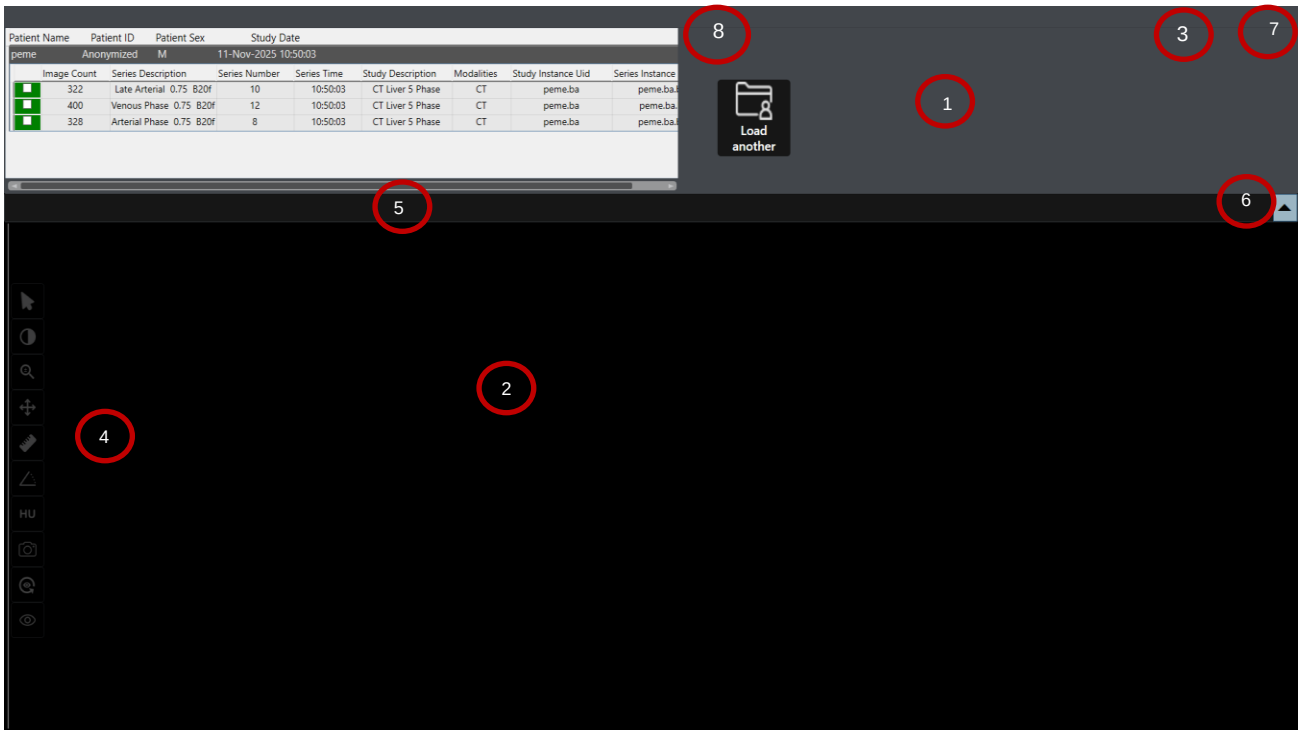


Figure 3.13 *Base Screen*

3.3.1 Task pane (Section – 1)

The Task Pane contains selection option for all functions (or task) to be performed by the user in each procedure workflow step. The number and type of these tasks varies from one procedure step to other.

3.3.2 Image window (Section – 2)

Loaded patient series is displayed in this window in various views as shown in the figure 3.14. The user has option to scroll between the image slices or change the orientation in this window.

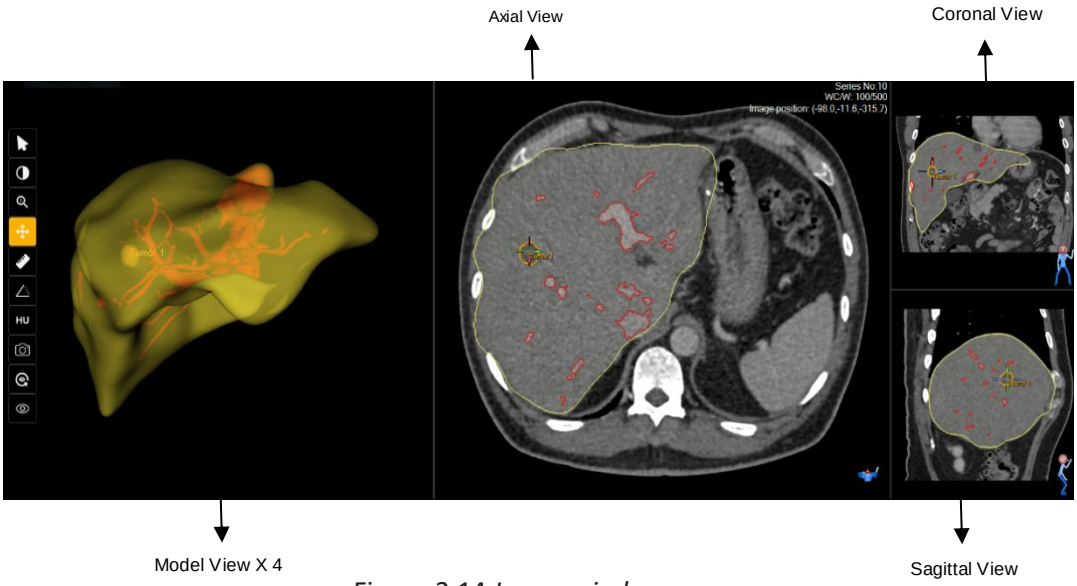


Figure 3.14 *Image window*

3.3.3 Device Status Icons (Section – 3)

This section of the application interface screen displays the status of various device related modules like Communication (1), Emergency (2), Docking (3), Tracker (4) , TiltSensor (5), DICOM Interface (6), PC Battery (7) and Device Battery (8), as shown in the figure 3.15.The icons changes from green to red based on their status respectively. The device status is monitored continually during the procedure and the information updated in the status icon almost instantly.

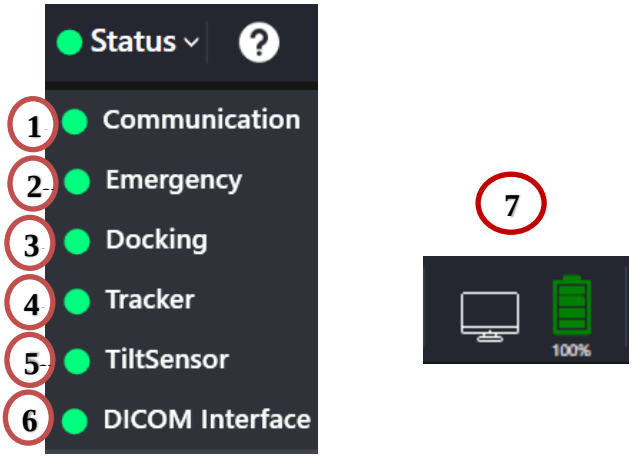
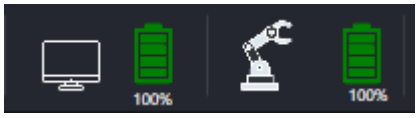


Figure 3.15 *Machine Communication Status Bar*

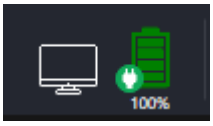
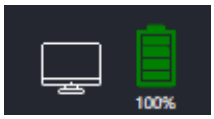
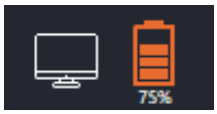
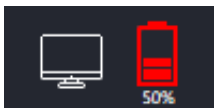
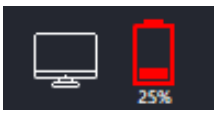
1. Communication - The Green color on this icon indicates a successful connection between the electromechanical arm and the planning station. The red color on this icon indicates a connection error.
2. Emergency - Green color on this icon indicates that the device is in functional stage and the red color on this icon indicates switch is pressed. Device cannot be used when 'Emergency switch' is triggered.
3. Docking - The Green color on this icon indicates the MAXIO® device in docked condition and the red color on this icon indicates the MAXIO® device is not docked.
4. Tracker - Green color on this icon indicates the Tracker is within the range and the red color on this icon indicates isn't within range and hence docking is not proper. MAXIO® can be operated only in case of successful docking.

5. TiltSensor- Green color on this icon indicates the TiltSensor is within the tolerance value and the red color on this icon indicates isn't within tolerance value and hence docking is not proper. MAXIO® can be operated only in case of successful docking.
6. DICOM Interface - The Green color on this icon indicates that the DICOM receiver module and the MAXIO® device are connected and the red color on this icon indicates that the DICOM receiver module and the MAXIO® aren't connected.
7. Battery Status - The battery status icon displayed in the status bar represents the battery with the lowest charge percentage between the PC battery and the device battery.

   Clicking the battery status icon displays a pop-up showing the charge percentage of both the PC battery and the Device battery.

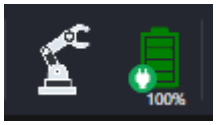


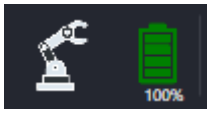
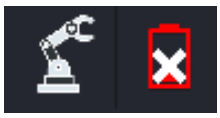
The table below provides an overview of the PC battery status icons and their corresponding descriptions

	**AC Power Connected**: The PC battery indicator shows a plug-in icon when AC power is connected.
	**Battery Charge ≥ 75%**: Green icon with four bars indicates the battery charge is 75% or more.
	**Battery Charge Between 75% and 50%**: Orange icon with three bars indicates the battery charge is between 75% and 50%.
	**Battery Charge ≤ 50%**: Red icon with two bars indicates the battery charge is less than 50%.
	**Battery Charge ≤ 25%**: Red icon with one bar indicates the battery charge is less than 25%.
	**Unknown Battery Status**: If the battery status cannot be determined, a cross (✕) symbol is displayed, indicating an unknown battery condition.

Device Battery Status

The table below provides an overview of the Device battery status icons and their corresponding descriptions

	**AC Power Connected**: The Device battery indicator shows a plug-in icon when AC power is connected.

	**Battery Charge ≥ 75%**: Green icon with four bars indicates the battery charge is 75% or more.
	**Battery Charge Between 75% and 50%**: Orange icon with three bars indicates the battery charge is between 75% and 50%.
	**Battery Charge ≤ 50%**: Red icon with two bars indicates the battery charge is less than 50%.
	**Battery Charge ≤ 25%**: Red icon with one bar indicates the battery charge is less than 25%.
	**Unknown Battery Status**: If the battery status cannot be determined, a cross (✕) symbol is displayed, indicating an unknown battery condition.

3.3.4 Tool bar (Section – 4)

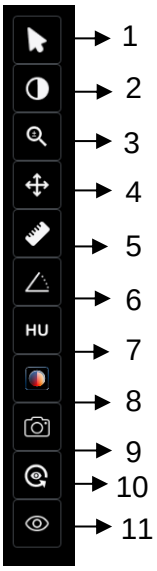


Figure 3.16 *Tool Bar*

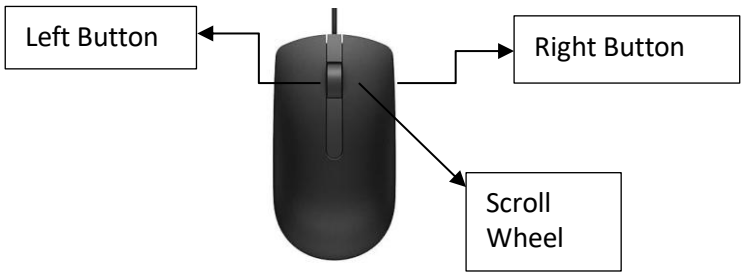
1. Arrow: Pointer tool can be used for the selection of objects and tool by clicking on. Place the pointer over the radio button and tools in any screen to display the tool tip. The Arrow tool is not applicable in 3D when the feature “High-quality rendering in 3D visualization” is enabled. In this mode, selection is performed by left-clicking and dragging the mouse instead of using the Arrow tool
2. Window Level for CT image: Select tool and left click in the touch pad / Mouse and Drag up and down, left and right sides in the 2D views to adjust the required brightness.
3. Zoom: Select the tool and left click in the touch pad / Mouse and scroll up to Zoom out and scroll down to Zoom in. The Zoom tool is not applicable in 3D when “High-quality rendering in 3D visualization” is enabled. In this mode, you can use the mouse wheel—scroll up to zoom in and scroll down to zoom out—and you can also right-click and drag upward to zoom in or drag downward to zoom out.
4. Pan: Select the tool and left click in the touch pad / Mouse and move the 2D/3D image by moving the cursor. The Pan tool is not applicable in 3D when “High-quality rendering in 3D visualization” is enabled. In this mode, panning is performed by clicking the mouse wheel and dragging.

5. Ruler: Select the tool, right click in the touch pad / Mouse and move the cursor to the desired point to measure the distance.
6. Angle: Select the tool, right click in the touch pad / Mouse and move the cursor to the desired point to measure the angle.
7. HU: Select the tool and place the cursor in the desired point in the 2D image soft tissue/bone/any other structure, to view the HU (Hounsfield unit) of the point is displayed corresponding to the structures.
8. Modify PET-CT Opacity: Utilize the "Modify PET-CT Opacity" option to change the opacity of the PET image and to fine-tune the window level.
9. Screen capture: Select the tool to capture the screen, the captured screen is saved and displayed in the report screen when the report button is selected. The desired image can be selected to show in the report.
10. Reset: Select the tool to revert the last step.
11. Text Show/Hide: Select the tool to show or hide the text of the patient details in image area.

3.3.5 Components Of Optical Mouse (Section – 5)

1. Left Button: For selecting and clicking items.
2. Right Button: For context menus and additional options.
3. Scroll Wheel: However over the 2D-image and scroll up/down to change the image slice.

   Click and hold the Mouse scroll wheel and then drag the Mouse left/right/up/down to adjust the window level and window width in 2D-image.



☞	Auto snapshots can be taken in segmentation, Plan, Position, Intra-Operative and Post procedure registration screen.

3.3.6 Information bar (Section – 6)

Display general information including prompts for the next procedure step, alerts and alarms.

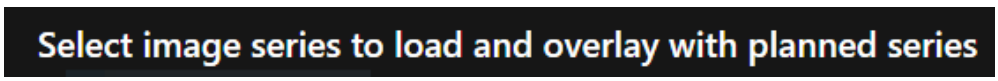


Figure 3.17 Information bar

3.3.7 Enlarge View Button (Section – 7)

This button helps to maximize or minimize the image window for a better image visualization as shown in the figure 3.18a & b below

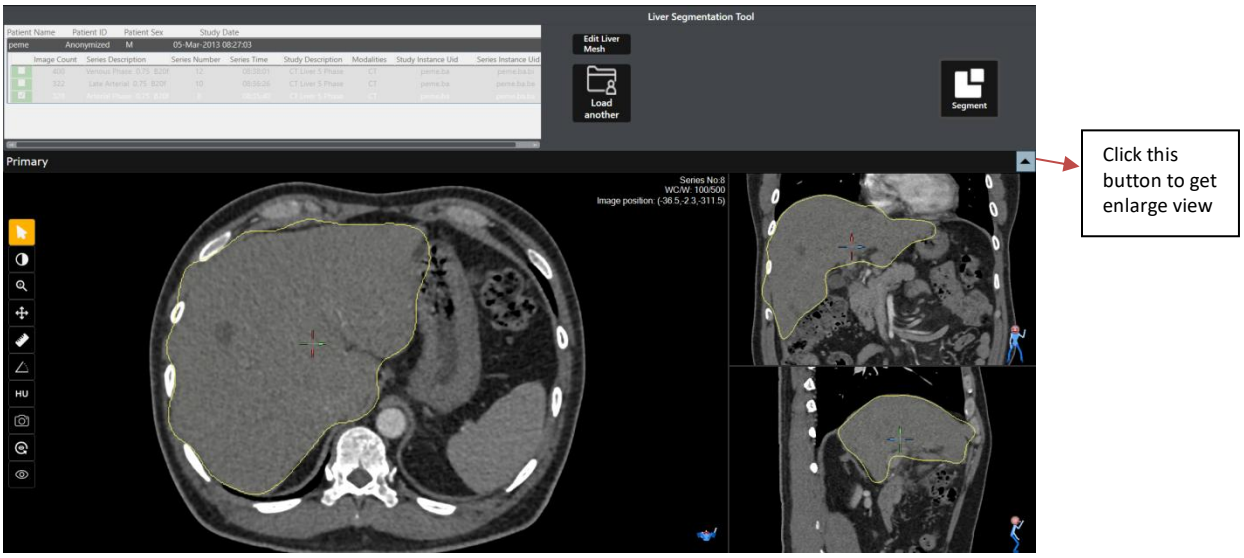


Figure 3.18 a) *Minimized Screen (default)*



Figure 3.18. b) Maximized Screen

3.3.8 System Function Buttons (Section – 8)

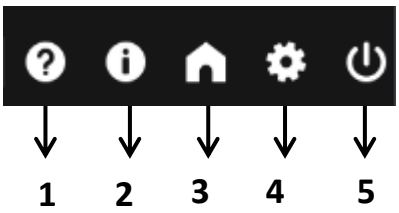


Figure 3.19 *System Function Buttons*

1. Help Button - Provides MAXIO® help to the user.
2. About Button – provides users with the manufacturer name, software version, build number, Basic

UDI-DI, UDI-DI, intended purpose and CE mark with NB ID of the device.

Version Number Format:

- X: Major-level change.
- Y: New requirement, improvement, or multiple bug fixes.
- Z: Patch release for a single bug fix related to regulatory requirements or device compatibility (e.g., V2.5.15.1).

Build Number Format: MAXIOUI_yyyymmdd.id

- **yyyy:** Year.
- **mm:** Month.
- **dd:** Date.
- **id:** Build identification number.(e.g., MAXIOUI_20261008.1).

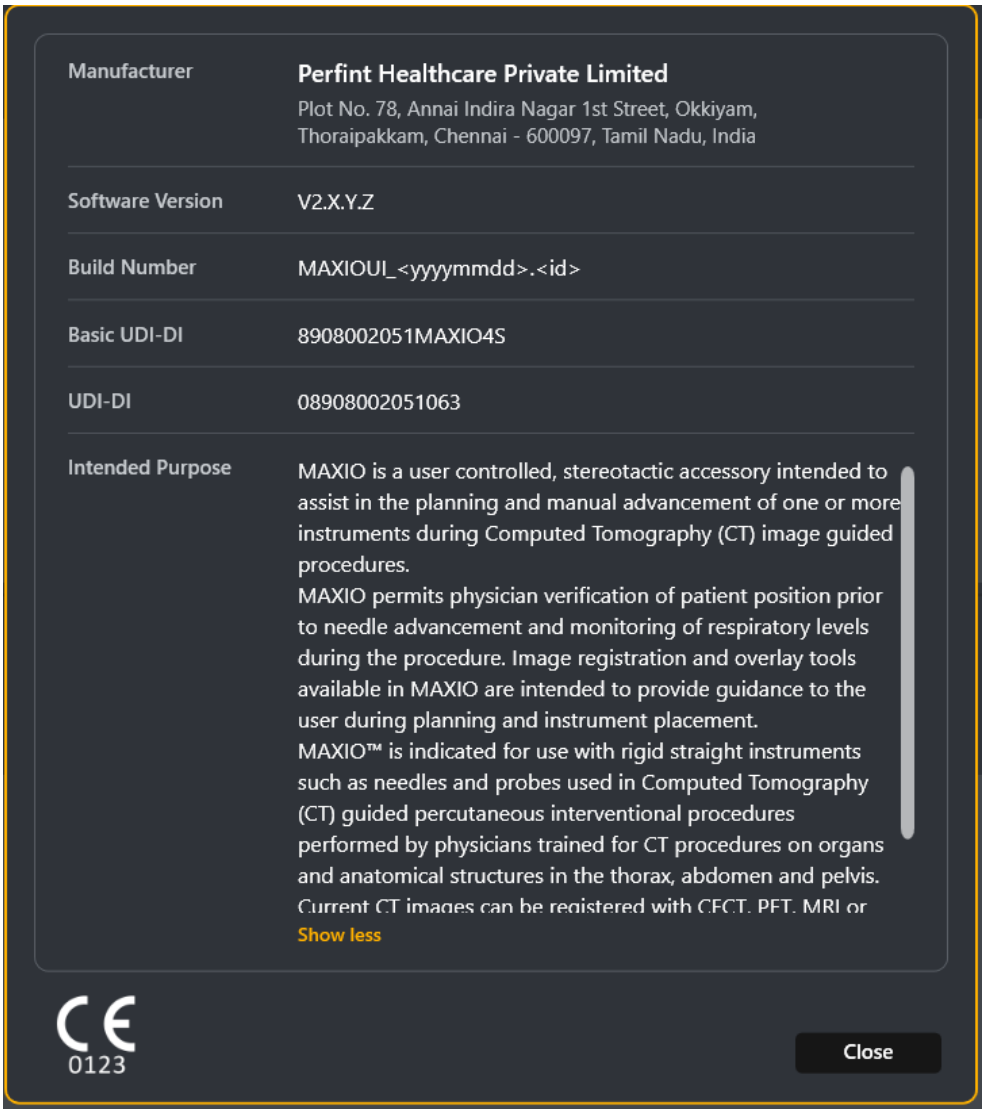


Figure 3.24 About screen

3. Home Button - Indicates the type of procedure, organ treated and the docking side.
4. Settings - MAXIO® values can be configured through this button. Below image shows in detail on functions of settings button.
5. Log OFF / Shutdown - Log OFF button helps to Logout from the procedure and takes user to the login screen. Shutdown button helps to shut down MAXIO®.

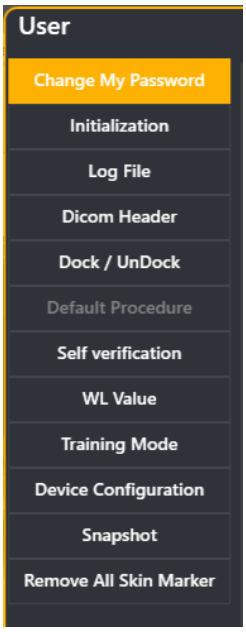


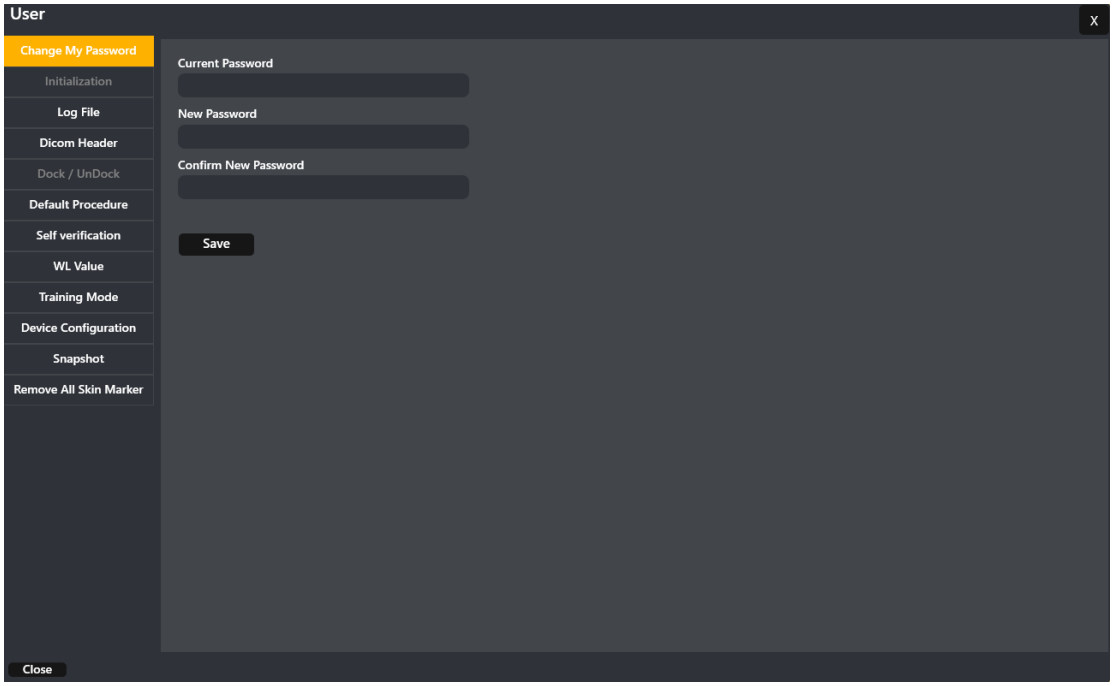
Figure 3.20 *Setting button functions*

1. Change My Password: The admin user has the option to change their password.

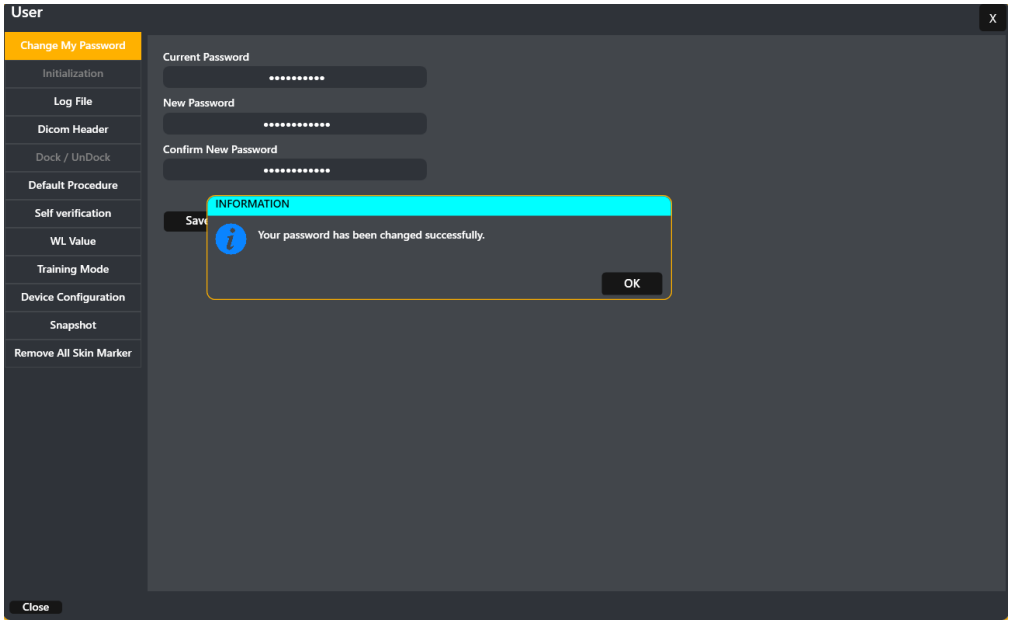
To Change user's password, follow the steps below

- Click Change My Password

☞	Ensure that the new password meets the following password requirements: ○ Minimum length: 8 characters ○ Maximum length: 15 characters ○ At least one uppercase letter (A–Z) ○ At least one lowercase letter (a–z) ○ At least one numeric character (0–9) ○ At least one special character (e.g., @, #, $, %)



- Enter Current Password , New Password and Confirm New Password and click Save



2. Initialization: After a successful Power-On Self-Test, MAXIO is initialized either by pressing the Home key on the control panel or by selecting Initialization in the application; the axes are homed to their reference positions and communication with the application is established. The device reports 'Ready' by showing all status indicators in green and becomes available for use only after initialization is successful
3. Dock/Undock: The user can dock/undock the electromechanical arm to the InstaReg mat.
4. DICOM header: Used to open DICOM header information of the loaded and selected CT image series.
5. Log file: Allows the user to browse and export log data related to their own previously performed procedures. The user can export only their own data and cannot access or export data belong to other users.
6. Default Procedure: Displays the type of procedure to be done on the patient (i.e) ablation or biopsy
7. Self-Verification: Self verification test is done by MAXIO® itself before starting the procedure and sets all the values, axis, motors in the center (midpoints)
8. WL : User can set values for window length and window width for different parts, as shown in figure 3.21
9. Training Mode: User can select the training mode only in setup screen and once the training mode is selected the docking and table marker verification can be skipped and user can load old patient image and different CT station image for training. User can't do position in training mode. PET-CT fusion is also supported in Training Mode. Ablation, biopsy and Parallel needle workflow videos can be used for training and for U.S users with segmentation, without segmentation and Parallel needle workflow videos can be used for training as shown in figure 3.22
10. Device Configuration: Gives device configured values, calibration values in User login for users reference. It allows users to turn off the Windows firewall to ensure smooth image transfer and restart the DICOM interface if images are missing during transfer.
11. Snapshot: Allows users to view and export their own procedure snapshots and generate procedure reports for a specified date range (DDMMMYYYY), including patient and procedure details, tumor segmentation, and needle planning and positioning details. Users cannot access other users' snapshots..
12. Remove All Skin Markers: The user can remove all the skin markers in the loaded images.

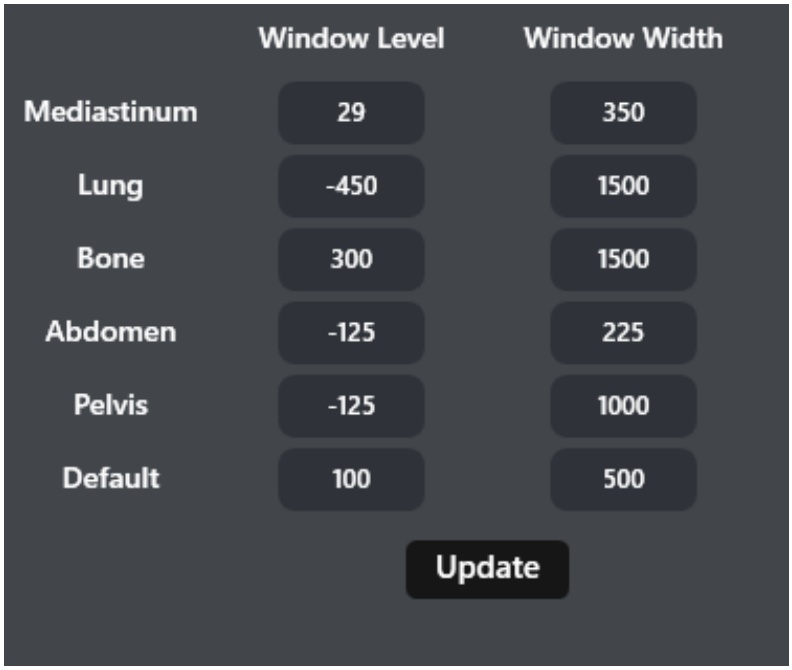


Figure 3.21 *Window level*

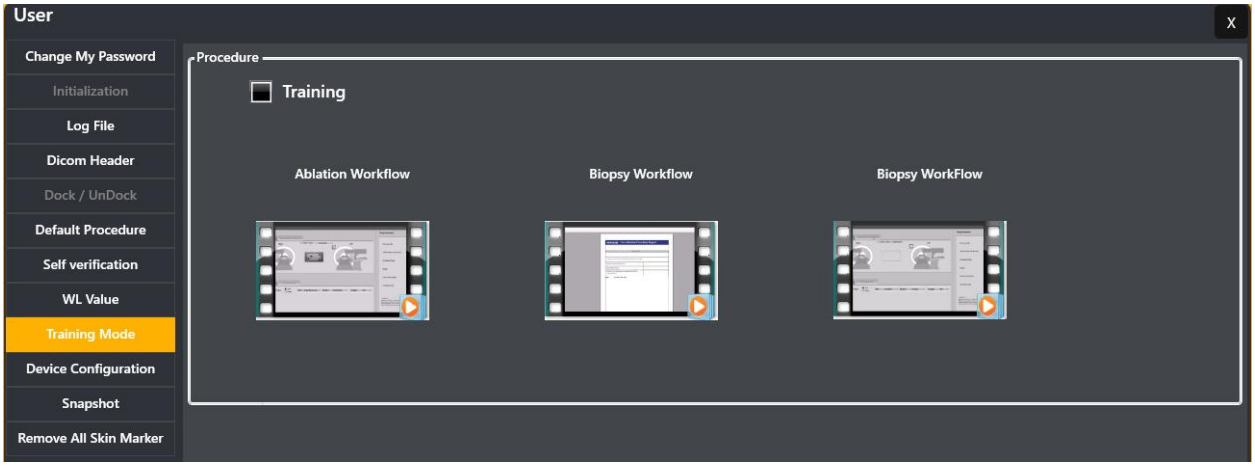


Figure 3.22 Application settings for training

3.3.9 Patient details (Section – 9)

Application displays the patient name and ID visible throughout the procedure as shown in the figure 3.23

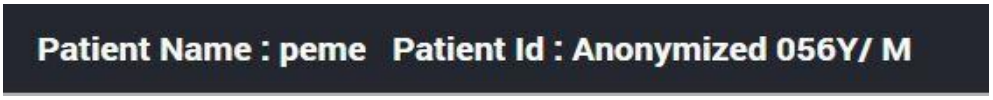


Figure 3.23 *Patient details*

4. PATIENT POSITIONING

4.1 Patient Positioning

The following preparatory measures are recommended when positioning the patient on the CT table for the CT guided intervention.

1. Position the patient's region of interest below the arrow indicated in the MAXIO® device range sticker placed on the CT table.
2. Position the patient on table such that the center of the patient on table is approximately aligned to ISO center of the gantry in reference to CT LASER indication.

	WARNING: Do not position the patient's region of interest above the arrow indicated on the MAXIO® device range sticker placed on the CT table.

4.1.1 Breath Hold Monitoring

Set up the Breath Hold Monitor on the patient. Prepare and train the patient on its usage.

See Appendix E: Patient Breath Hold Monitor and Immobilization Bed Setup. Refer Operator manual in Appendix K.

	Check the readiness of the breath hold monitor for use. Refer to manufacturer's instructions for workflow.

	WARNING: Do not use the breath hold device if the LED indicator does not display correctly, for example if the LED does not change with the patient's breathing or does not match the patient's actual breathing phase. Contact Perfint Customer Support
	WARNING: Patient cooperation is required for performing precision procedures. Patients who are not able to follow instructions for breath hold belt use should be evaluated by qualified physicians before using MAXIO® to perform procedures where a breath hold belt is necessary.
	WARNING: Breath Hold Monitor not usable on patient due to clinical situation specific to patient. • Breath Hold Monitor is used to ensure that the patient breath level during CT scan and during needle/probe insertion is maintained at the same level. • This is critical to ensure accuracy of needle placement based on the plan. • Alternate methods, including General Anesthesia, are used to maintain same breath level during CT scan and during needle/probe insertion based on clinical practice used during ablation procedures performed manually as well as based on clinical situation specific to the patient. However, MAXIO® has been verified only with the use of Breath Hold Monitor that is provided as an accessory. • It is the responsibility of the user to ensure that the patient breath level during CT scan and during needle/probe insertion is maintained at the same level.

4.1.2 Patient Immobilization

Use Patient Immobilizer bed to immobilize the patient after positioning the patient on CT table.

See Appendix E: Patient Breath Hold Monitor and Immobilization Bed Setup. Refer Operator manual attached in Appendix K. It is recommended to stock an additional bed for use in case of failure observed in the bed being used in procedure.

	WARNING: Patient movement during procedures may lead to incorrect positioning of the needle. Ensure patient movement is managed by patient immobilization throughout the entire procedure.

	Be sure to position the patient's region of interest below the Device Range Sticker on the CT table. Take special care to avoid contact with sharp / hot objects that could puncture the bed. If the bed does not hold rigidly after normal vacuum pump duration, contact Perfint support.

4.1.3 Skin Markers Placement

Patient position verification uses skin markers to establish a set of patient position reference points. These reference points can be checked before every needle/probe position to verify that the patient position has not changed. (See Section 8.1: Patient Position Confirmation Module for verification workflow details).

- Place a minimum of three skin markers provided with MAXIO® in irregular fashion (approximately 10cm apart in different slices in a triangular and nonlinear fashion, as indicated in Figure 4-1 below) near the area of interest on the patient's skin surface, after acquiring the scout image and prior to acquiring the first scan.
- Ensure that the markers are placed within the scan area and are not covered by the patient drape.
- Ensure that the skin markers are not pasted over the desired entry point.
- Ensure that the adhesive backing of the flaps are removed and skin markers are pasted completely on the patient skin.

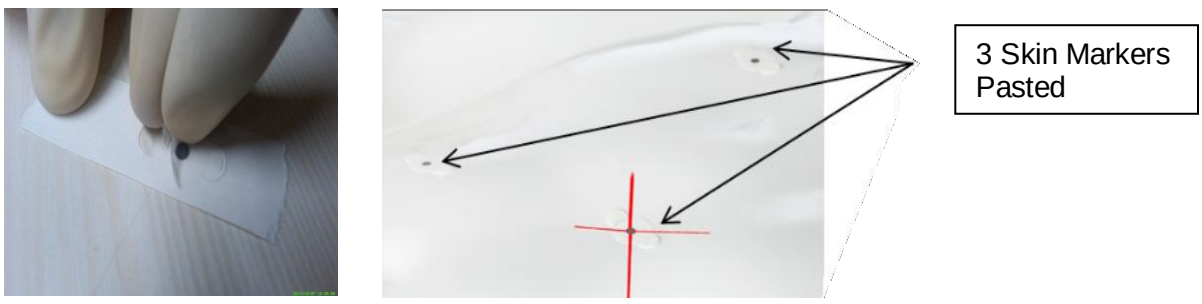


Figure 4.1. *Skin Marker Placement*

	WARNING: Improper placement of skin marker will lead to patient position verification failure and procedure will have to be aborted. Do not peel OFF skin marker until procedure end. Non availability of skin marker will lead to verification failure and procedure will have to be aborted.

5. IMAGING PROTOCOL & IMAGE TRANSFER

5.1 Recommended CT scan protocol

The user should always follow the below mentioned protocol for CT data acquisition, reconstruction and transfer.

Table 5.1 CT Scan Protocol

Requirement	Details
Patient Positioning	Head first, Foot first Patient should be scanned with proper breath hold instructions
Orientation	Supine and Prone
Scan Plane	Axial
Helical Acquisition	Yes, if possible
Slice Spacing	Contiguous No overlapping slices No gap
Field of View	• Large enough to include the entire Organ of Interest and the overlying skin surface containing the markers. • No re centering of patient image. • Maintain the same FOV for the entire scan / procedure. Minimum of 64 slices.
Pitch	1:1
Algorithm	Standard
Gantry Tilt	None (must be zero)
Matrix	512x512 (Must be a Square Matrix)
Reconstructed Slice Thickness	Reconstructed slice thickness should be 1mm - 3mm Scan using the thinnest possible slice thickness. A one millimeter (1mm) slice provides the best spatial accuracy. Scan using the same slice thickness throughout the procedure. Make sure that the images are reconstructed with no X, Y offset.

Reconstruction Offset	• Always scan and reconstruct the patient series with zero offset throughout the procedure. • Strap the patient tightly to the table. Do not Move the Patient throughout the procedure. • Do not change the patient position in the gantry (x-y-z coordinates) once you have started the scan. • For Recurring intra-operative series use as many slices as possible with the same setting as above. Increase in slices, would directly impact the precision of the system. • This protocol shall be used with gating whenever possible.
DICOM Meta Data	The CT system shall be compatible with the application for DICOM Image reception. Private DICOM tags containing UT (Unlimited Text) and UC (Unlimited Characters) value representations shall not Interfere with image reception or processing. The application shall ignore unnecessary private tags with unsupported or non-required UT and UC data types and shall continue to receive and process the required CT image data successfully.

5.2 Recommended MRI scan protocol

The user should always follow the below mentioned protocol for MRI data acquisition, reconstruction and transfer.

Table 5.2 MRI Scan Protocol

Requirement	Details
Patient Positioning	Head first, Foot first Patient should be scanned with proper breath hold instructions
Orientation	Supine and Prone
Scan Plane	Axial
Helical Acquisition	Yes, if possible
Slice Spacing	Contiguous No overlapping slices No gap
Field of View	Large enough to include the entire Organ of Interest (transverse and spinous coverage) No re centering of patient image.
Algorithm	Standard
Gantry Tilt	None (must be zero)

Matrix	512x512 recommended (N × N square matrix acceptable if FOV remains appropriate)
Number of Excitation (NEX)	2
Reconstructed Slice Thickness	Reconstructed slice thickness should be 1mm - 3mm Scan using the thinnest possible slice thickness. A one-millimeter (1mm) slice provides the best spatial accuracy. Scan using the same slice thickness throughout the procedure.

5.3 Imaging Considerations

Clinical guidelines should be followed for instructing patients to hold their breath during CT, PET and MRI scans. As per the requirements table in the previous section, patients must be scanned using HFS, HFP, FFS, FFP position.

	Scan only the required area. Image transfer will take long time for a large number of images.
	Do not use any skin marker other than that supplied or recommended by Perfint.

	Thinner slices enhance accuracy. A slice thickness of 1mm is recommended.
	Check of the timeliness of CT scan data is enforced by the MAXIO® planning workflow software. This is done through a configurable time limit that requires acknowledgement of a warning message in order to proceed with procedure planning with CT scan data created prior to the configurable time limit.
	Clinician confirmation also includes a check of patient name and patient ID for the CT scan data to match the active plan.
	Do not use flipped image for procedure [Example, Neurology view etc.,]. In the case of overweight patients, ensure the CT table height is lower than the device height.
	Make sure that there is no patient movement during CT scan
	MAXIO® provides a user-configurable time limit for generating a warning message to the clinician on the age of loaded scan data.
	Clinician confirmation is required to proceed with data created prior to the configurable time limit. Clinician confirmation also includes a check of patient name and patient ID for the scan data.
	User should not add the images in the series once scan is done, Each scanned series/recon series should have unique series ID.
	User should not use Biopsy RX mode for scanning.

☞	Make sure number of slices of PET-CT image is lesser than number of slices taken for CT image for better PET-CT Interventional Procedures

5.4 CT Image Transfer

CT scan images are transferred from the CT system to the MAXIO® planning station via an Ethernet interface. This interface may be through a hospital network if available, or through a direct Ethernet cable connection.

☞	MAXIO® is compatible with all commercially available DICOM 3.0 compatible CT systems.
☞	Integrity checks of CT scan data are performed during transfer from the CT system to MAXIO®.
☞	◆ A cross-check of the patient ID embedded in the CT scan data is provided to the user during image loading and in procedure summary screen for confirmation.
☞	A green status indicates that the DICOM Interface is active and a red status indicates that the DICOM Interface is not active.
	Call Perfint Service in the event of an inactive DICOM Interface status cannot be determined or resolved.
	The MAXIO® does not allow processing to continue with invalid CT data.
	◆ Check the patient physical orientation with what is displayed on the screen. Always set CT view to radiology view.

Once the transfer of CT data is completed, the CT scan images will be available for selection and loading into the planning workflow application. During loading process, integrity checks are performed to ensure only valid CT scan images are processed by the planning workflow software.

5.5 MRI Image Transfer

MRI scan images are transferred from the MRI system to the MAXIO® planning station via an Ethernet interface. This interface may be through a hospital network if available, or through a direct Ethernet cable connection

☞	A cross-check of the patient ID embedded in the MRI scan data is provided to the user during image loading and in procedure summary screen for confirmation.
☞	A green status indicates that the communication is active and a red status indicates that the communication is not active.
	Call Perfint Service in the event of an inactive communication status cannot be determined or resolved.
	The MAXIO® does not allow processing to continue with invalid MRI data.

Once the transfer of MRI data is completed, the MRI scan images will be available for selection and loading into the planning workflow application. During loading process, integrity checks are performed to ensure only valid MRI scan images are processed by the planning workflow software.

6. PROCEDURE PLANNING

6.1 Load Patient Image

Recently acquired images received in MAXIO® from CT are listed in an image grid in the task pane. If only one image series is transferred, image will be automatically loaded in the image window. If more than one series transferred, user has to select the desired image series by selecting the check box. The selected image series will be loaded in the image window.

MAXIO® implements Role-Based Access Control (RBAC), which separates User, Service, and Admin privileges. Access to the application requires authenticated user accounts. Users can view and access only their own patient image datasets and cannot view or access datasets belonging to other users.

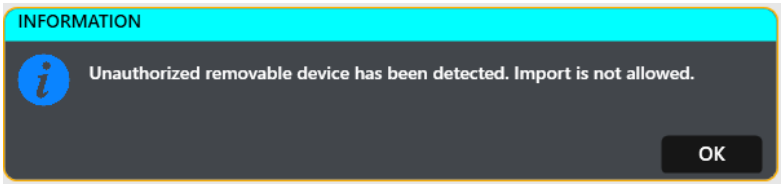
In case, user wishes to select another patient image data set, the 'Manage Patient' button can be selected. The Manage Patient Screen, as shown in figure 6.1 is displayed and the desired image data set can be selected and loaded.

1. Import study

On clicking the "Import study" button, the patient dataset is retrieved from the local directory or an external device connected to the MAXIO® device, to manage patient screen. In general, the "import study" button is used to load the images that are planned offline.

Import through Pen Drive

- Click the Pen Drive button on the Load Study screen when an authorized pen drive is connected. The application shall retrieve the dataset from the Maxio-Images folder.
- Click the Pen Drive button when an unauthorized pen drive is connected. The application shall display the following information.



2. Load Patient

Click "Load Patient" button to load the patient image dataset to a patient grid provided in the load screen. User can select the desired image series from the patient grid by selecting the corresponding check box. The selected image series will be automatically loaded in the image window.

☞	Series cannot be loaded as the current patient orientation is HFDR/HFDL; only HFS, HFP, FFS, FFP orientations are supported
☞	A check for gantry tilt is performed during the loading of CT/MRI scan data. If present, the system does not accept the data for use and a message is displayed to the clinician.

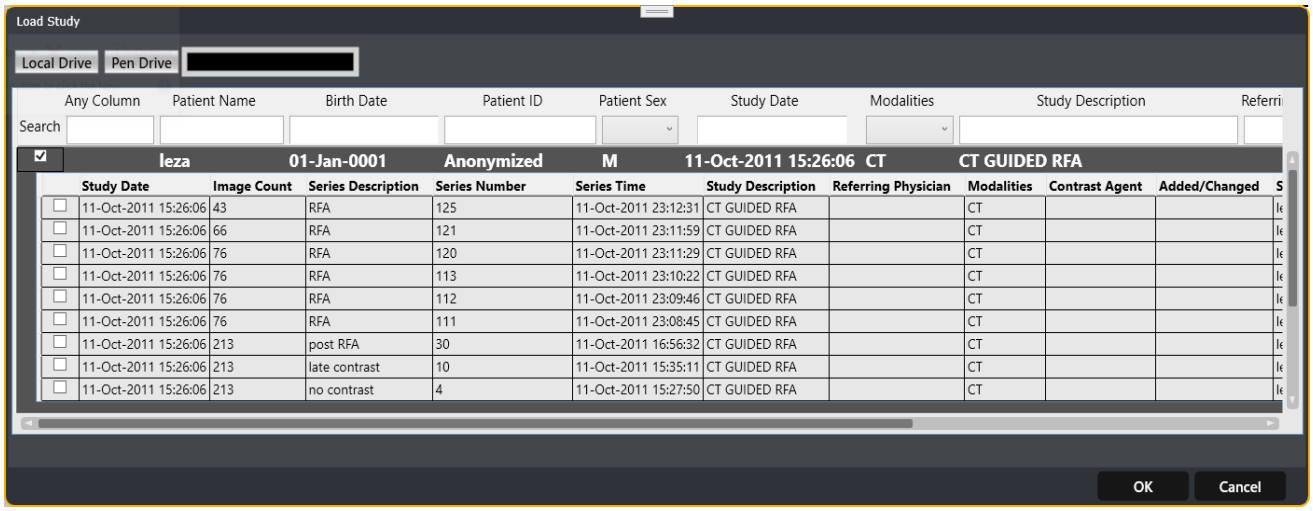


Figure 6.1. *Patient Browser Window*

3. Cancel

Use “Cancel” button to close manage patient screen.

4. Load series

Select the desired image series from the patient grid to load the image. When loading the image, application will display a confirmation message for the usage of Immobilizer bed. Press YES, if immobilizer bed is being used to the procedure, otherwise NO.

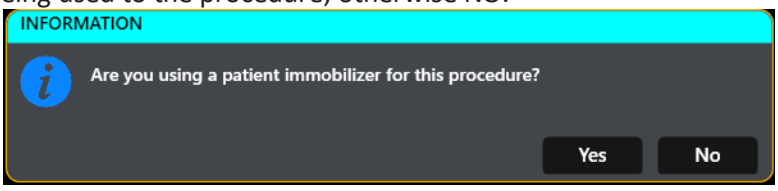


Figure 6.55 Patient Immobilizer Confirmation

The image that will appear will be the center image of the series. The other images of the series can be viewed either by scrolling the touch pad / Mouse or by using the scrollbar. The image window will show the axial, coronal and sagittal view of selected primary series as in the figure 6-2 below.

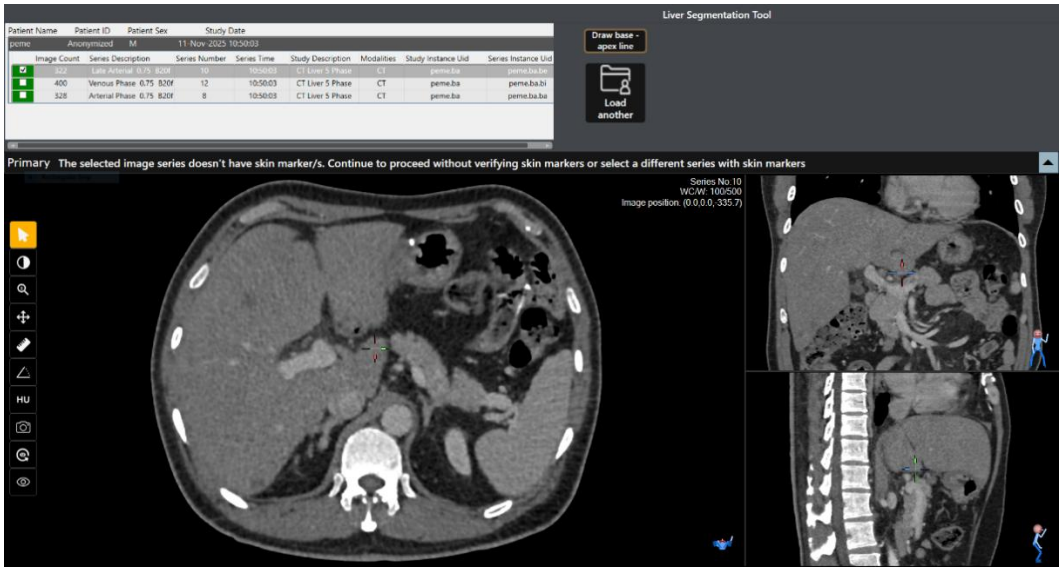
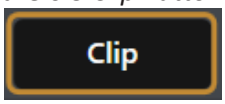


Figure 6.2 *Primary image series Loaded*

6.1.1 Clip the Image area

When the slices are more than 512, click on “CLIP” button to select slices/sections that are required for procedure planning by dragging upper and lower clipper showing in the coronal and sagittal view.

Figure 6.3 *Clip Button*



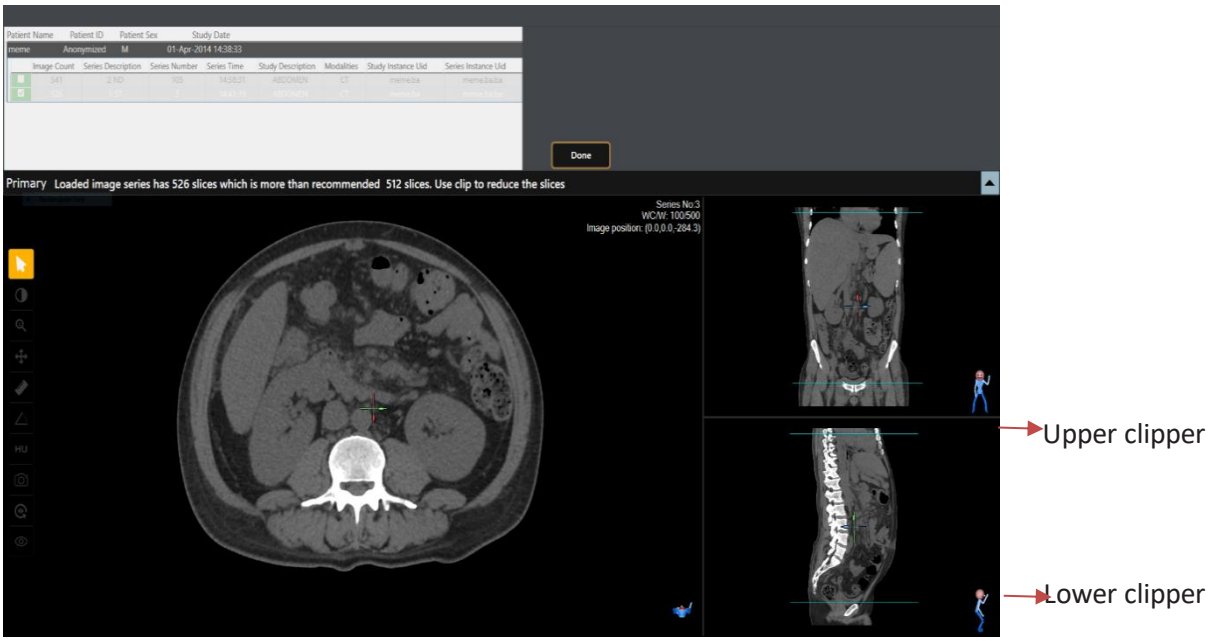


Figure 6.4 *Upper and Lower Clipper*

Select the image range to be used for planning. Once you have set the upper and lower clippers, use DONE button to clip it.

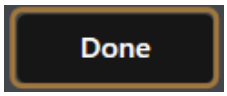


Figure 6.5 *DONE Button*

The user will be allowed to clip the series to only

☞	MAXIO will prompt the user for the Clip action if loaded series has more than 512 images

If a secondary image series of the patient is desired, click on the image series from the browser displayed on the task pane. Secondary image series will be loaded on the right side of image window as shown in the figure 6.6 below. To identify difference between the primary and secondary image series, a label is displayed above the information bar, as shown in Figure 6.6

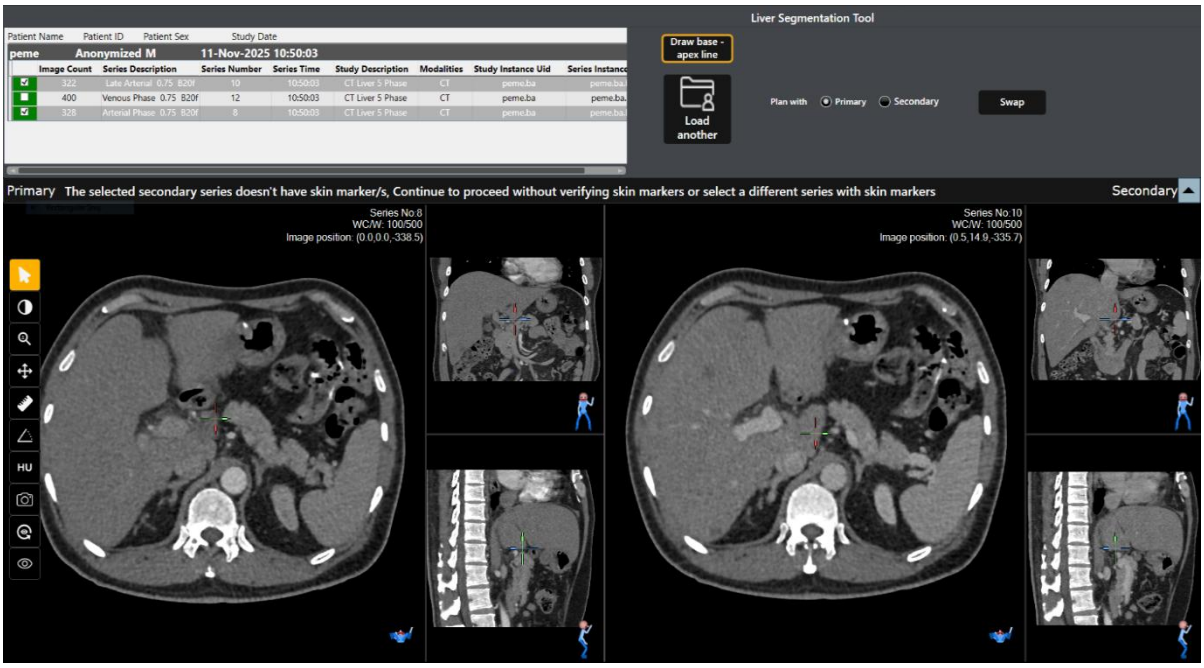


Figure 6.6 *Primary and Secondary Patient Images Loaded*

6.1.2 Swapping of Primary and Secondary Images

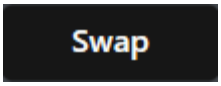


Figure 6.7 *Swap Button*

"Swap" button can be used to interchange between primary and secondary series. Click once on "Swap" button and give confirmation to swap the images.

6.1.3 Liver Segmentation

MAXIO® provides tool to segment the liver by marking the base and Apex points of the liver in the Multi planar reconstructed views.

To Segment Liver:

1. Mark Liver (Organ)- Scroll the image slices in the coronal view to the slice that shows the largest cross section of liver in both of the selected series.
2. Click the draw Base-Apex line button in the task pane and draw a line in the coronal view of both primary and secondary image by dragging the cursor from the base of the liver to the apex. Click Apex and Base button in the task panel to view them in the axial image and confirm. Click clear Base-Apex line button to clear the marked liver.
3. Click the Segment Liver button in the task pane to automatically segment the liver.
   Note: Liver segmentation will take a few minutes, with progress displayed by a progress bar in the task pane.

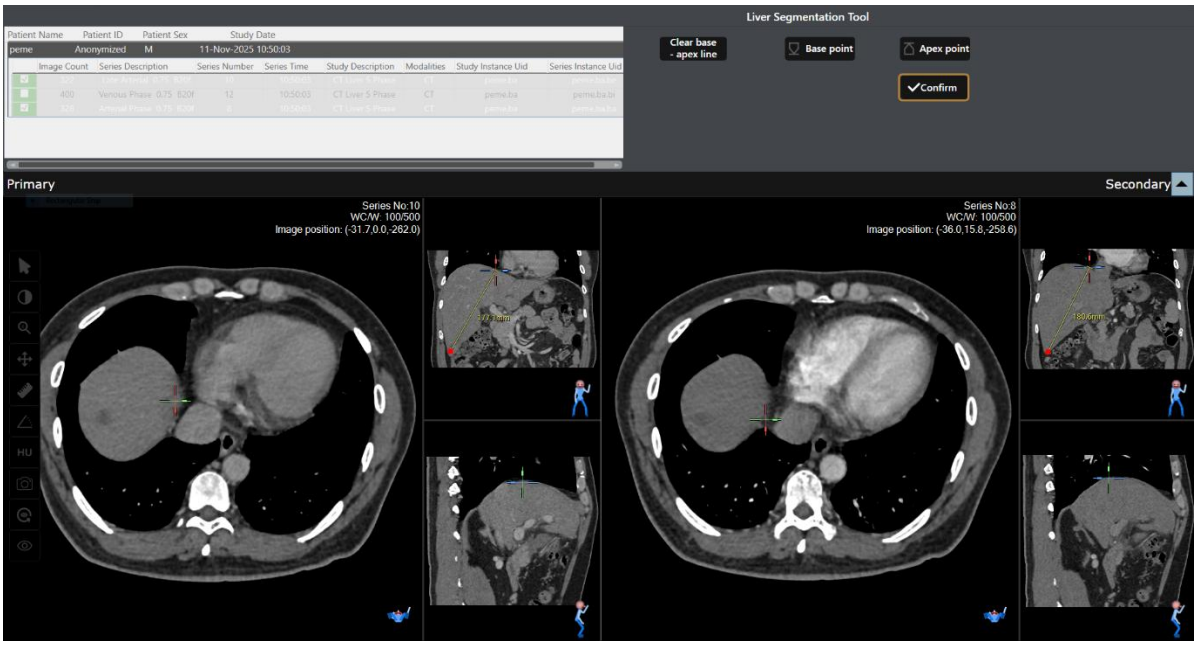


Figure 6.8 *Mark Liver*



Figure 6.9 *Liver Segmentation Progress Bar*

4. To refine the segmented liver, select the Edit Liver Mesh tool to make edits.

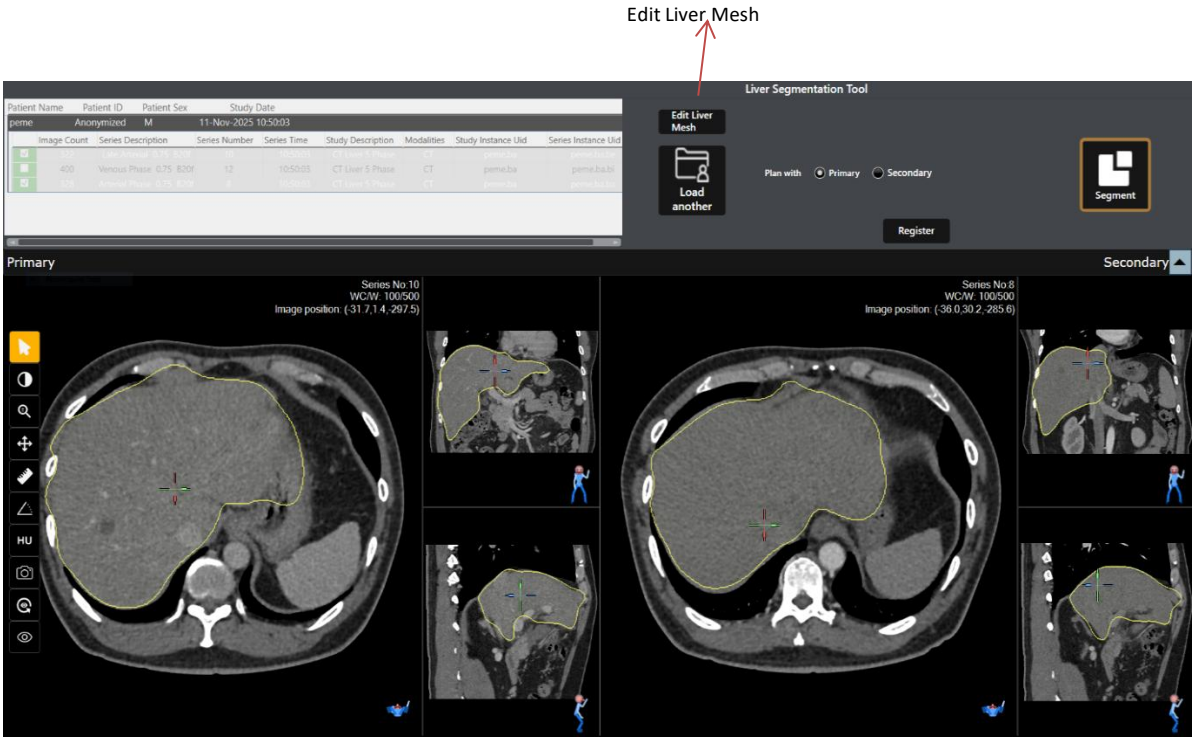


Figure 6.10 *Liver Segmentation Edit Screen*

5. Use the Edit liver mesh tools as shown in figure 6.11 below to edit the mesh shown in yellow color in the axial view

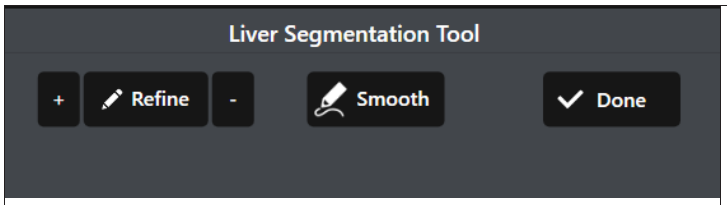


Figure 6.11 *Edit Liver Mesh Tools*

1. + / – To increment or decrement the mesh curve. Select and left click and drag the curve as desired.
2. Refine - To refine the curve edges. Select and left click and drag the mesh in axial view.
3. Smooth - Check the smooth button and left click and drag the mesh curves to smoothen the curves.
4. Done - To confirm the changes made.

6.1.4 Pre Procedure Image Registration

MAXIO® provides tool to register the primary and secondary image series. The registered images are then displayed in the image area. After segmentation is completed click the Register button to register the two image series. The registration progress will be displayed in the status bar as shown in figure 6.12



Figure 6.12 *Image Registration Progress Bar*

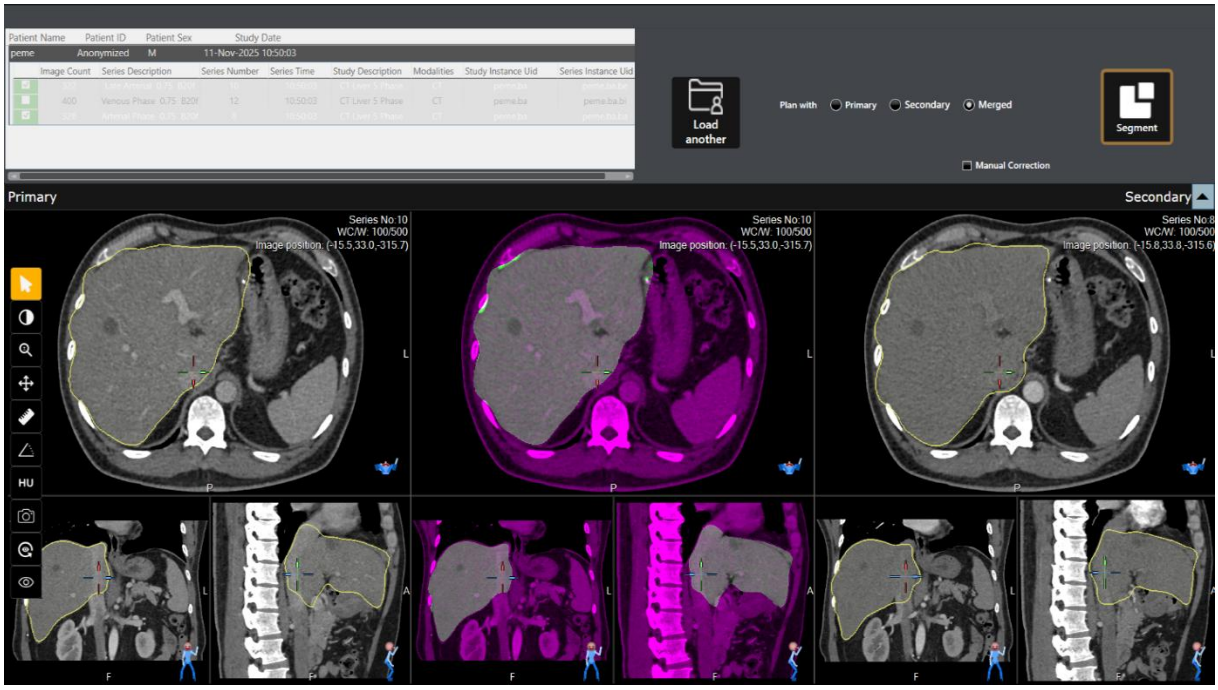


Figure 6.13 *Image Registration Screen*

6.2 Segmentation - ROI Creation

Click the Volume of interest icon in the Workflow Indication bar. The segmentation screen is displayed to the user where the user can segment a total of 7 VOIs including the Liver segmented in the last screen.

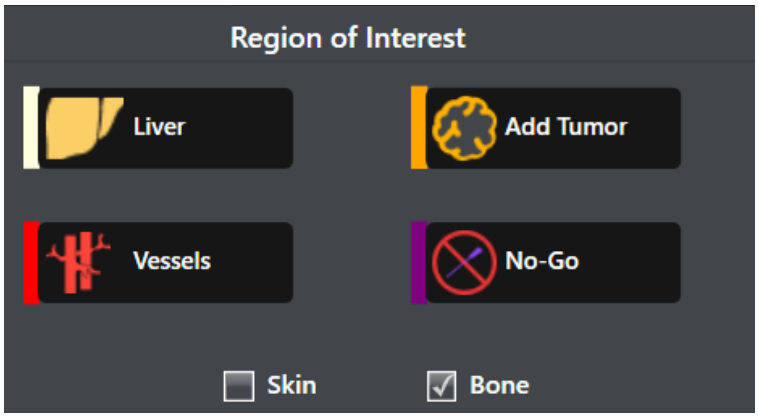


Figure 6.14 *Region Of Interest*

Click “Segment” icon to Navigate to Segmentation screen to segment the Region Of Interest.

6.2.1 Segmentation Presets

MAXIO® provides segmentation presets for Skin,Bone and Immobilizer Bed. Check the Skin and Bone checkbox to display the skin and bone in 3D and all 2D MPR views. Check Immobilizer Bed checkbox to display bed in all 2D view ports.



Figure 6.15 a) *Skin,Bone & Contrast Enhanced Vasculature test*

If the user is allowed to perform the Immobilizer Bed procedure, the Immobilizer Bed checkbox will appear.

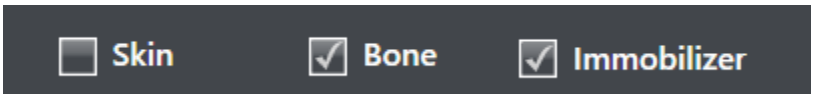


Figure 6.15 b)

6.2.2 Tumor Segmentation

User can segment the Region Of Interest as Tumor by following the below simple steps.



Figure 6.16 *Add Tumor Button*

1. Scroll the slices in axial view where tumor is best visualized. Select the “Tumor” button to segment the tumor.
2. Keep the Mark tool cursor at the center of tumor such that the boundaries displayed fully covers the tumor and left click to segment it, on the 2D viewports only . The segmented tumor is displayed in all the 3D, 2D MPR views.

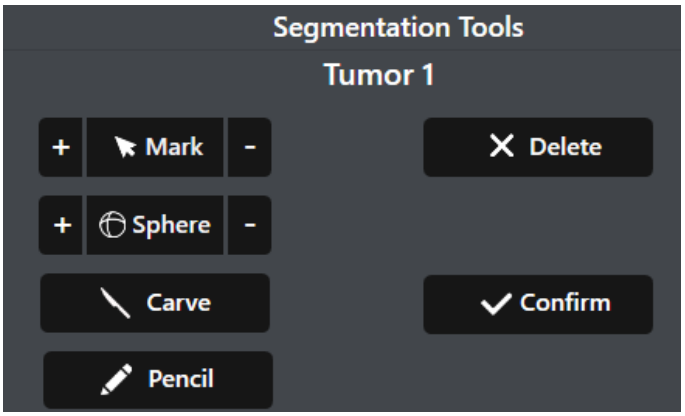


Figure 6.17 *Tumor Edit Tools*

3. Select '+' and '-' Mark edit tools to increase or decrease the marked tumor volume.
4. Select Sphere and left click and drag to increase the tumor volume, or right click and drag to decrease the tumor volume.

5. Select '+' and '-' edit tools in Sphere to increase/decrease the Sphere volume. Alternately, the Sphere tool can be increased/ Decreased by using the tools in the top left corner of the Image window. Scroll up and Scroll down buttons, to navigate through the slices, is also available as shown in the figure below.

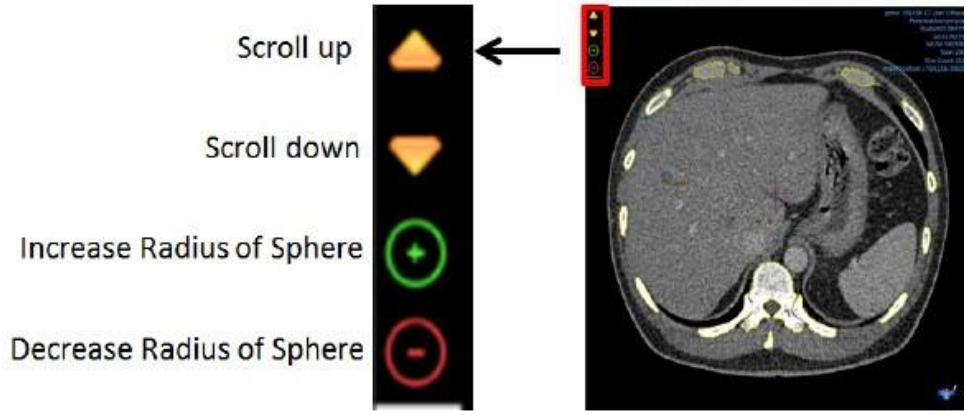


Figure 6.18 *Sphere edit Tools*

6. Select Carve to remove any part of the marked tumor volume. Click and drag to mark the portion to remove.
7. Select Cancel to cancel the tumor Segmentation
   Select Confirm to accept the segmentation. When selected, the segmented tumor will be displayed in the image window and the symbol will be displayed in the Task Pane.
8. Select Clear to clear the marked tumor volume. The segmented volume will be cleared.
9. After confirming tumor segmentation, performed it functionality in the tumor volume. Select Reset to clear the edited volume. The tumor volume will now be in the previous segmented state.
10. Click "ADD Tumor" to segment additional ROIs. Up to 4 tumors can be segmented in MAXIO®.

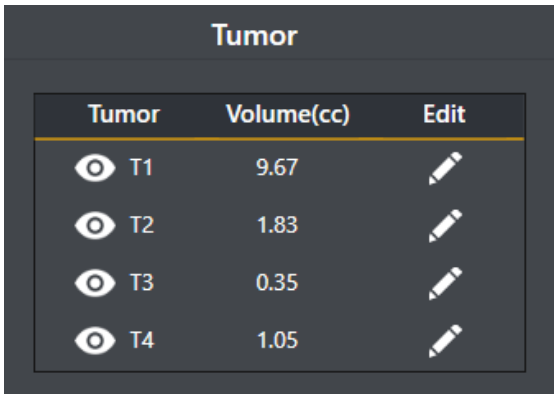


Figure 6.19 *Tumor Enable/Disable and Edit*

11. Segmented Tumor volume is displayed as shown in the above figure 6.19
12. The Tumor segmentation can be edited by clicking the 'Pencil' tool. The Segment edit tools are then displayed which helps to edit the segmented ROI.
13. The Segmented Tumors are labelled as 'T1', 'T2' and so on, based on the segmented Tumors.
14. The eye tool in the Tumor pane helps to Enable / Disable any of the segmented Tumor at any time. The selected VOI is enabled or disabled and will be displayed in 3D and all 2D views.
15. At any point of time the defined VOI can be cleared by selecting the desired VOI and clicking Clear.

6.2.3 NO GO Segmentation

NOGO region - A NOGO region is considered unsafe for trajectory planning (for instance, a critical structure such as the gall bladder), which a needle/tool cannot puncture. The planning system prohibits creation of a plan that includes trajectory planning through a NOGO region.

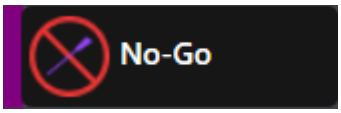


Figure 6.20 *NoGo Button*

Click NoGo button to segment NoGo regions. Follow similar steps as for Tumor segmentation to segment Other NoGo Region. Hover mouse in the bottom right corner of the 3D view, to display the following tools:

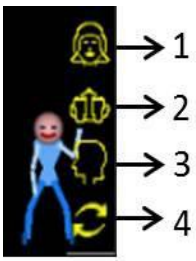


Figure 6.21 *Image viewing tools*

1. Front/Back view - Left click for front view and right click for back view.
2. Bottom/top view - Left click for bottom view and right click for top view.
3. Left/right view - Left click for left view and right click for right view.
4. Flip back-front - Left click to flip any of the above mentioned views to display its corresponding 180 deg view.

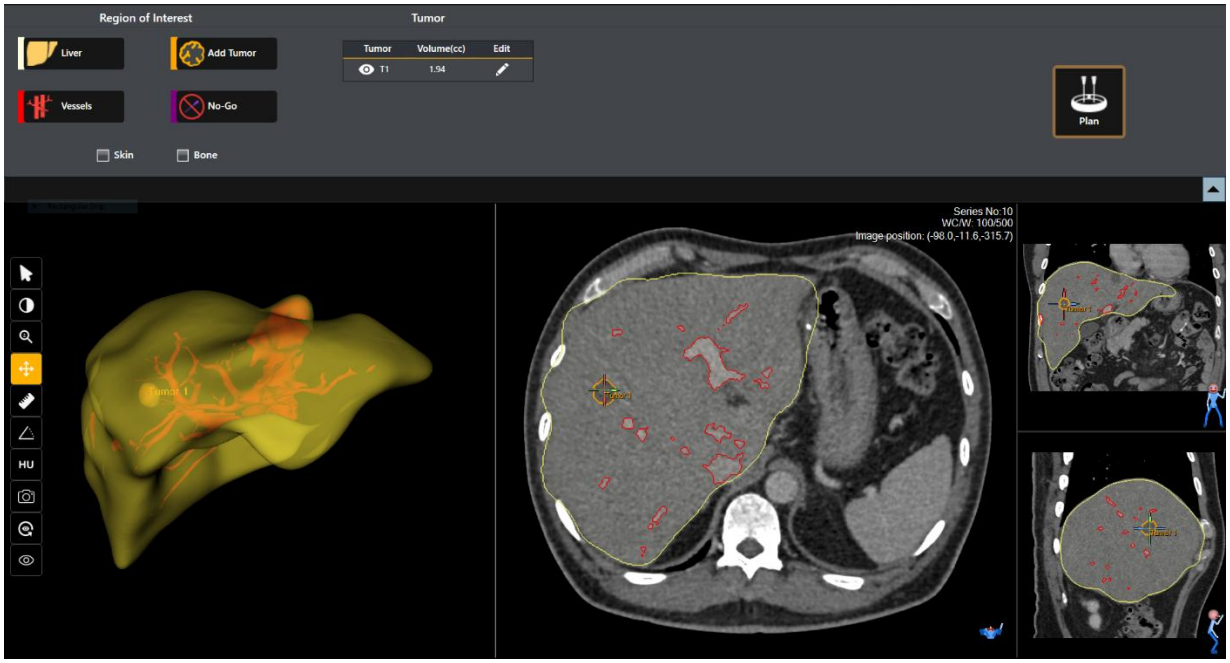


Figure 6.22 *Segmentation Screen*

Once all required VOIs are defined proceed to Planning probe trajectory for the defined tumor volume.

6.3 Probe Selection and Trajectory Planning

The probe planning screen automatically displays a simulated trajectory from a point on the skin surface to the center of the target volume (the target point). Create a plan by adjusting the entry point and target point in any of the views. MAXIO® supports trajectory planning of Single and Multiple needles/tools. Various Needle/Tool manufacturers supported by MAXIO® are explained in detail in the Section 6.3.1. Tool Selection.

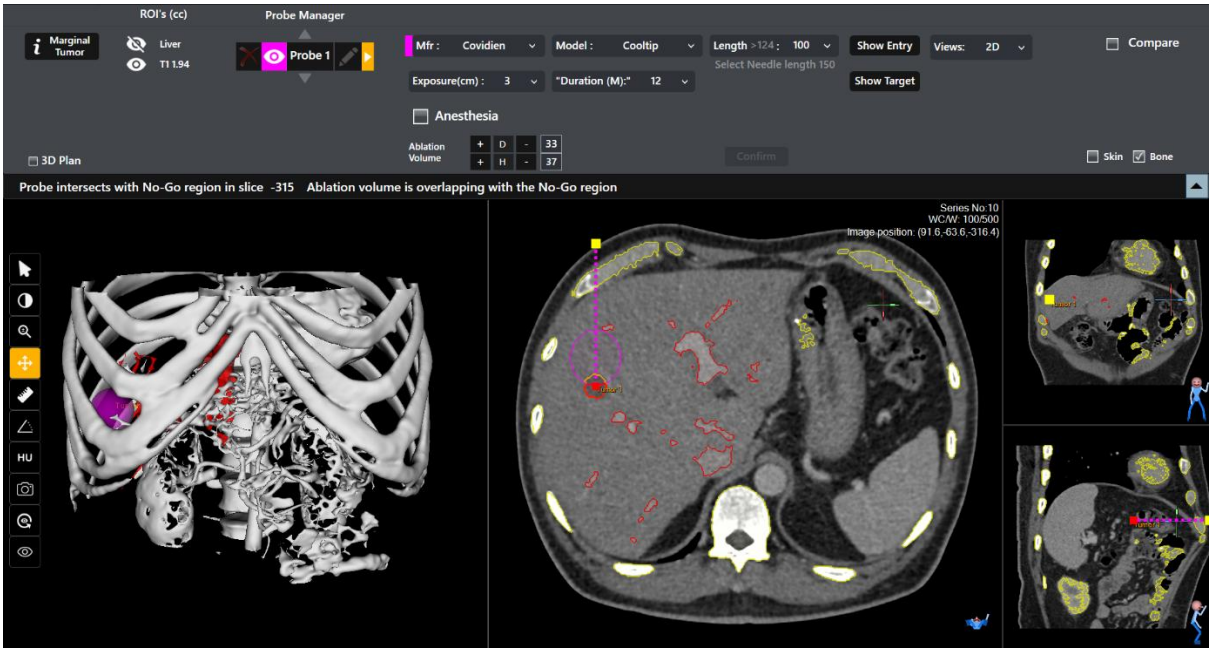


Figure 6.23 *Probe Selections and Trajectory Planning Screen*

6.3.1 Tool Selection

Click on the needle/tool and select the type of needle/tool that would be used for the procedure from the drop down list.

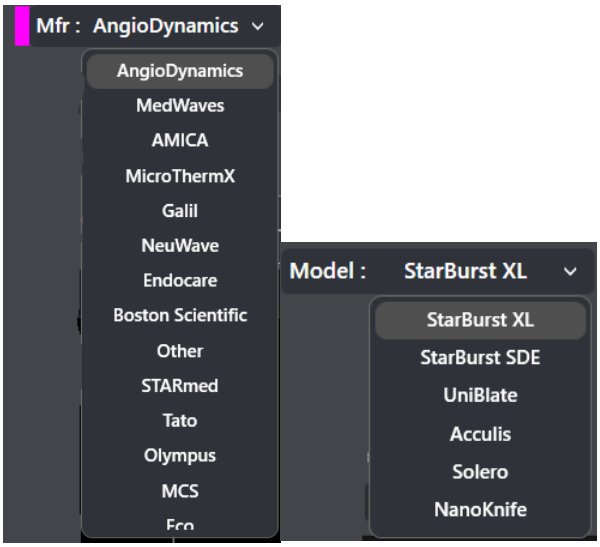


Figure 6.24 *Needle/Tool Library*

The simulation of probe shall be shown in the image window based on the needle/tool selected. In case, if the procedure is required to use a probe not provided in this library, plan the procedure with the 'Other' probe option.

☞	The list of needle/tool shown in the user manual is for reference only. The actual list of needle/tool may vary. Please ensure the availability of the needle/tool commonly used.

6.3.2 MAXIO® Assisted Ablation Procedures

Ablation specific features are available based on the type of needle/tool selected from the tool list.

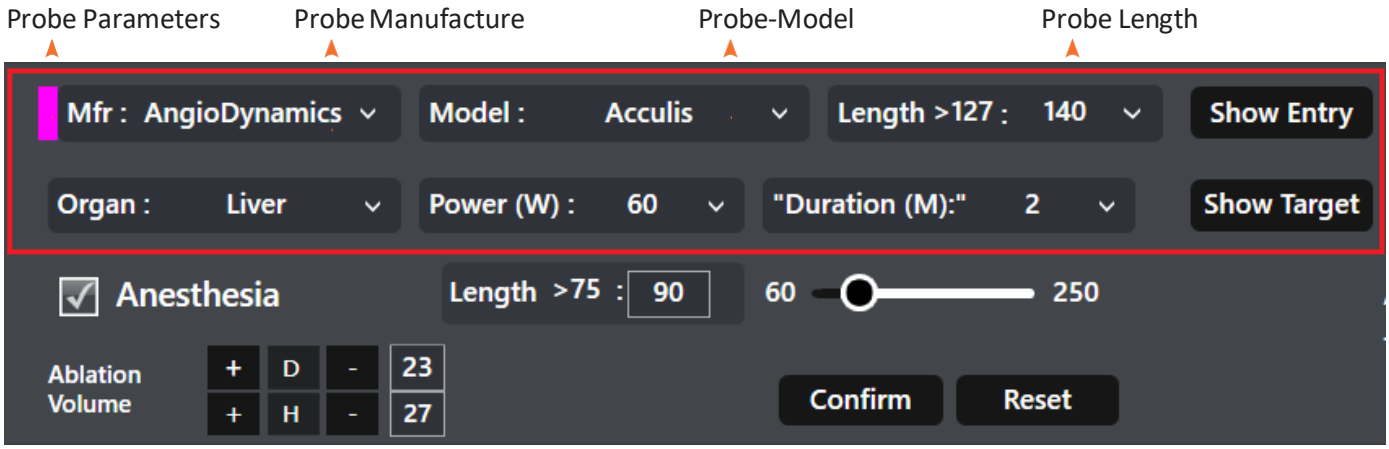


Figure 6.25 *Tool description - Ablation Procedure*

When an ablation probe is selected from the tool list:

1. Select the respective probe/needle/tool parameters which include manufacturer, model, length, exposure, power, duration and temperature as applicable for the ablation from the drop-down list as shown in the above figure.

2. Ablation Volume is displayed as a graphical presentation based on the selected probe parameters, in 3D and 2D MPR views in the image window. For multi probe/needle/tool plan in simultaneous mode, the ablation volume will be in green colour and if planned in sequential mode the ablation volume will be in probe/needle/tool colour.

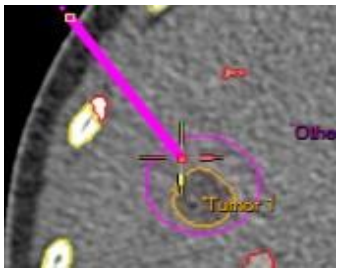


Figure 6.26 Ablation *Volume Display*

⚠	NOTE: The ablation volume displayed represents published manufacturer data created on a homogeneous mathematical liver tissue model that does not consider factors like saline perfusion, vasculature or any other real clinical condition. This may be used only as a starting point for user to estimate ablation volumes and under no condition be assumed to represent the expected ablation volume.
☞	MAXIO® does not control selection of probes or probe parameters in the ablation generator. MAXIO® is not connected to the probe or the ablation generator in any way. Ensure that the probes and probe parameters are chosen correctly as per plan.
☞	MAXIO®does not display the manufacturer's IFU data for Angiodynamics Nanoknife probe.
☞	NOTE: When Probe Manufacturer is selected as OTHER, enter the Handle length and Handle diameter as applicable to the specific needle.

3. Edit the displayed ablation volume Diameter (D) and Height (H), by increasing/decreasing the value using the '+' and '-' buttons.



Figure 6.27 *Ablation Volume Edit*

The displayed information can be used to fine tune the probe trajectory. Click confirm to confirm the edited ablation volume.

☞	WARNING: The displayed ablation volume for the chosen probe and settings is a reproduction of the data stated in the ablation device manufacturer IFU. This data does not take into account important in vivo tissue dynamics that can affect ablation size such as tissue vascularization, type, temperature and impedance.

4. Select Show Entry or right click over entry point in the image to show the entry point of the trajectory on the skin surface. Similarly, select Show Target or right click over target point in the image to show the target point of the trajectory.



Figure 6.28 *Show Entry/Target*

5. In a 3D angulation plan, the needle navigation from entry to target point is shown a sharing, which provides clear visualization of needle navigation in every slice to the user.

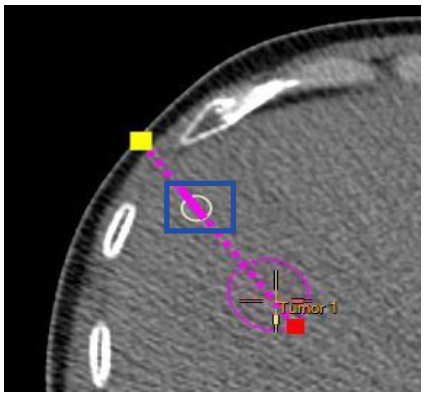


Figure 6.29 *Ring Indicator*

6. Click the Confirm button to finalize the plan.
7. After plan confirmation, Click 'Pencil tool' to edit the probe/needle/tool plan. Click eye indicator icon to Enable/Disable any of the planned probe/needle/tool at any time. The selected plan is enabled or disabled and will be displayed in 3D and all 2D views. Click the 'Red cross tool' to delete the probe.

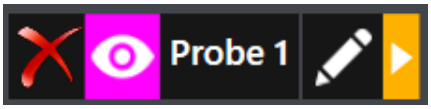


Figure 6.30 *Plan edit and Delete*

8. Select hide/show positioner to hide/show the positioner arm.



Figure 6.31 *Show / Hide positioner*

	WARNING: Treatment delivered close to critical structures could cause harm to the patient. Ensure the plan provides adequate clearance around critical structures.

6.3.3 Multiple Needle Plan

Ablation procedures can be planned with up to 6 needles. Use the Add Probe or Add Parallel Probe buttons to add needles / probe to the plan. The probe parameters can be set for each individual probe and MAXIO® displays the ablation volume for each needle/probe.



Figure 6.32 *Add Probe/Add parallel Probe*

There are two modes of multi-probe ablation plan. Select the appropriate plan mode.

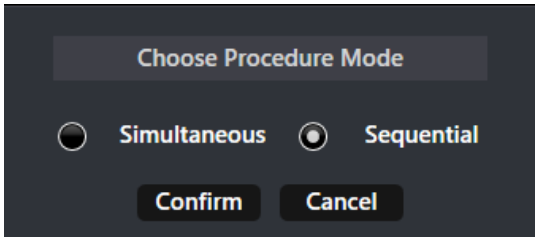


Figure 6.33 *Modes of Multi needle Plan*

Simultaneous Procedure mode

1. Simultaneous procedure mode refers to a single plan with multiple needles where all the needles are positioned before beginning the ablation procedure. Needles are inserted inside the patient, one at a time and after all the needles are inserted, the user proceeds with the ablation. In simultaneous mode, constraints such as inter-needle distance are considered and managed by MAXIO®.In this mode the sequence of needle insertion is determined by MAXIO®. In simultaneous procedure mode, the cumulative ablation volume is displayed in single color

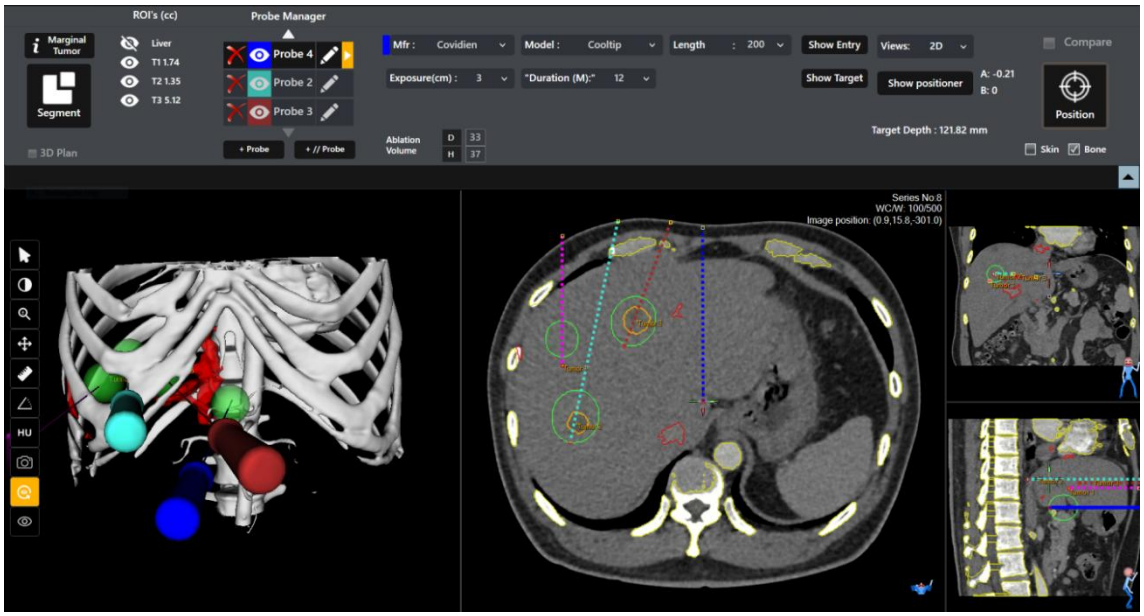


Figure 6.34 *Simultaneous Ablation plan*

Sequential Procedure mode

2. Sequential procedure mode refers to a single plan with multiple needles that are positioned sequentially for an ablation procedure. After each probe is inserted inside the patient, the user will proceed with ablation and remove the needle after completion. Then the next needle is inserted, ablation is performed and finally the needle is removed after ablation. Similarly, the remaining needles are positioned in this manner in a sequence. In sequential mode, since only one needle is inserted inside the patient at one time, there is no need for constraints such as inter-needle distance. Physician can decide the sequence of needle positioning. In sequential ablation mode, the ablation volume of each probe is shown in the respective probe color.

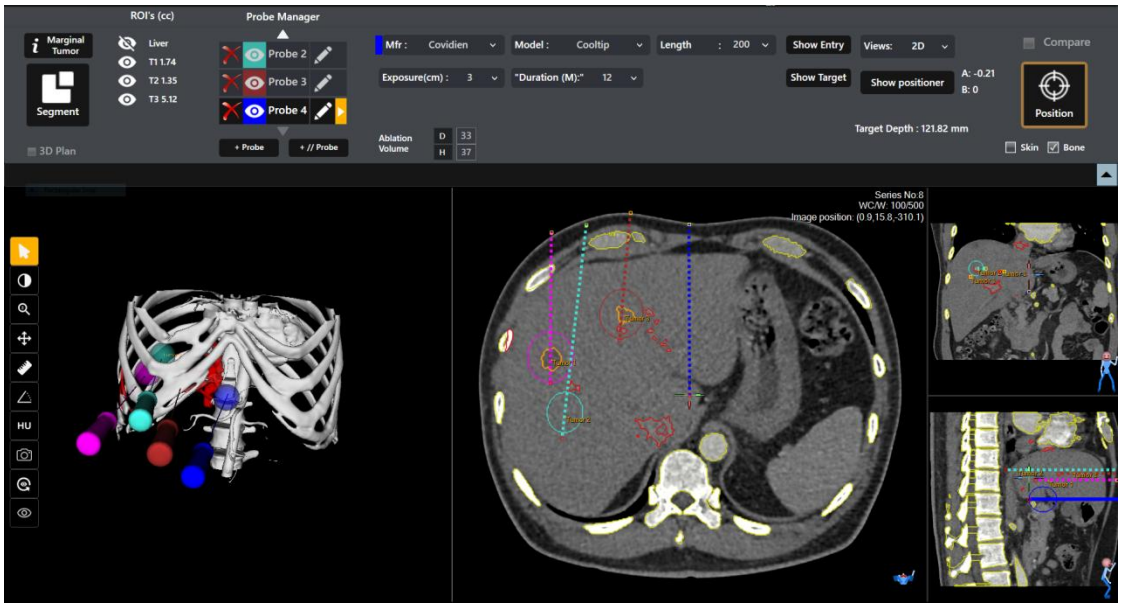


Figure 6.35 *Sequential Ablation Plan*

If multiple tumors are segmented, click the respective tumor number to show the cross hair in selected tumor in 2D MPR views. When Add probe is clicked, MAXIO® displays the target point of the probe trajectory in the centroid of the selected tumor.

The ablation volumes of various probes can be visualized and a decision can be made on which probe can be used to provide optimum results for the treatment as indicated in Figure 6.36

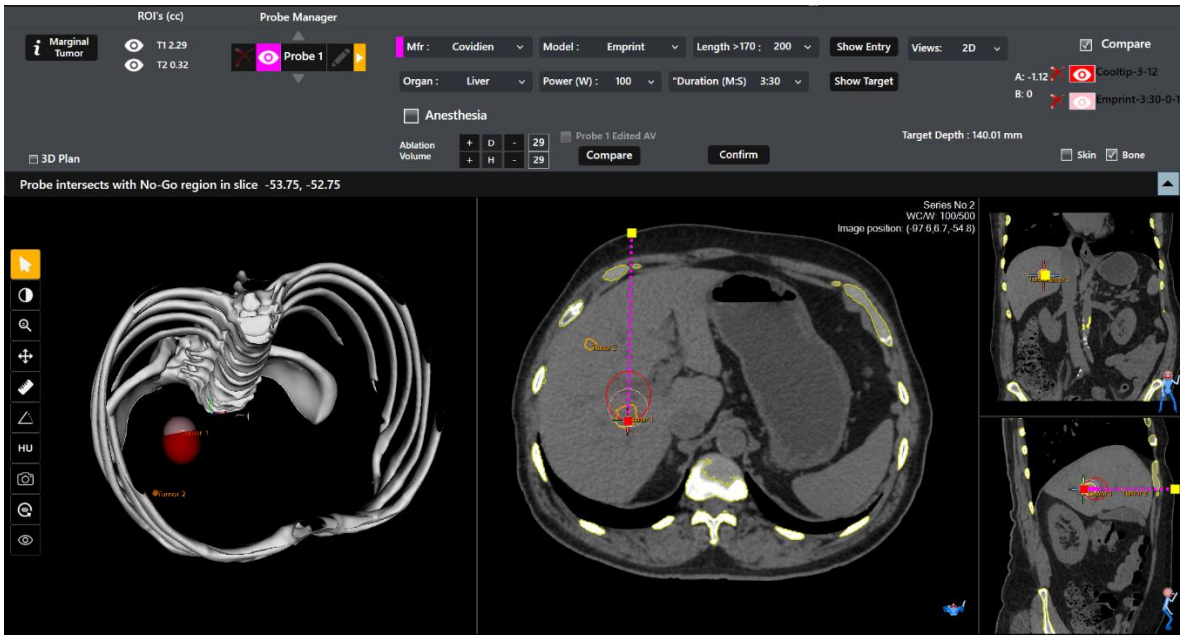


Figure 6.36 *ablation zone comparison features for probes*

Functions of the probe comparison:

By checking the compare check box on the top right corner, ablation volumes of various needles can be visualized for their ablation zone coverage for the selected needle target.

1) The default needle will be visible in the compare option.
2) Select inputs of needle required for comparison and click compare button, and the needle will be overlayed onto the default needle target, with this visual information, user can

assess which probe will be suitable for the operation.

3) If another probe setting is to be compared add the inputs and then click compare button.
4) After making the decision on which needle to proceed with the user shall click the delete icon “x” of the probes that are not needed and keep only the probe required and click confirm to proceed with the plan

Note:

- If user is still unsure of what needle to proceed with, instead of clicking the “x” delete button, user can click the eye icon, the icon turns into a crossed eye. Visible probe will be confirmed. The hidden probes remain in background; they can be confirmed if user wishes to go with the other compared optimal probe volume. Clicking delete button will delete the needle volumes in comparisons and user has to reenter the inputs of needle to compare.
- Multiple needles of the same manufacturer can only be planned; an error popup will arise in confirming use of different manufacturers for multi probe plan.

6.3.4 Parallel probe plan

MAXIO® provides the option for planning multiple needles parallelly. The parallelity is maintained throughout the trajectory from entry point till target point. The needle can be added parallelly to any of the previously placed needle. After placing the parallel needle, user is also given the option to uncheck parallility and reposition the entry or the target points.

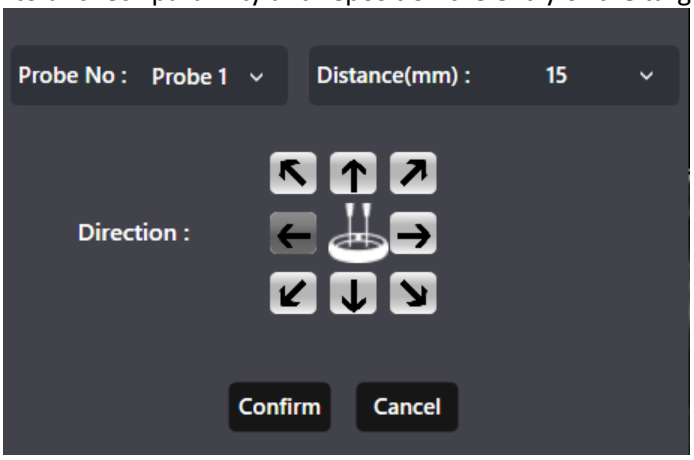


Figure 6.37 *Parallel needle window*

1. Click ‘Add Parallel Probe’, Parallel needle window appears.
2. Select the Probe number in the drop down and select the distance 15 mm/20 mm/enter value and choose the required distance between the probes.
3. Select the arrow direction and click confirm button.

If the added needle is moved, it will move parallelly to the selected probe number in the parallel needle planning window. User can uncheck the parallel check box and edit the entry and target point if desired.



Figure 6.38 *Parallel needle edit*

Distance between the probes will be displayed, if the manufacturer selected as Angiodynamics /Galil and model as, Nanoknife for Angiodynamics / all model for Galil probe/tool.

Click the Confirm button to finalize the plan.

☞	NOTE: When potential needle to needle intersections are identified, a message is displayed in the Information Bar in the image window. Re plan to eliminate

	potential intersections.

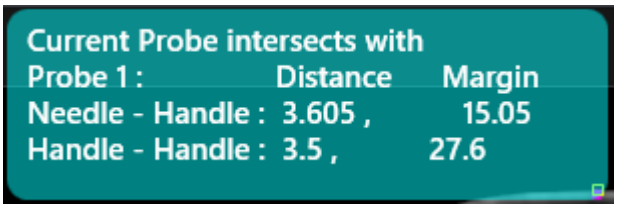


Figure 6.39 *Collision alert*

6.3.5 Anesthesia Plan

The anesthesia planning option enables planning of local anesthesia delivery along the planned trajectory up to the required depth for each probe.

To plan for Anesthesia:

1. Click Anesthesia checkbox on the task panel. The anesthesia slider will appear on planned trajectory as shown in figure 6.40 below.
2. Scroll the image where the anesthesia slider appears and move the slider to the required anesthesia delivery depth.
3. Enter or set the length of anesthesia needle to be used.

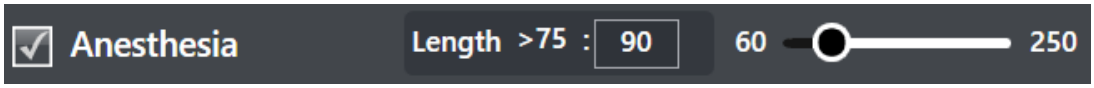


Figure 6.40 *Anesthesia Length Selection Slider*

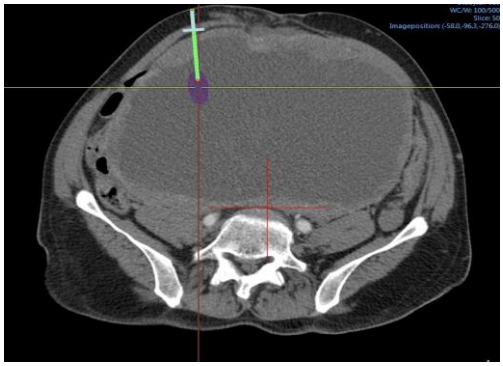


Figure 6.41 *Anesthesia Planning Screen*

6.3.6 Ablation Margin in Planning

The **Ablation Margin** option in the planning module becomes active when the tumor (for which a specific probe is planned) has any remaining volume not covered by the planned ablation probes. When this occurs, information is displayed in a table indicating the range of image slices where the uncovered tumor volume is located.

1. For example, in a case with a **Segment 3 tumor**, plan for **three probes** such that the ablation volume fully covers the tumor, as shown in the image below.

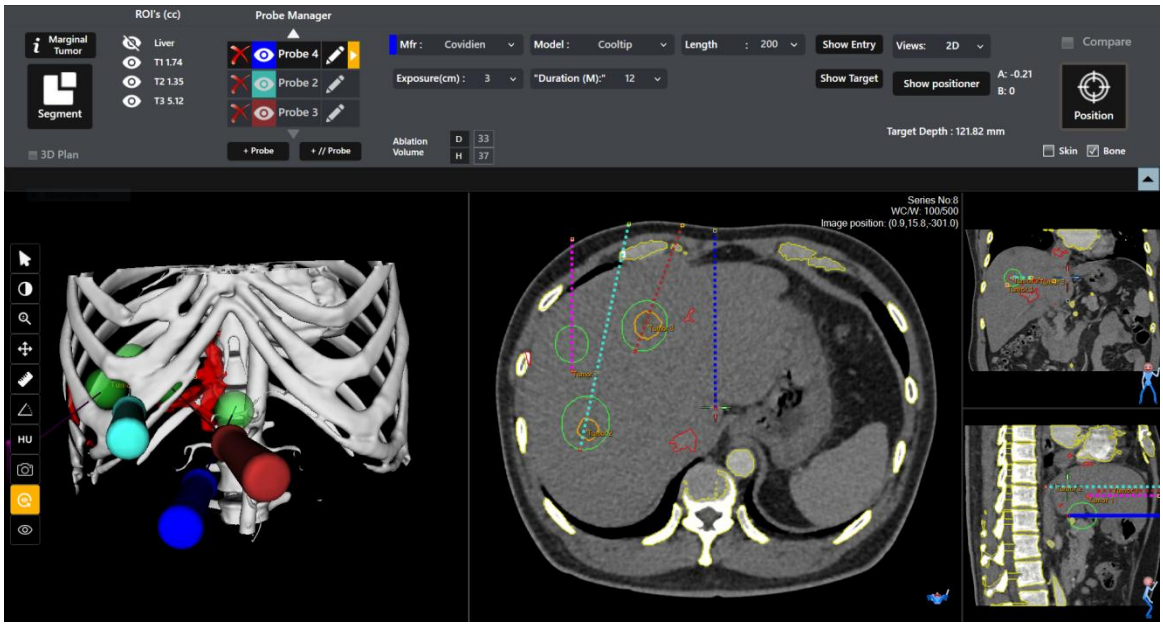


Figure 6.51 *Ablation Margin in planning screen*

2. The system highlights **uncovered tumor regions** in **red**, indicating the slices where the tumor is not covered by the planned probes.

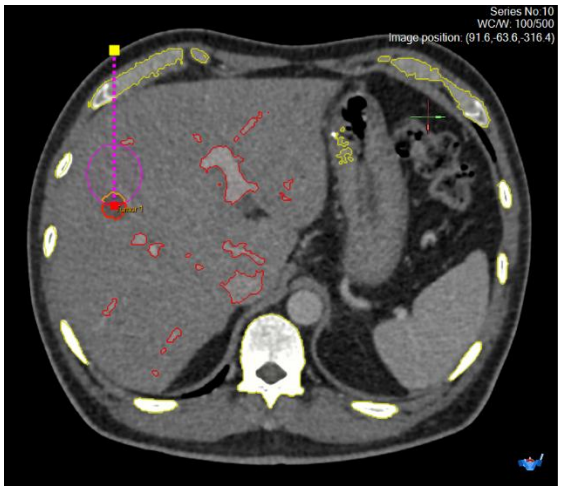


Figure 6.52 *Visualization of uncovered tumor area*

You can also check the specific slice numbers that contain uncovered areas by clicking the **Marginal Tumor** button.

3. Clicking the **Marginal Tumor** button opens a table listing the slice numbers with uncovered tumor regions. Each slice number in the table is a **hyperlink**. Click a slice number to automatically navigate to the corresponding slice in the image viewer.

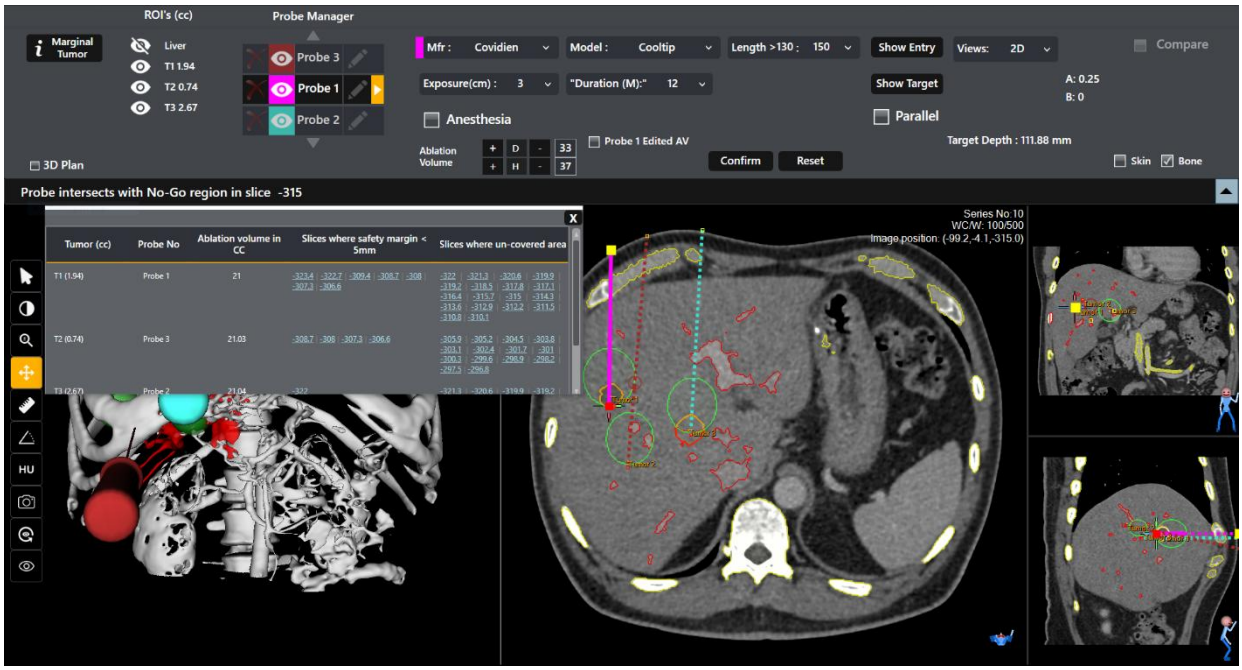


Figure 6.53 *uncovered tumor area table*

4. The table also displays **slices where safety margin < 5 mm**, indicating areas not covered within the required safety margin. Each slice number is a **hyperlink**. click a slice number to automatically navigate to the corresponding slice in the image viewer.



Figure 6.54 *Safety margin in planning screen*

5. You can adjust the probe placement while keeping the **Marginal Tumor** table open.
   Edit the plan to ensure the tumor is fully covered, and verify the updated coverage directly in the table.

6.3.7 Display Positioner

Select the Display Positioner button in the Task Pane to view the position of the electromechanical arm of MAXIO® based on the trajectory planned for the selected probe. Use this view to determine if there is a chance of contact between the patient and MAXIO®. This option graphically represents the A, B and EE axis on the image screen.

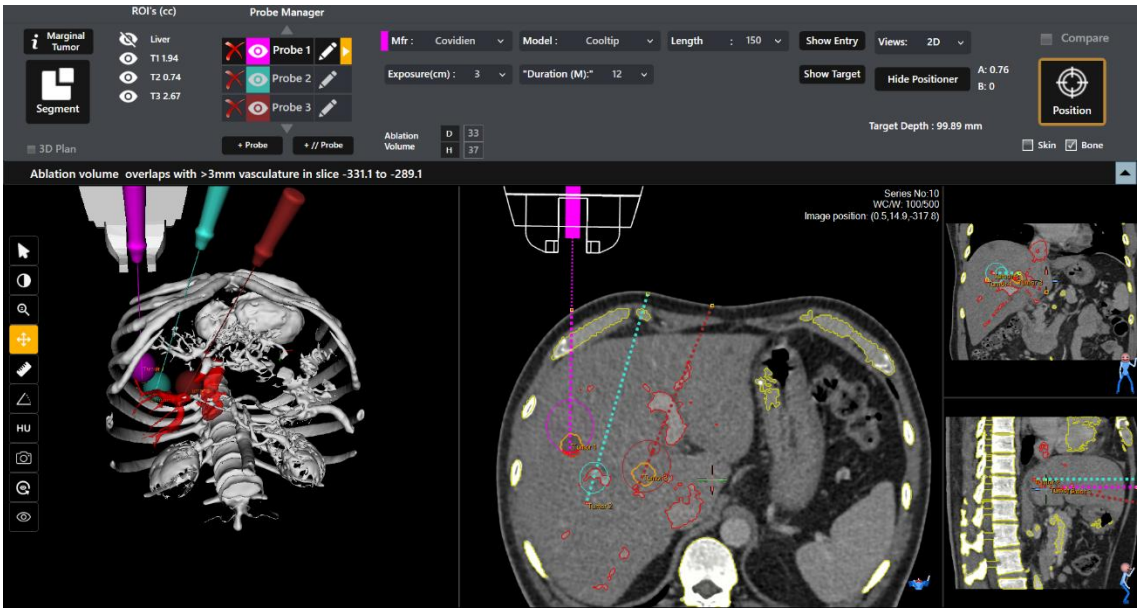


Figure 6.42 *Show Positioner*

6.3.8 MAXIO® for other Interventional Procedures

For procedure that need only trajectory planning and not requiring segmentation of organs and critical structures, use the Other procedure workflow by selecting the Procedure type as 'Biopsy', 'Pain management' or 'Other' option in the procedure setup screen.

If single series of the patient image is transferred, MAXIO® automatically loads the image series If more than one image series is transferred, user can choose the series to perform procedure.

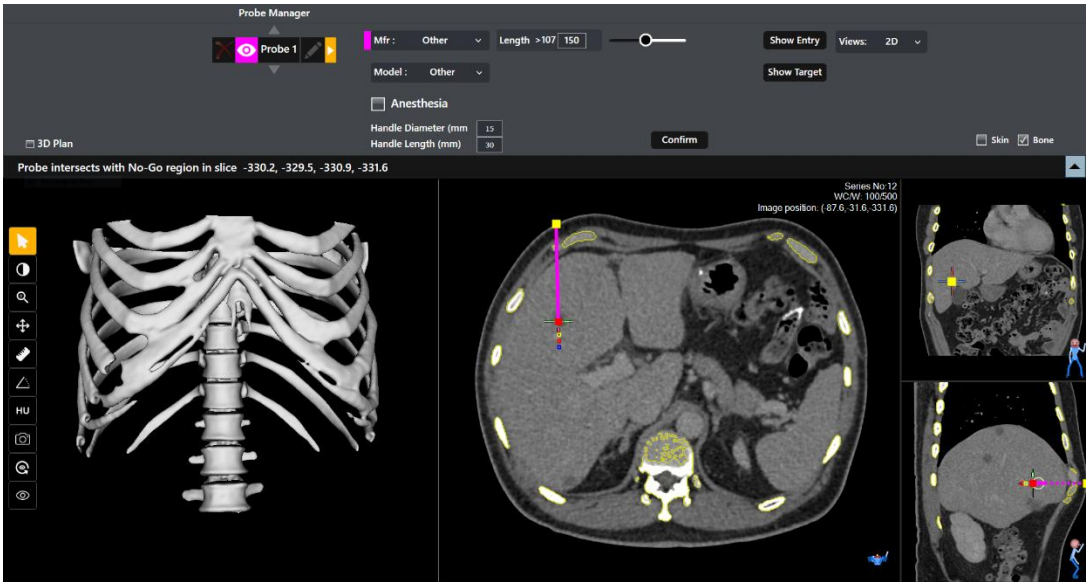


Figure 6.43 MAXIO® *for Other IO Procedure*

1. Navigate to the Segmentation screen by clicking the "Segment" button.

   The user can also bypass segmentation without marking the tumor by clicking the "Plan" button.
2. The probe planning screen automatically displays a trajectory line in the image window.
3. To create a plan, set the target point in any of the 2D views and adjust the entry point in any of the 2D/3D views.
4. Use the Needle Length slider to set or enter the length of needle. Set the handle diameter and length in mm. Select Confirm to proceed with the plan
5. Select Add Probe or Add Parallel Probe button to plan for multiple needle plan.

☞	Ensure the selected needle is of the appropriate length for the procedure.
☞	MAXIO® displays biopsy gun length in the needle trajectory, if the Procedure type is chosen as Biopsy. For Pain management and Other procedure types, Needle trajectory alone is displayed.

Continue with Anesthesia planning and check for display positioner as explained in previous sections.

Biopsy Gun Length:

The throw length of the biopsy gun is marked as yellow, red, and blue points from the tip of the probe, representing 1 cm, 1.5 cm, and 2 cm needle throw, respectively.

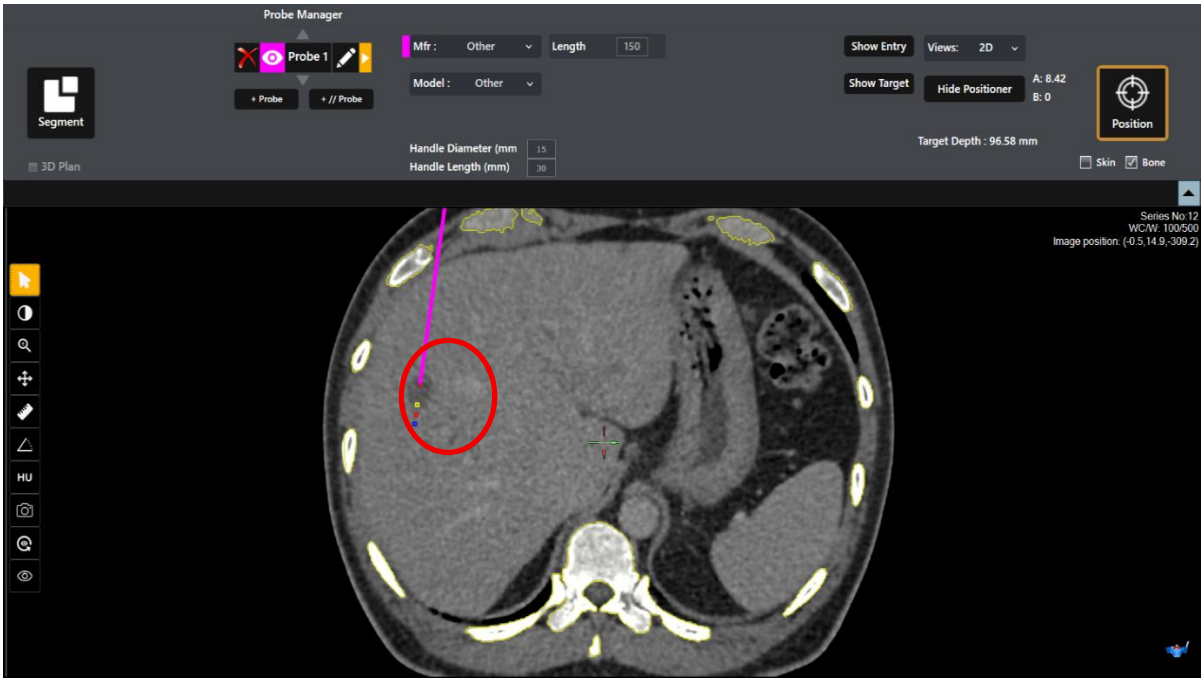


Figure 6.44 *MAXIO displays Biopsy gun length*

6.3.9 MAXIO® for PET-CT Interventional Procedures

We can also use MAXIO for PET-CT images for interventional procedures.

1. To load PET-CT image →Send PET-CT image to MAXIO software.

☞	NOTE: Load the PET-CT Image by Transferring the CT Image Series First, Followed by the PET Image Series.

2. CT image series are indicated in yellow color when it has the associated PET images as shown below.

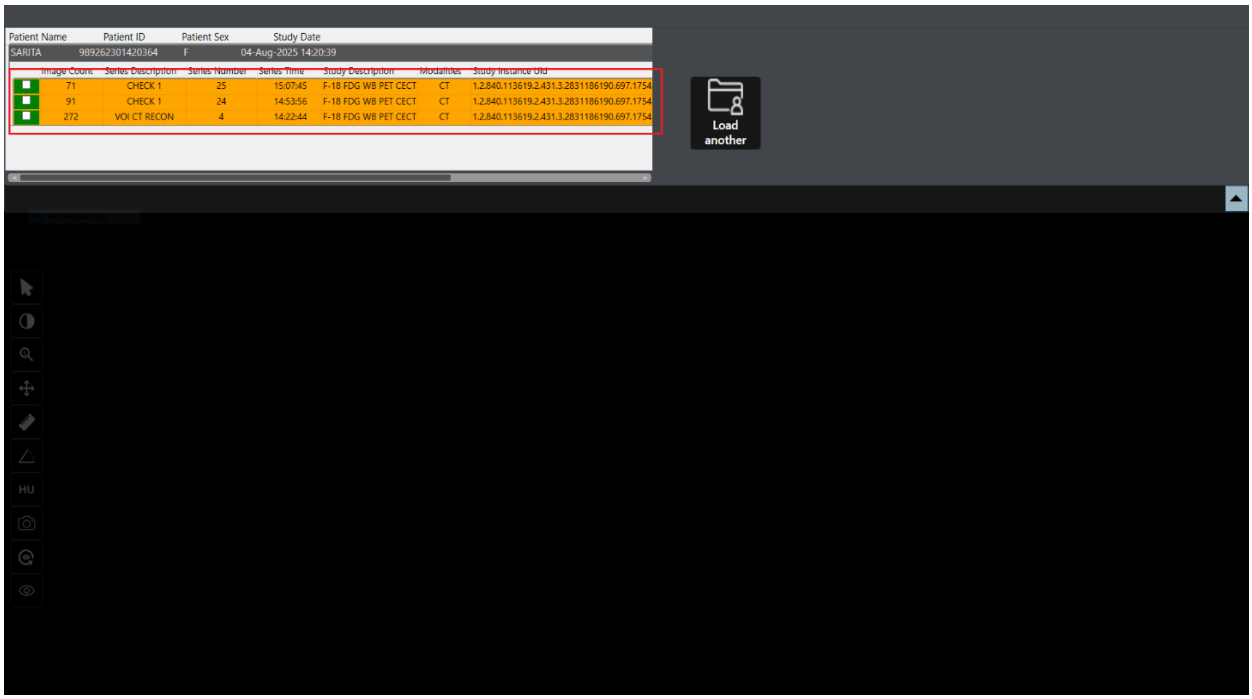


Figure 6.45 PET Datasets

3. Load CT image in the displayed screen (Fig6.46) then use Load PET option

☞	NOTE: The user can load the PET series from the below shown screen (Fig6.46) for all workflows

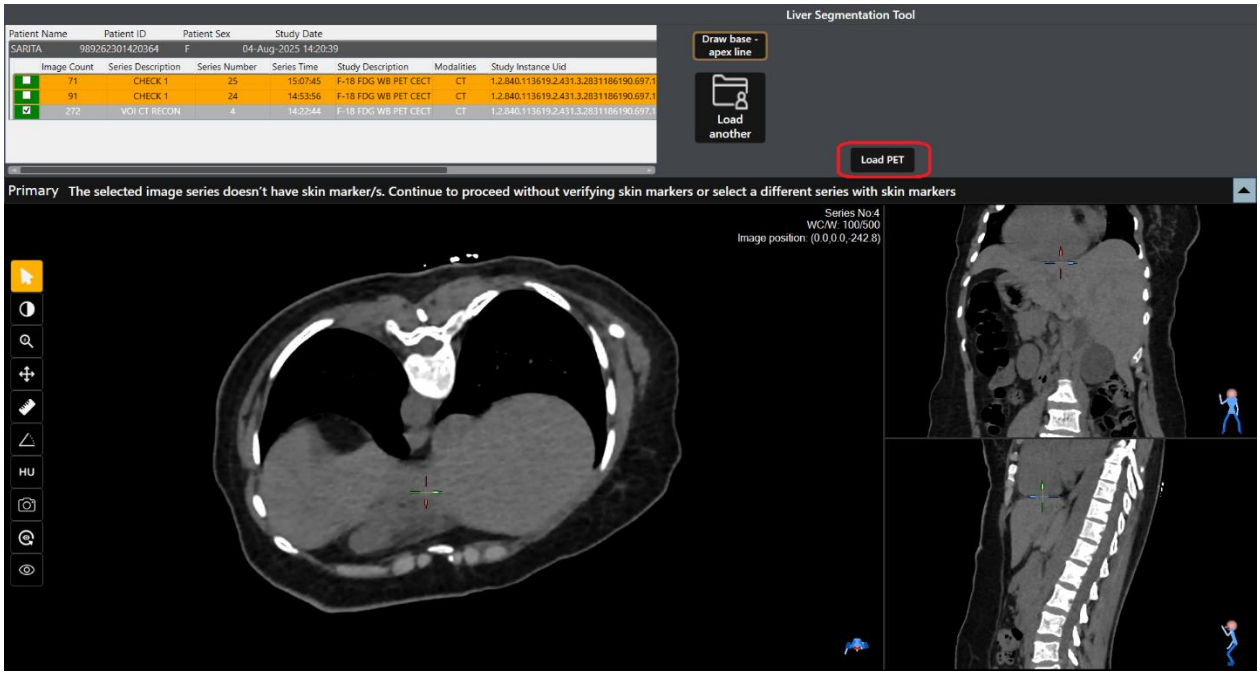


Figure 6.46 Load PET button



Figure 6.47 Load PET button to load PET

4. In the list of PET image select the Image series which we are going to use and click Load PET option.



Figure 6.48 Load PET button

5. To modify the opacity of the PET image and adjust the window level, utilize the "Modify PET-CT Opacity" option located within the tools section. Then, simply manipulate the associated slider to achieve the desired effect.

6. A user-adjustable slider allows configuration of the SUV (Standardized Uptake Value) window used in PET-CT image fusion. By default, the SUV range is 0–30 g/ml. and the maximum value can be adjusted between 30 and 100g/ml The selected SUV range is applied to overlay the PET signal onto the CT image. The fusion display dynamically updates in real time to reflect any slider adjustments.

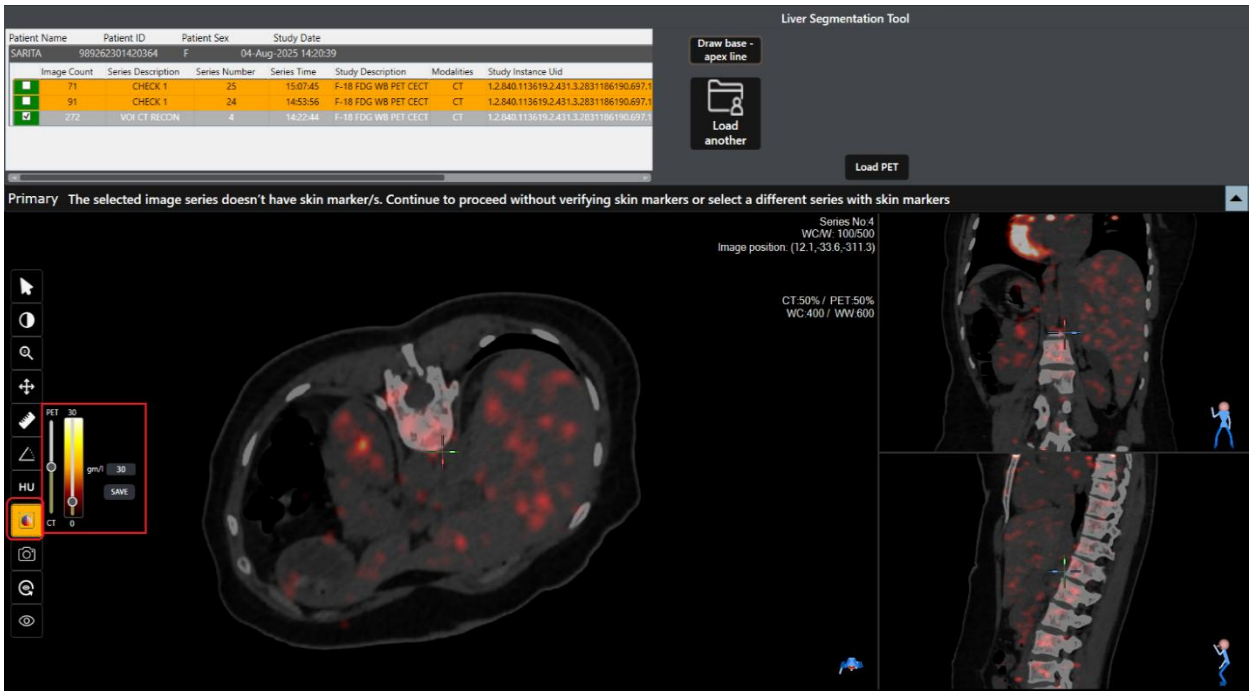


Figure 6.49 PET SUV Adjustment

7. The maximum SUV value can be changed in the g/ml textbox. After clicking Save, if the entered value exceeds the allowed maximum range, an alert will be displayed as shown in the image below

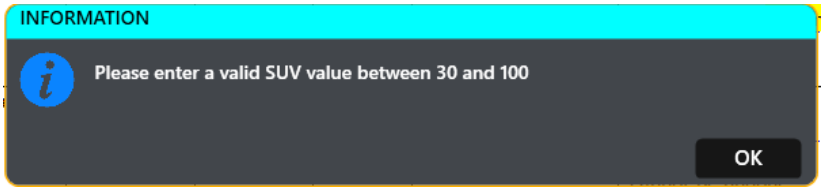


Figure 6.50 SUV Value range

8. Follow the steps from 6.2.1 to continue procedure.

6.3.10 MAXIO® for registered CT-MRI Interventional Procedures

We can also use MAXIO for registered CT-MRI images for interventional procedures.

1. **Send CT and MRI Images**

   Send the CT and MRI image data to the MAXIO application from the CT console

2. **Assign Studies (if CT and MRI are from different studies)**

   If the CT and MRI images belong to different studies, they must be assigned before performing the CT–MRI registration procedure.

   - Click the **Load Patient** button.
   - Confirm the CT image series using the **Confirm Patient** button.

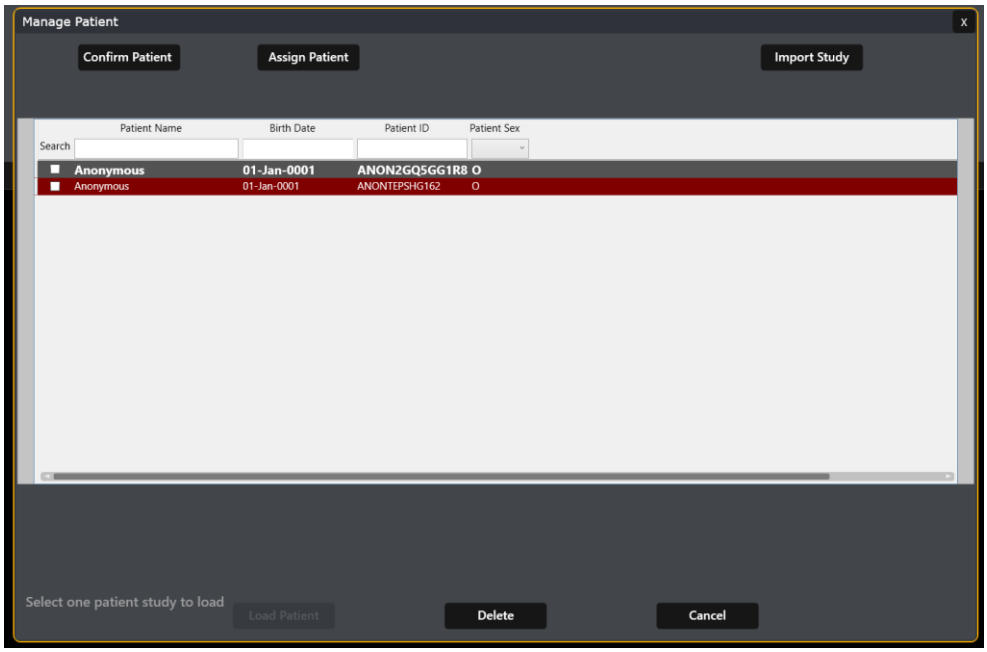


Figure 6.55 *CT-MRI Manage patient screen*

- Select the CT study and the unconfirmed MRI study, then click the **Assign Patient** button. Click “Yes”.

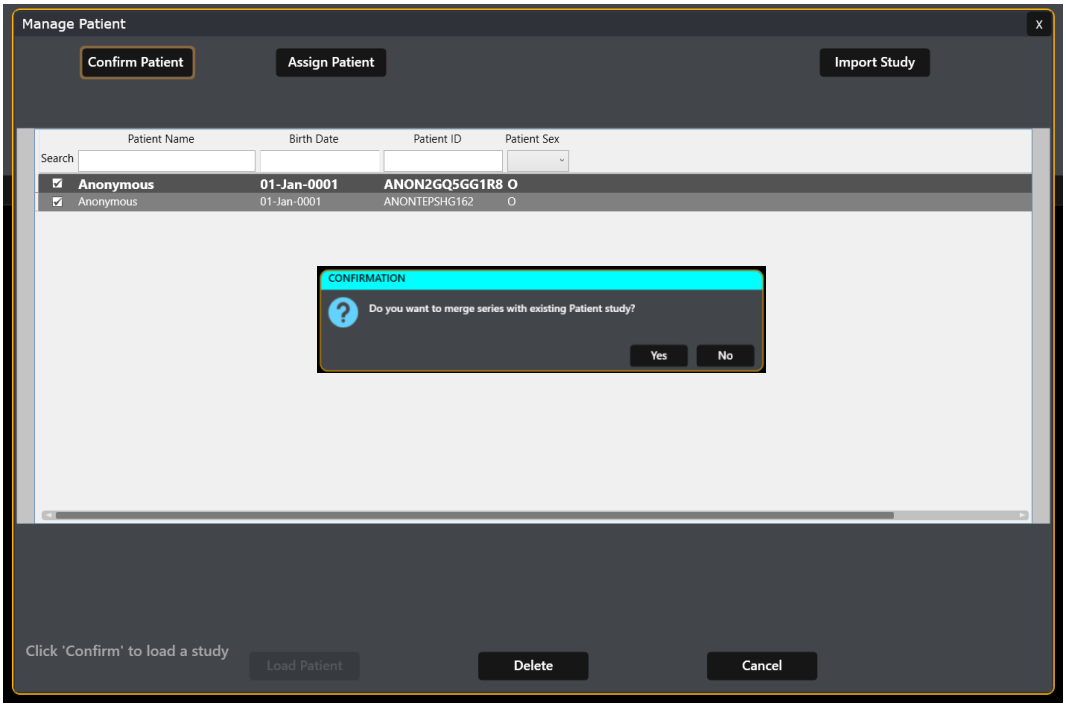


Figure 6.56 *Assign Patient confirmation*

- The MRI study will be assigned to the corresponding CT study, as shown in the example image below.

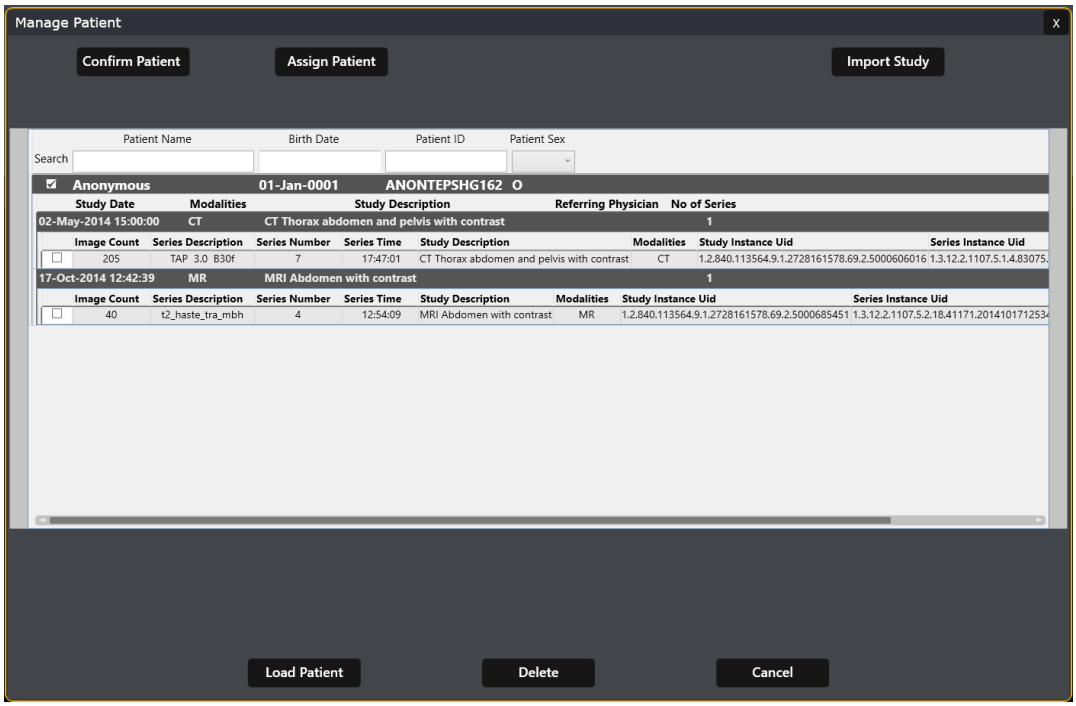


Figure 6.57 *Assigned Patient list*

3. **Load CT and MRI Images**

   Load both CT and MRI images onto the display screen. Upon successful loading, Mark the Liver. After Liver registration the **Registration: CT–MRI** window will appear.

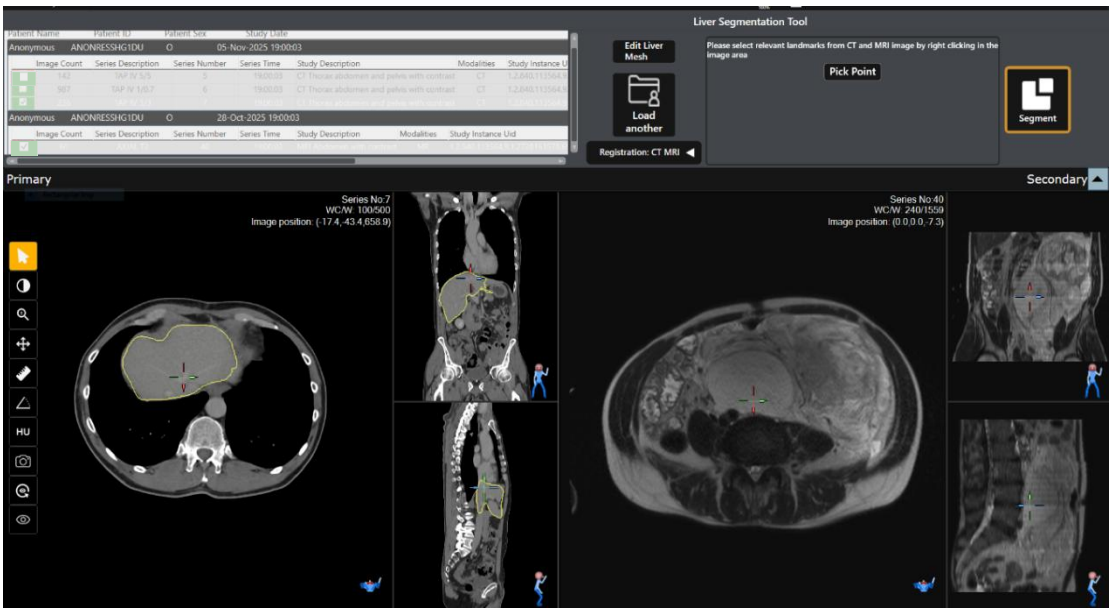


Figure 6.58 *CT-MRI Loaded*

4. **Pick Landmark Points**

   Click the **Pick Point** button to select corresponding landmark points on both CT and MRI images.

   - Choose the same anatomical or relevant locations in both images by right-clicking in the image area.

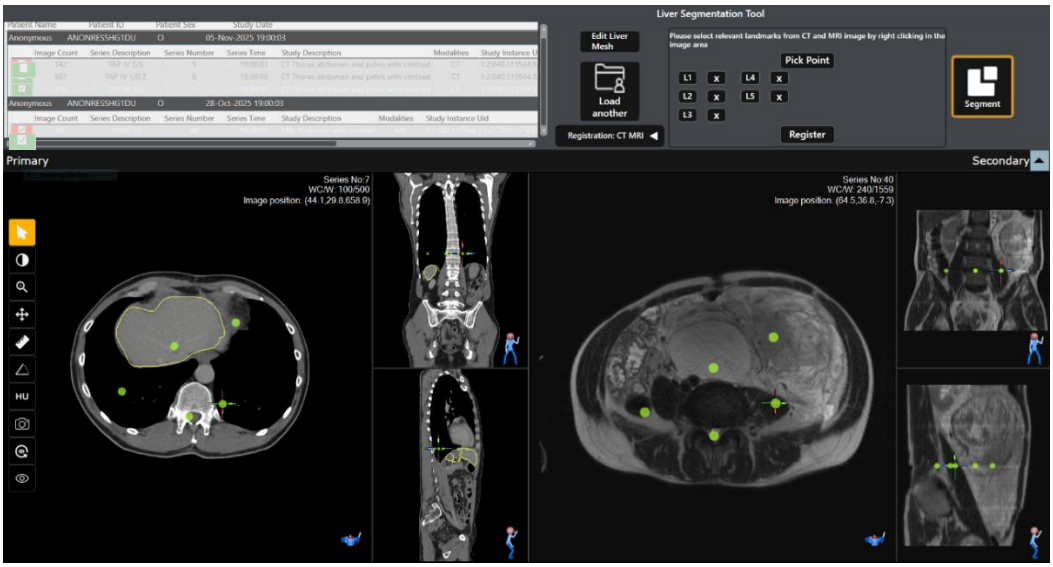


Figure 6.59 *Landmark point marked*

- If a landmark point is incorrect, it can be deleted using its corresponding **Delete** button.

5. **Register Images**

   After selecting the minimum (3) required number of landmark points, click the **Register** button.

   The registered images will be displayed in **Magenta (CT)** and **Green (MRI)**. The registration progress will also appear in the status bar (see Figure 6.70)



Figure 6.70 *CT-MRI Registration Progress Bar*

☞	NOTE: Maximum allowed landmark points up to 8

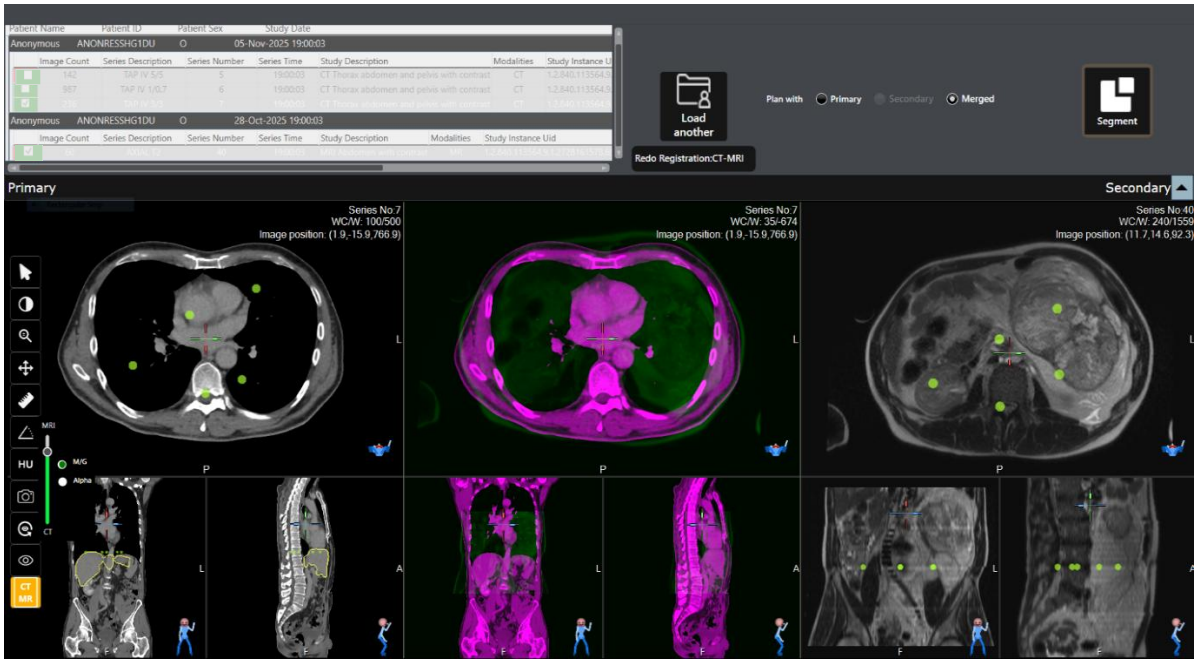


Figure 6.71 *CT-MRI Registered image*

6. **Adjust Opacity and Window Level**

To modify the opacity of the registered images and adjust the window level, use the **Modify CT–MRI Opacity** option in the **Tools** section.

Move the slider to achieve the desired balance of **Magenta/Green (M/G)** and **Alpha** blending.

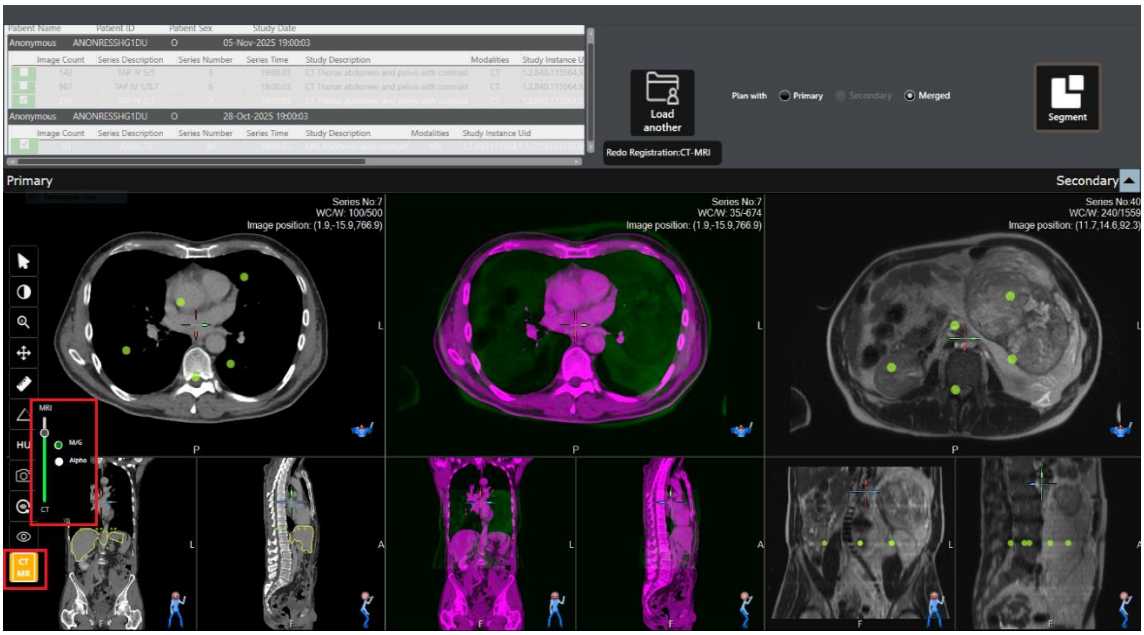


Figure 6.72 *Magenta/Green*

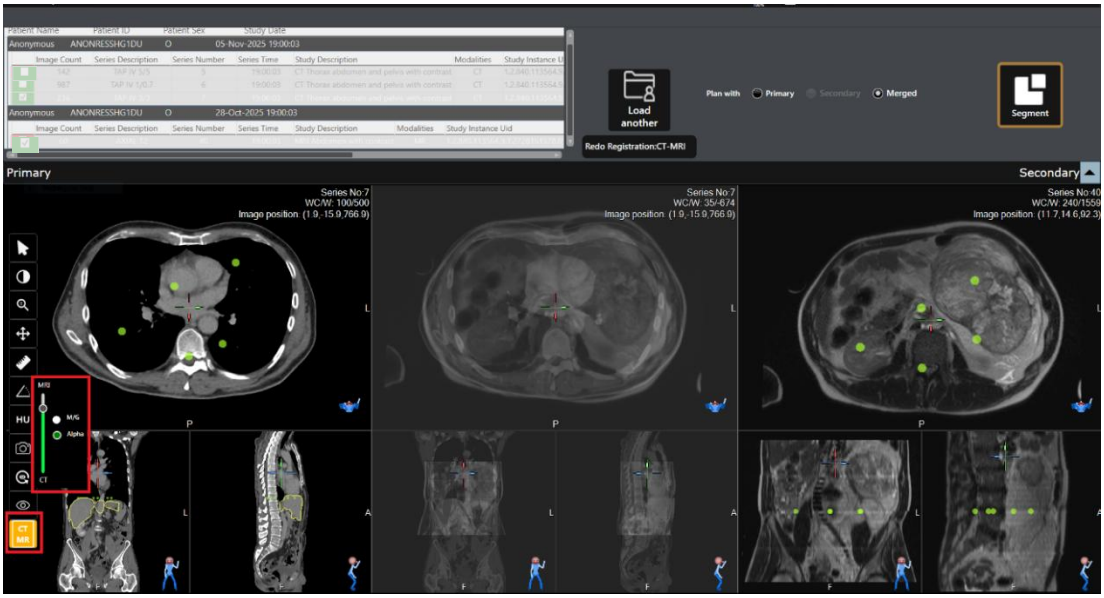


Figure 6.73 *Alpha Blending*

7. **Redo or Re-register**

To redo the registration, click the **Redo Registration: CT–MRI** button. You may re-register using the existing landmark points or delete them and create new points as needed.

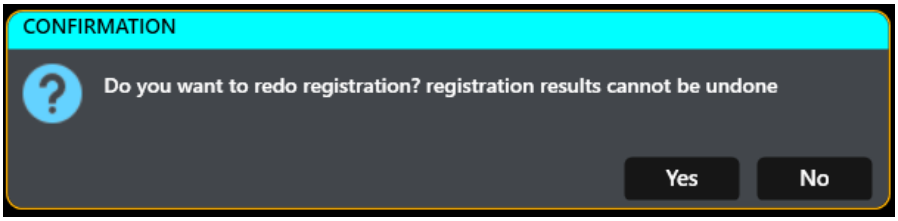


Figure 6.74 *Confirmation for Redo Registration*

8. Proceed with the workflow using either the **Registered Image** or the **CT Image** as required

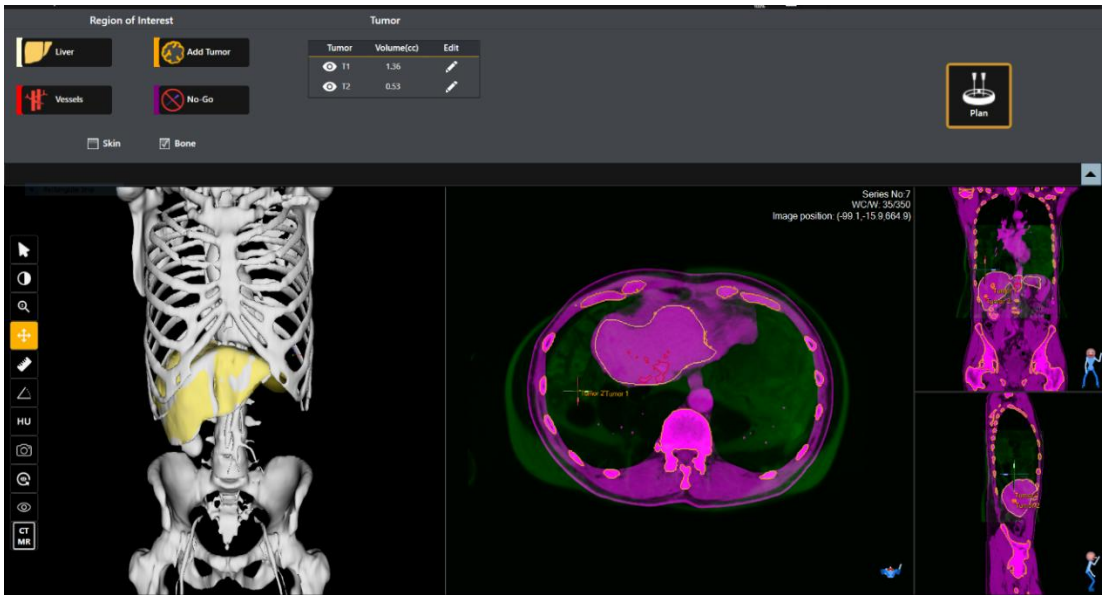


Figure 6.75 *Segmentation screen with registered CT-MRI image*

☞	Robotic positioning will be done in CT coordinates; MRI image overlay is only to help in the identification of lesions

9. Follow the steps from 6.2.1 to continue procedure.

7. PATIENT SKIN PREPARATION

Follow appropriate clinical practices for skin preparations. Ensure to cleanse the incision area and rest of the extremities as per standard hospital and clinical practice.

1. Clean the skin markers with the same sterile solution used for patient skin preparation, if the skin markers are placed in the sterile zone. Ensure the skin markers are clean and clearly visible.
2. Drape the patient for the procedure, ensuring the skin markers are not covered by the drape. If needed, cut the drape using sterile scissors to increase the opening.

	NOTE: Ensure that the skin markers are not covered by the patient drapes. In case the drape holes are not big enough, use a sterile scissor to cut the drape hole such that all the skin markers are exposed
	WARNING: Ensure that skin markers do not get peeled off during cleaning. Use fresh skin markers and redo scan incase skin marker peels off.

8. PROBE/TOOL POSITIONING

Select the Device Positioning workflow status icon. The Device Positioning screen is displayed.

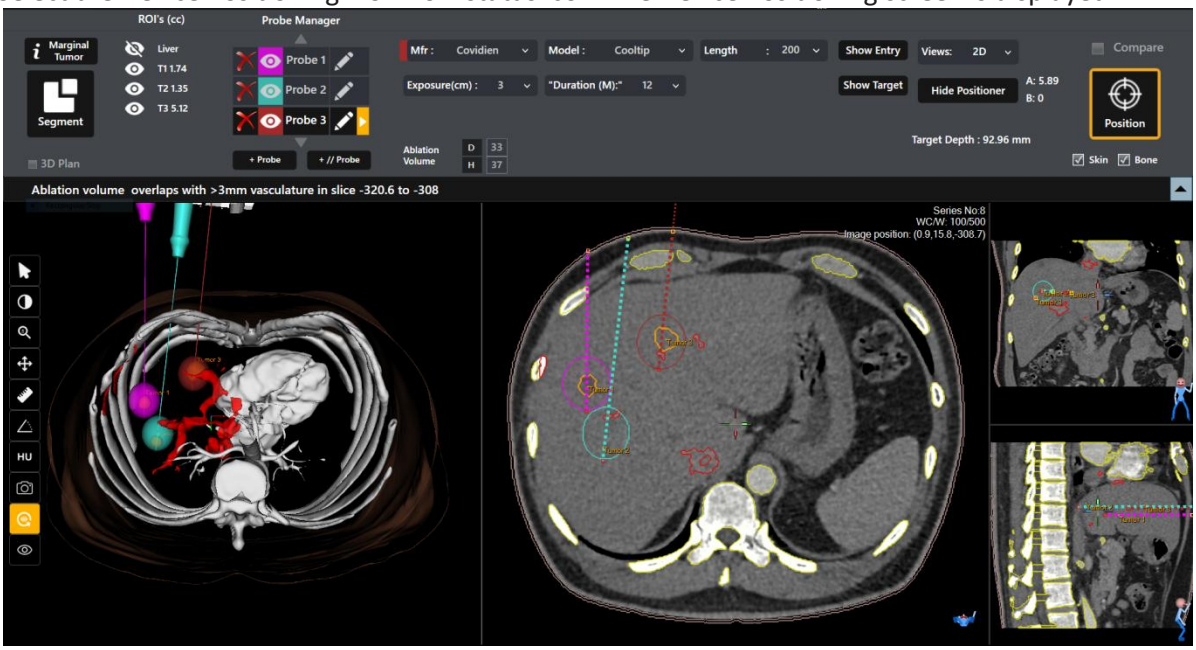


Figure 8.1 *Device Positioning Screen-Skin Marker*

8.1 Patient Position Confirmation Module

This module is provided for verification for any change in the patient position prior to needle/tool placement. The module includes QA/Skin markers provided with MAXIO® system and a laser cross-hair unit mounted on the End Effector axis



Figure 8.2. *Laser cross-hair verification*

	NOTE: Ensure that the End Effector Grippers are kept open when laser is turned on

	WARNING: The laser unit is defined as a Class 2 laser product. Do not look directly into the laser beam.
	WARNING: Prolonged exposure to the laser beam may be injurious to health. Turn off the laser immediately following use.

Patient Position Confirmation:

Patient position confirmation is the process of establishing a set of patient position reference points through markers on the patient's skin surface. These reference points can be checked before every needle/probe insertion to verify that the patient position has not changed.

See Patient Preparation at chapter 7 and section 4.1.3 for instructions on placing skin markers.

To confirm the patient position:

1. MAXIO® automatically highlights all the skin markers in the image and enables the Position button.
2. Click the Position button for Skin marker, MAXIO® automatically selects the sequence of skin marker to be verified.
3. "Arm laser" message is displayed in the device information box. Arm laser in the device.
4. Move CT cradle to the value indicated in the pop up window.
5. Acknowledge the Pop up. Device positions for the selected skin marker.
6. For the simultaneous and sequential positioning of the probes, positioning takes place in the following steps:
7. If there is no patient movement, Laser cross-hair aligns over the selected skin marker.
8. If the Laser cross-hair falls on the skin marker, click "Yes, Verify 2 of 3" in the pop up displayed. , otherwise click "No, Verify next".
9. On acknowledgement, device positions for the next skin marker in the sequence.
10. If the Laser cross-hair falls on the skin marker , click "Yes, Verify 3 of 3" in the pop up displayed, otherwise click "No, Verify next"
11. If more than three skin markers are placed, choose the skin marker manually to verify.
12. When three skin markers are verified successfully, MAXIO® allows to position probe. Click, "Yes, go to position probe" in the pop up displayed.
13. If the LASER cross-hair not aligns for one or more markers, re-scan the patient and plan on the new images.
14. For the simultaneous positioning of 2nd probe positioning takes place in the following steps:
15. If the skin marker position point is within the device range application will position the skin marker above the placed probe handle.
16. If the placed probe comes between skin marker and Laser cross hair, skin marker position takes place in two steps. After first step position, application displayed information to press the position foot switch continuously for second step position till the position completed. "Arm laser" message is displayed in the device information box. Arm laser in the device, Laser cross-hair aligns over the selected skin marker.

☞	NOTE: Ensure that the skin markers are not covered by the patient drapes. In case the drape holes are not big enough, use a sterile scissor to cut the drape hole such that all the skin markers are exposed.
☞	Clinician review and confirmation cannot be completed if there is an error reconstructing the planning image
☞	The planning workflow enforces clinician review and confirmation of QA/Skin markers on planning images

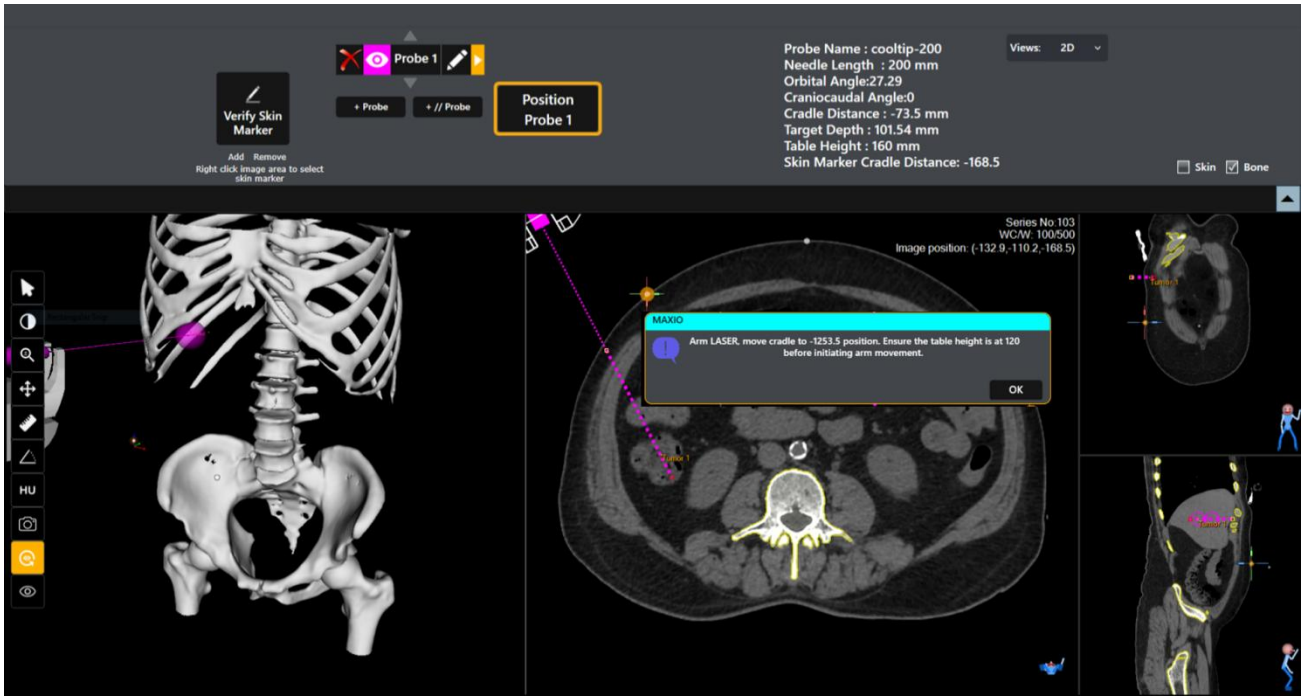


Figure 8.3 *Patient Position Confirmation*

⚠	WARNING: Patient movement during or between image acquisition and planning may lead to inaccurate case of a failed Patient Position Confirmation (if the laser cross hair is not aligned with one or more skin markers), the patient must be rescanned and a new procedure planned.
⚠	WARNING: Clean the skin markers with the same sterile solution used for patient skin preparation, if the skin markers are placed in the sterile zone.

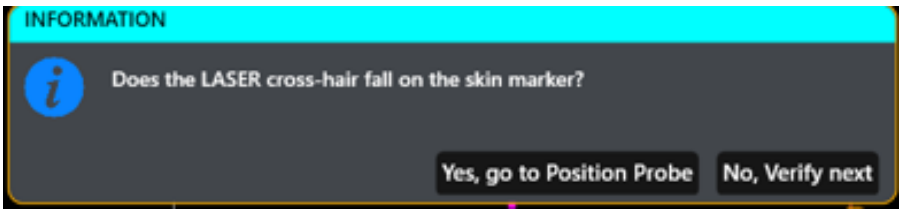


Figure 8.4 *Skin marker completion popup*

8.1.1 Positioning for probe placement

	WARNING: Patient movement after patient position confirmation and before needle placement may lead to in correct positioning of the needle. Care should be taken to avoid patient movement throughout the procedure. In case of any patient movement detected, repeat patient position confirmation before needle placement

1. Click the position button in the task pane.
   - The plan values for the first probe are displayed on the planning station and are transferred to the MAXIO electro mechanical arm.

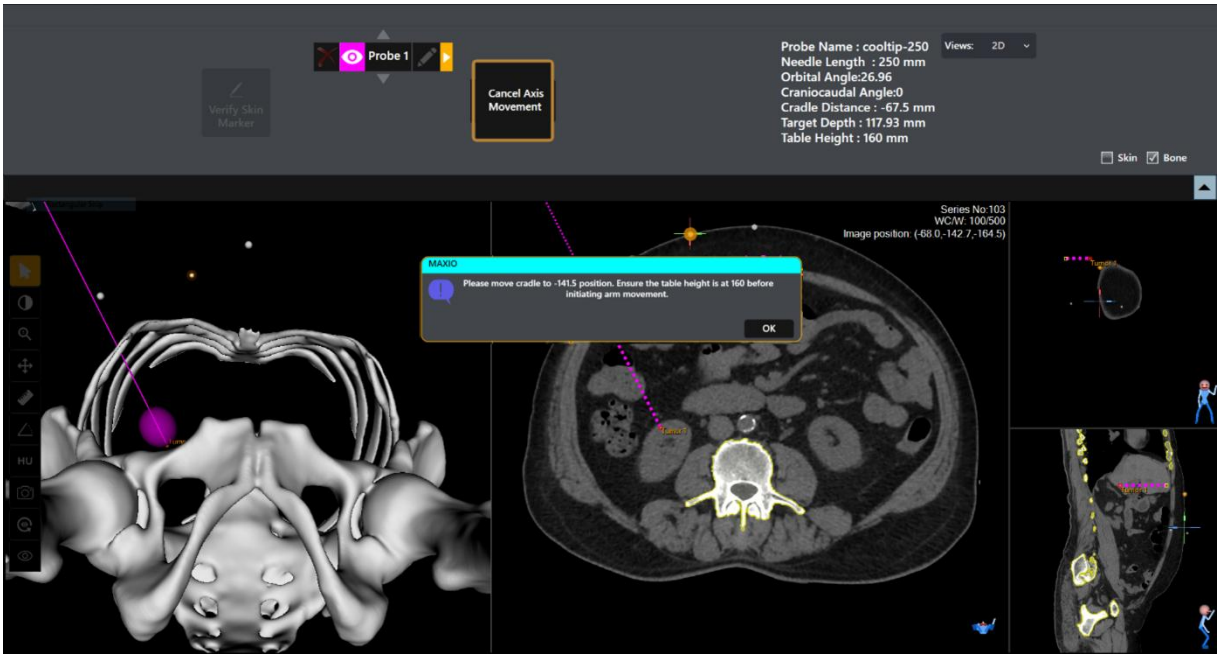


Figure 8.5 *Position probe*

2. The cradle position values for the CT table are displayed on the planning station



Figure 8.6 Cradle value displayed on CT gantry

3. Move the CT table to the cradle position for needle placement.

	WARNING: Accidental touching of gantry controls or any change in the table position may lead to inaccurate cradle positioning. Inaccurate cradle positioning will lead to inaccurate positioning of the needle. Cradle should be moved to the precise value displayed in the application every time the CT table is positioned.

4. Press the position button on the control panel (or step on the yellow Foot Switch) to position the device for probe placement.

- Enable the Laser Arm and verify that the laser is aligned with the correct entry point on the skin surface.
- If a local anesthesia plan is made, the device will first set the position for anesthesia and then for probe placement.



Figure 8.7 *Position anesthesia*

5. Positioning for Anesthesia Placement

- Place needle guide on the End Effector and press clamp/release button on the control panel(Blue Foot Switch) to clamp the needle
- Ensure needle guide is clamped tightly and insert needle through the needle guide.
- Deliver local anesthesia along the trajectory.
- Press the Clamp/Release button on the Control Panel (Blue Foot Switch) to unclamp and release the needle guide.
- Press Pullback button on the control panel (Black Footswitch) to pullback the device away from the patient.
- Verify Anesthesia needle placement or proceed to probe positioning.
- Press HOME and POSITION key in the control panel to position device for planned probe.
- Click position button in the task pane. Move CT table to the cradle position for needle placement.
- Place needle guide on the End Effector and press the Clamp/Release button on the control panel (Blue Foot Switch)to clamp the needle guide.
- Select the needle guide based on the gauge of the needle used
- Ensure the needle guide is clamped tightly by the End Effector before inserting the needle.

	Press the Emergency Stop key immediately to stop all axes if any unexpected or uncontrolled axis movement is observed
	WARNING: Long needles and those thinner than 18G are noted to bend during insertion. Where possible use short and thicker needles.
	WARNING: Needles that are held too tight or too loose may result in inaccurate placement of needles.

6. Optional: Give local anesthesia at the entry point to numb the skin surface for needle insertion. Insert the anesthesia needle through the End Effector and leave on patient skin surface to make the entry point.

- Deliver the local anesthesia around the point indicated by the anesthesia needle over the skin surface, in a circular fashion
- Make a nick on the skin with blade for large bore needles.



Figure 8.8. *Surface Local Anesthesia*

⚠	WARNING: Under sequential placement continuing to next probe placement without removing placed needles will result in collision and may result in harm to patient.

☞	NOTE: If the nick made after anesthesia does not match with procedure position, check the cradle values to ensure they have not moved
☞	NOTE: Perfint recommends that the MAXIO® System be utilized to deliver anesthesia precisely in the planned trajectory. However, the physician must make this determination as appropriate for each procedure

7. Insert the probe through the needle guide.
   - Ensure that the patient is asked to hold breath to the required level indicated by the breath hold monitor system during needle insertion and insert needle to the full extent of the chosen length.

⚠	WARNING: • Breath Hold Monitor not usable on patient due to clinical situation specific to patient. • Breath Hold Monitor is used to ensure that the patient breath level during CT scan and during needle/ tool insertion are maintained at the same level. • This is critical to ensure accuracy of needle placement based on the plan. • Alternate methods, including General Anesthesia, are used to maintain same breath level during CT scan and during needle/tool insertion based on clinical practice used during ablation procedures performed manually as well as based on clinical situation specific to the patient. However, MAXIO® has been verified only with the use of Breath Hold Monitor that is provided as an accessory. • It is the responsibility of the user to ensure that the patient breath level during CT scan and during needle/tool insertion is maintained at the same level
⚠	WARNING: Using needle of length other than the selected needle length will result in inaccurate placement and may result in harm to patient. Insert needle to the full extent of the chosen length (until the needle handle/hub rests on the needle guide).
⚠	WARNING: Bending the needle during insertion will result in inaccurate placement of the needle. Insert needle carefully to prevent bending.

	WARNING: Abnormal patient movement during needle insertion may result in harm to the patient. In case of abnormal patient movement during or after needle insertion, • Pull the needle out from the patient immediately. • Press the Clamp/Release button on the Control Panel to release needle guide from the End Effector, or • Press the Emergency Switch to release Needle guide from End Effector.

8. Press the Clamp/Release button on the Control Panel (Blue- Foot Switch) to unclamp and release the needle guide.

	WARNING: Holding the needle by the end effector when inside the patient body for a long time may result in laceration as patient breaths. Ensure that needle insertion is done as quickly as possible and that the end effector is released as soon as needle insertion is completed
	WARNING: In case Clamp/Release button failed to function, Press the Emergency Switch to release Needle guide from End Effector.

9. Press the Pullback button on the Control Panel (Black-Foot Switch) to move the electromechanical arm away from the patient.
    - If needed, press the Cancel Axis Movement button to cancel the procedure any time, before completion of the End effector clamp-release cycle.



Figure 8.9 *Cancel Axis movement*

10. Once MAXIO® has released the needle guide and moved away from the patient, the cradle can be moved inside the CT gantry for a check scan (see section 8.2 below)

	WARNING: Moving the cradle before disengaging the End Effector from the needle guide may result in harm to the patient. Do not move the cradle before disengaging end effector from the needle guide

8.2 Probe/Tool Verification

On completion of Probe/tool insertion, the clinician can perform a CT scan of the patient and transfer the same to MAXIO® planning station to verify the needle/tool placement.

1. Transfer the images to the MAXIO® planning station.
2. Click Verify button in the task pane as shown in the figure. 8.10 This will take the user to image registration screen.



Figure 8.10 *Verify Probe Placement*

3. Select the series to load the image.
4. MAXIO will automatically overlay the selected series with the planned series, if the slice count is less than 64. Options such as Mark liver for organ based registration and Overlay, can be used to verify the probe placement in Planned Vs Check-scan image, if the slice count is more than 64.
5. Click Overlay button to overlay the primary and secondary series if the patient hasn't moved in the check-scan image.
6. If the secondary series has full liver, Click Mark liver followed by Segment and Register.
7. Intra Operative registration happens. Verify the correctness of the registration. Check if the registration is good to continue. If it is not, Click Manual Correction button to sphere edit the portion in liver. Click CORRECT to correct the edited portion or REVERT to revert back the changes made.

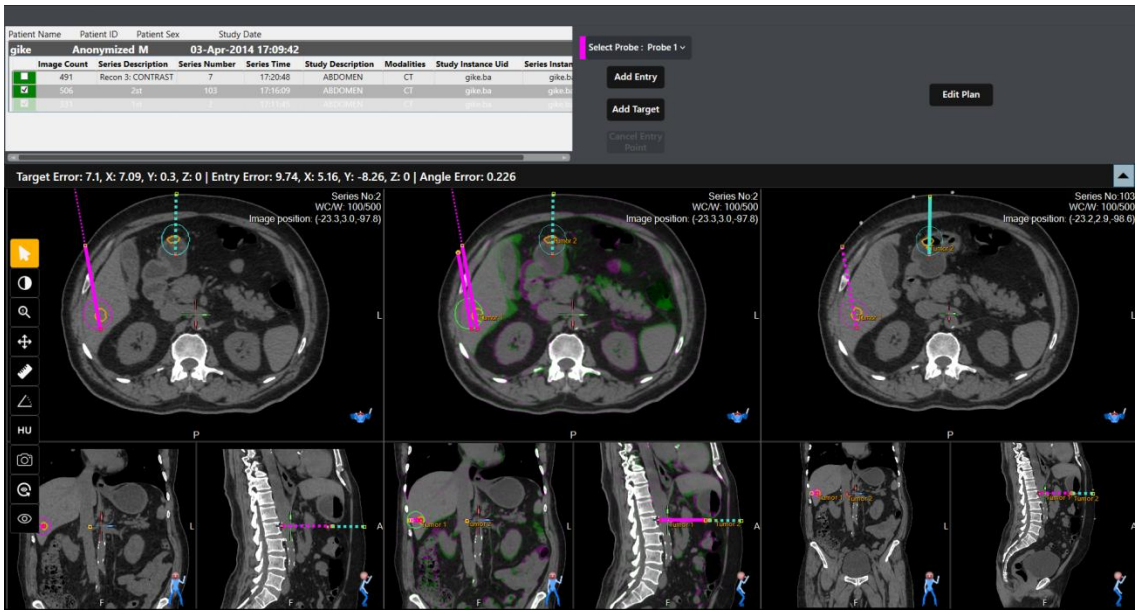


Figure 8.11 *Intra-Operative Registration*

8. Click "CONTINUEPLAN" to continue for further probe placement in cases where the probe/tool is placed exactly as per plan.
9. Compare option can be used to assess the current plan with an alternate plan by selecting an entry and target to analyze options before proceeding Further.
10. The information bar displays the **3D distance** between the planned and actual **entry points** and **target points**, as well as the **plan-to-actual angle** for comparison.

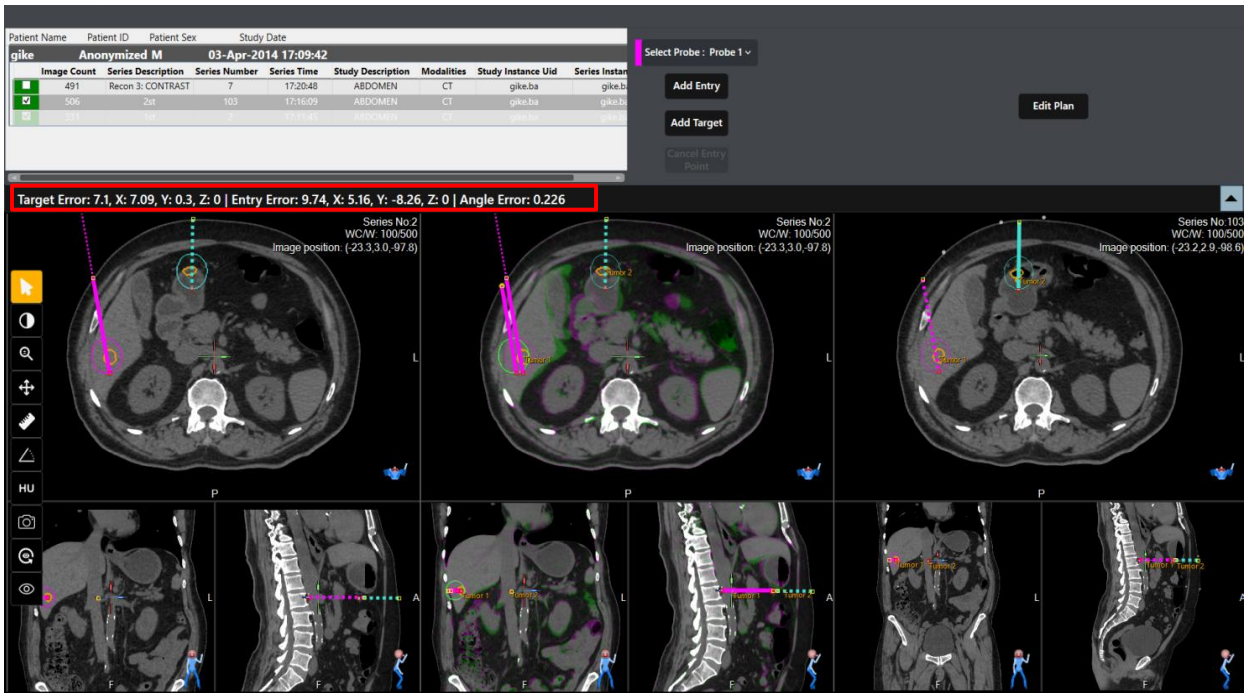


Figure 8.12 *Needle deviation*

11. Application shall display the needle placement deviation in the following format both Entry and Target
    Target Error:<3D Distance >, X:<Distance in X-Axis>, Y:< Distance in Y-Axis>, Z:< Distance in Z-Axis>
    Entry Error:<3D Distance >, X:< Distance in X-Axis>, Y:< Distance in Y-Axis>, Z:< Distance in Z-Axis>
    Angle Error: <Difference in Angle >

12. If no other probe/tool is planned, perform ablation procedure and navigate to post-procedure verification screen.

8.3 Port Plan and Edit Plan for Multiple Probe/Tool

In case, there is marginal deviation observed in the registered image, the user can port the plan from primary series to check scan image. Click edit plan to edit the remaining probe/tool plan in the newly acquired check scan image based on the actual probe/tool placement and continue the remaining probe placement.

9. POST PROCEDURE VERIFICATION

On completion of the procedure, the clinician can perform a CT scan of the patient and transfer the same to the MAXIO® planning station to verify the effectiveness of procedure.

1. Transfer images to the MAXIO® planning station. Click “Refresh list” button to refresh the Patient image loaded screen.
2. Select the series to load the Post ablation image.
3. Click Mark ablated region button and mark the ablated region in the secondary image and confirm. If multiple tumors are ablated, mark the ablated region of all the tumors in the secondary image and confirm. Use the edit tools as appropriate.
4. If the user had segmented liver in the planned image, then mark and segment liver in the loaded Post ablation (Secondary series) image and Register. Else, click Intensity Registration to register the planned image (primary series) and Post ablation image (secondary series).

In the registered image user can see the planned ablation volume and segmented tumor registered with marked ablated region. “3D view" of the registered image is displayed by default. The user can load another post ablation series and verify the ablation effectiveness.

5. Uncheck the loaded post ablation image
6. Click Refresh button
7. Load the new post ablation image and perform the above mentioned steps.

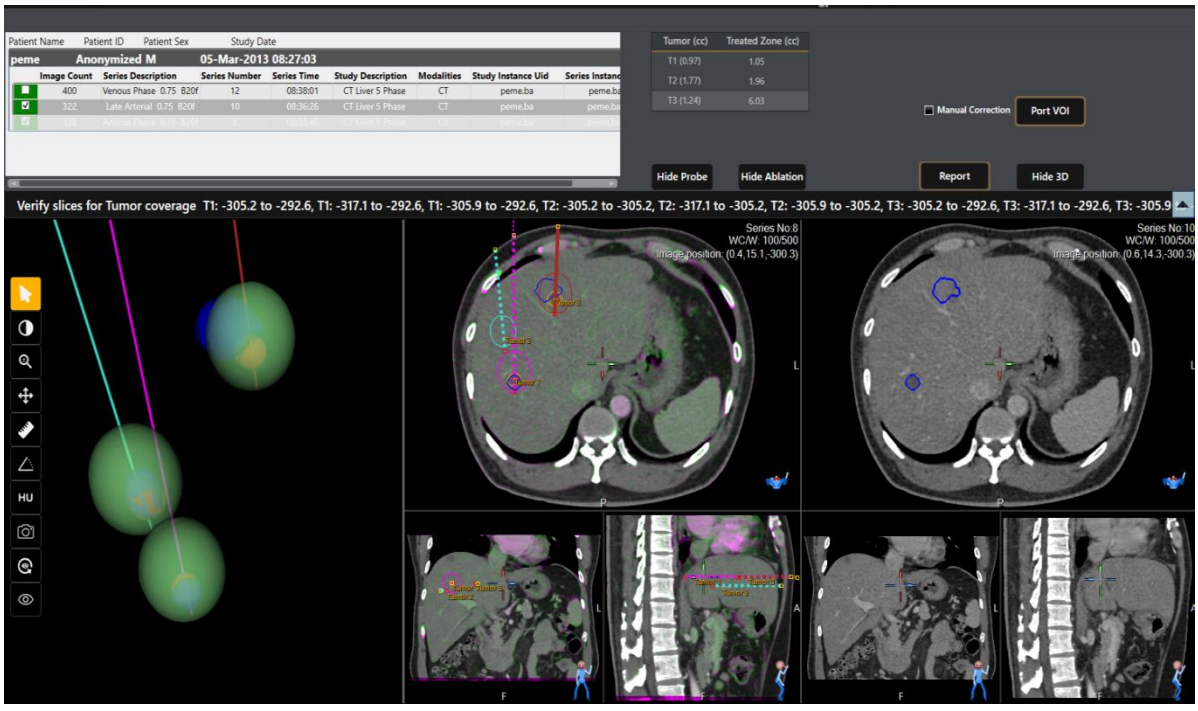


Figure 9.1 *Post Procedure Validation*

9.1 Ablation Margin in PostVerify

The **Ablation Margin** option in the PostVerify module becomes active when the tumor has any remaining volume not covered by the achieved ablation volume. When this occurs, information is displayed in a table indicating the range of image slices where the un-ablated tumor volume is located.

1. After completing post-procedure verification, click the **Port VOI** button. The registration progress

will be displayed in the status bar as shown in figure 9.3



Figure 9.3 *Image Registration Progress Bar*

2. The system highlights **un-ablated tumor regions** in **red**, indicating the slices where the tumor is not covered by the achieved ablation volume.
   The **achieved ablation volume** is displayed in **blue**, and the **actual tumor** is shown in **orange**.
   You can also check the specific slice numbers that contain un-ablated areas by clicking the **Marginal Tumor** button.

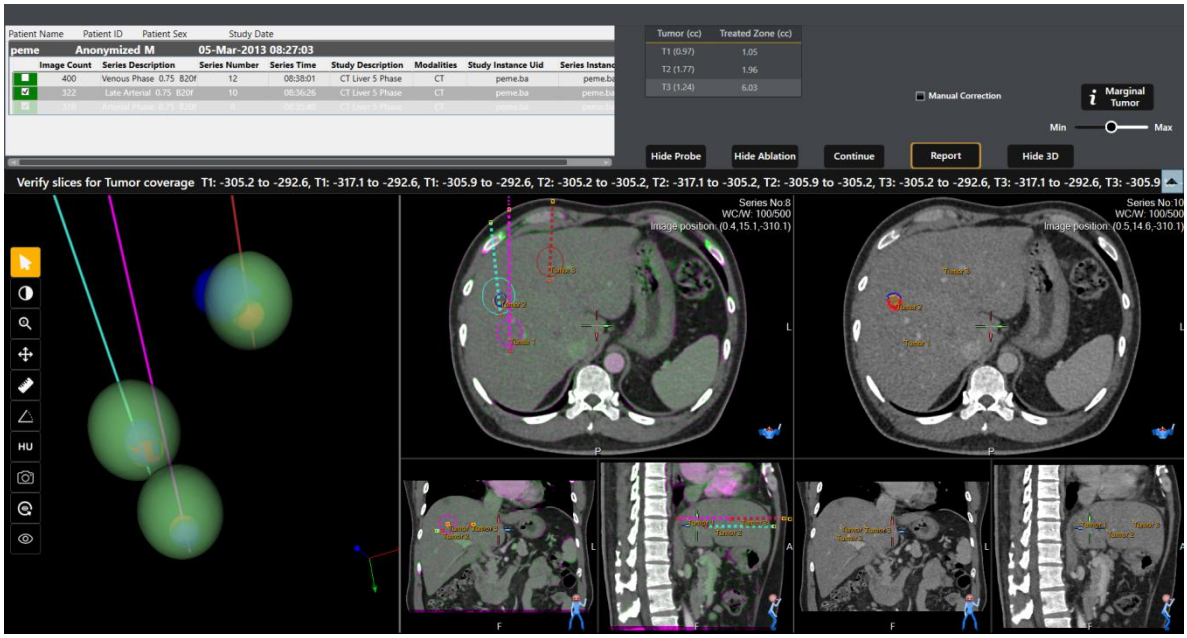


Figure 9.4 *Post verify screen after Port VOI*

3. Clicking the **Marginal Tumor** button opens a table listing the slice numbers with un-ablated tumor regions. Each slice number in the table is a **hyperlink**. Click a slice number to automatically navigate to the corresponding slice in the image viewer.

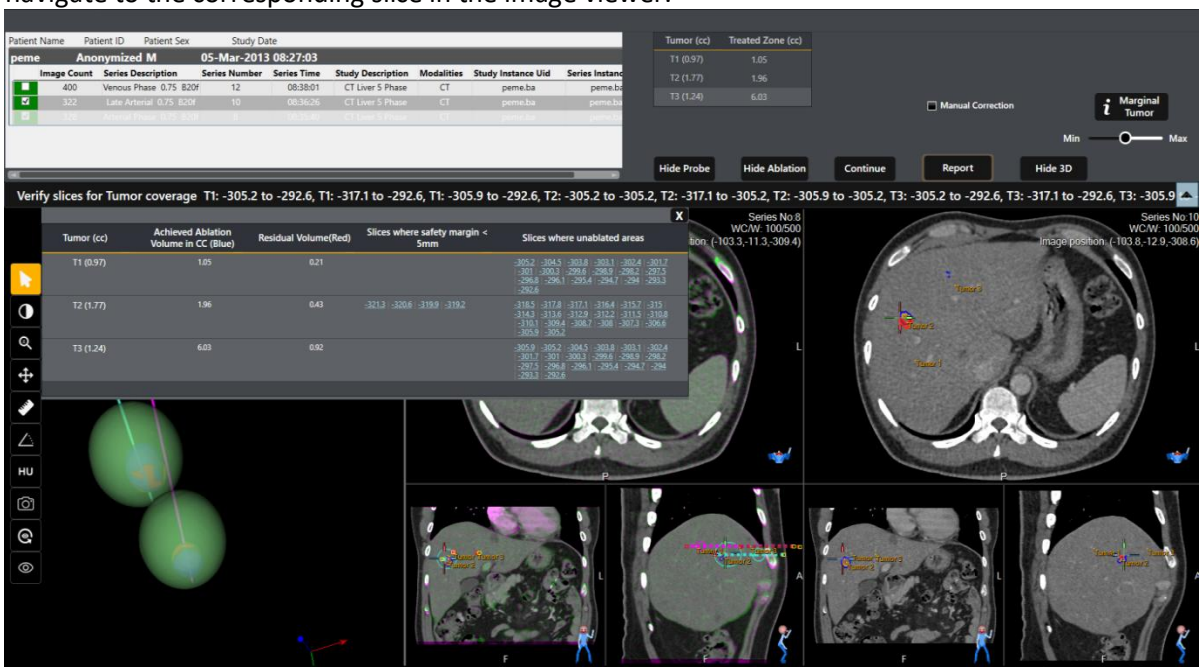


Figure 9.5 *Unablated area table*

4. The table also displays slices where the **safety margin is less than 5 mm**, indicating areas that are not ablated within the required margin. You can adjust the **safety margin value** by moving the **slider (0–10 mm)** while keeping the **Marginal Tumor** table open. Verify the updated safety margin coverage directly in the table.

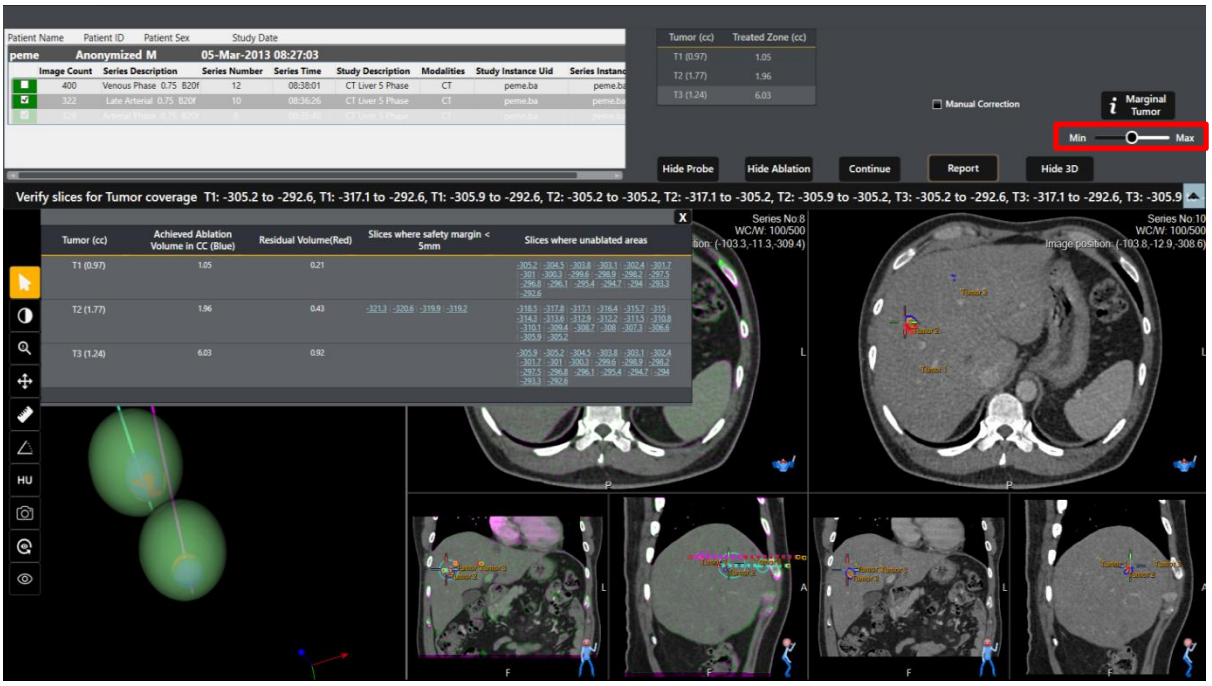


Figure 9.6 *Safety margin slider*

9.2 MAXIO® Procedure Report

After completion of the procedure, clinician can create a procedure report.

1. Click Report button.
2. Choose images to be included in the procedure report and confirm.

A procedure report is created as shown below, and can be saved.

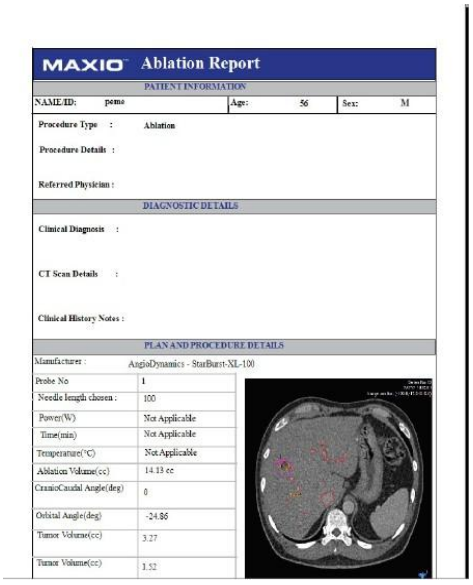


Figure 9.2 *Report screen*

9.3 Device Undocking

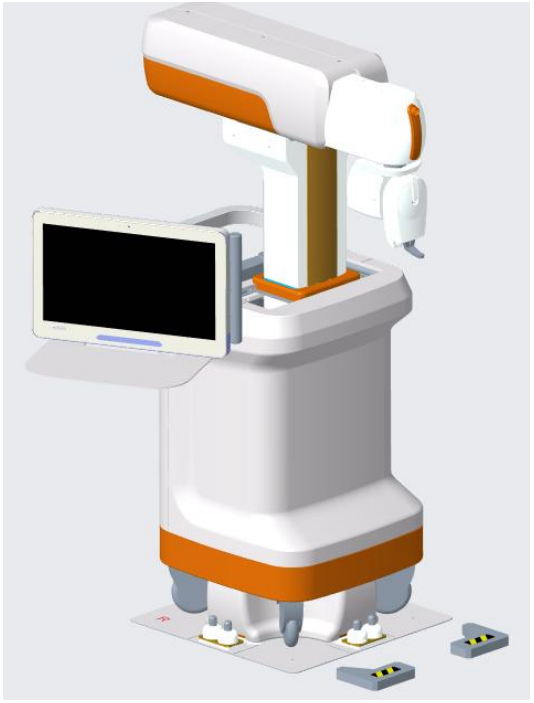
For undocking the device, press the “Dock” key on the control panel. This releases the mechanical lock and the wheels are lowered down. MAXIO® can be pulled and moved away from the docking station. Docking/Undocking can also be performed from the software using “DOCK”, “UNDOCK” buttons in settings.

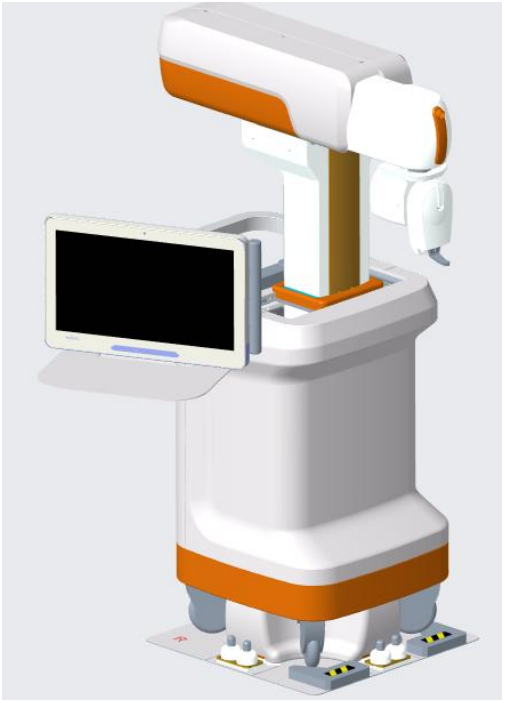
	After undocking, ensure that the rubber plug is placed back onto the InstaReg mat.
	Ensure that the patient movement is managed during a procedure to avoid inaccurate needle positioning.
	Do not change or move the system (e.g., table height) during a procedure. Be cautious while moving the cradle.
	Confirm that the CT gantry console is secure from accidental pressing of gantry controls. Gantry / Table movement between procedure may lead to wrong positioning
	Select the needle guide according to the needle gauge. Do not use a needle guide that does not match the needle gauge.
	Confirm needle guides are clamped tightly by the End Effector before inserting the needle.
	In case of abnormal patient movement, when the needle is held by the grippers pull out the needle to avoid any injury.

After Undocking the device, press ‘Home‘ key on the control panel, to move the device axes to the compact parking condition. Switch OFF the PC and Device in the connector panel.

9.4 Device Parking

- Parking stopper is fixed on the floor space allocated for parking the device in the CT room.
- Rotate Monitor Arm away from the wall to keep the MAXIO device closer to Wall/CT gantry.
- The device should be moved slowly and stop when the Castor wheel touches the stopper (straight edge).
- When the device is parked on this parking space, the stopper will not allow the castor wheel to move further to prevent the device from hitting the wall or other devices/solid objects during parking.
- After device touches the Parking stopper lock the Castor wheels.
- During Procedure Unlock the Castor wheels, Pull back the device and move toward docking plate.
- Unlock the Castor wheels and move MAXIO from the parking area to the docking area on left or right of the CT table. Disconnect the AC power supply if MAXIO battery was charging at parking area.





10. DEVICE PARKING AND TRANSPORTING

This chapter describes the measures to be taken while parking and transporting MAXIO®.

10.1 Moving the Device

When moving or transporting the system, follow the precautions below to ensure the maximum safety for personnel, the device, and other equipment. In case of any accidental damage during movement or transportation, call Perfint Service.

Before moving the device, perform the following steps

1. If the device is in docked condition, press the docking switch in the control panel to undock the device.
2. Press the Home key to position the device in HOME.
3. Remove the Sterile Drape and disposable grippers and trash in biohazard containers.
4. Shut down the planning station.
5. Disconnect all cables. To prevent damage to the Power Cord, DO NOT pull excessively on the cord or makes sharp bends while wrapping.
6. Unplug the power cord (if the system is plugged in).

	MAXIO®has to be parked and transported in the Home Position.
	In case of any damage during device movement/transport, call Perfint Service
	Special attention must be given to the Grippers/ Holder arm during device movement or transport. Grippers/ Holder arm may get damaged due to accidental hits.
	Always switch OFF and disconnect from the power supply before device transport.
	Do not use the device if a castor does not rotate freely, the device drags or pulls to one side, or the device wobbles during movement. This may indicate damaged castor wheels or loosened screws. Contact Perfint Customer Support
	Always use the handle to move the system. Avoid scraping or collision of the device with other devices and building structures. Limit movement to slow walk.
	Two people are needed to move the unit in inclined plane.
	Attempts by one person could result in injury or damage. Maximum allowable floor inclination is restricted to 5 degree.
	The maximum allowable height of obstacles over which the device may be moved shall not exceed 20 mm.

10.2 Parking the Device

The parking area should be a 3x3 feet free area at any corner at the CT room having a 5A power socket for battery charging. Also, a 3 feet path from the parking to docking area must be maintained.

Steps to be followed for parking

1 Move the equipment to the parking lot and properly park the equipment.

2 Lock the castor wheels.

10.3 Transporting the Device

Use caution while transporting the system using vehicles. In addition to the instructions used for moving the system also perform the following steps:

1. Before transporting, place the system in its special storage case.
2. Ensure that the system is firmly secured while inside the vehicle.
3. Secure system with straps to prevent motion during transport.

	In case of any help in device transport call Perfint Service.

11. BATTERY STORAGE AND HANDLING INSTRUCTION

11.1 Device Regular Use

MAXIO® device needs to be connected to AC mains power during regular use. MAXIO® device supports two battery backups

1. Device battery: EXIDE EP1234W or EP 9/7 AH (EXIDE Power safe)
2. PC battery: ONYX ZEUS-BAT03 (14.4 VDC)

As standby power source during unexpected AC mains off situation, so that the device can continue functioning until the device is connected to an alternate AC power source.

	If the MAXIO® device battery charge becomes critically low during a procedure, loss of essential performance may occur, which could result in inaccurate needle placement. Ensure the device is sufficiently charged or connected to AC power before use.

The MAXIO® device will alert you to the percentage of charge remaining in the Device battery with a series of steady Green (>75%), Yellow (<75%) and Red (<50%) indication through MAXIO® software, and an alarm that will beep during AC power interruption. If the Device battery charge level falls below 75%, the device gives periodic beep and the duration of the beep increases with reducing charge. Remember, the Device battery needs to be charged to 100% every day. The Device battery continues to charge whenever the device is connected to AC mains, so always keep the device connected to AC main switch AC mains switch ON condition to avoid running out of Device battery backup.

During procedure if the Device battery falls below 50% (Red) with no AC mains, it is recommended to reconnect to AC mains as soon as possible to continue the procedure. The 50% of Device battery charge is intended to be used to move the device safely out of the procedure area. Do not continue the procedure when the Device battery charge falls below 50% and AC mains not available.

NOTE: Frequent operation of the device while Device battery charge levels are below 50% will significantly reduce the life of Device battery and may void battery warranty.

BATTERY MAINTENANCE / PRECAUTIONS

1. Battery backup is for emergency power backup until the AC main is restored and not to continue/complete the procedure with battery.
2. Connect the device to the AC mains and turn it ON. When switched ON, the device and PC will power up and its battery (Device and PC) will begin charging. Keep the device connected to the AC mains for at least 8 hours when not in use to ensure the internal battery is fully recharged and available for backup during an AC mains power failure.
3. If the device was not used (Connected to AC mains) for more than 2 weeks, recharge for 8 hours prior to use.

11.2 Device Storage Instructions

Short Term Storage - If the MAXIO® device will be idle for up to 2 months, the Device battery and PC

should be fully charged before storage.

Plug power cord into appropriate wall outlet for at least 8 hours to fully charge the Device battery and PC, prior to turning System Mains switch on.

Disconnect device from power source and store.

Long Term Storage - If the MAXIO® device will be idle for 2 months or more, the batteries should be removed from the device by an authorized service personnel and to be stored as given below.

Store battery in cool, dry area while MAXIO® device is out of use. Optimal storage temperature is -5°C to 35°C.



Battery voltage should be checked by an authorized service personnel every three (3) months. Connect the battery to the MAXIO® device and follow instructions given in section 1above to fully recharge the battery and follow the device storage indications given in this section.

Contact Perfint Customer Care for any clarifications, support regarding battery removal, recharge and information about how storage might impact the battery warranty.

	NOTICE: Warranty on fully charged batteries left in an unused state for more than three (3) consecutive months is automatically void. Warranty on fully discharged batteries left in an unused state for more than three (3) consecutive days is automatically void.

11.3 Change Device Batteries

	WARNING: Do not remove or replace the batteries while device is located in an oxygen rich or hazardous environment. Sparking may occur.

BATTERY REPLACEMENT

Only the following batteries are compatible with this system:

1. Device battery: EXIDE EP1234W or EP 9/7 AH (EXIDE Power safe)
2. PC battery: ONYX ZEUS-BAT03 (14.4 VDC)

Installing batteries other than the listed above will void the product warranty. Failure to heed this warning may result in severe damage to batteries, device power module and possible fire hazard.

12. SYSTEM MAINTENANCE AND CLEANING GUIDE

12.1 Overview

This section describes the routine maintenance procedure to be performed by the user. Maintaining MAXIO® system according to the following guidelines facilitates in prolonging the life of the system.

12.2 Visual Inspection

Visually examine the following before every procedure:

1. Connectors on cables for any mechanical defects.
2. Entire length of electrical and power cables for cuts or abrasions. Equipment for loose hardware.
3. Castors for proper locking operation.
4. Laser unit is to be intact and if it can be held in both positions (straight and downward). Set the laser module facing downwards before switching ON the device.

	Call Perfint Service in case of any such defects.

12.3 Cleaning

The cleaning instructions provided in table 12.1 must be followed daily for cleaning the device and the related accessories. Prior to device cleaning always perform the following activity:

1. Shutdown and switch OFF the MAXIO® system.
2. Remove the power cable to disconnect from power supply.
3. Unlock the wheels and move the MAXIO® to a free space.

Table 12.1 MAXIO® *Cleaning Instructions*

S No	Component	Cleaning Instruction
1.	MAXIO® device axes and wave cover.	Use a cloth damped in water to wipe the external surface of the device and its axes. Use sterile drape covers in order to reduce the risk of patient infection. Use regular hospital cleaning agents like Virex II 256 to clean the axis in case of any spill.
2.	MAXIO® Console, touchpad.	Use a damp cloth to wipe the parts before every procedure.
3.	InstaReg mat.	Use any regular hospital cleaning agent like Virex II 256 to clean the InstaReg mat
4.	Patient immobilization bed.	To clean, wipe thoroughly with water based antiseptic cleaner or foam. Allow to dry before next patient use. The immobilizer bed is protected with Anti- Microbial coating to aid with infection control during and between uses. This

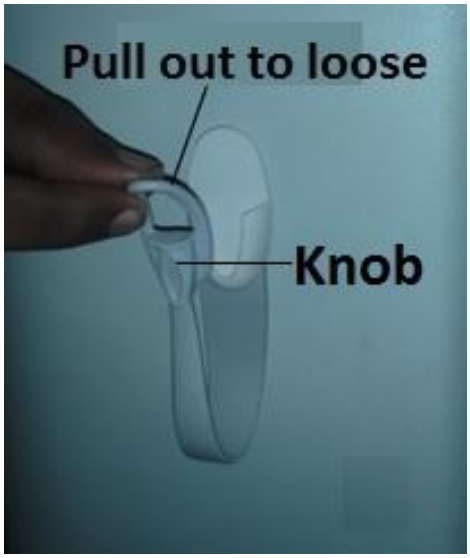
		coating is permanently bonded with the bed and cannot be washed off.
5.	Breath hold monitor unit	Use a damp cloth to wipe and clean the unit and belt.

☞	Consult component labels regarding the reusability and sterilization requirements to ensure that they are met.
⚠	Personal Protective Equipment (per 29 CFR 1910.1030 (d)(3)) must be worn during cleanup operations to prevent contact with infectious substances.

12.4 Storage

When not in use, park the MAXIO® system in the specified parking area. Please refer to Chapter 10 for device parking instructions. Store the device accessories, Disposables and consumables in Dark, Cool, Dry place and temperature of 0°c to 50°c and closed place.

Store the device accessories and consumable in a cool and closed rack.
Roll the power cord cable and place it in the cable hanger as per the below image.





12.5 Servicing

There are no user serviceable/repairable parts of the MAXIO® other than the fuse replacement. Users are advised to call Perfint Service for any concerns or questions regarding operation of the MAXIO®.

Contact the local Service representative for parts or preventive maintenance of the system

⚠	The MAXIO® must be visually inspected before every procedure. A preventive maintenance schedule must be followed according to the MAXIO® Service Manual. For any repairs, please contact the Perfint Service.

	To avoid electrical shock hazards, do not remove panels or covers from the machine.
	There is no user serviceable/repairable part of the MAXIO®. Call Perfint Service for any concerns or questions regarding the operation of the MAXIO®.

12.5.1 Fuse Replacement

In case the system is not powering ON, check for the fuse and replace if necessary, as per the instructions given below:

1 Power OFF the device and remove the power supply cord.

2 Press and pull the fuse socket in the connector panel as given in the figure below.

3 Check for fuse connectivity using a Multimeter. Check if the fuse wire is broken.

4 In such cases, replace the fuse with the same type of rating (250V, 3.15A, SB). MAXIO® packing includes one spare replacement fuse.

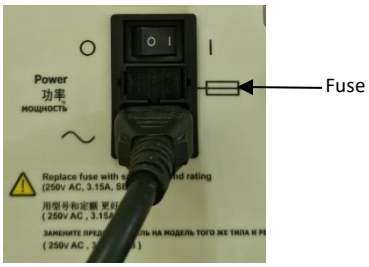


Figure 12.1 *Fuse Replacement*

12.5.2 Calibration Check

Users are instructed to perform calibration check for the device after every 20 procedures. In case of any deviation in system calibration, system has to be calibrated. Contact Perfint Service for system calibration.

Instructions for calibration check

12.5.3 Requirements

- Calibration Phantom (provided by Perfint).
- 18 G LP Needle - 120mm and 18G needle Guide.
- Service login

	Perform a calibration check with the guidance of Perfint support.
	Do not load green phantom images in user login.

12.5.4 Steps for Calibration check

1. Place the calibration phantom on the CT patient table in the region specified by the device range sticker. Set CT cradle value to ‘zero’ at center of the phantom.

2. Scan and send the phantom images to MAXIO®. Follow all the steps for a normal procedure workflow.
3. Click the gantry cross hairs option to display the cross hairs over the phantom image.
4. Plot the target point on the gantry cross hairs center and entry point on the vertical line on the surface of phantom.
5. Send the values and position the device for the plan.
6. Insert the needle on the phantom for the displayed cradle position.
7. Release EE and perform the check scan. Transfer the check scan image to MAXIO® planning station. Load the image through the probe position verification screen. Confirm device accuracy.
8. The needle should be exactly straight and aligned to the vertical line of the gantry cross hairs in case of proper calibration.
9. In case of any deviation in the needle positioning, MAXIO® system has to be recalibrated. Call Perfint Service for calibration.

12.5.5 Disposal

At end of life, send the device to Perfint for disposal. If this is not possible, dispose of device, accessories and disposables including batteries and electronic waste as per local country disposal regulations.

Before MAXIO is transferred, returned or disposed of, contact Perfint service to securely erase all patient data from the system.

	Do not dispose the device, accessories and disposables as general waste.
	Do not reintroduce a decommissioned or refurbished device into clinical use without inspection, requalification, and written authorization from Perfint.

13. SYSTEM SECURITY

MAXIO® includes security controls that protect patient data, the application and its communication interfaces against unauthorised access and cybersecurity threats. These controls complement the security measures of the healthcare organisation; they do not replace them.

Perfint Healthcare Pvt. Ltd. (Perfint) is responsible for the security of the MAXIO system as delivered, its communication interfaces, and the software update mechanism.

The healthcare organisation is responsible for the security of its hospital network and infrastructure, the connected CT scanner and PACS, administration of MAXIO user accounts after installation, and physical security of the procedure room and the MAXIO system.

Global System View

Figure 13.1 shows the MAXIO system and its operating environment: the all-in-one PC, display and application software; the wired connections between them (Ethernet, HDMI, USB); the external interface to the CT scanner and PACS; and the trust boundary at which external data (DICOM import, USB media) enters the system.

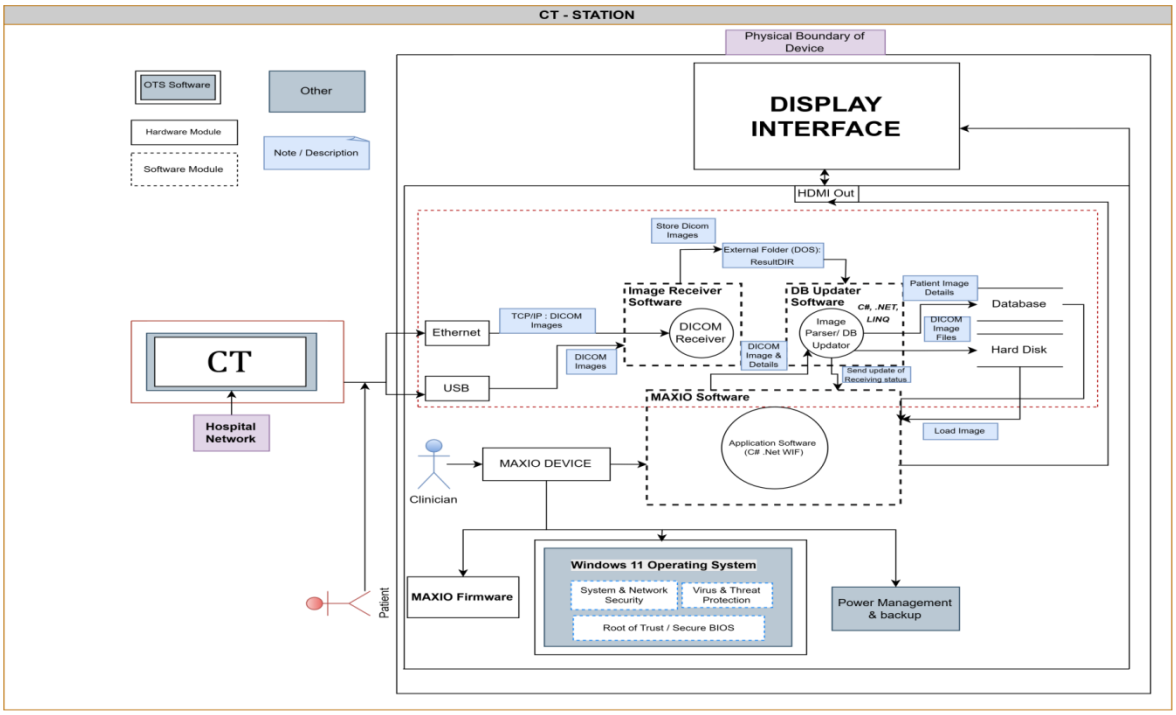


Figure 13.1 Global System Architecture View

13.1 Security Features

User authentication: Access to MAXIO requires an individual user account and password. Passwords must be at least 8 characters. Users must not share credentials; each user logs in with their own account.

Role-based access control: Each user is assigned a role ([Operator, Administrator, Service]) and can use only the functions and data permitted by that role. The Service role is reserved for Perfint-authorised personnel.

Audit trail: MAXIO logs user logins, patient data access and export, and system and configuration events

with user ID and time stamp. Users can view and export log entries for their own activities.

Firewall: A host firewall permits only the connections listed in 13.2. Do not disable or modify the firewall.

Antivirus: Real-time antivirus and threat protection is installed and enabled on the system. This enables the identification and mitigation of potential threats, further fortifying the system against security risks.

The antivirus protection should remain enabled and up to date. Do not disable or modify antivirus settings without authorization from Perfint Healthcare Pvt. Ltd.

Secure boot: MAXIO runs on Windows operating system with Secure Boot and BIOS enabled.

Data encryption at rest: Patient data on the MAXIO database is encrypted

Controlled external connections: MAXIO receives DICOM data only with the CT scanner and PACS configured by the hospital IT department (IP address, AE Title, port). USB import and export is available only to logged-in users whose role permits it.

Secure software updates: MAXIO installs only update packages digitally signed by Perfint. Each package is verified against the Perfint signature and scanned for malware before installation; a package that fails either check is rejected.

13.2 Network Ports and Interfaces used by MAXIO

MAXIO uses the interfaces below. The hospital IT department uses this list to configure the network and firewall.

Interface	Protocol	Port	Direction	Purpose
Ethernet	TCP (DICOM)	1110	Incoming	Image receipt from CT scanner / PACS
USB 3.0 (or above)	USB	—	Bidirectional	Import and export of images and data via USB drive

MAXIO connects to the CT scanner and PACS using a static IP address, AE Title and port configured by the hospital IT department. Only DICOM data is transmitted. Connect MAXIO only to a hospital network segment restricted to the CT scanner and PACS.

MAXIO does not require, and must not be connected to, the internet. MAXIO has no remote-access or remote-service interface.

13.3 Secure Configuration

MAXIO is shipped with unused ports, services and accounts disabled and secure default settings applied. Do not disable the firewall, antivirus or access-control features. Contact Perfint technical support before changing any network or security-related setting.

13.4 Software updates and patches

Perfint provides software updates and security patches for MAXIO, including operating-system patches. Automatic Windows Update is disabled. All updates are installed only by Perfint-trained and authorised service personnel. Each release is version-identified so the installed version can be confirmed on screen. Before an update is installed, service personnel back up system data and settings to allow recovery if the update does not complete.

Perfint informs the healthcare organisation of security-relevant updates through Field Safety Notice or

Field Advisory Note

Do not install software on MAXIO from any source other than Perfint.

13.5 Backup and Restore

MAXIO does perform automatic backup of database. Before software updates or maintenance, Perfint service personnel back up and, if needed, restore system data and configuration according to Perfint procedures. If data loss, corruption or a failed update is suspected, contact Perfint technical support. Do not modify or restore application data manually.

13.6 Software Bill of Materials

MAXIO includes third-party and open-source software components. A software bill of materials is maintained for every released version and is available to the healthcare organisation on request.

13.7 Practices to Maintain Security

- Keep MAXIO in a controlled-access area.
- Connect MAXIO only to the hospital network segment described in 13.2; never to the internet.
- Give each user an individual account; deactivate accounts of users who leave.
- Log off the session when leaving the system.
- Connect only USB devices authorised by your organisation.
- Install only updates provided by Perfint.

13.8 Suspected compromise of MAXIO

- When no clinical procedure is in progress, disconnect MAXIO from the network and all external devices, and then power it down.
- Do not delete log data.
- Do not return MAXIO to clinical use until Perfint technical support has confirmed it is safe.
- Contact Perfint technical support for investigation and resolution.

APPENDIX

Appendix A1: Performance Characteristics

S No	Parameter	Values
1.	Needle positioning accuracy	2mm RMS spatial error between the planned target and the actual needle tip for a needle length of 120 mm. Verified on non-moving phantom
2.	Trajectory angulation range	• Orbital angle: ±90° from the vertical for lateral entry. • Cranio-caudal angle: ±60° from the vertical.
3.	Compatible needles	• Type: Rigid- straight • Thickness: 22G, 21G, 20G, 19G, 18G, 17G, 16G, 14G, 13G, 11G; • Length :60 mm to 250 mm
4.	Image input requirements	• Image Interface :DICOM 3.0 series • Matrix: 512 × 512 (Must be a square matrix) • Reconstructed slice thickness: 1 mm to 3 mm. (1mm Recommended); • Gantry tilt: 0°; • Reconstruction offset: zero reconstruction offset
5.	Measurement functions	Linear distance measurement is performed using the Ruler tool, with an accuracy of ±5% of the actual linear distance. Angular measurement is performed using the Angle tool, with an accuracy of ±1° of the actual angle. Check-scan needle deviation (target error, entry error, angle error) is computed between the planned points and the needle entry and tip points marked by the user on the check-scan image.The precision of marking is limited by the slice thickness of the check-scan series.

Appendix A2: Technical Specifications

A2.1 Technical Parameters

S No	Parameter	Values
1.	Compatible Modality	CT, PET-CT, CT-MRI
2.	Imaging Interface	DICOM 3.0
3.	Needle Positioning Accuracy	2 mm RMS for a needle length of 120 mm on a non-moving phantom.
4.	User Interface	Computer Monitor Display

A2.2 Physical Attributes

S No	Parameter	Values
1.	Height	1310mm/4.3 feet
2.	Width	775mm/2.5feet
3.	Depth	850mm/2.8feet
4.	Weight	250Kg/551£
5.	Max. Allowable floor incline in during mobility	5°
6.	Positioning of the device with respect to CT system	InstaReg
7.	Device Controls	Control panel switches and foot switches.

A2.3 Electrical Specifications

S No	Parameter	Values
1.	Mains Voltage	100 - 240 VAC
2.	Line frequency	50 /60 Hz
3.	Length of power cable	Up to 8 Meters/26 feet
4.	Power usage	300 Watts
5.	Mains Isolation External: done by the user	Power supply cord shall be plugged where both poles (L & N) are isolated simultaneously.

A2.4 Mechanical Specification

S No	Parameter	Values
1.	Mobility	4 Castor wheels with locks
2.	X range	600 +20 / -0 mm
3.	Y range	450 +20 / -0mm
4.	Z range	180 +20 / -0mm
5.	A range	± 95° +10 / -0°
6.	B range	± 95° +10 / -0°

A2.5 PC Specification

S No	Parameter	Values
1.	Operating system	Windows 11 Pro
2.	System configuration	All-in-one PC 22” LCD Screen resolution: 1920 x 1080 (Full HD) Intel core™ i9-13900U TE 24 cores 5.00GHz, 32GB RAM and internal storage of 1TB

A2.6 Compatible Needle

S No	Parameter	Values
1.	Thickness (Gauge)	22, 21, 20, 19, 18, 17, 16, 14, 13, 11
2.	Length (mm)	60mm to 250mm
3.	Type	Rigid-Straight

A2.7 Needle Bush/ Needle Guide

S No	Parameter	Values
1.	Compatible needle gauge	22, 21, 20, 19, 18, 17, 16, 14, 13, 11
2.	Sterilization	Single use - Disposable (ETO Sterilized)

A2.8 Procedure Verification

S No	Parameter	Values
1.	QA/Skin marker & Laser crosshair unit	Yes

A2.9 Environmental conditions

S No	Parameter	Values
1.	Operating temperature	15 to 40°C
2.	Transport and Storage temperature range	0 to 50°C
3.	Humidity	50% to 95% RH non condensing

4.	Air Pressure	700 to 1060 hPa

A2.10 Safety

S No	Parameter	Values
1.	Wheels with Lock	Yes
2.	Detachable Needle guide	Yes
3.	Emergency Switch	Yes

A2.11 Conformance to Standards

S No	Standard	Compliant
1.	IEC 60601-1, IEC 60601-1-2, IEC 60601 -1- 6, IEC 60601 -1- 8, ISO 14971, IEC 62304, IEC 62366-1 ,ISO 15233-1, IEC 81001-5-1	Yes

A2.12 Laser

S No	Parameter	Values
1.	Classification	Class II in accordance with FDA standard 21 CFR 1040.10(a)(3)(I) and with European Australia/New Zealand laser safety standards 73/23/EEC - 98/37/ EG, 9/336/EEC, EN 50081-1, EN-31252, EN-31252, EN 55022, EN 60825-1 and AS/NZS 2211:1997
2.	Wavelength	650nm

A2.13 Accessories

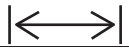
S No	Parameter	Values
1.	Foot Switch	Standard
2.	Optical Mouse	Standard
3.	Patient Immobilizer bed	Standard
4.	Breath Hold Monitor	Standard
5.	Abdominal Biopsy Phantom	Optional

A2.14 Consumables

S No	Parameter	Values
1.	Grippers (Left and Right)	Standard (Only for US)
2.	Sterile Drape (MAXIO Drape and Touchpad Drape)	Standard
3.	Needle Bush/ Needle Guide	Standard
4.	Needle Stabilizer	Standard
5.	QA/Skin Marker	Standard

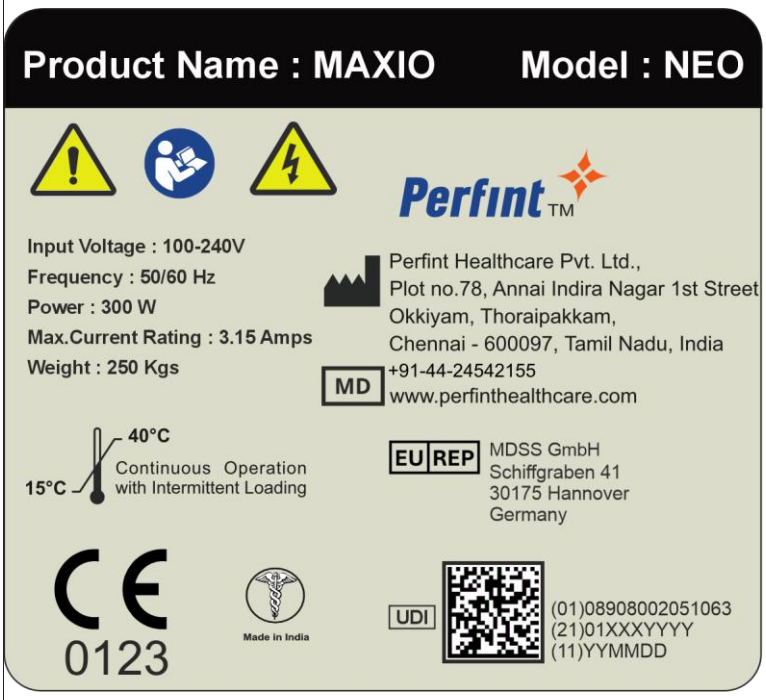
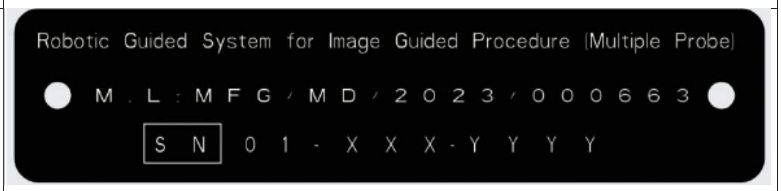
Appendix B: MAXIO® Device Symbols & Labels

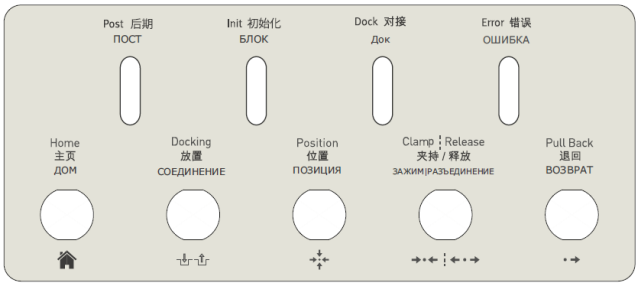
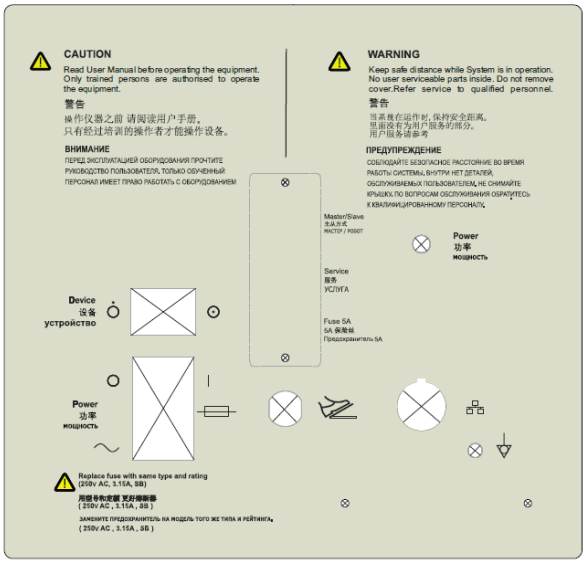
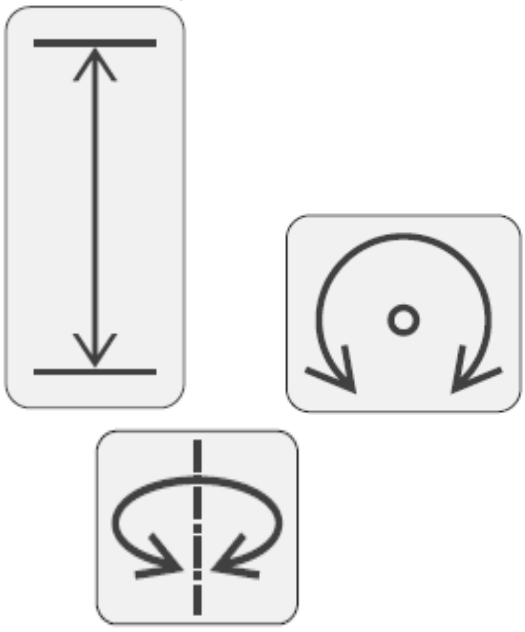
B.1 Device Symbols

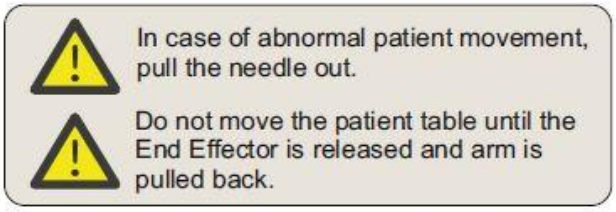
	Indicates the power “OFF” position on power switch.
	Indicates the power “ON” position on power switch.
	Indicates “OFF” position of line power switch.
	Indicates “ON” position of line power switch.
	Indicates emergency switch. Press the emergency switch to stop all axes movement in case of any emergency.
	Indicates Alternating Current. Device should be operated only by connecting to 100-240V, 50/60Hz line power.
	Indicates line power.
	Indicates the rotational axis of the device. (Orbital and cranial/caudal).
	Indicates linear axis of the device (X, Y).
	Indicates the undocking and docking of the device to the InstaReg mat respectively.
	Foot Switch: To identify a foot switch or a connection for a foot switch.
	Indicates the switch to position all axes of the device to as per plan.
	Indicates the switch to pull back the device to give clearance to the patient/doctor for post needle placement activities.
	Indicates the switch to position the device to its HOME/INIT position & to Toggle between anesthesia and position.
	Indicates the switch to clamp the EE.
	Indicates the switch to release the EE.
	To identify fuse boxes and their location.
	General Warning.
	Follow instructions for use in the User Manual to operate the machine.
	Warning: dangerous voltage, take care while plugging power cord to the device.
	The MAXIO® is manufactured solely by Perfint Healthcare Pvt ltd.

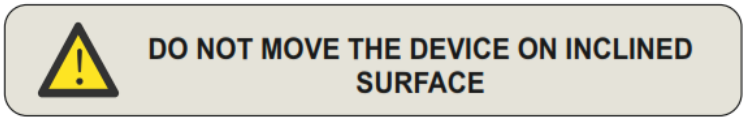
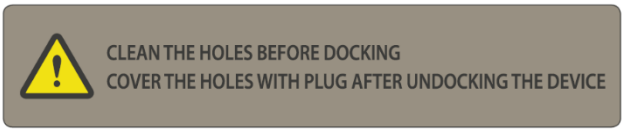
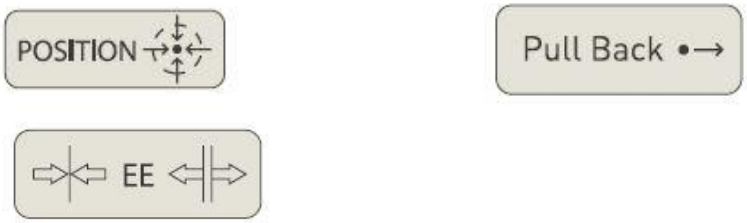
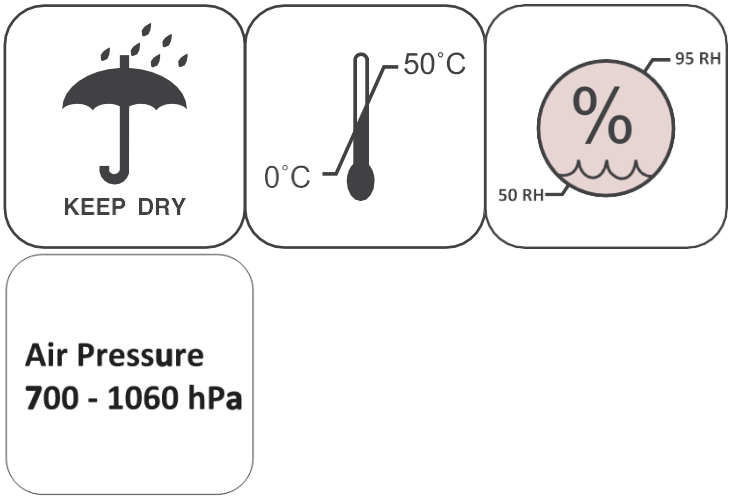
	
	The device should be operated in between 15 to 40 degree C.
	MAXIO® uses class II lasers. The user and the patient should avoid extraneous contact with the laser beam.

B.2 MAXIO® Device Labeling Details

Product logo label	MAXIO NEO
Manufacturer label	
Site Registration Number – IMDR (India)	

Control panel label (Multilanguage)	
Connector panel label (Multilanguage)	
Movement limited in both directions: To indicate that a linear movement is possible in both the indicated directions with in predetermined limits.	
Emergency	

Warning labels	
Caution laser	
Patient movement warning sticker	
Device movement warning sticker	
Device instructions	
Home instruction label	
Do not lean	

MAXIO® range of operation sticker for CT table	
Step-Down Height Limitation Label	
Movement Restriction Label	
Table marker	
I-DOCK clean indication	
Foot switch control labels	
Packaging storage label	

Fork lift entry prohibited	
Package Handling Label	

B.3 Tilt and shock indicators

Overview

Improper handling during transportation may harm the equipment inside the package, even if the package itself is undamaged. To make it easier to detect, if the handling during transportation has been improper, a set of Tilt & Shock indicators have been attached to the transportation box.

Position of the Tilt & Shock Indicators

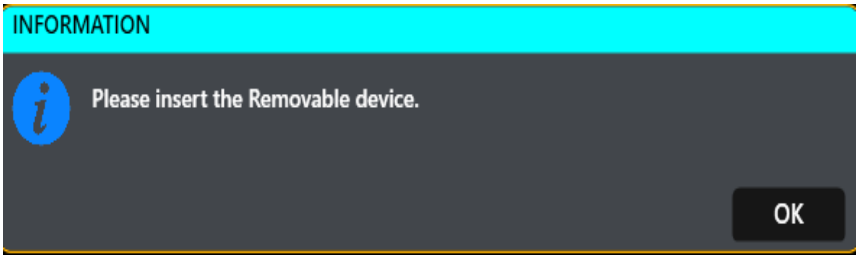
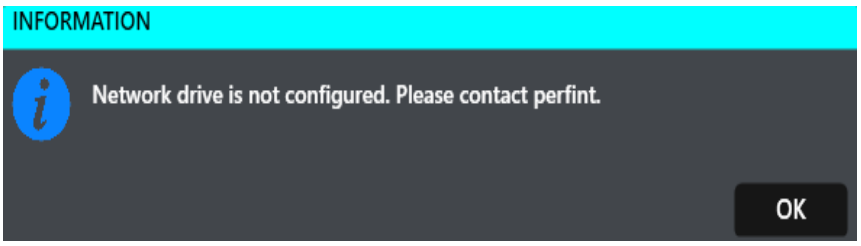
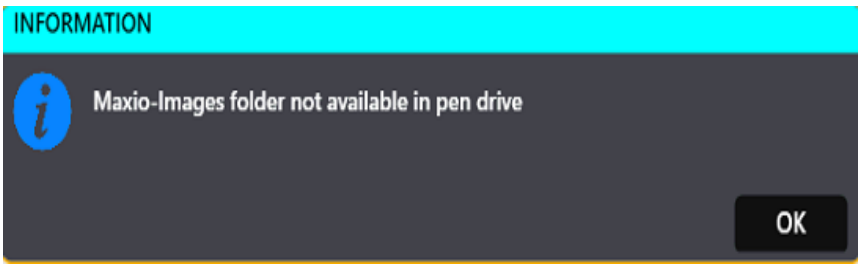
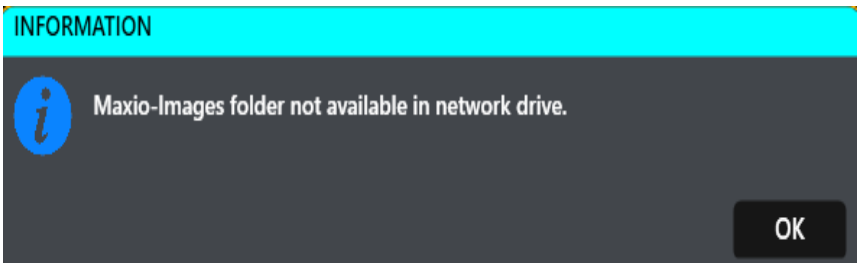
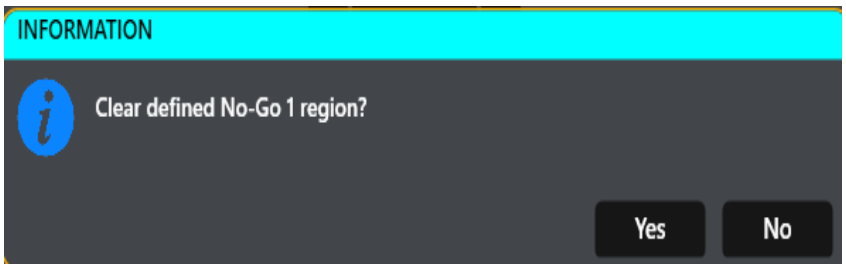
The Tilt & Shock indicators have been attached to the right side of the transportation box as illustrated in the figure below.

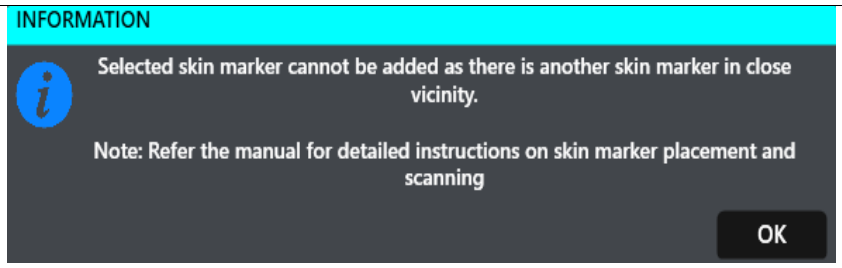
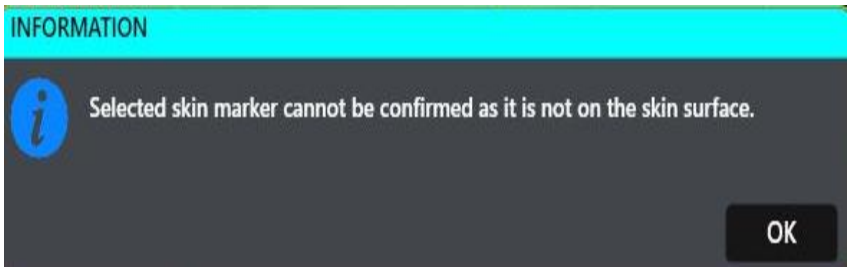
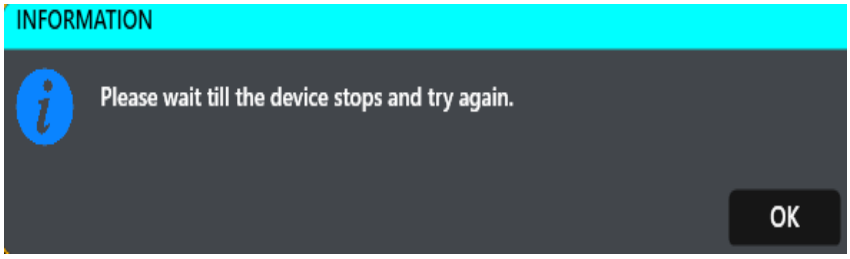
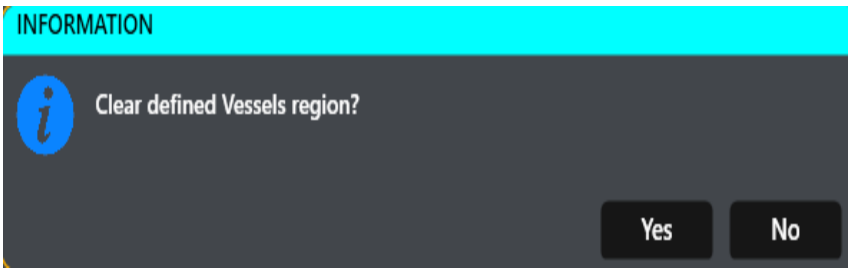
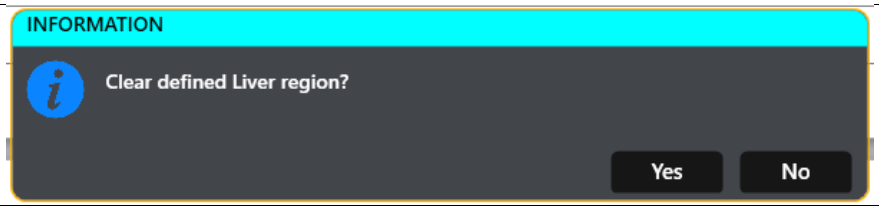
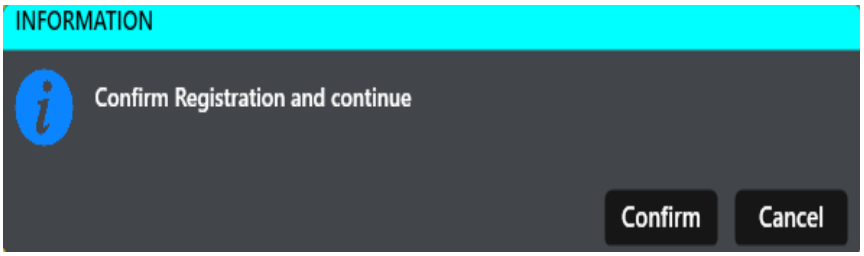


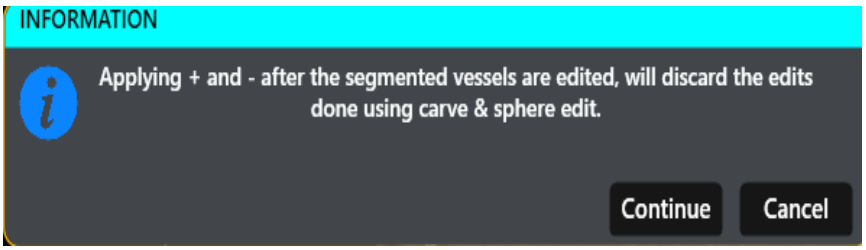
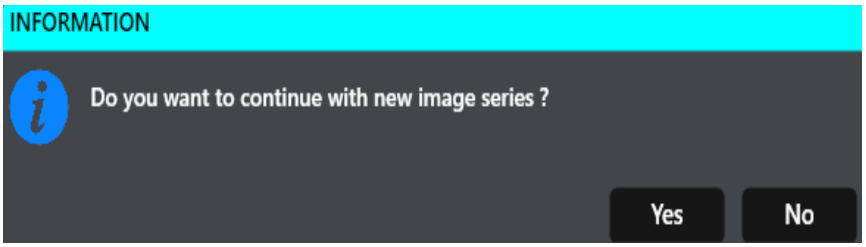
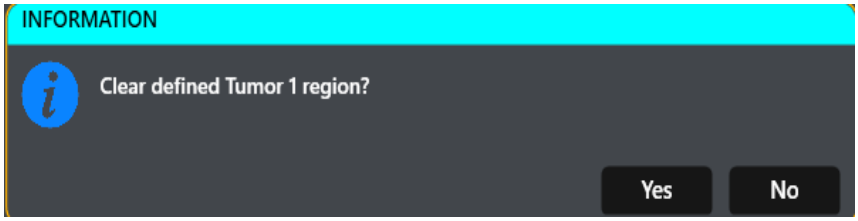
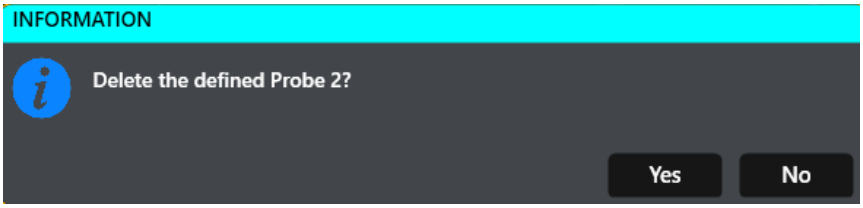
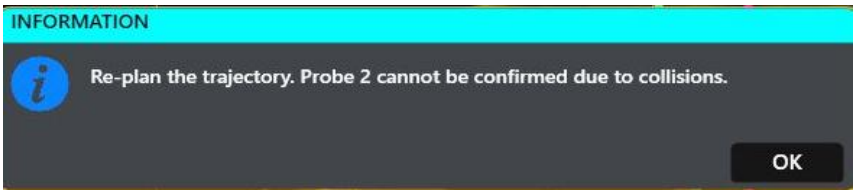
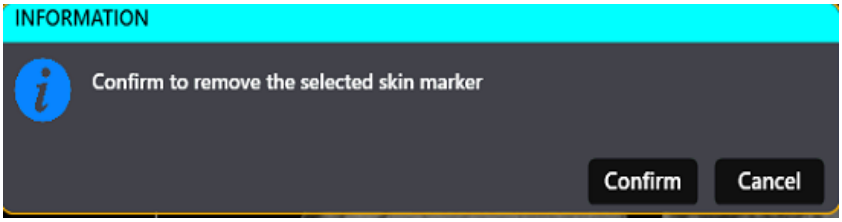
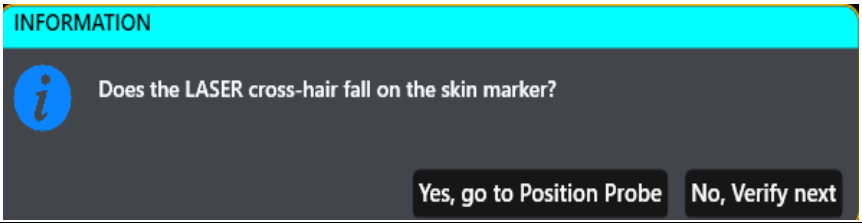
Figure 12.2 *Tiltwatch & Shockwatch*

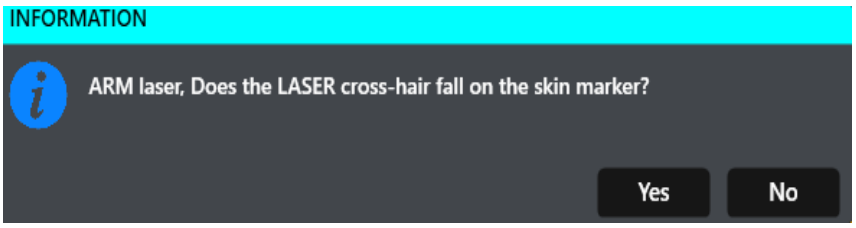
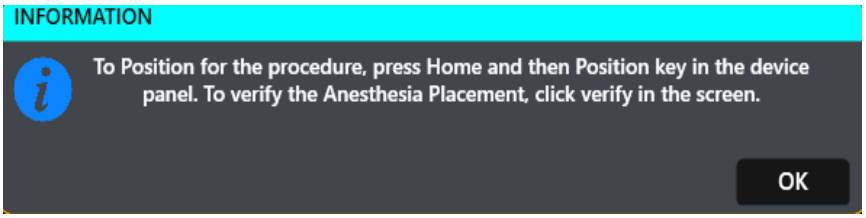
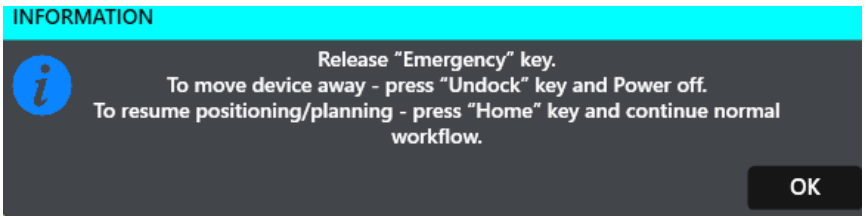
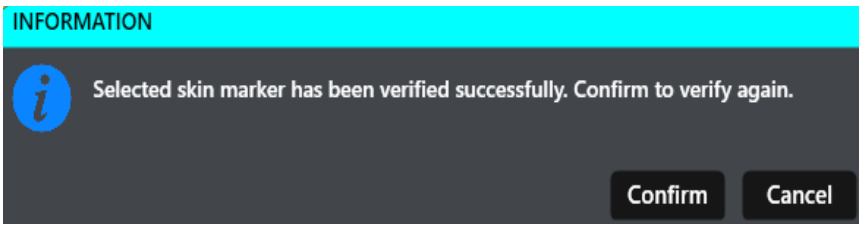
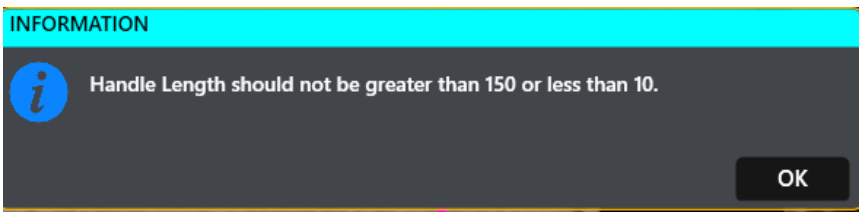
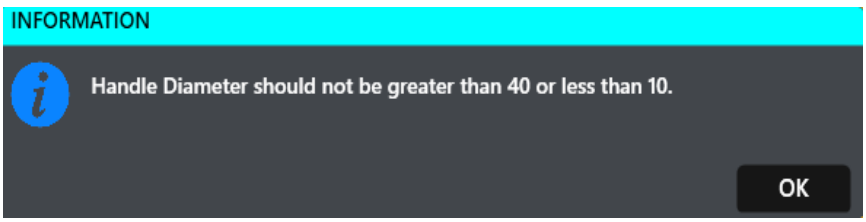
Tilt & Shock indicator's position on right side of transportation box

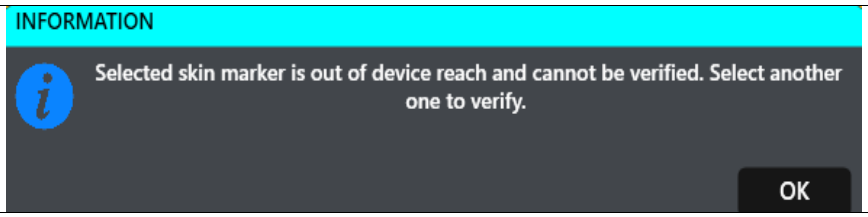
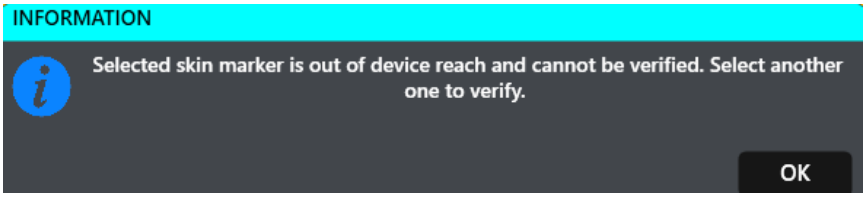
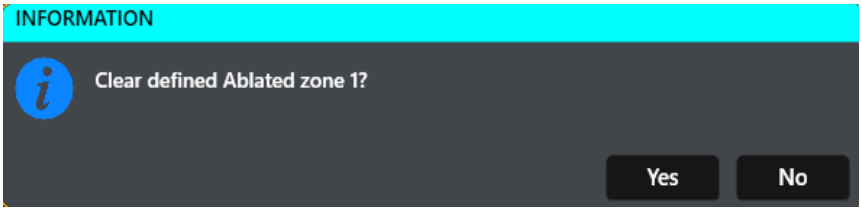
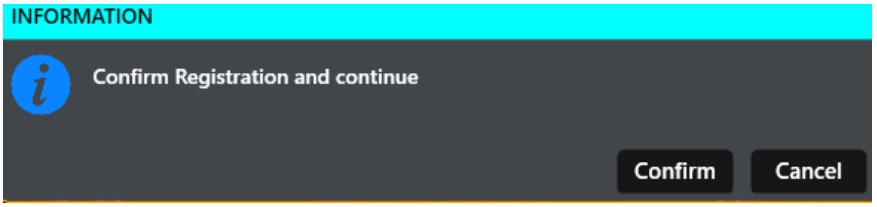
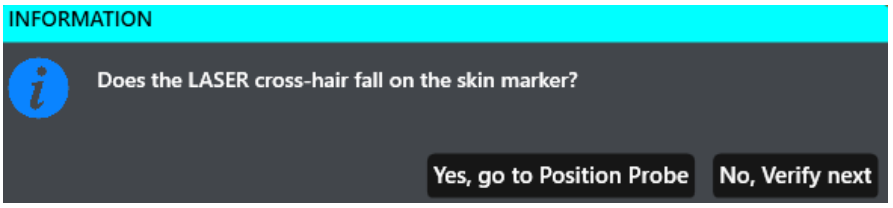
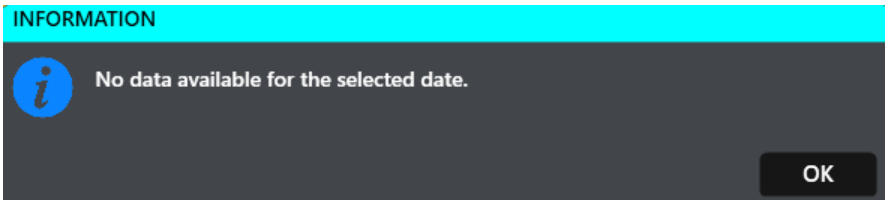
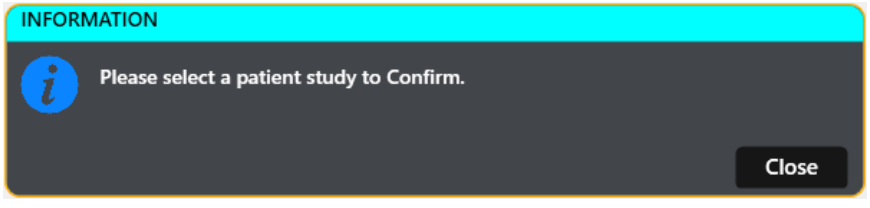
Appendix C: Alarms, Warnings & Information

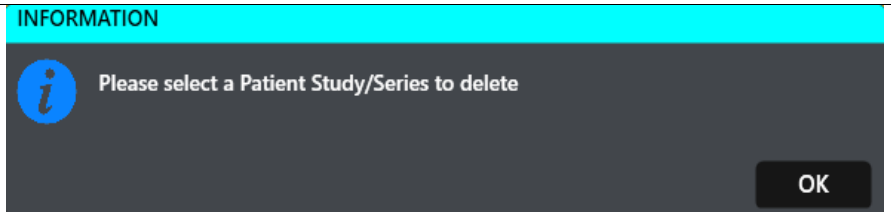
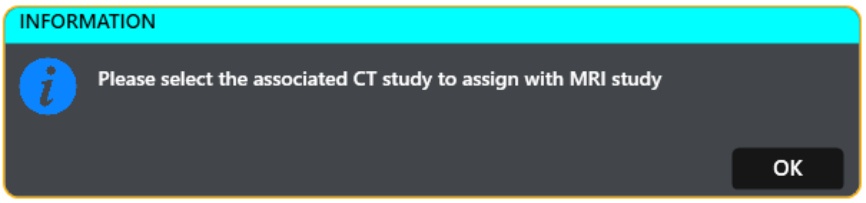
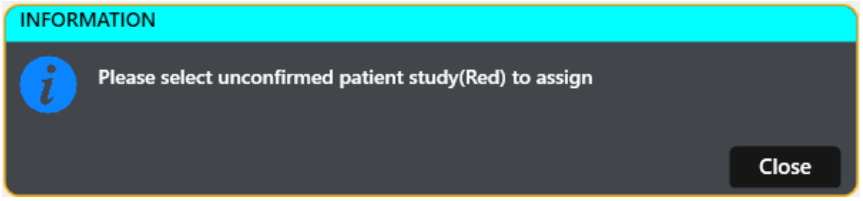
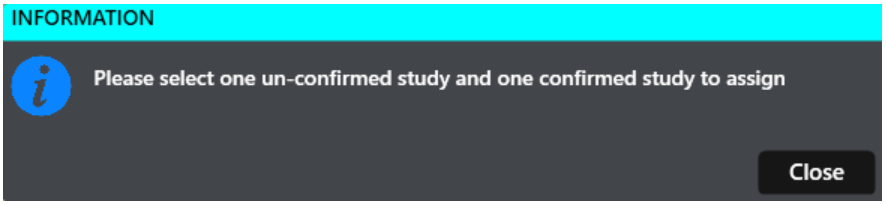
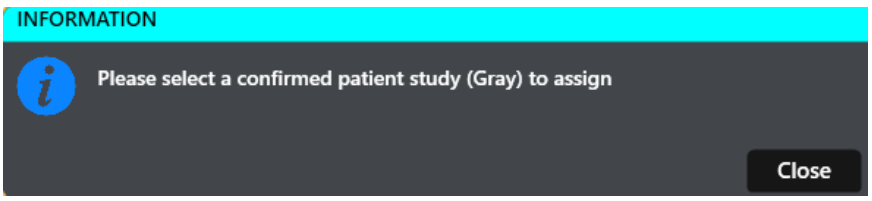
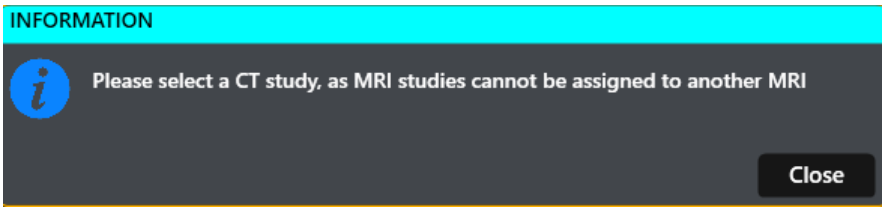
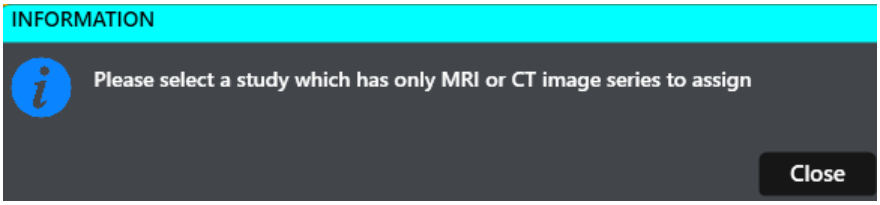
Low Priority		
Causation	**Message Displayed**	**Origin**
Removable Device is not inserted		Application
On clicking Local Drive in Import study window, without network drive configured in the device.		Application
Appears if the user clicks pen drive in Import study window without Maxio - Images folder in it.		Application
Appears if the user clicks local drive in Import study window without Maxio - Images folder in it		Application
Confirmation for clearing a Region other NoGo		Application

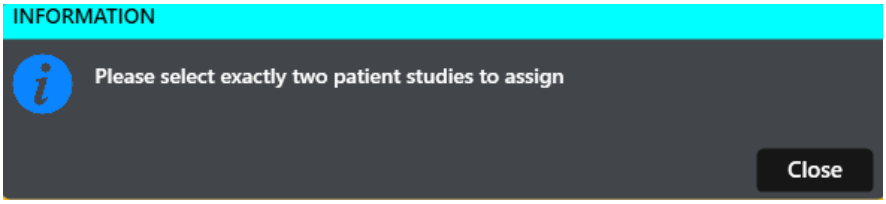
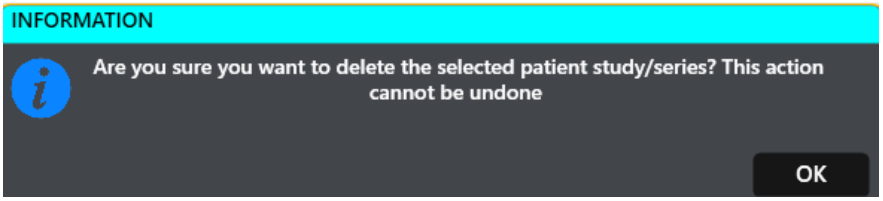
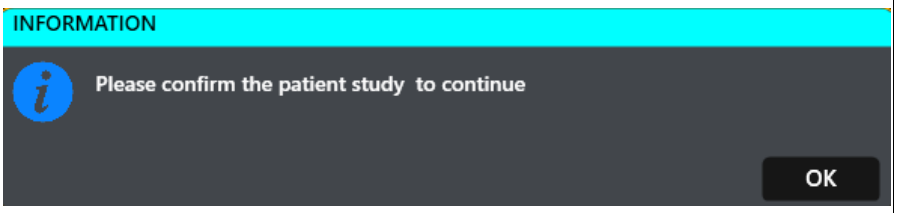
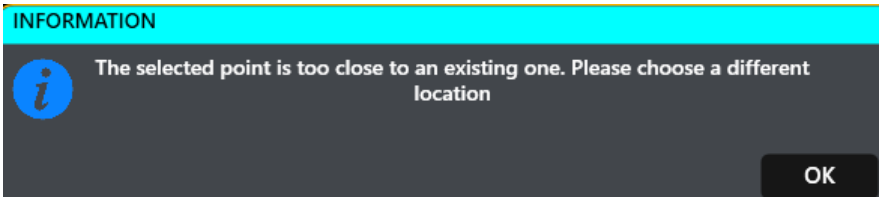
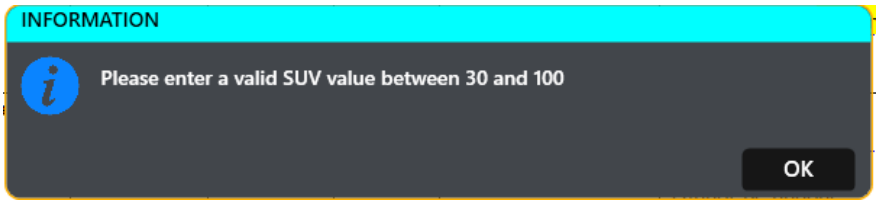
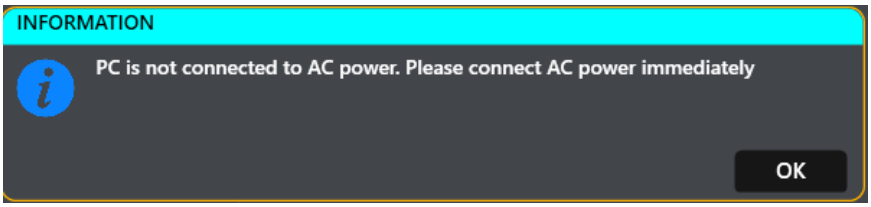
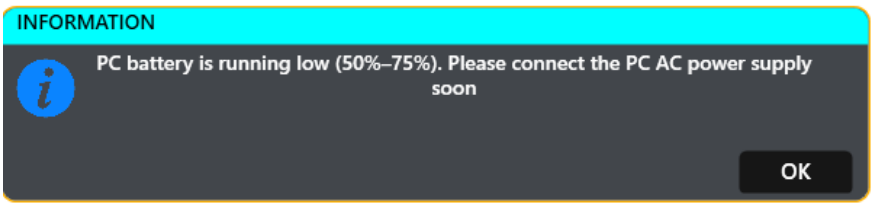
Appear when user selects a skin marker which is in close vicinity of another skin marker position		Application
Appear when selected skin marker is not on skin surface		Application
User tries to perform the device movement activity before Completing the existing movement		Application
Confirmation for clearing a Region Vessels		Application
Confirmation for clearing a Liver Region		Application
Confirmation of Registration moving from select patient screen to segmentation screen		Application

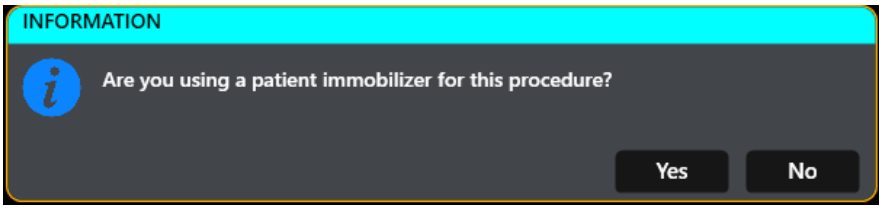
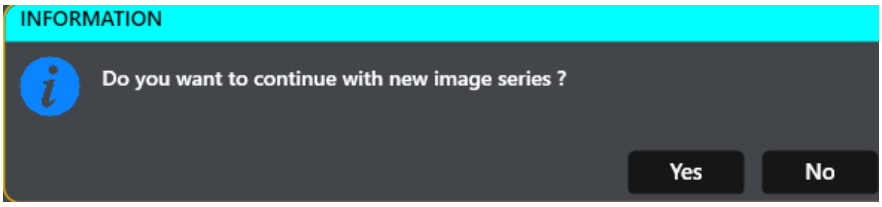
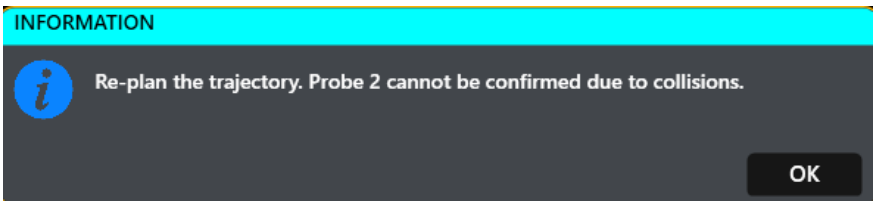
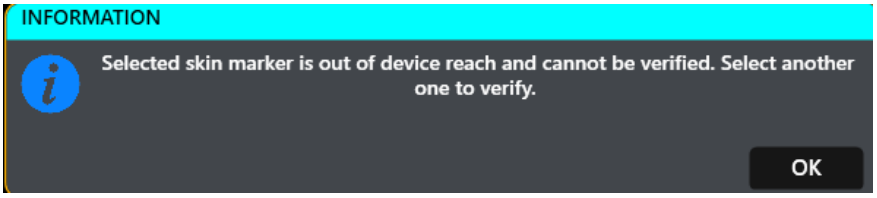
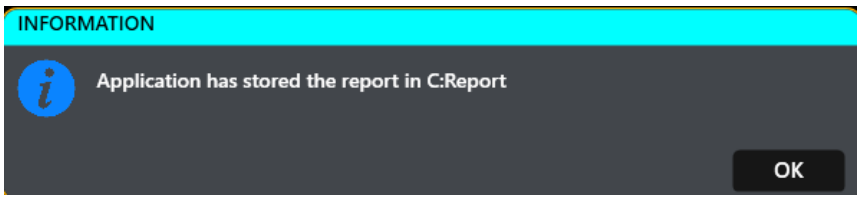
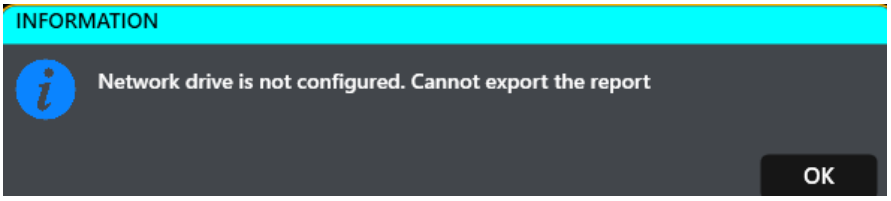
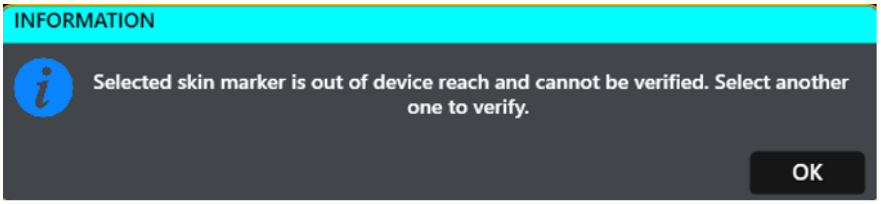
Editing the segmented vessels		Application
When user tries to load a new study in plan screen, in other procedure.		Application
Confirmation for clearing a Region Tumor		Application
User delete the defined Probe		Application
To Avoid probe collisions		Application
Appears when user selects the skin marker to remove.		Application
Appears during positioning for Skin Marker other than two step Positioning		Application

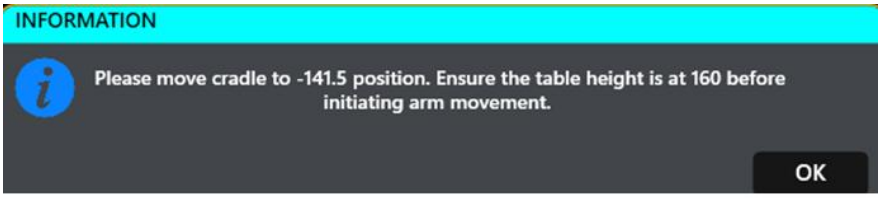
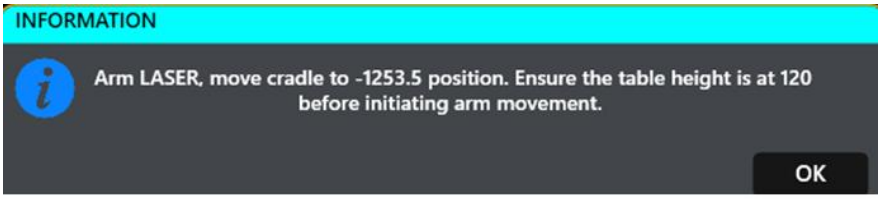
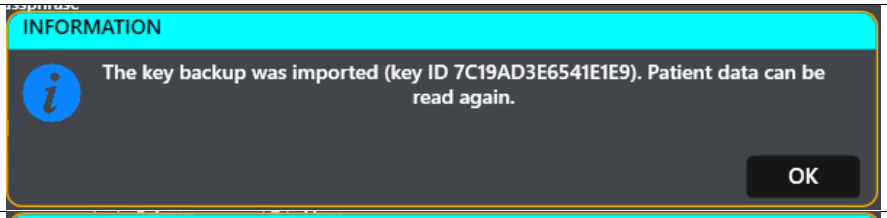
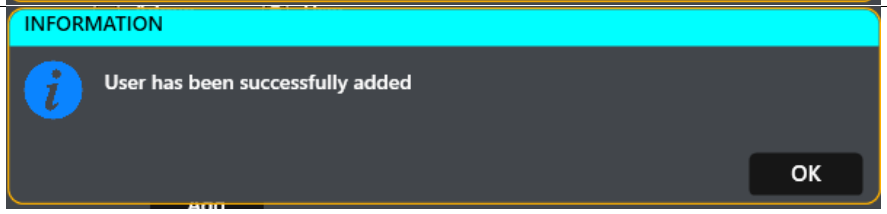
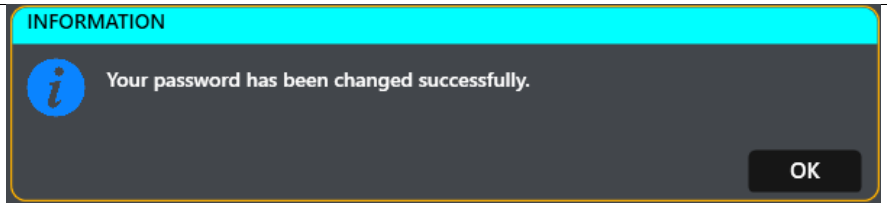
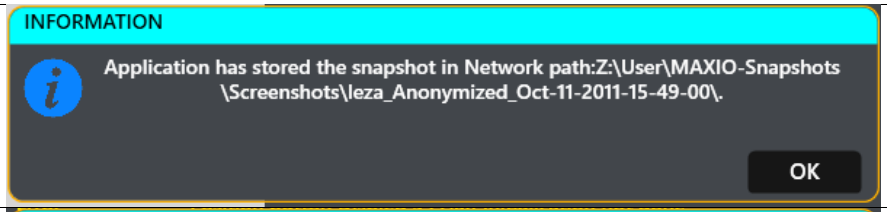
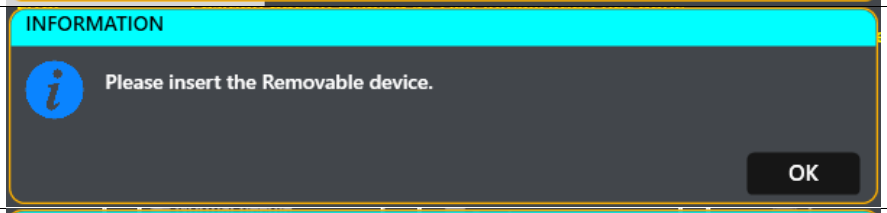
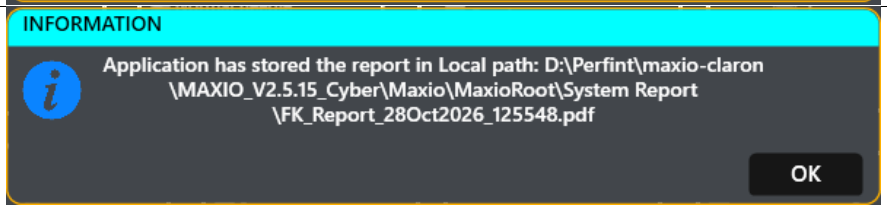
Appears during positioning for Skin Marker using two step positioning		Application
Verify anesthesia position		Application
When user presses the emergency key in device.		Application
User tries to verify the already verified skin marker?		Application
In the Other probe user enters the Handle length greater than 150 and less than 10		Application
In the Other probe user enters the Handle diameter greater than 40 and less than 10		Application
User tries to verify the improper skin marker.		Application

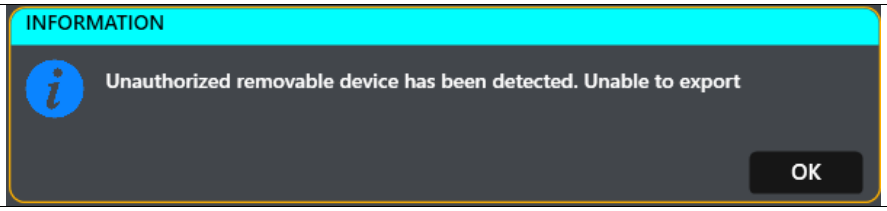
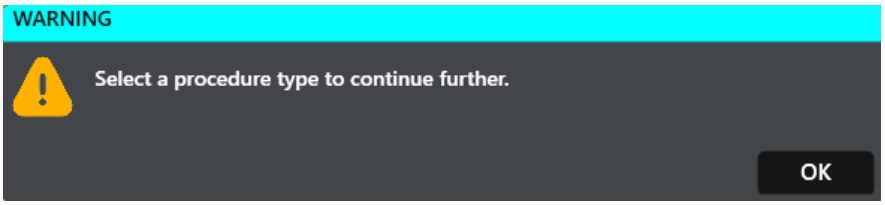
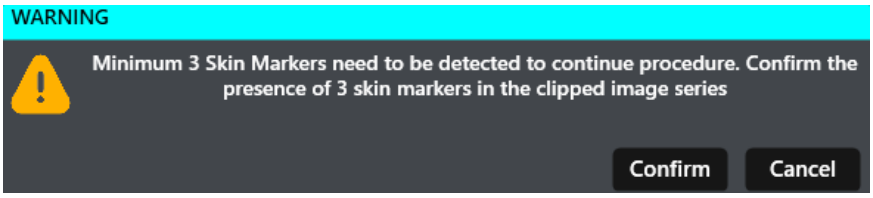
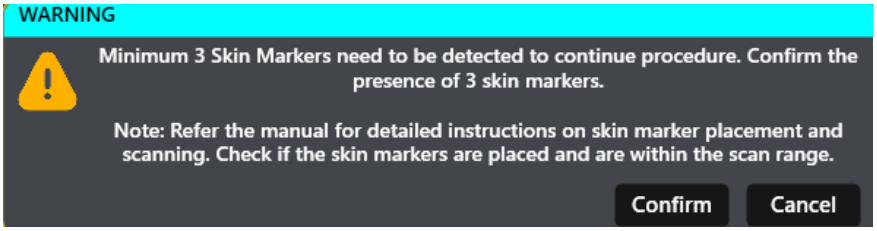
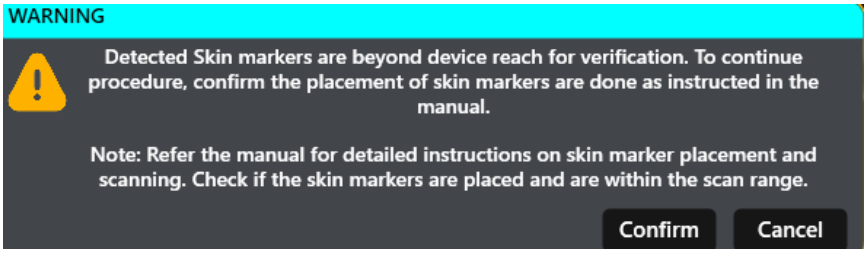
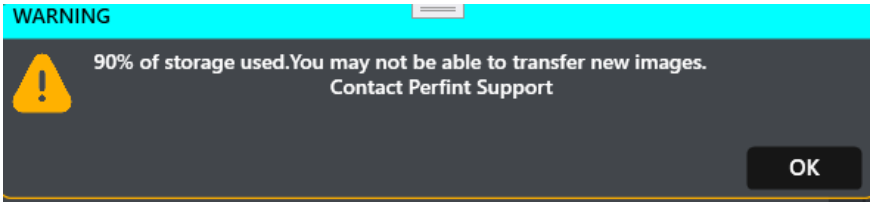
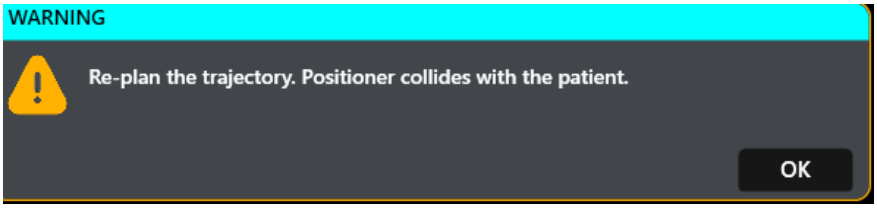
		
Appear when user selects a skin marker which is in close vicinity of another skin marker position		Application
Appear when clear the ablated Zone		Application
Appears when primary and secondary series are registered and segment button is clicked.		Application
Appears during positioning for Skin Marker using two step Positioning		Application
Appears when there is no procedure data available between the dates selected by the user in snapshot tab		Application
Appear When User tries to confirm patient study without selecting any patient data		Application
Appear When User		Application

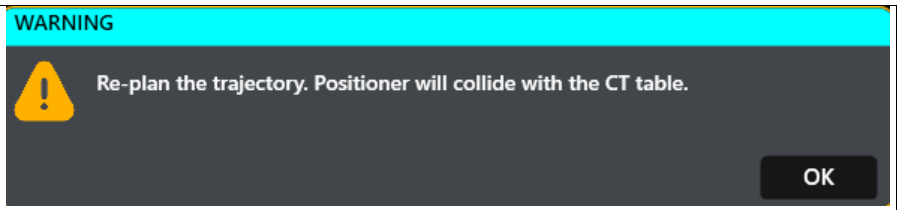
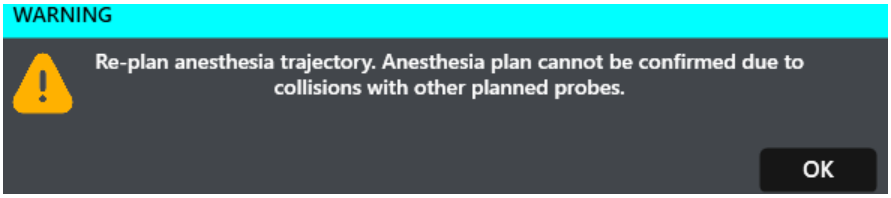
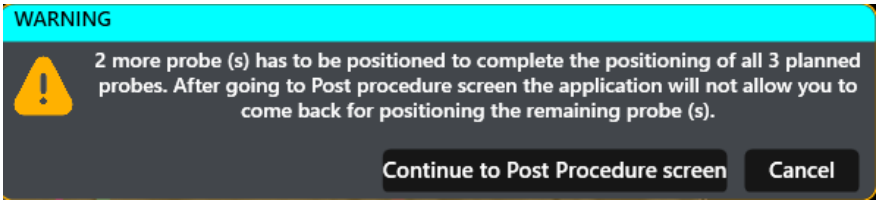
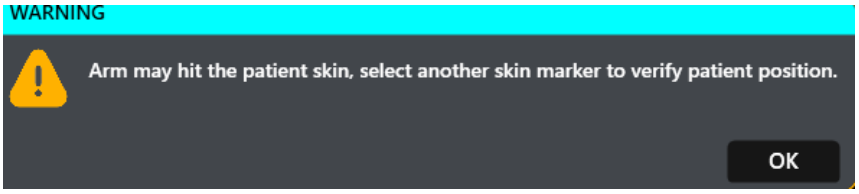
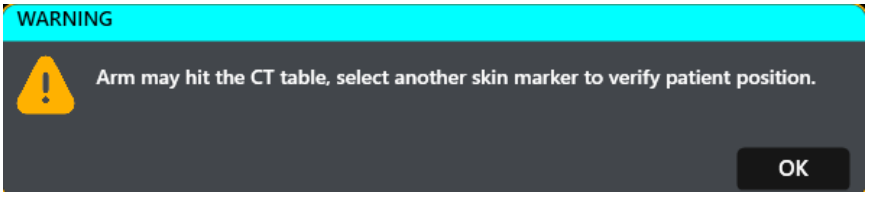
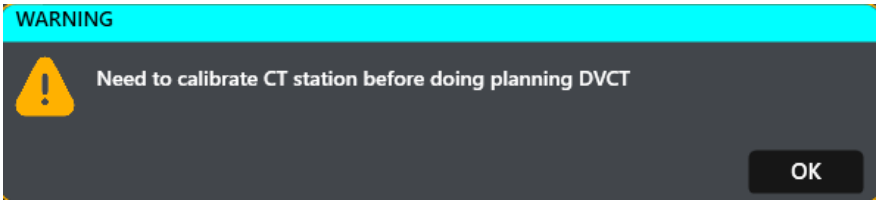
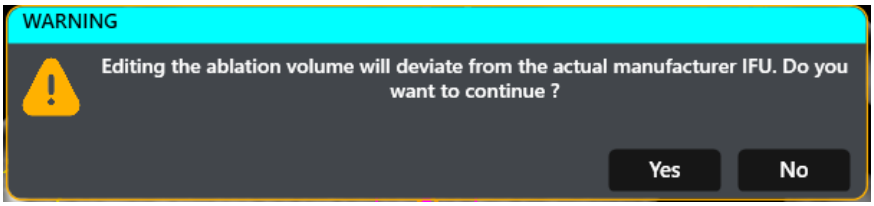
tries to delete patient study without selecting any patient data		
Appear When user tries to confirm MRI study without selecting CT		Application
Appear When user tries to assign already confirmed studies		Application
Appear When user tries to assign two un-confirmed studies		Application
Appear When user trying to assign a study without selecting a confirmed study		Application
Appear When user trying to assign two studies which has only MRI image series		Application
Appear When a user tries to assign unconfirmed study that contain both CT and MRI image series with a confirmed study		Application

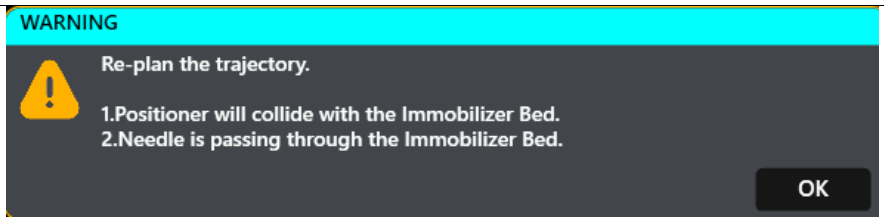
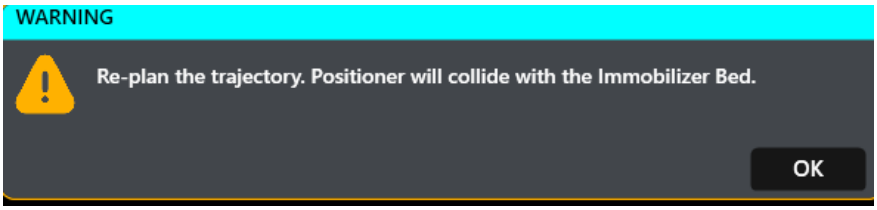
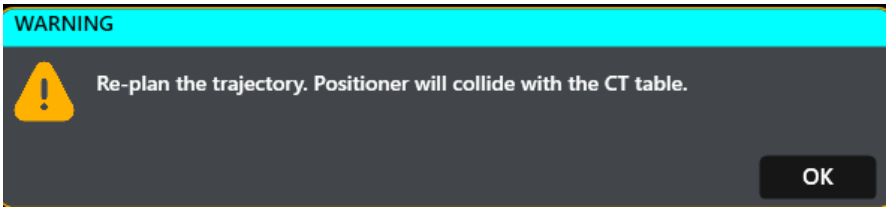
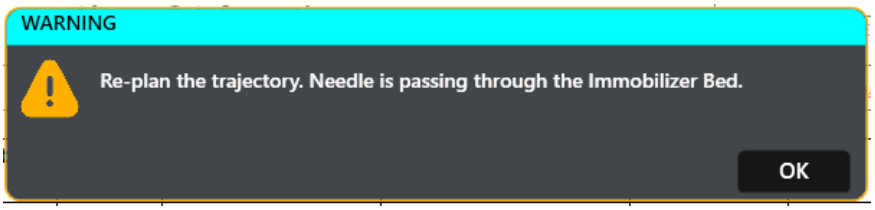
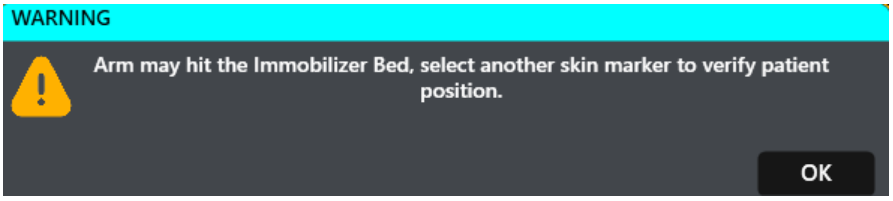
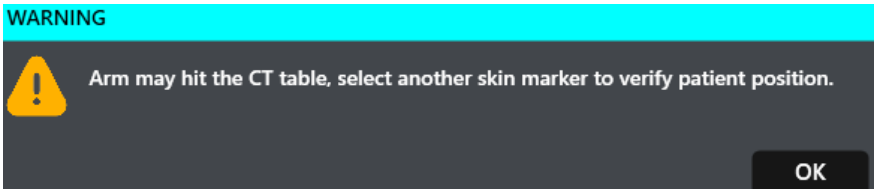
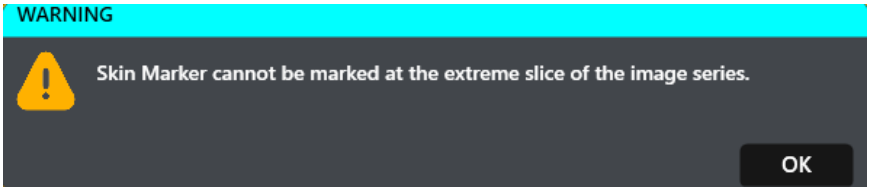
Appear When user tries to assign more than two patient studies		Application
Appear When user trying to delete loaded patient study/series		Application
Appear When the user attempts to load both primary and secondary image without confirming		Application
Appear when user tries to take landmark points close to already taken points		Application
Appear When the user attempts to save an SUV value that is outside the allowable range		Application
Appear When Application detects the PC battery status as low and AC power is not connected.		Application
Appear When Application detects the PC battery status as low (Below 75%) and AC power is not connected.		Application

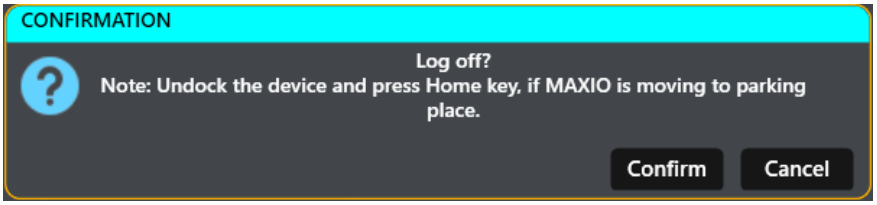
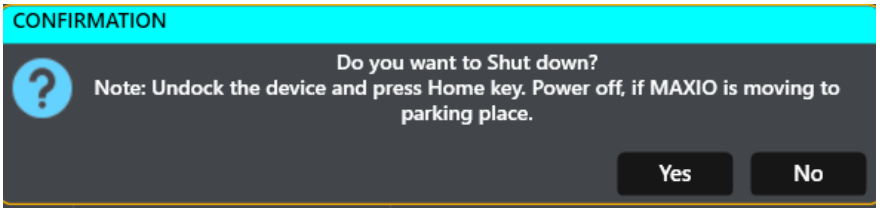
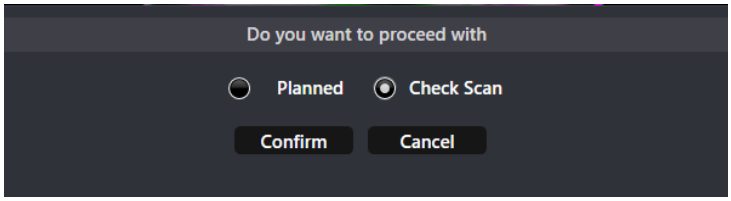
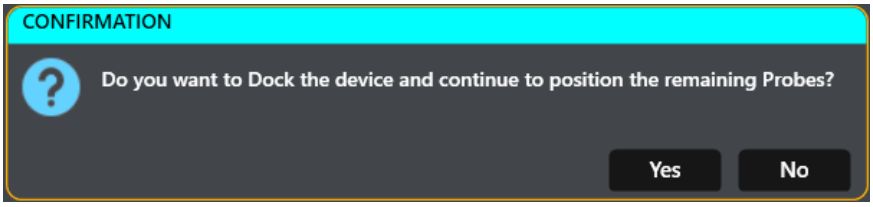
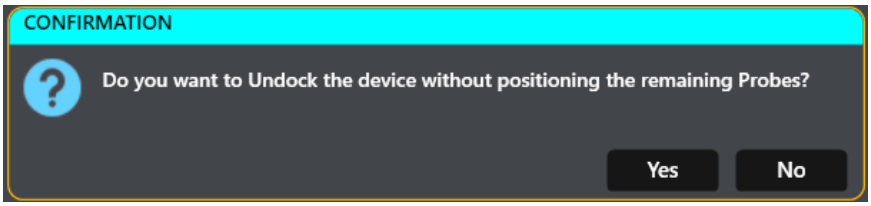
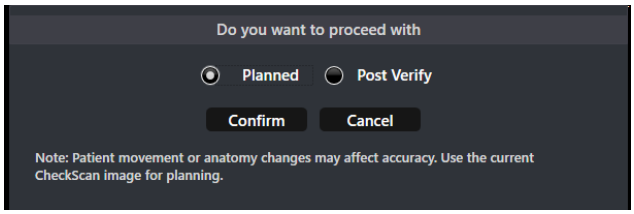
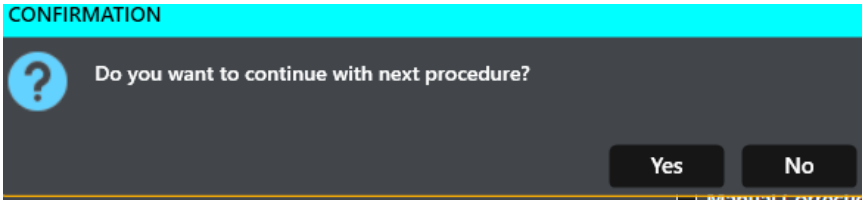
Appears when user load image		Application
When user tries to load a new study in plan screen, in other procedure		Application
Appears when user tries to confirm a probe that collides with another confirmed probe.		Application
User tries to verify a improperly placed skin marker.		Application
Appears when user saves or exports the final report.		Application
Appears when user exports the final report, without configuring the network drive in the device.		Application
Appears when user cancels the table marker verification since it is not satisfactory		Application

For Probe / skin Marker positioning the needle in the planned region		Application
When verify Skin marker is pressed.		Application
Appears when the user clicks Import Key Backup in the Patient-Data Key Backup tab under Settings		Application
Appears when the user clicks Add in the User Management tab		Application
Appears when the user clicks Save in the Change My Password tab.		Application
Appears when user exports the snapshot.		Application
Appears when user exports the log file in service login without inserting removable device.		Application
Appears when user clicks Report under Product Configuration in service login		Application

Appears when user exports the log file in service login using an unauthorized removable device.		Application
When user tries to go to loading screen without selecting procedure type		Application
Appear when device does not detect at least 3 skin markers in the clipped image series		Application
If skin marker is mandatory and device does not detect at least 3 skin markers in the loaded image series		Application
If skin marker is mandatory and User tries to load an image series that has skin markers beyond device reach		Application
No disk space available: Displayed when default disk space is full. New images shall be automatically transferred to D:drive		Application
Positioner when collide with the patient body		Application
Appear when positioner is		Application

Colliding with table		
Appears when Anesthesia collides with other probe		Application
Probe is not positioned		Application
In Sequential Procedure, for the selected skin marker, arm will collide with patient skin.		Application
In Sequential Procedure, for the selected skin marker, arm will collide with CT table		Application
When user tries to confirm a probe without calibrating respective CT station		Application
When ablation volume is modified from the actual manufacturer IFU		Application
Appear when positioner and needle		Application

colliding with Immobilizer Bed		
Appear when positioner colliding with Immobilizer Bed		Application
If the probe is about to collide with the CT table		Application
Appear when needle is colliding with Immobilizer Bed		Application
Appears when the positioner collides with the immobilizer bed while reaching the selected skin marker.		Application
For the selected skin marker, when there is possibility of arm colliding with CT table		Application
When user selects a skin marker that is placed at extreme slice		Application

User tries to log off the device		Application
User tries to shut down the device		Application
Appears when Continue Plan is clicked after registration		Application
Confirmation pop up when user tries to dock device after undocking MAXIO in between the procedure		Application
Confirmation pop up when user tries to Undock device in between the procedure		Application
Appears when continue clicked after intensity registration		Application
New button is clicked		Application

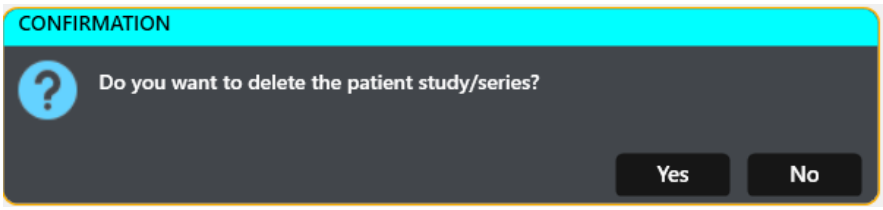
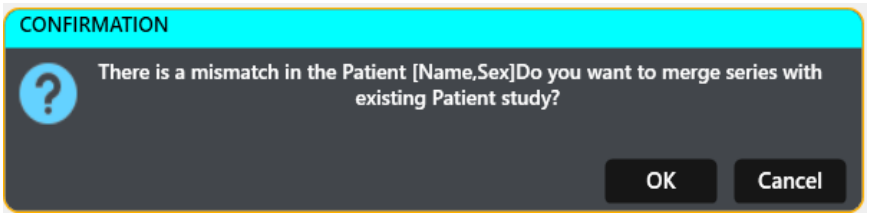
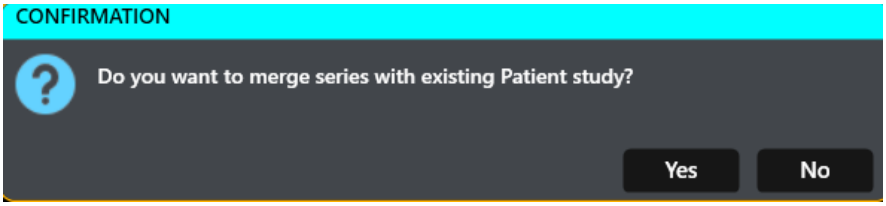
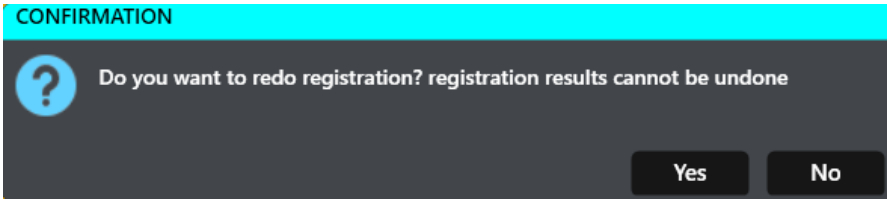
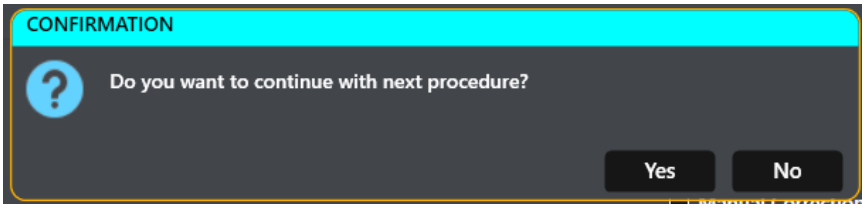
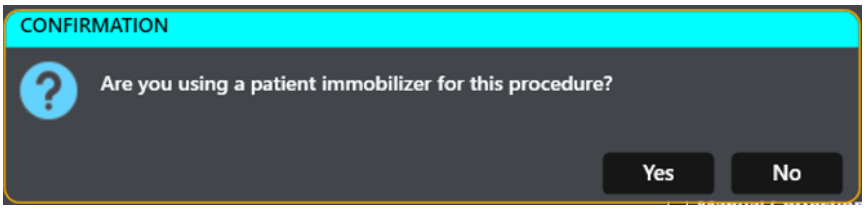
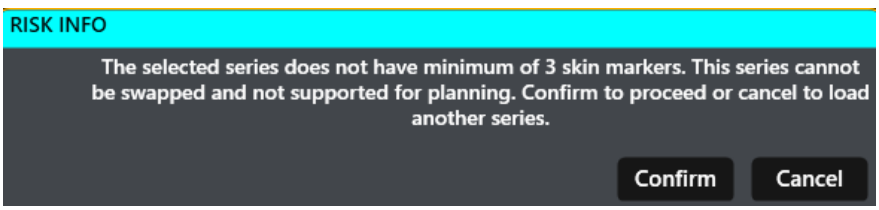
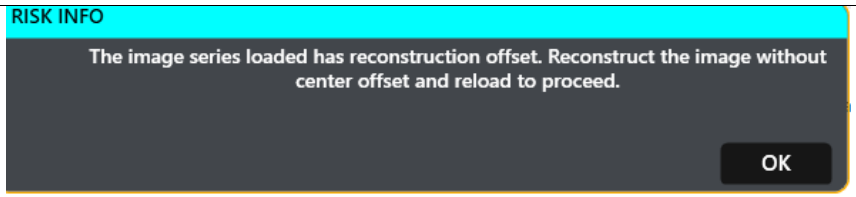
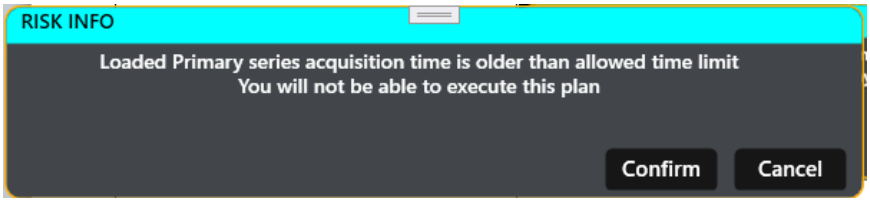
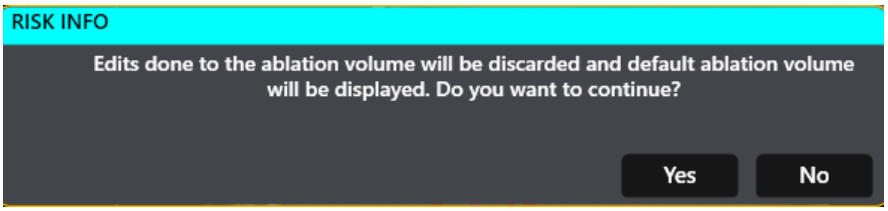
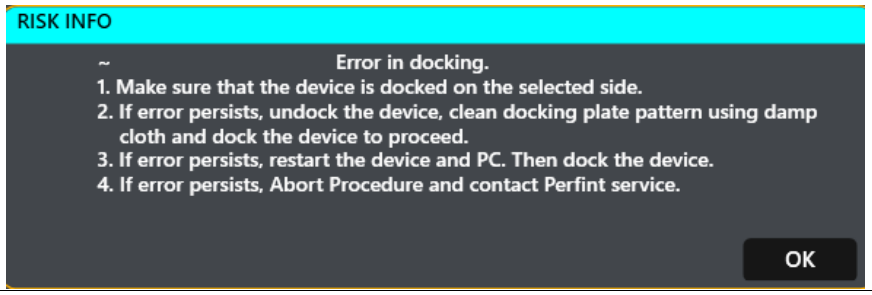
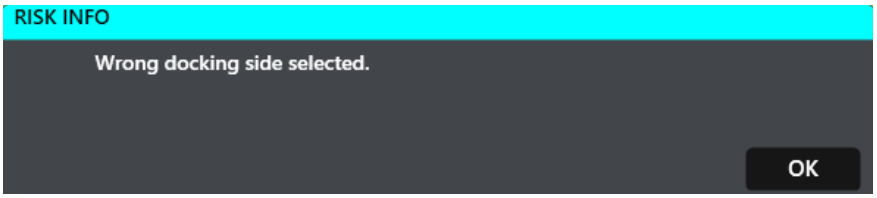
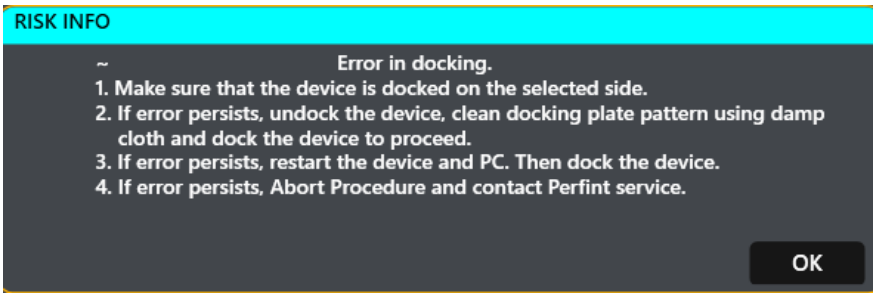
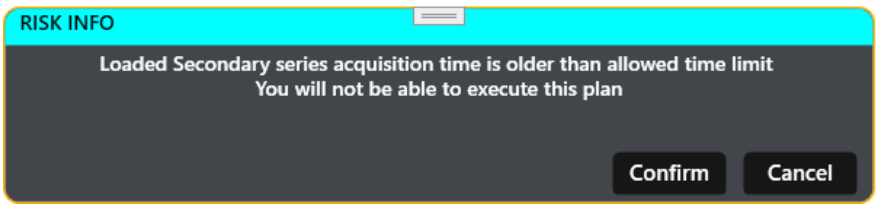
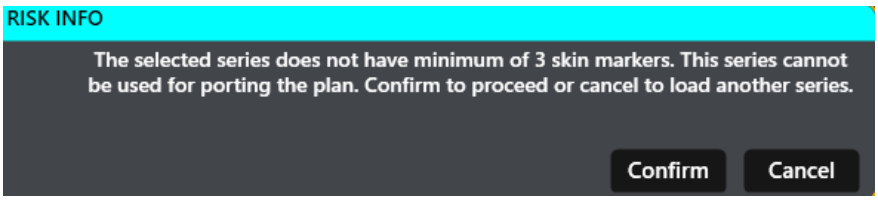
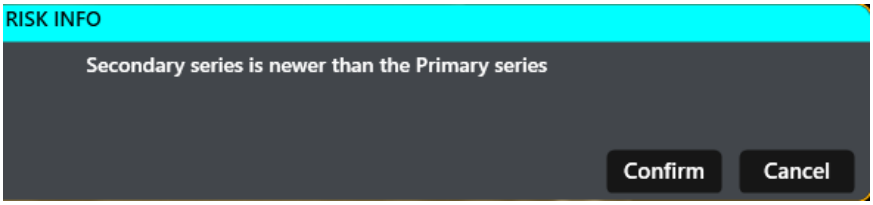
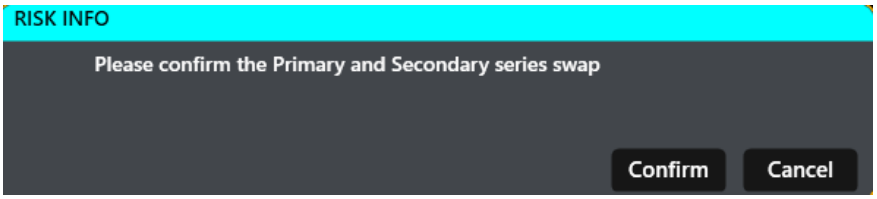
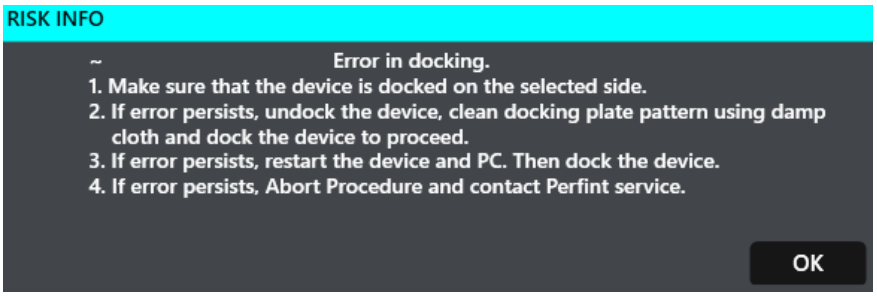
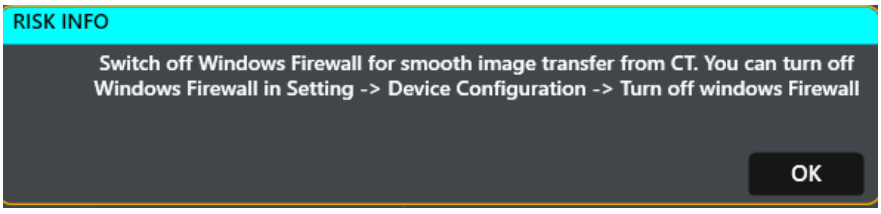
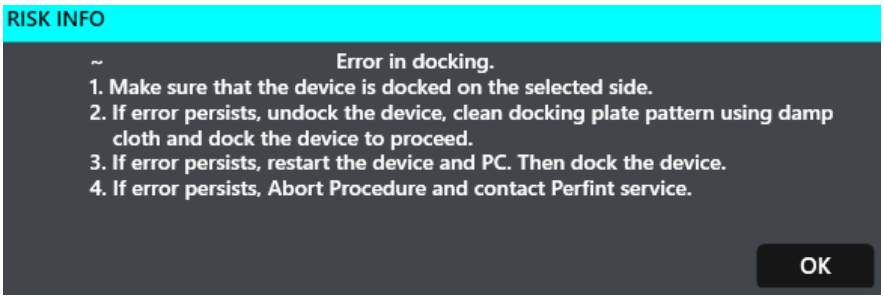
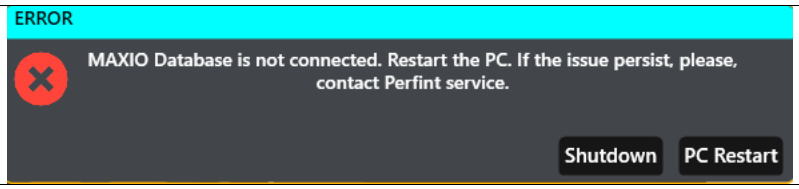
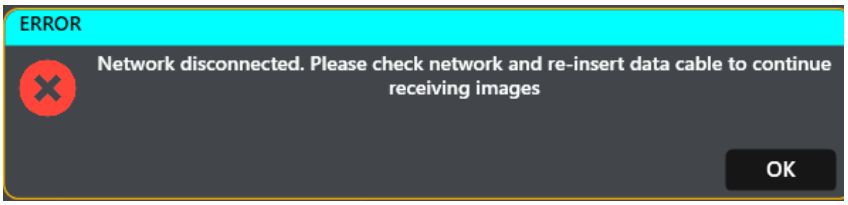
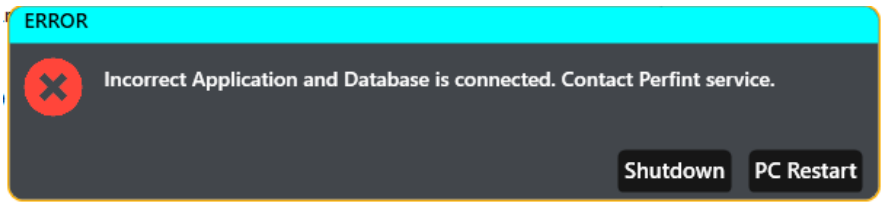
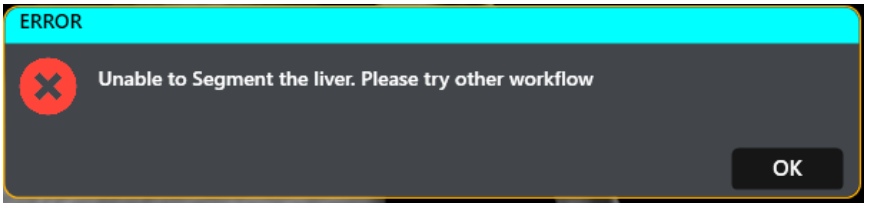
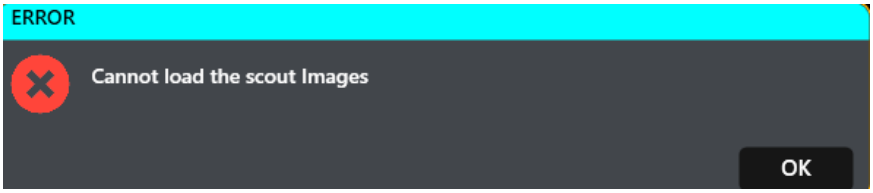
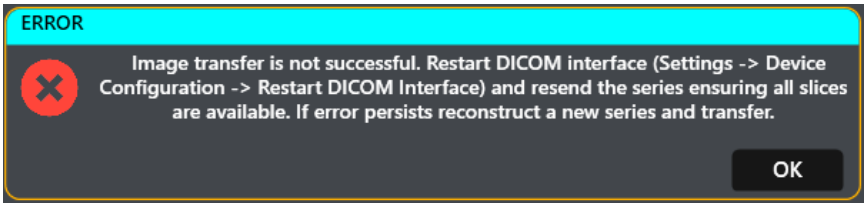
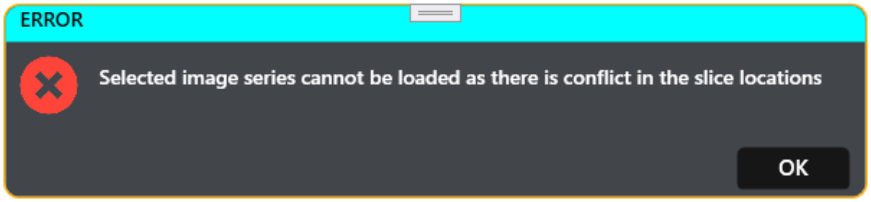
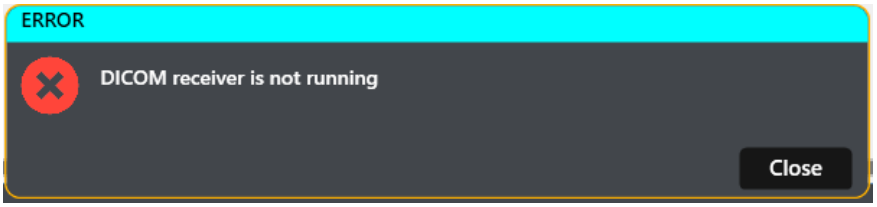
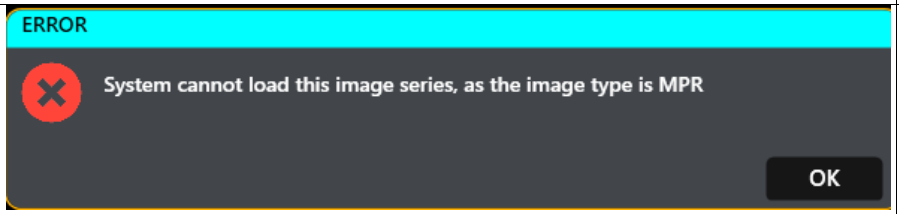
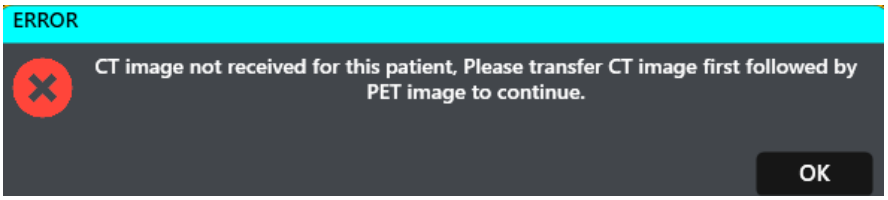
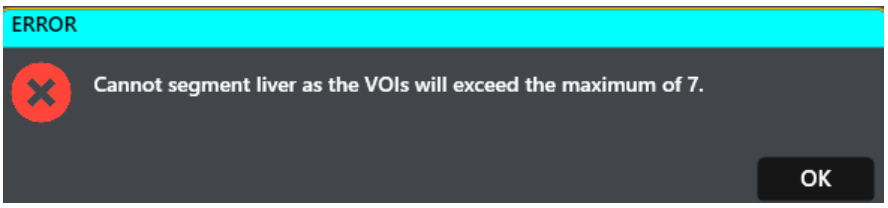
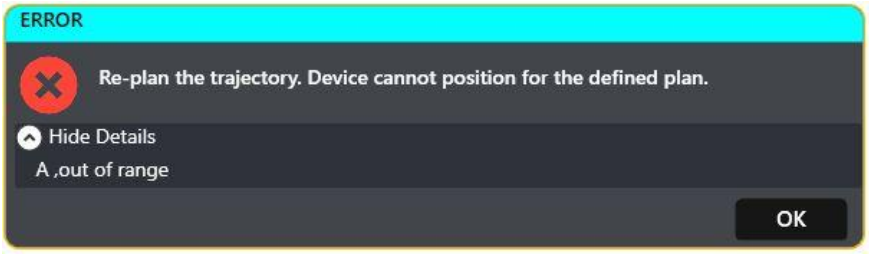
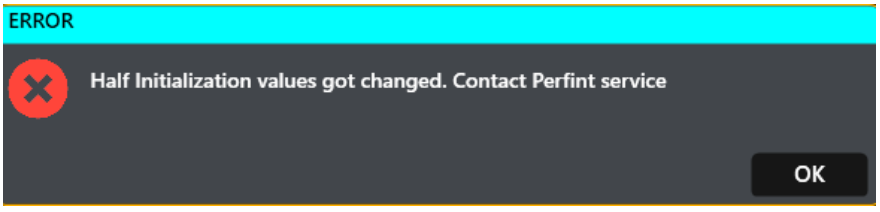
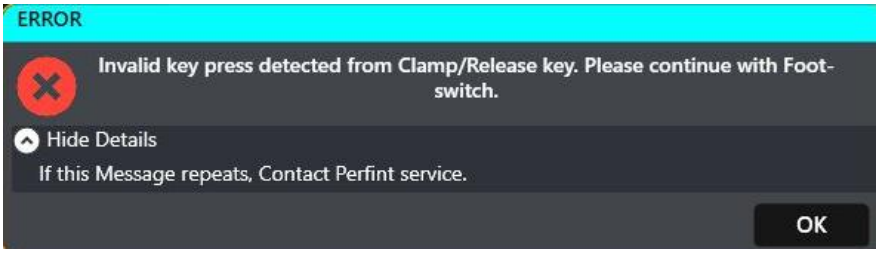
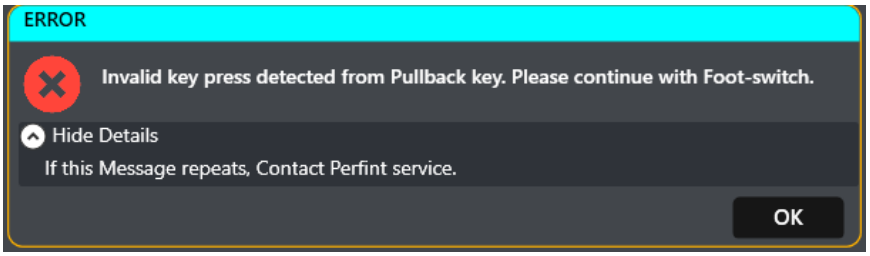
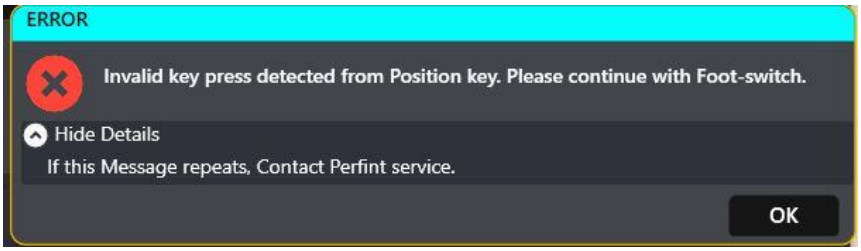
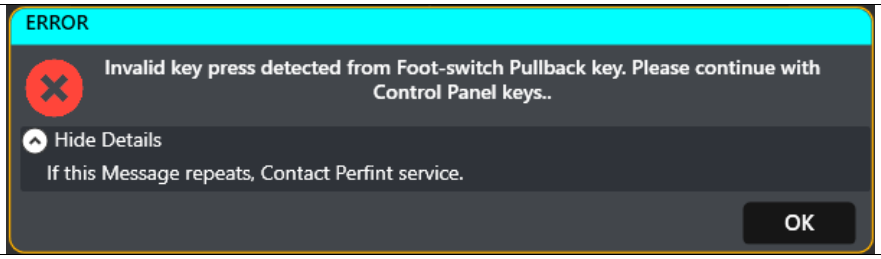
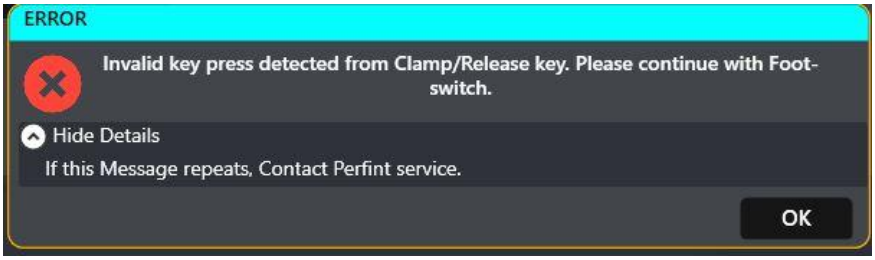
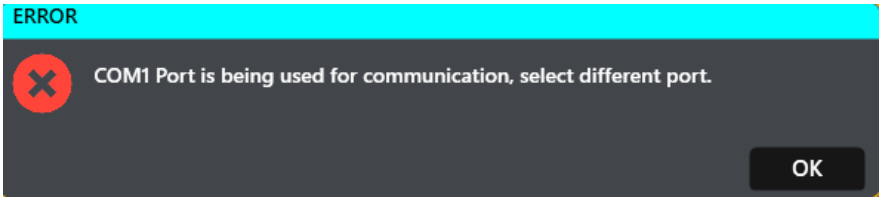
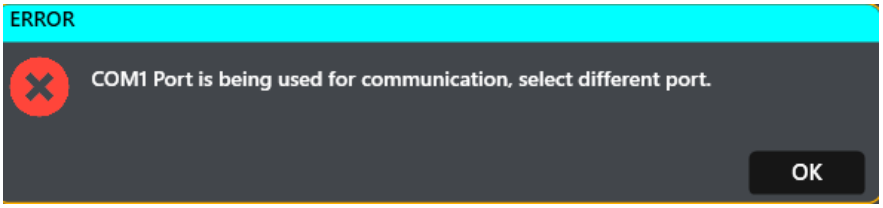
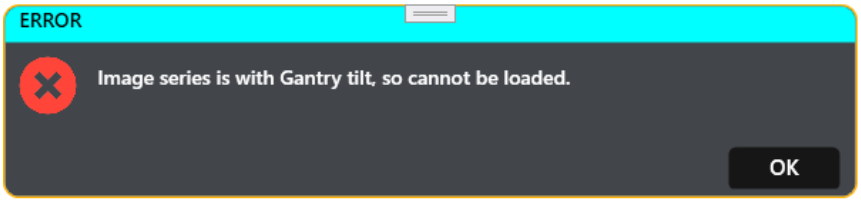
Confirmation pop up when user tries to delete the patient study/series		Application
Appear When user tries to Assign Patient that does not match fields [Patient Name, Sex, DOB] with the Confirmed and Un-confirmed studies		Application
Appear When user tries to assigning the patient		Application
Appear When user tries to Redo CT-MRI Registration		Application
When Next button is clicked		Application
Appears when patient image loading		Application
User loads the secondary series which does not have minimum number of skin markers.		Application

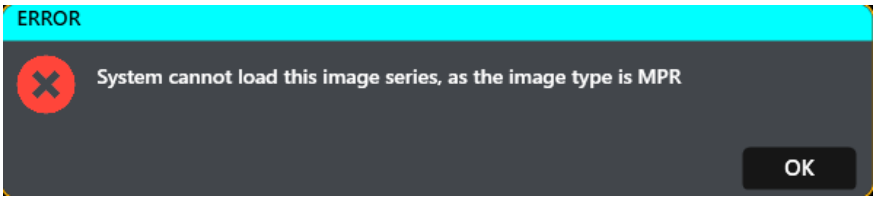
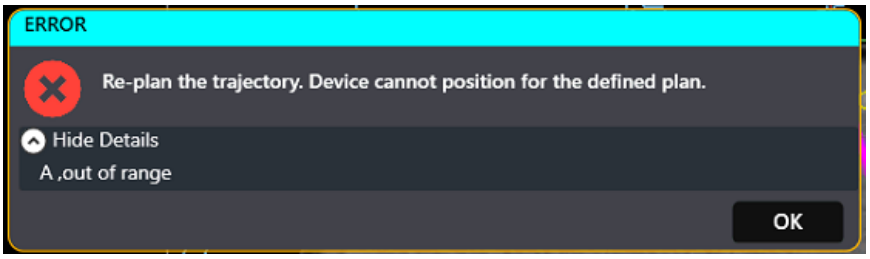
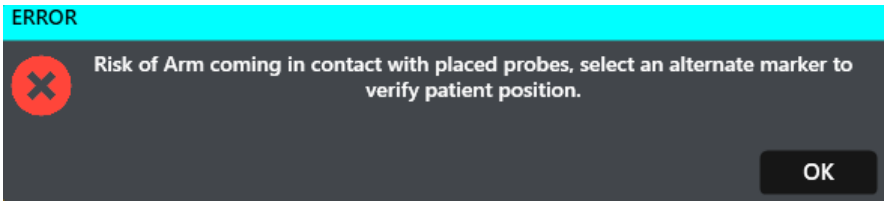
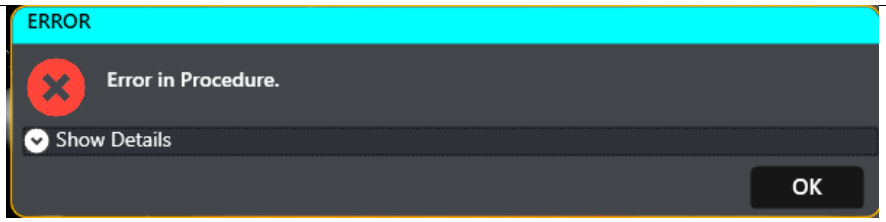
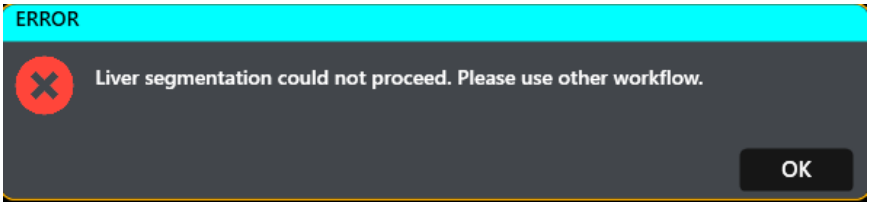
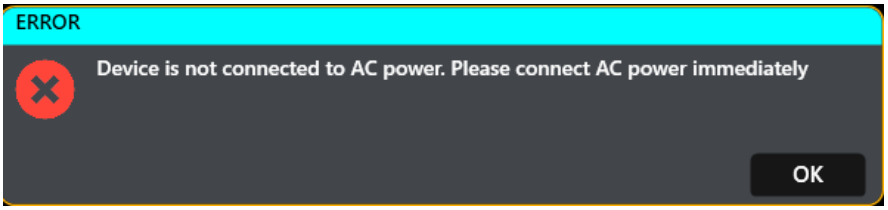
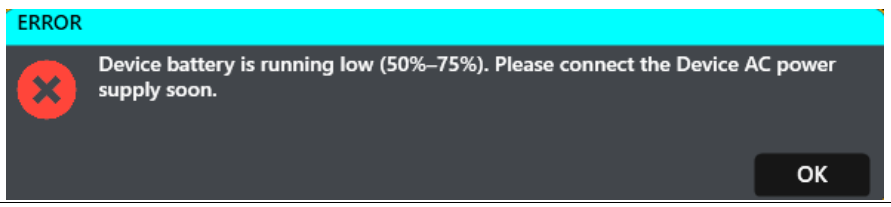
Image series having Offset Tag		Application
When user tries to load the primary series which has the time outside the configured time limit.		Application
Appears when user tries to reset the edited ablation volume		Application
If pattern is not clear during probe Position		Application
If the selected docking side and actual docking side is different		Application
Error in Tracker while skin Marker verification or Probe Position		Application
When user tries to load the Secondary series which has the time outside the configured time limit.		Application

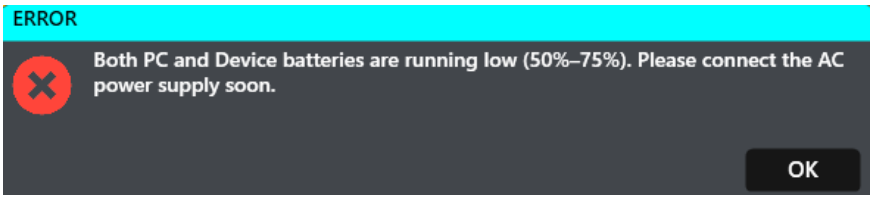
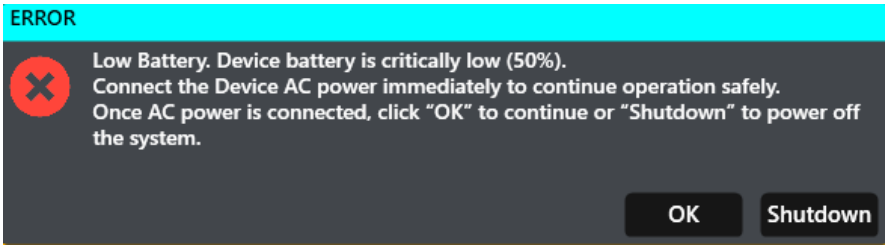
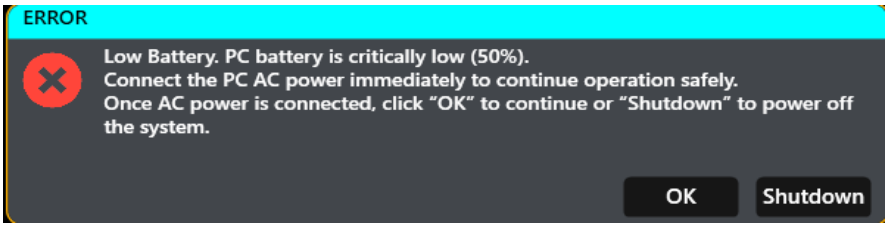
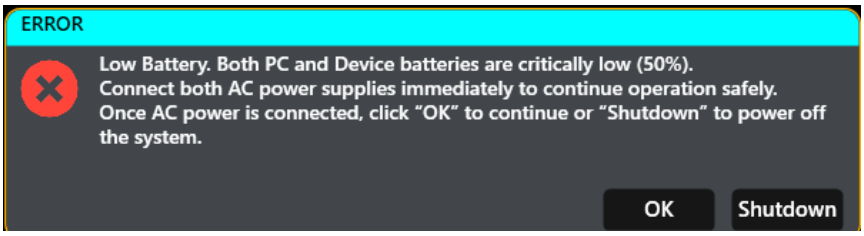
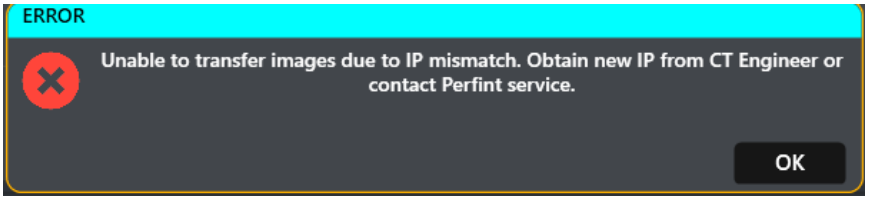
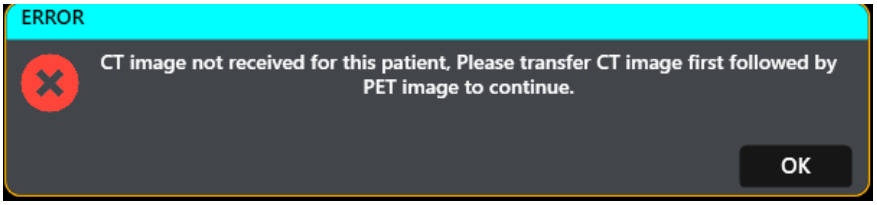
If skin marker is mandatory and User loads the check scan series which does not have minimum no.of skin markers		Application
Selected Secondary image is acquired later than the primary image		Application
Confirmation for swap of Primary & secondary series		Application
Tracker error occurs while verifying Table marker		Application
When Windows Firewall is ON		Application
Instareg error occurs while verifying Table marker or when confirming first probe or while positioning probe.		Application
When database is not connected and the application starts to run		Application

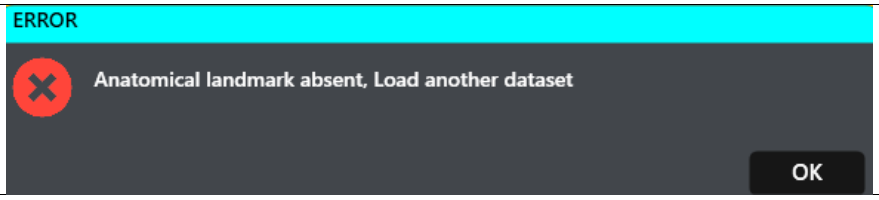
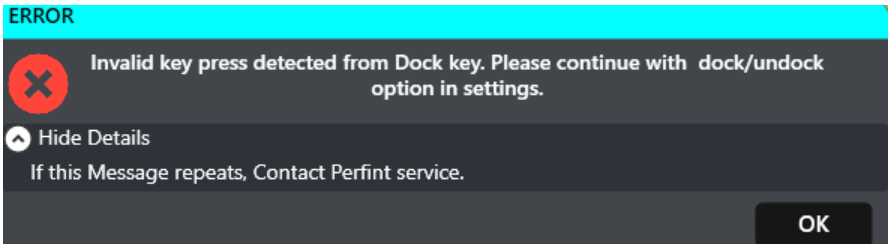
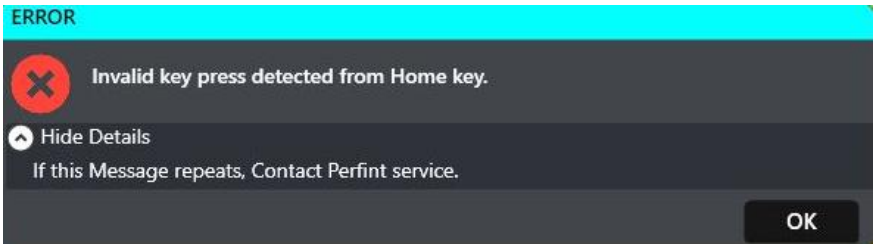
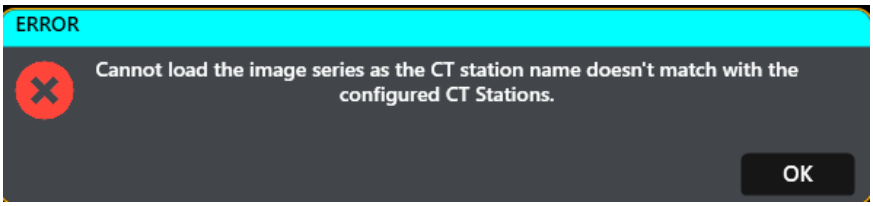
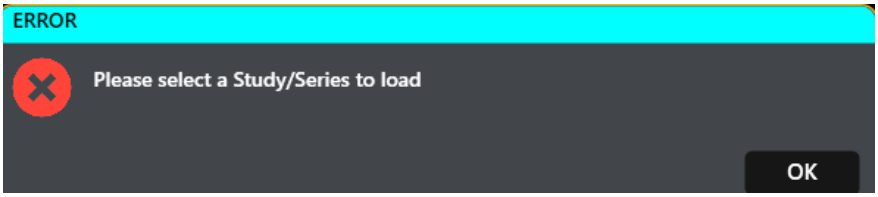
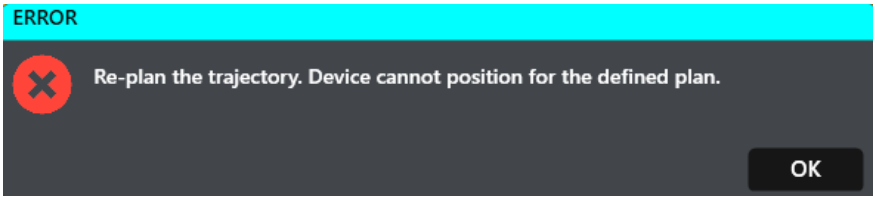
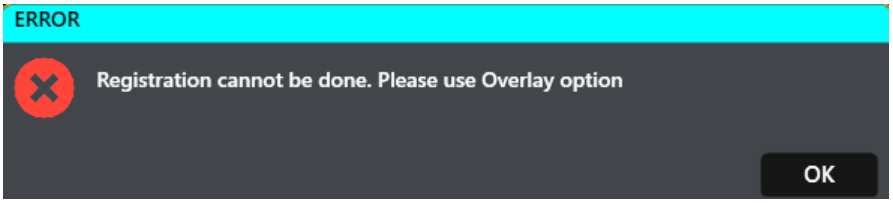
		
Network disconnected from the MAXIO system		Application
In correct database is connected		Application
Appear when liver is not Segment		Application
User tries to load the scout image		Application
Appear when slices are missing		Application
When duplicate slices are added		Application
Appears when user tries to load image without switching on the DICOM receiver		Application

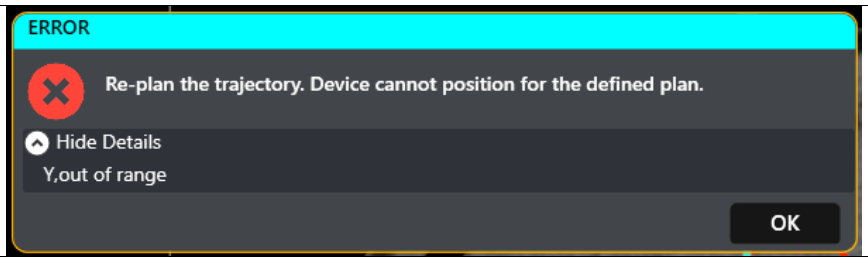
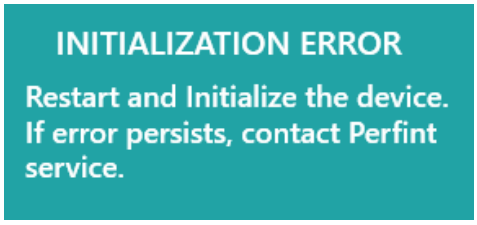
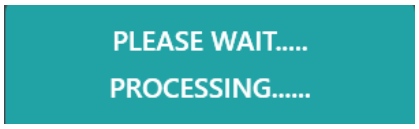
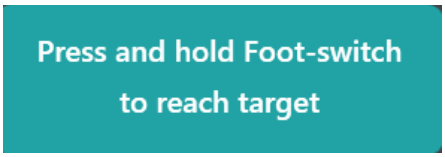
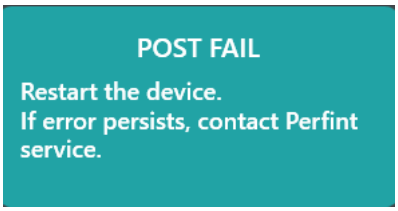
When MPR image is loaded		Application
Appears when user transfers only PET image		Application
Appears when attempt to add liver as 7th ROI		Application
Appear when planned probe is out of device range		Application
When user clicks verify skin marker button without selecting skin marker.		Application
Application detects the half initialization values changed		Application
If the clamp/release key is Continuously pressed.		Application

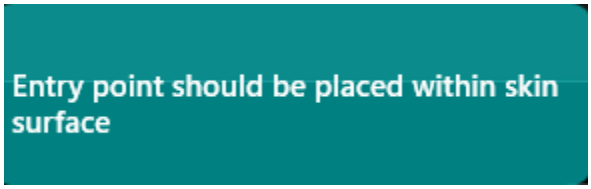
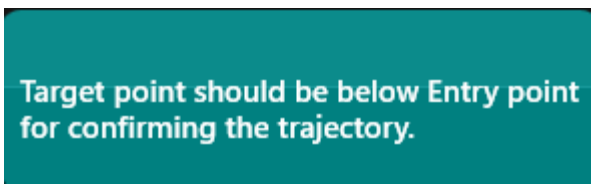
If the Pullback key is continuously Pressed		Application
If the Foot-switch Position key is continuously pressed		Application
If the Foot-switch pullback key is continuously pressed		Application
If the Foot-switch Clamp/Release key is continuously pressed		Application
When trying to use tilt sensor port		Application
When the tilt sensor port which is already being used is selected		Application
User tries to load images with gantry tilt		Application

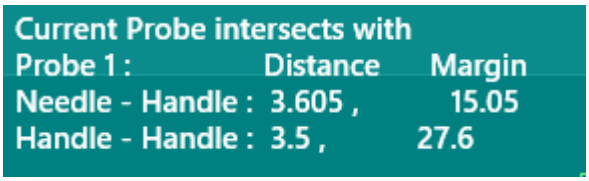
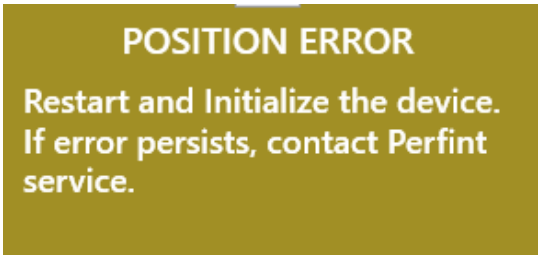
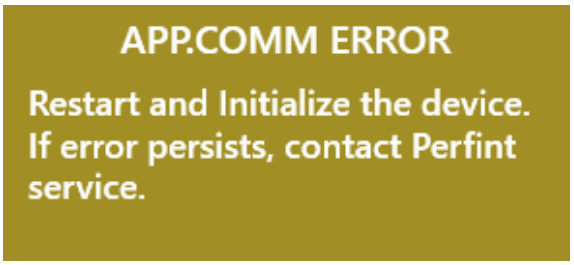
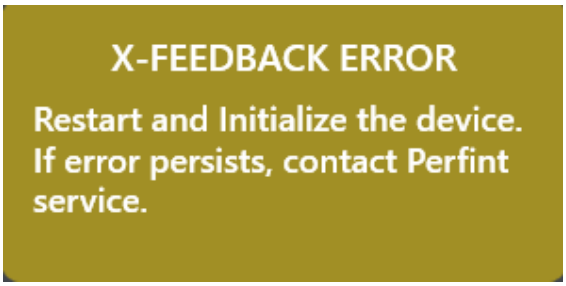
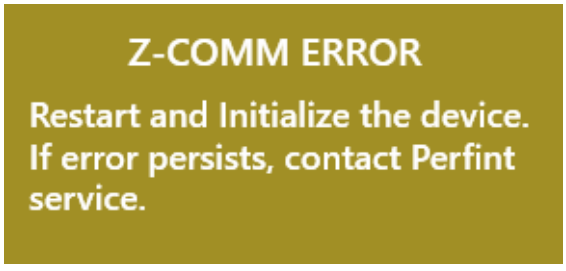
when MPR image is loaded		Application
When probe plan is out of device Reach		Application
In Simultaneous Procedure, for theselected skin marker, arm will collide with probes		Application
When error occurs between the device boards during the procedure.		Application
Liver Segmentation fails		Application
Appear When Application detects the Device battery status as low and AC power is not connected.		Application
Appear When Application detects the Device battery status as low (Below 75%) and AC power is not connected		Application

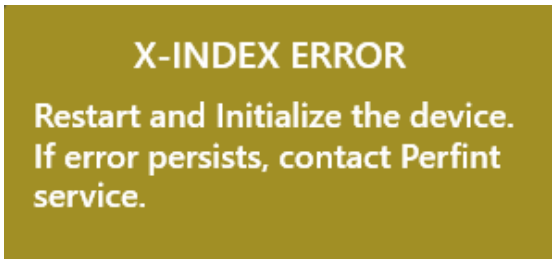
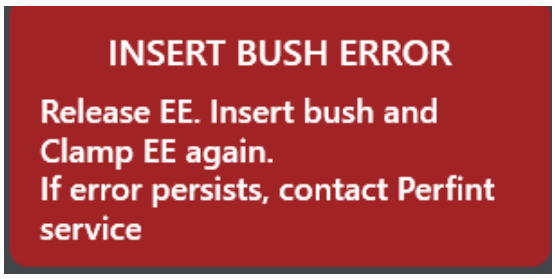
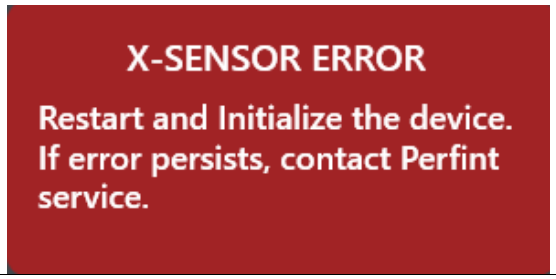
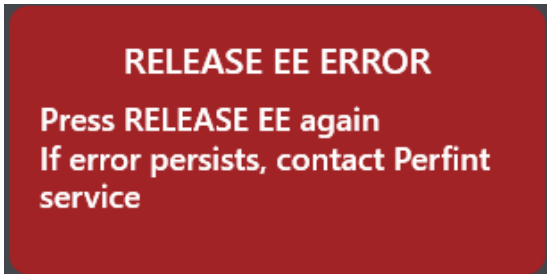
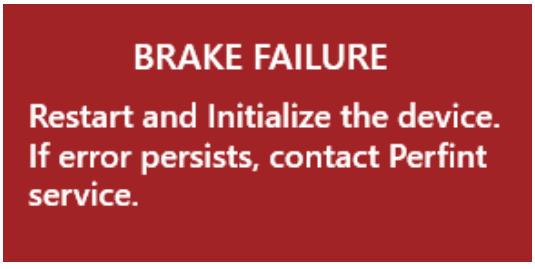
Appear When Application detects both Device and PC battery status as low (Below 75%) and AC power is not connected.		Application
Appear When Application detects the Device battery status as critical (Below 50%) and AC power is not connected		Application
Appear When Application detects the PC battery status as critical (Below 50%) and AC power is not connected		Application
Appear When Application detects both PC and Device battery status as critical (Below 50%) and AC power is not connected		Application
When configured IPV4 address is changed		Application
Appears when user transfers only PET image		Application
When user tries to load phantom image which has no skin or bone		Application

		
If the dock key in control panel is continuously pressed.		Application
If the Home key in control panel is continuously pressed.		Application
When trying to load image series from CT station name that is not added in the application		Application
When user tries to click 'ok' without selecting any study/series		Application
Planned Probe is out of device range		Application
Appears when registration between plan series and check scan series fails		Application

When needle is planned out of device reach		Application
Device will display initialization is not successful message after receiving INIT error command from application software. This is due to mismatch of initialization values		Device
Indicates the user to press position for positioning the probe		Device
Cross checking the position values with Application		Device
After moving to the required position displaying “LOCK EE”, waiting for first EE key press to Lock EE		Device
In simultaneous procedure, appears after completion of Step – 1movement for the 2nd probe Onwards		Device
Indication of an axis POST fails in the device on power ON.it can arise due to limit switch and/or motor and/or encoder not working in one or more axis.		Device
After pressing position key if Y is not at zero position, Y will move to either zero position or Release Y position and then moves to required position		Device

Displaying the Anesthesia movements		Device
After removing the needle and opening EE, we have to pull back the X, Z and Y arms sequentially back or forth by pre-set distance by user pressing pullback key.		Device
Appears during positioning for skin marker verification		Device
After moving to the required position displaying “INSERT BUSH”, waiting for first EE key pres		Device
After device has positioned, If EE arms are fully opened “LOCK EE ” else “INSERT BUSH” is displayed		Device
Displaying the positioning movements		Device
Appears if the LASER is not armed during table marker verification/ skin marker verification		Device
Appears when network is disconnected		Application
When entry point is not placed within the skin surface		Device
During planning choosing entry point below target point		Device

When needle is positioned beyond the limit		Device
In the simultaneous planning, if intersection detected between the probes.		Device
Medium Priority		
After moving to required position if current position of axis in device and send position values is/are not matching, device will display this error message		Device
Indicating the communication between device and application is lost		Device
If motor and/or encoder is not working properly during an axis movement		Device
1. If one of the slave board communications is gone bad. 2. If one of the communication wire in the slave bus is gone bad.		Device

Indicating Index Error in case missing of index during FI or HI in a linear axis in the device. Can arise due to any failure related to encoder.		Device
High Priority		
Indicating incorrect insertion of bush and advising to release EE Can arise due to inner limit switch of EE not working or motor not working properly		Device
Indicating Emergency stop in the device, when Emergency button is pressed manually		Device
1. If the axis moved more than its allowable range. 2. If the limit switch is not working properly during axis movement in a procedure		Device
Indicating incorrect release of EE and advising to press EE once again. Can arise due to outer limit switch of EE not working or motor not working.		Device
Indication for Y-Brake failure in device. Can arise if free fall movement of y axis occurs.		Device
User Input Guidance Messages		

Empty User name	Enter User name	Application
Empty Password	Enter Password	Application
Invalid User Name	Invalid User Name	Application
Valid user name and invalid password	Invalid Password	Application
Appears if Caps lock is on	Caps lock is on	Application
Appear when License will be expired in 15 days	License will expire in 8days. Contact Perfint Service	Application
Communication is not configured	Maxio device communication is not configured, Contact Admin/Service	Application
If the user has not completed the Half initialization in the Setup screen	Half initialization not done. Press Home key to initialize the device.	Application
Appears when user does not select patient study or when more than one patient study is selected in the Manage patient	Select one study to load	Application
Appears while user does not select a study.	Import a study to load	Application
Dataset loaded with station name that is not registered	Series cannot be loaded as the CT station name does not match with configured CT station.	Application
Appear in settings tab when user tries to remove all the detected skin markers settings	Do you want to remove all the detected skin markers?	Application
In the Setup screen, when User has not switched ON the device.	Device communication not available. Switch on the device.	Application
Appears when User selects the wrong docking	Wrong docking side selected, choose the correct docked location	Application
After positioning the table marker in user mode	Does the LASER cross-hair fall on the table marker? On clicking Yes, device will move to home position. Dis-arm the LASER. [Yes] [No]	Application
Appears after the device is docked and Tracker is green	Proceed to table marker verification	Application
License file is expired	License Expired. Contact Perfint	Application
Appear when loading the image in	Removing noise in the image, Removing couch, Performing Skin & Bone Segmentation, Detecting Fiducial Skin Marker	Application

select patient		
Appear when login to the select patient screen	Click Load Patient button to choose the patient	Application
When user tries to load image orientation other than HFS, FFS, HFP, FFP	Series cannot be loaded as the current patient orientation is HFDR/HFDL, only HFS, HFP, FFS, FFP orientations are supported. Note: If the current patient orientation is beyond HFS, HFP, FFS, or FFP, an error will occur.	Application
Appears when the Image have slice thickness less than the recommended.	Slice thickness is {0} mm against recommended slice thickness of {1} mm for better accuracy	Application
When user is in Training mode	Cannot position in training mode	Application
When user tries to load another series when a series is already loaded	Uncheck loaded series to load another series	Application
When user tries to load a series of a different CT station other than the Selected CT	Series cannot be loaded as the CT station name does not match with selected CT station.	Application
When anesthesia needle length is lesser than the required	Selected Needle length is lesser than the required	Application
Confirmation for adjusting the anesthesia needle length	Adjust the slider along Needle trajectory to set the anesthesia delivery point	Application
When planned needle length is greater than the accepted range	Planned Needle length should be lesser than {0}	Application
When needle length is lesser than the required, for ablation Probe type	Select Needle length {0}	Application
When planned needle length is not within the accepted range in non ablation procedure	Select Needle length between {0} and {1}	Application
Appear Ablation volume is Covering the No-Go region in plan Screen	Ablation volume is covering the NO-GO region	Application
Appears when listed series' slice count is less than the recommended slice	Series cannot be loaded as the slice count {X} is less than the recommended slice count {64}	Application

count		
Slice thickness is more than recommended	Image series cannot be loaded as the current slice thickness is {0} mm which is beyond the recommended slice thickness {1) mm	Application
User tries to press the 'continue' button to change anesthesia to probe position.	To Position for the procedure, press Home and then Position key in device panel.	Application
When Position Done is clicked	Select Verify to verify the positioned probe.	Application
After positioning one probe among other probes	Verify probe # position or continue to position the next probe	Application
In simultaneous procedure, appears after completion of Step - 1 movement for the 2nd probe onwards	Press and hold Foot-switch to reach target.	Application
Appears during two step verification after completion of first step positioning.	Press and hold Foot-switch for skinmarker verification	Application
Appears in sequential mode from second probe onwards	Make sure the placed probe is removed from the patient body.	Application
If skin marker is mandatory, it is displayed when detected skin marker is less than mandatory number of skin markers.	Add {0} more skin marker(s) to proceed with skin marker verification.	Application
When moving for skin marker verification	MOVING POINT Q1 MOVING AXIS	Application
If the device key is pressed continuously.	Invalid key press detected	Application
Appear when patient study is not Selected	Select one patient study to load	Application
After positioning the table marker in user mode	Does the LASER cross-hair fall on the table marker? On confirmation, device will move to home position. Unarm the LASER. [Yes] [No]	Application
When enters the table marker verification tab in setup screen	Move the patient table (cradle) back to full extent and ensure the patient table height is at {X}.Arm LASER to initiate axis movement to verify table marker	Application
Image have slice thickness	Slice thickness is 1.25 mm against recommended slice thickness of 1 mm for better accuracy	Application
Information displayed	Note: After completing the first step docking, press dock button for	Application

about the two step docking in Dock/ Undock settings	second step docking.	
To skip anesthesia positioning	Press Home key in device to skip anesthesia positioning	Application
Appears when Training mode is selected in settings	To uncheck the Training mode, Log off and Login.	Application
Appears when Training mode is not selected except in set up screen	Log off and Login to select Training mode in setup screen	Application
Appear in settings tab when user tries to remove all the detected skin markers settings	Do you want to remove all the detected skin markers?	Application
In device un dock state, user tries to press the un dock button in settings.	Device is already Undocked.	Application
In device dock state, user tries to press the dock button in settings.	Device is already Docked.	Application
More than 7 VOIs defined	Cannot segment more than {7} VOIs	Application
Appears when attempt to add liver as 7th VOI	Cannot segment liver as the ROIs will exceed the maximum of {7}.	Application
In the simultaneous planning, if intersection detected between the probes.	Current Probe intersecting with {#}	Application
In Add parallel probe, if target point is outside the patient body based on the selected / entered values	Probe cannot be placed on selected image region.	Application
Position Done Click	Select Verify to verify probe positioning	Application
After positioning one probe among other probes	Verify probe # positioning or continue to position the next probe	Application
Appears in sequential mode from second probe onwards	Make sure the placed probe is removed from the patient	Application
Selected series older than configured time	Series cannot be loaded as the acquisition time is greater than the configured time limit.	Application
Selected Series doesn't have skin Marker	The selected series doesn't have skin marker/s, Continue to proceed without verifying skin markers or select a different series with skin markers	Application

Appears in setup summary	Ablation Volume is a graphical representation as per Energy device Manufacturers IFU and may not take into account important in-vivo tissue dynamics that can affect ablation size such as vascularization, type, temperature and impedance.	Application
Loaded series is different from planned series	Series cannot be loaded as the patient orientation is different {X} from the planned series	Application
Prompt the user to load the Check scan series	Select Image series to load and overlay with planned series	Application
Appears when plan is being ported	Porting Plan	Application
Loaded series is different from planned series	Series cannot be loaded as the patient orientation is different {X} from the planned series	Application
When user is in post ablation Screen	Select Mark to segment the Ablated zone	Application
Confirmation for adjusting the anesthesia needle length	Adjust the slider along trajectory to set the anesthesia delivery point	Application
Anesthesia requires greater needle/ applicator length	Selected Anesthesia Needle length is lesser than the required	Application
When planned anesthesia needle length is lesser than the accepted range	Select Anesthesia needle length between {0} and {1}	Application
When planned anesthesia needle length is greater than the accepted range	Planned Anesthesia needle length should be lesser than 250	Application
Appear Ablation volume is covering the No-Go region in plan screen	Ablation volume is overlapping with the No-Go region	Application
If the user has not completed the Half initialization in the Setup Screen	Half initialization not done. Press Home key to initialize the device.	Application
If the Device is not docked in Setup screen	Dock the Device	Application
Instructions to use bed and breathe belt.	Note: Please refer the user manual for details of Immobilizer bed and Breath Monitoring device	Application
When user tries to load the scout images	Cannot load the scout images	Application
When user confirms a	Verify slices {N_1} to {N_n} for Tumor {X} coverage.	Application

probe with residual percentage of tumor not covered by probe's ablation volume		
If user is in non-ablation workflow and tries to select more than 2 images	Select maximum of 2 images for report generation	Application
Information displayed about the two step docking in Dock/Undock settings	Note: After completed the first step docking, Press dock button for second step docking.	Application
In device un dock state, user tries to press the un dock button in settings.	Device is already un-docked.	Application
In device dock state, user tries to press the dock button in settings.	Device is already docked.	Application
If the device key is pressed continuously	Invalid key press detected	Application
Appears when Training mode is selected in settings	To uncheck the training mode - log off and login to proceed.	Application
Appears when Training mode is not selected except in set up screen	Logoff and Login to select Training mode in Setup screen	Application
Appear slice thickness > 3 mm	Series cannot be loaded as the current slice thickness is 5 mm which is beyond the recommended slice thickness 3 mm	Application
One VOI have multiple disconnected Regions	One VOI cannot have multiple disconnected regions, mark a region that is attached to the initial region	Application
To skip anesthesia	Press Home key in device to skip anaesthesia	Application
More than 4 tumor region is marked	Cannot segment more than {0} Tumors.	Application
More than Selected Tumor configuration region is marked	Cannot segment more than {0} Tumors.	Application
More than Selected No Go configuration region is marked	Cannot segment more than {0} NoGo's.	Application
More than 7 VOIs defined	Cannot segment more than {0} VOIs	Application

Appears when mandatory number of skin markers are not verified automatically.	Select SkinMarkers manually to continue the skinmarker verification	Application
Appears when not able to form the sequence for auto skin marker positioning after first probe.	Select Skin Markers to verify	Application
If user is in ablation workflow and tries to select more than 4 images	Select maximum of 4 images for report generation	Application
After completing the Self marker verification	Is Self-Marker Verification within tolerance limit? On clicking Yes, device will move to Home position. Disarm the LASER	Application
User tries to verify the Self marker in docking state	UnDock the device.	Application
User presses the Dock/ undock button in settings before completing the existing process.	Please wait, Device has not completed the process.	Application
User presses the Undock button in settings during the procedure.	Undock button press is ignored since procedure is in process	Application
User tries to Dock/ undock button in settings while communication is not available.	Communication is not available	Application
Confirmation for Overlay	Overlaying...Assuming there is no patient movement in between scans	Application
Half initialization not done	Half Initialization not done , Continue with HalfInitialization	Application
Appear when image slice stack ruler length is greater than 50 mm	Slice stack ruler length should be greater than 50 mm	Application
Appear while primary series / check scan series / post image series is more than 512 slices	Loaded series has {X} which is more than recommended 512 slices. Use clip to reduce the slices	Application

Image series older than the configured time is selected.	Image series cannot be loaded as the acquisition time is older than allowed time limit.	Application
Image series older than the configured time is selected.	Image series cannot be loaded as the acquisition time is older than allowed time limit.	Application
Appears when marking the liver region with both primary and secondary CT images	Mark both the primary and secondary liver from Base to Apex in Coronal View	Application
Appear when imageslice stack ruler length is lesser than 50 mm	Slicestack ruler length should be greater than 50 mm	Application
Ablation volume crossing the liver boundary in plan screen	Ablation volume is crossing the Liver boundary	Application
Appears when Probe intersects with No-go region in plan screen	Probe intersects with No-Go region in slice #	Application
Ablation volume touches the vasculature in plan screen	Ablation volume overlaps with >3mm vasculature.	Application
Confirmation of manual correction in check scan screen	Registration correction done	Application
Prompt the user to load the checkscan series	Select image series to load and overlay with planned series	Application
When user tries to confirm without selecting any image	Please select at least one image	Application
If user is in ablation workflow and tries to select more than 4 images	Select maximum of 4 images for report generation.	Application
If user is in non-ablation workflow and tries to select more than 2 images	Select maximum of 2 images for report generation.	Application
Appears when checkscan needle verification by marking entry and target in registered image	Target Error:<3D Error>, X:<Error in X-Axis>, Y:<Error in Y-Axis>, Z:<Error in Z-Axis> Entry Error:<3D Error>, X:<Error in X-Axis>, Y:<Error in Y-Axis>, Z:<Error in Z-Axis> Angle Error: <Angle Error>	Application
To instruct the user to do segment liver or Organ based registration	Choose Intensity based registration or Segment liver to perform organ-based registration	Application
When user is in post ablation screen	Select Mark tool to segment the Ablated zone	Application
In the simultaneous	Current Probe intersecting with {#}	Application

planning, if intersection detected between the probes.		
Appear when marking the liver region	Mark Liver from Base to Apex in Coronal View	Application
Confirmation for adjusting the anesthesia needle length	Adjust the slider along trajectory to set the anesthesia delivery point	Application
Ablation volume crossing the liver boundary in plan screen	Ablation volume crossing the liver boundary	Application
Appears when Probe intersects with No-go region in plan screen	Probe intersection detected with No-Go region in slice #	Application
Ablation volume touches the vasculature in plan screen	Ablation volume touches >3mm vasculature	Application
Ablation volume is nearer to the No- Go regions	Ablation volume is within 3mm of the No-Go regions	Application
In Add parallel probe, if target point is outside the patient body based on the selected / entered values	Probe cannot be placed on selected region.	Application
When user confirms a probe with residual percentage of tumor not covered by probe's ablation volume.	Verify slices {0} to {1} for Tumor {2} coverage.	Application
To instruct the user to use smaller 18-gauge in position screen	Long needles and needles smaller in diameter than 18-gauge may bend during insertion. Use short thicker needles where possible.	Application
During the Anesthesia check scan Verification	Do not Press Home key in Check Scan Verification screen	Application
Appear while primary series / checkscan series / post image series is more than 512 slices	Loaded image series has {0} slices which is more than recommended 512 slices. Use clip to reduce the slices	Application
Appear while Secondary series is more than 512 slices	Secondary image series has more than 512 slices. Use clip to reduce the number of slices	Application
Appears when listed series' slice count is less than the recommended slice count	Image series cannot be loaded as the slice count {0} is less than the recommended slice count {1}	Application
Series selected is	The selected image series doesn't have skin marker/s. Continue to	Application

without skin markers	proceed without verifying skin markers or select a different series with skin markers	
Appears when marking the liver region with the primary image as CT and the secondary image as MRI	Mark the primary liver region from Base to Apex in Coronal View	Application
When needle length is lesser than the required	Selected Needle length is lesser than the required	Application

Appendix D: Device Messages

The device messages indicate the device activity. The device status messages are displayed in the procedure information window on the MAXIO® monitor. The device messages are broadly classified into following 4 categories

1 Initialization messages - Include initialization related messages
2 Procedure/Movement related messages - Include procedure/home moving axis related.
3 InstaReg messages - Includes docking related messages.

Initialization	
INITIALIZATION.? PRESS HOME KEY	This message prompts the user to perform device initialization by pressing the "Home key" in the control panel.
INITIALIZING	This message indicates that the device axes are initializing
INITIALIZATION SUCCESSFUL	On completion of successful initialization, this message will be displayed to the user. This also indicates that the device is ready to be used for a procedure.
INIT-ERROR	In the event of unsuccessful initialization, this message is displayed.
Needle Position Procedure	
ANESTHESIA MOVE CRADLE TO	This message is displayed when a local anesthesia plan is sent to the device. The message displays the cradle top position to which the patient table has to be moved.
NEEDLE POSITION MOVE CRADLE TO	This message is displayed when a local anesthesia plan is sent to the device. The message displays the cradle top position which the patient table has to be moved.
PLEASE WAIT PROCESSING	Internal device check of the axes position values with the software before positioning.
MOVING Y	This message indicates the movement of Y axis to position for a particular plan.
ANESTHESIA MOVING AXIS	Displaying the Anesthesia movements.
X- COMM-ERROR	Indicating Internal Communication Error
X - SENSOR-ERROR	Indicating Sensor Error
X-INDEX-ERROR	Indicating Index Error in case missing of index during FI or HI in linear axis.
ERR. INSERT BUSH	Indicating incorrect insertion of bush and advising to release EE.
ERR. RELEASE EE PRESS RELEASE EE	Indicating incorrect release of EE and advising to press EE once again.
EMERGENCY STOP	Indicating Emergency stop.
APP. COMM ERROR	Indicating there is no communication with Application PC.
X-OUT OF RANGE	Indicating the corresponding axis movement value is out of range.
RELEASE X OUT OF RANGE	Indicating Release X value is out of range.

RELEASE Y OUT OF RANGE	Indicating Release Y value is out of range.
POSITION ERROR PRESS POSITION	After moving to required position if current position of axis and given position values is not matching, device will display this error message.
BRAKE- FAILURE	Indication for Y-Brake failure in device.
NEEDLE POSITION ABORTED	Cancel procedure display DURING Needle Position.
ANESTHESIA ABORTED	Cancel position display during Anesthesia positioning.
NEEDLE POSITIONING MOVING AXIS	Displaying the positioning movements.
INSERT BUSH	After moving to the required position and if the EE is fully open this message is displayed after the first EE key press. This message prompts the user to insert the bush (selected based on the needle to be used for the procedure). If the EE is already in the half closed state, message "LOCK EE" is displayed.
LOCK EE	This message prompts the user to lock the EE and clamp the bush with the help of second EE key press.
RELEASE EE	Once the bush is securely clamped, the user can insert the needle/tool through the bush. On completion of needle insertion, the EE must be released which is indicated by the message RELEASE EE, demanding for third EE press.
PULL BACK RELEASE XZ	This message prompts the user to press the “Pullback’ key to move the X, Y and Z arm back by some distance, to provide clearance to the clinicians.
PULL BACK RELEASE Y	This message prompts the user to press the “Pullback” key to move the X and Y arms back completely to its extreme position.
MOVING AXIS PLEASE WAIT…	Display message during pull back of X and Y axes. Wait for next command.
PRESS HOME FOR NEEDLE POSITION	This message prompts the user to press the “Home” key to set the device to position for a procedure after completing anesthesia position.
HOME MOVING AXIS	Display message when the device axes are moving to the Home position. This is triggered by the “Home” key press on completion of a procedure and when the device is not docked
InstaReg messages	
DOCKING	Display message “Docking”, when dock key is pressed in the device undocked state
UNDOCKING	Device shows message “Undocking”, when dock key is pressed in the device docked state

☞	Ensure that the error beep is audible in the CT environment. Call Perfint Service in case of such error conditions.

Appendix E: Patient Movement Management References

E.1 Patient Immobilizer Bed Setup



Figure E.1 Patient Immobilizer Bed

1. Keep the Immobilizer Bed on the CT table at the appropriate location with the air inlet valve of the bed located at the left side of the CT gantry near the end of the CT table.
2. Connect one end of the air hose with the bed and the other end with the compressor port of the pump.
3. Connect the immobilizer bed pump power cord to power and switch to on position.
4. Inflate the bed using the pump so that the beads are loose and free flowing.
5. Switch ON the pump and remove the air hose from the bed.
6. Connect the air hose; one end with the bed and the other end with the vacuum port of the pump.
7. Hold the bed around the patient, so that it embraces the patient around the sides.
8. Switch ON the pump; wait till the bed becomes rigid embracing the body.
9. If necessary, adjust the holding during deflating to ensure complete embracing.
10. Switch OFF the pump, remove the hose from bed and remove the straps of the bed.

E.2 Breath Hold Monitor Setup



Figure E.2 Breath Hold Monitor

1. Place the patient on the bed with both hands folded behind the head.
2. Wrap and tie the breath belt around the patient body at the appropriate location according to the procedure.
3. Place the base unit on the CT table then place the satellite unit in the docking slot of the base unit. Next, connect the base unit with breath belt using the provided cable.

4. Instruct the patient on how to hold their breath with the satellite unit.
5. Instruct patient to hold breath at a comfort level and record the LED lights on the base unit.
6. Instruct patient to repeat holding their breath at the same level it was first recorded. Patient to know his breath hold by looking at the satellite unit LED or by following doctors instructions.
7. Perform scan.

E.3 Mode of Anesthesia

Device supports the following mode of anesthesia:

- General Anesthesia
- Local Anesthesia
- Accessories are to be used based on the mode of anesthesia.

☞	Work flow enforces clinician confirmation of proper positioning markers on reconstructed planning images.
☞	Workflow enforces clinician confirmation of proper positioning markers on CT scan images
☞	Workflow enforces clinician to verify skin marker position before every probe placement.

Under General Anesthesia (GA) check if the patient needs a vacuum bed to restrain patient movement. If it is required, place the patient gently over the patient immobilizer bed on the CT couch.

Under General Anesthesia (GA), the patient might not need the Breath Hold Monitor. Ensure the patient breath is maintained at the same level during scan and probe/tool insertion.

E.4 QA/Skin Marker Positioning

Place a minimum of 3 radiolucent markers on the patient body in the region of interest in a nonlinear fashion as in the figure shown below.

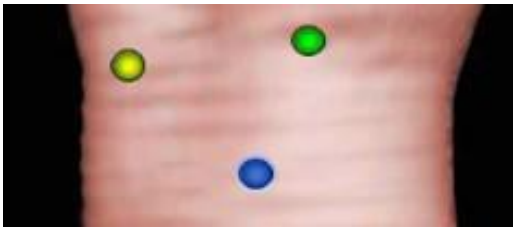


Figure E.3 Skin Marker Positioning

Appendix F: Warranty Information

Limited Warranty

Perfint warrants that the MAXIO® shall materially perform in accordance with the specifications set forth in the User Manual. Perfint EXPRESSLY DISCLAIMS ANY WARRANTY AS TO THE OVERALL EFFECTIVENESS OF THE SYSTEM FOR THE PURPOSES OF CUSTOMER USE AND MAKES NO REPRESENTATION AS TO MERCHANTABILITY OR USEFULNESS FOR ANY PURPOSE OTHERWISE.

- The standard warranty period for all warranties, with the exception of the warranty of title, patent and copyright, is 12 months from the date of install or 15 months from the date of shipment whichever occurs the earliest. The warranty period may change based on the contract.
- Subject to the limitations and exclusions stated below, Perfint will repair or replace, at no additional cost to Customer, any defective Hardware or Software for the period of the contract as defined in the Quotation.

Perfint shall not be liable, expressly or implied, for:

a) Repairs or modifications performed other than by Perfint or a Perfint authorized service personnel or repair facility. MAXIO® contains no user serviceable / replaceable part.

b) Use in any manner or medical procedure, other than that for which it is designed. Either of which shall void this warranty.

For information on the system warranty, refer to the Perfint Terms and Conditions.

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b) Damage caused by use of the System for purposes other than those for which it was designed.
c) Damage caused by disasters such as fire, flood, wind and lightening, or other acts of nature.
d) Damage caused by unauthorized attachments, components or modifications; or
e) Damage caused by any abuse or misuse by Customer.

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Perfint has taken due care in preparing this manual including research, development and testing. This document describes the state of Perfint knowledge respecting the subject matter herein at the time of its publication, and may not reflect the state of the art at all times in the future. Perfint has carefully reviewed this document for technical accuracy. If errors are suspected, the user should consult with Perfint prior to proceeding. Perfint makes no expressed or implied warranty of any kind with regard to this equipment, or the supplemental documentation in this manual.

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Appendix G: Glossary

3D Visualization	Anatomical representation of tumor in 3 dimensional formats in body.
AMC	Annual Maintenance Contract-Service maintenance contract for any equipment with customer.
ARM	Alarm - Any kind of system state that calls for user input to proceed further. An alarm can be a caution, a warning or an error.
Ablation Zone	Volume (of tumor) to be ablated.
Admin	One of the default login types. All users logged in as admin, enjoy special administrator privileges and can do a number of admin settings for the MAXIO® system.
A axis	Angular axis that delivers orbital angle and spans over patients body width.
Biopsy	A Biopsy is a medical test commonly performed by a surgeon or an interventional radiologist involving sampling of cells or tissues for examination.
Breath hold monitor	One of the MAXIO® accessories used for monitoring the breath hold levels of patient.
B axis	Angular axis that delivers craniocaudal angle and spans over patients body length from head to toe.
CT	Computer Tomography [CT Scanner].
Contrast CT	CT scan taken after applying contrast agents.
Check Scan Image	The CT image that is taken after placing the probe.
Clinician	Interventional Oncologist / Interventional Radiologist.
Craniocaudal Angle	Angle measured with respect to an imaginary axis which runs from head to toe.
Component	One of the parts that make up a system. A component may be subdivided into other components.
Collision Avoidance	An algorithm of the MAXIO® software that ensures that there is no needle - needle or needle - device axis collision in case of multiple needle/probe plans. This algorithm also determines these quence in which multiple needles must be placed for simultaneous multiple needle plans.
Clip	To select a subset (or cut) of images from a large image series.
Clamp	Engage the end effector to hold the needle bush.
Cc	Cubic centimeter (measurement of volume)
DICOM	Digital Imaging and Communications in Medicine.
Docking	Process of locking the system to the calibrated reference point in the CT room.
Device	Refers to the electromechanical part of MAXIO® system.
DOF	Degree of Freedom.
EE (End Effector)	The end axis of the MAXIO® system is called as End Effector that consists of two clamping Grippers to clamp the needle guide in

	place.
Entry Point	Point on the skin surface for entry of needle/ probe.
Ethernet	Communication protocol for data transfer - used here for the transfer of DICOM image data from CT to MAXIO® system.
FNAC	Fine Needle Aspiration Cytology - Collection of cells/material from Tumor or diseased area
FDA	Food and Drug Administration.
FOV	Field of View - Scanning area measurement in medical imaging.
FFS	Feet First Supine
FFP	Feet First Prone
GUI	Graphical User Interface.
GA	General Anesthesia. Administration of drug to deactivate nervous system temporarily.
Go Region	The region which is marked for the probe to go through or end at.
Gauge	Standard measure of needle thickness.
Grippers	Grippers (Left and Right) are fixed in the End effector and are intended to clamp the needle guide.
HCC	Hepato Cellular Carcinoma: Type of cancer arising from liver.
HU	Hounsfield Unit [CT number] - Used to measure the density in CT image.
HIS	Hospital Information system - Server and access facility for Patients medical information.
HFS	Head First Supine.
HFP	Head First Prone.
Half Initialize	This operation will be performed by the system after each power on by the user from device HOME key or from software. This will position the system in ZERO co-ordinates. With this position reference only next procedure movements will happen.
Hazard	A condition that is a prerequisite to a safety mishap.
Home	Parking configuration of the MAXIO® system.
IO	Interventional Oncology.
IR	Interventional Radiology.
IEC	International Electro technical Commission.
ISO	International Standards Organization.
Image	CT DICOM 3.0 image.
Image series	Collection of image slices obtained from a single CT scan for a specific diagnosis.
InstaReg Mat	A specific pattern plate pasted on the floor near the CT table. This gives the calibrated reference point for device operation during procedure.
IFU	Instructions for Use.

Initialize	Astartupprocessthattakesallthemechanicalaxestoitsconfigured zeroposition and gets the device ready for procedure.
Intraoperative	In course of the procedure.
Instrument Guide	Needle Guide is also called Instrument guide.
KOL	Key Opinion Leader.
LCD	Liquid Crystal Display.
LED	Light Emitting Diode.
Left Side Docking	When the device is docked on the left side of the CT station.
MR	Medical Records Where maintaining Patients records.
Manually Advanced	To guide manually through tissues.
Manual Registration	Registration using the user identified points on respective CT images.
N/A	Not Applicable.
NAD	No Abnormality Detected
Needle Guide	Plastic split bushes that facilitate to guide the needle /ablator in position.
Needle Sag	Downward curve or fall of the needle caused by weakness or excessive weight
NO-GO region	Region defined by clinician though which probe will not be allowed to pass by software system.
Orbital Angle	Angle measured with respect to an imaginary axis passing through the patient laterally from one side to the other.
PET-CT	Positron Emission Tomography with CT Scan. Combined CT Scan and Nuclear Imaging.
PACS	Picture archiving and communication system. Server and access facility of Medical Imaging.
Primary Image	The main image data.
Procedure	A medical procedure is an activity directed at or performed on an individual with the objective of improving his health, treating disease or illness.
Procedure Implementation	Execution of the planned procedure in the plan order of sequence.
Procedure planning	Trajectory Plans for the procedure to be performed.
Planning Station	Comprises of the CPU, Monitor, I/O interface and the MAXIO® software.
Probe	RF electrodes which are inserted into tissues to deliver RF energy.
Precise	Exactly.
Push	Transfer of images from CT console to MAXIO® Planning Station.
Position	Used for positioning the device arms over the patient as per the plan.
Pull back	Takes the device arms away from the patient.
POST	Power On Self-Test - the first startup self-check of the MAXIO® system.
Patient immobilizer bed	One of the MAXIO® accessories used to minimize patient movement during procedure.

Patient body marker	Another name for skin marker.
QA	Quality Assurance.
RFA	Radiofrequency Ablation- A medical procedure where part of the tumor or other dysfunctional tissue is ablated using the heat generated from the high frequency alternating current to treat a medical disorder.
RMS	Root Mean Square.
RCC	Renal cell Carcinoma/Regional Cancer Center.
ROI	Region of Interest. An area on a digital image that circumscribes a desired anatomic location. Image processing systems permit drawing of ROIs on images. The average parametric value is computed for all pixels within the ROI and returned to the operator.
Registration	Image Registration is the process of estimating an optimal transformation between two image series.
RA	Risk Analysis.
Recon	Reconstruction - term used with reconstruction of acquired CT images.
Release	Disengage the end effector and release the needle guide.
Secondary image	Contrast Enhanced CT image.
System	The MAXIO® device and the accompanying software.
Safety	Freedom from conditions that can cause death, injury, or occupational illness.
Subsystem	A secondary or subordinate system within a larger system.
Screen	Monitor.
Segmentation	A MAXIO® tool that helps to select and cut out only a type of organ/tissue/organ.
Skin marker	QA markers pasted on the patient body surface.
TAP	Thorax/Abdomen/Pelvis
Tumor Segmentation	Delineation of tumor in each CT slice with segmentation tools.
Trajectory Determination	The path from entry to target point in body.
Tool	Used to describe the universal set of all tools (needles/probes) that are used for various IO procedures.
Target point	The point marked at the center of desired point of the target structure, where the procedure is to be performed.
Trajectory	The imaginary line connecting the entry point and the target point. Also, defined as the planned path in which the needle/probe should traverse.
Table Marker	QA markers pasted on the table to check for docking correctness.
Track Pad	One of the input devices of the planning station.
Touch Pad / Mouse	Another name for track pad.
User	One of the default login types.
VOI	Volume of Interest-A ROI defined in 3 dimensions

V & V	Verification (Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled) and Validation (Confirmation by examinationandprovisionofobjectiveevidencethattheparticularrequirements for a specific intended use can be consistently fulfilled).
VR	Volume Rendering. 3D Color imaging of CT images.
Validation	Establishing by objective evidence that device specifications conform to user needs and intended uses.
Verification	Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.
User	One of the default login types.
WIF	With In-Sight Framework- Collection of software components aimed at enabling efficient and rapid development of medical vision and visualization software.
X axis	The electromechanical axis that covers left to right of patient when on CT table.
Y axis	The electromechanical axis that covers the patient depth (top to bottom).
Z axis	The electro mechanical axis that moves parallel to the patient length (head to toe).

Appendix H: Trouble shooting Guidelines

S No	Error Condition	Troubleshoot Actions
1	Device not powering ON - The MAXIO® is intended to be operated by electricity only. Battery backup is provided for any emergency recovery. In case the device fails to power up, check the following:	• Check if the Main switch, the device ON switch and the PC ON switch at the connector panel are all in "ON" state. • Check for proper power supply connection. If you hear continuous beeps check the battery to ensure it is adequately charged. Device will work only if more than 50% charged. Connect to the power supply and proceed. • If POST Fails, Check the emergency switch to ensure it is in the released condition. • Reboot the device. Repeat the reboot process upto three times in case unsuccessful, the first time. • For repeated POST failures/other device error condition that are indicated by the device error LED in the control panel, contact Perfint Service.
2	Device Not Initializing	• Check for power supply connection, battery status and ensure that the Emergency Key is in released status. • Switch Off and reinitialize the device • If error still exists, contact Perfint Customer Service.
3	Device Dock is unsuccessful - Dock status icon in the device icon braised	• Check for any stain on the pattern in the InstaReg mat. Clean the mat properly. • Check for any debris or foreign particles in the locating holes-clean the same. • Switch OFF - On the system, reinitialize and re dock. • If problem still exist, contact Perfint Service.
4	Not receiving DICOM images - (DICOM) Interface (Image Transfer) icon in the device icon bar is red). When the MAXIO® is installed, the DICOM connectivity is established with the respective CT scanner and/ or workstation. When the MAXIO® is switched ON, it continuously checks for proper DICOM connection. If you experience difficulty in sending the CT image to the MAXIO® system, try the following:	• Check for Ethernet cable connection at the connector panel of the device and at the CT console or Ethernet router connected to the CT console. • Restart MAXIO's service for CT Image Receiver. Option is at Settings -> Device Configurations -> Restart Image Receiver • Verify whether the images were sent to the MAXIO® itself with the help of a CT technician. • Contact MAXIO® administrator and check for any change in configuration values for MAXIO®/CT • Restart MAXIO® again and send the images. • In case if the problem still exists, call Perfint Service.

5	Emergency key Activated During the Procedure - (Emergency status icon in the device status icon bar is red). If the user has pressed Emergency switch in between a procedure, the user can continue from the procedure workflow step after doing the following steps:	• Release "Emergency" Key • To resume positioning/planning - Press "Home" key and follow normal workflow
6	No communication between planning station and Device - Communication icon in the device status icon bar is red.	• Ensure that the device is initialized. • Switch OFF-ON the system and check whether the communication status is green • If problem exists call Perfint Service.
7	Device Dock Error during procedure – Dock status icon in the device icon bar is red.	• Check if the device is docked fully • Undock the device. Switch OFF and ON the device and dock again.
8	Tracker icon in Red during procedure	• Make sure the device is docked on the correct side • Undock the device, clean docking plate pattern using damp cloth and dock device again to proceed • If error repeats, restart device and PC • If error persists, contact Perfint Service
9	System is not communicating and continues beep sound from device	• Connect the system to line power if not connected. • Switch on the Main switch in the connector panel.
10	Monitor - If the monitor does not display anything or the quality is poor, check the following:	• Check whether the PC ON/OFF switches at the Connector panel is ON. • Switch on the monitor power switch and check if the power key light is glowing. • Check for proper monitor connection behind the monitor. • Check the contrast brightness settings by tuning the button below the monitor.
11	Touchpad / Mouse	Contact Perfint Service, If the touch pad / Mouse is not working.
12	Invalid License/License Expired	Contact Perfint Service
13	SQL server error	Contact Perfint Service
14	Tilt Sensor Error	• Check the connections and configure the correct COM port • Reconnect the cable properly to resolve the issue.
15	In the event of an unexpected closure or crash of the MAXIO application	OnStartup application should allow the user to manually relaunch the MAXIO application using the Start button. If the application does not reopen automatically.

Appendix I: Warnings, Cautions and Notes

I.1 Warnings

	Do not use MAXIO® outside the scope of “the indications of use”. MAXIO® is intended to be used only by qualified clinician trained by Perfint Certified Application Specialist. Perfint shall not be responsible for any damage arising out of MAXIO® misuse or “Off-label” use.	Page 19
	Ensure that Needle bush/ Needle guide is chosen such that they have same gauge marking on both sides. Incorrect use of Needle bush/ Needle guide would result in inaccurate results.	Page 27
	Use sterile gloves for the gripper assembly. Always insert the sterile drape cover supplied with the MAXIO®, on the electro mechanic alarm, before gripper assembly.	Page 33
	Always clean the metal grippers with regular hospital disinfectant solution before procedure and after the procedure is completed	Page 33
	Needles thinner than 18G may necessarily be not rigid. Ensure that needles do not bend during insertion. Also, where possible use short and thicker needles.	Page 27
	Handling the drape without sterile gloves may result in infection or other injury to the physician. Always use sterile gloves when inserting the sterile drape and always insert the sterile drape cover on the electromechanical arm before gripper assembly.	Page 31
	Do not look into the laser beam. The laser unit is defined as a Class II laser product. Care should be taken such that neither the patient nor the clinician directly looks into the laser beam.	Page 34
	Accidental damage to MAXIO® may result in an electrical hazard which could cause harm to a patient or an operator. In case of accidental damage to MAXIO®, immediately detach the power cord to isolate MAXIO® from the power supply.	Page 37
	Ensure right level of access is provided to MAXIO® operators. For non admin operators users of MAXIO®, provide only user level access.	Page 54
	Ensure that the IP address for MAXIO® planning station is provided and managed by the hospital IP administrator. With such IP address, MAXIO® shall communicate with the CT console within the local PACS and shall not be used to connect to the external Internet.	Page 54
	Ensure that the computers/servers connected to MAXIO® Planning station are protected with Anti-Virus and Anti-Malware software.	Page 55
	WARNING: Loose or improper docking of MAXIO® to the InstaReg mat may result in inaccuracies in the procedure. User cannot perform the procedure if, the Docking or Tracker status icons on the Main Screen do not display green. Additionally, Do not perform the procedure if the table marker verification is not successful. Contact Perfint Customer Support for MAXIO® servicing.	Page 56

	WARNING: MAXIO® docking procedure cannot be completed successfully in the event of damage to the InstaReg mat and hence MAXIO® stereotactic arm cannot be activated for instrument placement. Contact Perfint Customer Support for InstaReg mat servicing.	Page 56
	WARNING: MAXIO® docking procedure cannot be completed successfully if dust, dirt, liquid or any other material is present on the pattern or in the locating holes in the mat. Hence MAXIO® stereotactic arm cannot be activated for instrument placement. Carefully follow cleaning instructions (see Section 12) to keep the holes in the plate clean.	Page 57
	WARNING: Wrong selection of docking side could result in device registration failure; user should take care while choosing docking side to continue the procedure.	Page 57
	WARNING: Wrong selection of CT station could result in device registration failure; user should take care while choosing CT station to continue the procedure.	Page 57
	WARNING: Do not proceed with the procedure if the laser crosshair does not fall on the table marker during table marker verification. A mismatch indicates that the device positioning has been disturbed. Contact Perfint Customer Support. NOTE: Device positioning may be disturbed by an accidental impact, a change in axis range, or a change in laser arm position	Page 58
	WARNING: Do not position the patient's region of interest above the arrow indicated on the MAXIO® device range sticker placed on the CT table.	Page 70
	NOTE: The ablation volume displayed represents published manufacturer data created on a homogeneous mathematical liver tissue model that does not consider factors like saline perfusion, vasculature or any other real clinical condition. This may be used only as a starting point for user to estimate ablation volumes and under no condition be assumed to represent the expected ablation volume.	Pages 59, 87
	Patient cooperation is required or performing precision procedures. Patients who are not able to follow instructions for breath hold belt use should be evaluated by qualified physicians before using MAXIO® to perform procedures where a breath hold belt is necessary.	Page 70
	WARNING: Do not use the breath hold device if the LED indicator does not display correctly, for example if the LED does not change with the patient's breathing or does not match the patient's actual breathing phase. Contact Perfint Customer Support	Page 70
	Patient movement during procedures may lead to incorrect positioning of the needle. Ensure patient movement is managed by patient immobilization throughout the entire procedure.	Page 71
	WARNING: Breath Hold Monitor not usable on patient due to clinical situation specific to patient. Breath Hold Monitor is used to ensure that the patient breath level during CT scan and during needle/probe insertion is maintained at the same level. This is critical to ensure accuracy of needle placement based on the plan. Alternate methods, including General Anesthesia, are used to maintain same breath level during CT scan and during needle/probe insertion based on clinical	Pages 70, 111

	practice used during ablation procedures performed manually as well as based on clinical situation specific to the patient. However, MAXIO® has been verified only with the use of Breath Hold Monitor that is provided as an accessory. It is the responsibility of the user to ensure that the patient breath level during CT scan and during needle/probe insertion is maintained at the same level.	
	Improper placement of skin marker will lead to patient position verification failure and procedure will have to be aborted. Do not peel OFF skin marker until procedure end. Non availability of skin marker will lead to verification failure and procedure will have to be aborted.	Page 71
	Check of the timeliness of CT scan data is enforced by the MAXIO® planning workflow software. This is done through a configurable time limit that requires acknowledgement of a warning message in order to proceed with procedure planning with CT scan data created prior to the configurable time limit.	Page 74
	Clinician confirmation also includes a check of patient name and patient ID for the CT scan data to match the active plan.	Page 74
	Do not use flipped image for procedure [Example, Neurology view etc.,]. In the case of overweight patients, ensure the CT table height is lower than the device height.	Page 74
	Call Perfint Service in the event of an inactive communication status cannot be determined or resolved.	Page 75
	The MAXIO® does not allow processing to continue with invalid MRI data.	Page 75
	The MAXIO® does not allow processing to continue with invalid CT data.	Page 75
	 Clinician confirmation is required to proceed with data created prior to the configurable time limit. Clinician confirmation also includes a check of patient name and patient ID for the scan data.	Page 74
	 Check the patient physical orientation with what is displayed on the screen. Always set CT view to radiology view.	Page 75
	User should not add the images in the series once scan is done, Each scanned series/recon series should have unique series ID.	Page 74
	User should not use Biopsy RX mode for scanning.	Page 74

	Treatment delivered close to critical structures could cause harm to a patient. Ensure the plan provides adequate clearance around critical structures	Page 88
	Ensure that skin markers do not get peeled off during cleaning. Use fresh skin markers and redo scan incase skin marker peels off.	Page 105
	The laser unit is defined as a Class 2 laser product. Do not look directly into the laser beam.	Page 107
	Prolonged exposure to the laser beam may be injurious to health. Turn off the laser immediately following use.	Page 107
	Make sure that there is no patient movement during CT scan	Page 74
	Call Perfint Service in the event of an inactive DICOM Interface status cannot be determined or resolved.	Page 75
	Patient movement during or between image acquisition and planning may lead to inaccurate case of a failed Patient Position Confirmation (if the laser cross hair is not aligned with one or more skin markers), the patient must be rescanned and a new procedure planned.	Page 108
	Clean the skin markers with the same sterile solution used for patient skin preparation, if the skin markers are placed in the sterile zone.	Page 108
	Patient movement after patient position confirmation and before needle placement may lead to incorrect positioning of the needle. Care should be taken to avoid patient movement throughout the procedure. In case of any patient movement detected, repeat patient position confirmation before needle placement.	Page 109
	Accidental touching of gantry controls or any change in the table height may lead to inaccurate cradle positioning. Inaccurate cradle positioning will lead to inaccurate positioning of the needle. Cradle should be moved to the precise value displayed in the application every time the CT table is positioned.	Page 109
	Long needles and those thinner than 18G are noted to bend during insertion. Where possible use short and thicker needles.	Page 110
	Needles of different brand vary in the needle outer diameter. While choosing the Needle bush/ Needle guide for a gauge needle, ensure the Needle bush/ Needle guide is not too tight or too loose.	Page 27
	Under sequential placement continuing to next probe placement without removing placed needles will result in collision and may result in harm to patient.	Page 111

	Using needle of length other than the selected needle length will result in inaccurate placement and may result in harm to patient. Insert needle to the full extent of the chosen length (until the needle handle/hub rests on the needle guide.	Page 111
	Bending the needle during insertion will result in inaccurate placement of the needle. Insert needle carefully to prevent bending.	Page 111
	Needles that are held too tight or too loose may result in inaccurate placement of needles.	Page 110
	Abnormal patient movement during needle insertion may result in harm to the patient. In case of abnormal patient movement during or after needle insertion, Pull the needle out from the patient immediately. Press the Clamp/Release button on the Control Panel to release needle guide from the End Effector, or Press the Emergency Switch to release Needle guide from End Effector.	Page 112
	Moving the cradle before disengaging the End Effector from the needle guide may result in harm to the patient. Do not move the cradle before disengaging end effector from the needle guide.	Page 112
	Ensure that the patient movement is managed during a procedure to avoid inaccurate needle positioning.	Page 118
	Do not change or move the system (e.g., table height) during a procedure. Be cautious while moving the cradle.	Page 118
	Confirm that the CT gantry console is secure from accidental pressing of gantry controls. Gantry/ Table movement between procedure may lead to wrong positioning	Page 118
	Select the needle guide according to the needle gauge. Do not use a needle guide that does not match the needle gauge.	Page 118
	Confirm needle guides are clamped tightly by the End Effector before inserting the needle.	Page 118
	In case Clamp/Release button failed to function, Press the Emergency Switch to release Needle guide from End Effector.	Page 112
	In case of abnormal patient movement, when the needle is held by the grippers pull out the needle to avoid any injury.	Page 118

	Always switch OFF and disconnect from the power supply before device transport.	Page 120
	Press the Emergency Stop key immediately to stop all axes if any unexpected or uncontrolled axis movement is observed	Page 110
	If the MAXIO® device battery charge becomes critically low during a procedure, loss of essential performance may occur, which could result in inaccurate needle placement. Ensure the device is sufficiently charged or connected to AC power before use.	Page 122
	Warranty on fully charged batteries left in an unused state for more than three (3) consecutive months is automatically void. Warranty on fully discharged batteries left in an unused state for more than three (3) consecutive days is automatically void.	Page 123
	Do not remove or replace the batteries while device is located in an oxygen rich or hazardous environment Sparking may occur.	Page 123
	Call Perfint Service in case of any such defects.	Page 124
	Do not load green phantom images in user login.	Page 126
	Personal Protective Equipment (per 29 CFR 1910.1030 (d)(3)) must be worn during cleanup operations to prevent contact with infectious substances.	Page 125
	The MAXIO® must be visually inspected before every procedure. A preventive maintenance schedule must be followed according to the MAXIO® Service Manual. For any repairs, please contact the Perfint Service.	Page 125
	To avoid electrical shock hazards, do not remove panels or covers from the machine.	Page 126
	There is no user serviceable/repairable part of the MAXIO®. Call Perfint Service for any concerns or questions regarding the operation of the MAXIO®.	Page 126
	To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.	Page 203

	The MAXIO device has been tested and found to operate normally when placed adjacent to or stacked with other equipment. Therefore, such placement is not expected to result in improper operation.	Page 205
	Do not use the device if a castor does not rotate freely, the device drags or pulls to one side, or the device wobbles during movement. This may indicate damaged castor wheels or loosened screws. Contact Perfint Customer Support	Page 120
	Do not dispose the device, accessories and disposables as general waste.	Page 127
	Do not reintroduce a decommissioned or refurbished device into clinical use without inspection, requalification, and written authorization from Perfint.	Page 127
	Electromagnetic testing has been conducted with the cables and accessories provided by the Perfint. The use of other cables or accessories may result in increased emission or decreased immunity of the MAXIO device.	Page 205

I.2 Cautions

	The choice of parking area is dependent on the customer, but has to be defined in the pre installation site documentation. MAXIO® movement are depends on where the parking area is and the route from the parking area to the docking location.	Page 36
	Using incorrect power supply cords could result in damage to the system. Use power supply cords meeting national requirements of the respective country in which the equipment is used.	Page 37
	Connecting devices not supplied with MAXIO® may result in unexpected behaviors. Do not connect devices that are not supplied with MAXIO®.	Page 37
	MAXIO® will not operate without successful completion of Power On Self-Test (POST). If first try is unsuccessful, repeat steps and try again. If still unsuccessful contact Perfint Customer Support (if POST LED on the Control Panel does not display green).	Page 38
	in the event of an Call Perfint Service unsuccessful electromechanical arm initialization.	Page 38
	Always use only sterilized Needle bush/ Needle guide for procedures	Page 27
	Be sure to position the patient's region of interest below the Device Range sticker on the CT table. Take special care to avoid contact with sharp / hot objects that could puncture the bed. If the bed does not hold rigidly after normal vacuum pump duration, contact Perfint support.	Page 71

	Check the readiness of the breath hold monitor for use. Refer to manufacturer's instructions for workflow.	Page 70
	MAXIO® has to be parked and transported in the Home Position.	Page 120
	In case of any damage during device movement/transport, call Perfint Service.	Page 120
	Special attention must be given to the Grippers/ Holder arm during device movement or transport. Grippers/ Holder arm may get damaged due to accidental hits.	Page 120
	Always use the handle to move the system. Avoid scraping or collision of the device with other devices and building structures. Limit movement to slow walk.	Page 120
	Two people are needed to move the unit in inclined plane.	Page 120
	Ensure the mains power plug is always accessible. Do not place the device in a position that makes disconnection from the power supply difficult	Page 205
	Do not reuse grippers. Dispose used grippers in biohazard containers. Reusing grippers can result in infection and may cause serious illness to patient due to contaminants from previous usage.	Page 33
	Do not reuse Needle Guide. Dispose used Needle guide in biohazard containers. Reusing the Needle Guide can result in infection and may cause serious illness to patient due to contaminants from previous usage.	Page 33
	Reusing the Touchpad Drape can result in infection and may cause serious illness to patient due to contaminants from previous usage	Page 32
	Reusing the drape can result in infection and may cause serious illness to patient due to contaminants from previous usage. Do not reuse drape. Dispose used drapes in biohazard containers.	Page 31
	DO NOT REUSE: Reusing needle stabilizers can result in infection and may cause serious illness to patient due to contaminants from previous usage. Do not reuse needle stabilizers. All used stabilizers must be disposed in biohazard containers.	Page 29
	Reusing the Needle Holder can result in infection and may cause serious illness to patient due to contaminants from previous usage	Page 30
	Attempts by one person could result in injury or damage. Maximum allowable floor inclination is restricted to 5 degree.	Page 120
	The maximum allowable height of obstacles over which the device may be moved shall not exceed 20 mm.	Page 120

I.3 Notes

☞	MAXIO® prompts the user to the next key press activity by lighting the respective LED lights during the procedure workflow, in the control panel.	Page 23
☞	When pressing the keys, wait for a response and avoid pressing the key multiple times.	Page 23
☞	⚠ Always use sterile holder for procedures.	Page 30
☞	⚠ Always use only sterile grippers for procedures	Page 33
☞	Each gripper sterile pack contains a pair of left and right grippers.	Page 33
☞	⚠ Always use sterile drape for procedures.	Page 31,32
☞	⚠ NOTE: Always use sterile needle stabilizers for procedures.	Page 29
☞	Note: Ensure a unique IP address is assigned to the MAXIO system. The same IP address should not be used for any other device within the network.	Page 36
☞	MAXIO® cannot be used without successful initialization of each axis to the zero position.	Page 38
☞	Always use sterile gloves before opening the sterile pack. Always use sterile drape covers on the machine before use.	Page 38
☞	The planning station may be powered ON separately from the main device being powered ON in order to conduct procedure planning activities independent of the main device	Page 38
☞	Auto snapshots can be taken in segmentation, Plan, Position, Intra-Operative and Post procedure registration screen.	Page 64
☞	Scan only the required area. Image transfer will take long time for a large number of images.	Page 74
☞	Do not use any skin marker other than that supplied or recommended by Perfint.	Page 74
☞	Thinner slices enhance accuracy. A slice thickness of 1mm is recommended.	Page 74
☞	MAXIO® is compatible with all commercially available DICOM 3.0 compatible CT systems.	Page 75
☞	Integrity checks of CT scan data are performed during transfer from the CT system to MAXIO®.	Page 75

☞	⚠ A cross-check of the patient ID embedded in the CT scan data is provided to the User during image loading and procedure summary screen for confirmation	Page 75
☞	A cross-check of the patient ID embedded in the MRI scan data is provided to the user during image loading and in procedure summary screen for confirmation.	Page 75
☞	A green status indicates that the communication is active and a red status indicates that the communication is not active.	Page 75
☞	A check for gantry tilt is performed during the loading of CT/MRI scan data. If present, the system does not accept the data for use and a message is displayed to the clinician.	Page 76
☞	⚠ MAXIO® provides a user-configurable time limit for generating a warning message to the clinician on the age of loaded scan data.	Page 74
☞	Make sure number of slices of PET-CT image is lesser than number of slices taken for CT image for better PET-CT Interventional Procedures	Page 75
☞	MAXIO® will prompt to the user for the Clip action if loaded series has more than 512 images.	Page 78
☞	The list of needle/tool shown in the user manual is for reference only. The actual list of needle/ tool may vary. Please ensure the availability of the needle/tool commonly used	Page 86
☞	When Probe Manufacturer is selected as OTHER, enter the Handle length and Handle diameter as applicable to the specific needle.	Page 87
☞	MAXIO® does not display the manufacturer's IFU data for Angiodynamics, Nanoknife probe.	Page 87
☞	MAXIO® does not control selection of probes or probe parameters in the ablation generator. MAXIO® is not connected to the probe or the ablation generator in any way. Ensure that the probes and probe parameters are chosen correctly as per plan.	Page 87
☞	WARNING: The displayed ablation volume for the chosen probe and settings is a reproduction of the data stated in the ablation device manufacturer IFU. This data does not take into account important.in vivo tissue dynamics that can affect ablation size such as tissue vascularization, type, temperature and impedance.	Page 87
☞	⚠ When potential needle to needle intersections are identified, a message is displayed in the Information Bar in the image window. Re plan to eliminate potential intersections.	Page 91
☞	MAXIO® displays biopsy gun length in the needle trajectory, if the Procedure type is chosen as Biopsy. For Pain management and Other procedure types, Needle trajectory alone is displayed.	Page 96
☞	Ensure the selected needle is of the appropriate length for the procedure.	Page 96
☞	NOTE: The user can load the PET series from the below shown screen (Fig6.46) for all workflows	Page 97

☞	NOTE: Maximum allowed landmark points upto 8	Page 102
☞	Robotic positioning will be done in CT coordinates; MRI image overlay is only to help in the identification of lesions	Page 104
☞	Ensure that the skin markers are not covered by the patient drapes. In case the drape holes are not big enough, use a sterile scissor to cut the drape hole such that all the skin markers are exposed.	Page 105,108
☞	Ensure that the End Effector Grippers are kept open when laser is turned on.	Page 106
☞	The planning workflow enforces clinician review and confirmation of QA/Skin markers on planning images.	Page 108
☞	Clinician review and confirmation cannot be completed if there is an error reconstructing the planning image.	Page 108
☞	If the nick made after anesthesia does not match with procedure position, check the cradle values to ensure they have not moved.	Page 111
☞	Perfint recommends that the MAXIO® System be utilized to deliver anesthesia precisely in the planned trajectory. However, the physician must make this determination as appropriate for each procedure.	Page 111
☞	After undocking, ensure that the rubber plug is placed back onto the InstaReg mat.	Page 118
☞	NOTE: Load the PET-CT Image by Transferring the CT Image Series First, Followed by the PET Image Series.	Page 69
☞	Holding the needle by the end effector when inside the patient body for a long time may result in laceration as patient breaths. Ensure that needle insertion is done as quickly as possible and that the end effector is released as soon as needle insertion is completed.	Page 112
☞	In case of any help in device transport call Perfint Service.	Page 121
☞	Consult component labels regarding the reusability and sterilization requirements to ensure that they are met.	Page 125
☞	Perform a calibration check with the guidance of Perfint support.	Page 126
☞	Ensure that the error beep is audible in the CT environment. Call Perfint Service in case of such error conditions.	Page 176
☞	Workflow enforces clinician confirmation of proper positioning markers on reconstructed planning images.	Page 181
☞	Workflow enforces clinician confirmation of proper positioning markers on CT scan images.	Page 181
☞	Workflow enforces clinician to verify skin marker position before every probe placement.	Page 181

	The device does not have direct contact with the patient; therefore, the applied part is not applicable.	Page 203
	Do Not rotate the PC more than 90° (±).	Page 36
	Ensure that the new password meets the following password requirements: ○ Minimum length: 8 characters ○ Maximum length: 15 characters ○ At least one uppercase letter (A–Z) ○ At least one lowercase letter (a–z) ○ At least one numeric character (0–9) ○ At least one special character (e.g., @, #, $, %)	Page 40,67

Appendix J - Safety, EMI/EMC and Alarm System Details

J.1 Safety and EMI/EMC Details

J.1.1 Device Classification

The MAXIO system belongs to Class I medical electrical equipment. There is no specific frequently used function for the device. The device is used for treatment as per the defined clinical workflow and intended use specified by the manufacturer.

	To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
	The device does not have direct contact with the patient; therefore, the applied part is not applicable.

J.1.2 Mode of Operation

a. Standby / Idle Mode
   - System powered ON, communication established between MAXIO PC and electromechanical arm.
   - GUI active, capable of receiving DICOM data.

b. Initialization / Homing Mode
   - Upon command, individual axes (X, Y, Z, A, B) perform homing.
   - Only the commanded axis moves; others remain stationary.
   - Represents normal startup sequence.

c. Planning Mode
   - System imports and processes DICOM 3.0 CT images.
   - 3D reconstruction, target/entry point selection, and trajectory calculation performed on the Console.
   - No electromechanical arm movement.

d. Active Positioning Mode
   - Upon clinician's command (Position), the electromechanical arm executes positioning along X, Y, Z axes with angular movement (A and B).
   - Motors operate to achieve required trajectory and probe/tool path.

e. Needle Guidance / Tool Placement Mode
   - Arm holds the selected position to guide manual needle insertion.
   - Axes are energized to maintain alignment; no active motion.
   - GUI continuously provides positional feedback.

f. Battery Backup Mode (Pull-back / Undocking)
   - In case of power loss, the system uses its backup battery to retract axes and enable safe undocking.
   - This mode does not support procedure execution.

g. Error / Recovery Mode

- In case of user interruption, emergency stop, or system error, the device halts motion.
- Safety alarms and information will be pop up in the GUI.
- A continuous buzzer will sound under the following conditions:
  - In the event of a device error, the device cannot be used for the procedure.
  - When the emergency key is pressed, the user can switch off the machine to reset the alarm.
  - When the battery is low or the device is not connected to AC power, the user can switch off the machine to reset the alarm.

The MAXIO is intended for use in the electromagnetic environment specified in the tables below. Follow the recommendations given therein.

J.1.3 Durability, Ageing, and Biological Degradation

Based on material specifications, manufacturing processes, and the manufacturer's relevant tests and calculations, the materials and components used in the MAXIO® system are selected and validated to withstand expected conditions of use and cleaning over the intended service life.

Under normal use, maintenance, storage, and environmental conditions as specified in this user manual, corrosion, ageing, mechanical wear, and degradation due to biological agents such as bacteria, plants, or animals are not expected to result in unacceptable risk or loss of basic safety or essential performance.

To maintain safety and performance throughout the service life of the system:

- Use the MAXIO® system only in the specified environmental conditions.
- Perform cleaning, disinfection, and maintenance as described in this user manual.
- Inspect the system and accessories regularly for signs of damage, corrosion, or excessive wear.
- Do not use the system if visible damage or abnormal behavior is observed.

J.1.4 EMI/EMC related Warnings:

The MAXIO device is suitable for use in hospital environments
The essential performance of the MAXIO system is its ability to accurately and guide the physician to insert a needle into the planned target location within the patient's body, as determined by the treatment or procedure plan. Loss or degradation of this performance could result in: • Incorrect needle placement, leading to inaccurate targeting of the lesion, • Potential injury to adjacent critical structures. Remedial Actions in Case of Loss or Degradation: • Pull the needle out. • Press the Clamp/Release button on the Control Panel to release needle bush from the End Effector. • Press the Emergency Switch to release Needle Bush from End Effector.

	The MAXIO device has been tested and found to operate normally when placed adjacent to or stacked with other equipment. Therefore, such placement is not expected to result in improper operation.

List of cables and maximum length are listed below.

Power Cord	8m
Ethernet Cable	10m
Foot Switch	6m

	Electromagnetic testing has been conducted with the cables and accessories provided by the Perfint. The use of other cables or accessories may result in increased emission or decreased immunity of the MAXIO device.

The MAXIO is not considered portable RF communication equipment.

The emission and immunity characteristics of MAXIO make it suitable for use in hospital environments (CISPR 11 Class A).

No deviation from this collateral standard (IEC 60601-1-2) and allowance used.

Maintaining Basic Safety and Essential Performance (Electromagnetic Disturbances)

To maintain the MAXIO System's basic safety and essential performance with respect to electromagnetic disturbances during its expected service life:

1. Use only Perfint-supplied accessories and cables. Using other accessories may affect electromagnetic compatibility (EMC).
2. If abnormal behaviour is observed (e.g., movement error, targeting inaccuracy, or display issue),
    - Stop the procedure immediately.
    - Pull the needle out safely.
    - Follow the remedial actions described in the user manual.
3. Do not open the system covers or attempt troubleshooting on your own. Switch off the equipment.
   Contact Perfint Service Personnel for inspection or repair.

	Ensure the mains power plug is always accessible. Do not place the device in a position that makes disconnection from the power supply difficult.

Guidance and manufacturer's declaration – electromagnetic emissions

(Refer EMC Emission Test and Results, below)

The product MAXIO is intended for use in an electromagnetic environment as specified below. The customer or the user of the product MAXIO should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The product MAXIO 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 product MAXIO is suitable for use in all establishments other than domestic, and those directly connected to the

Harmonic emissions IEC 61000-3-2	Class A	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 product MAXIO or shielding the location.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

(Refer EMC Immunity Test and Results, below)

The product MAXIO is intended for use in the electromagnetic environment specified below. The customer or the user of the product MAXIO should assure that it is used in such an environment.

IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the product MAXIO requires continued operation during power mains interruptions, it is recommended that the product MAXIO be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the A.C. mains voltage prior to application of the test level.			
Guidance and manufacturer's declaration – electromagnetic immunity– for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING (Refer EMC Immunity Test and Results, below)			
The product MAXIO is intended for use in an electromagnetic environment as specified below. The user of the product MAXIO should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –Guidance**
Conducted RF IEC 61000-4-6	3 Vr ms 150 kHz to 80 MHz	[V1] V	Portable and mobile RF communications equipment should be used no closer to any part of the product MAXIO, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and dis there commended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a should be less than the
Conducted RF IEC 61000-4-6	3 Vr ms 150 kHz to 80 MHz	[V1] V	Portable and mobile RF communications equipment

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz		should be used no closer to any part of the product MAXIO, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and dis there commended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a should be less than the compliance level in each frequency range [b] Interference may occur in the vicinity of equipment marked with the following symbol:

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.

a. 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 product MAXIO is used exceeds the applicable RF compliance level above, the product MAXIO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the product MAXIO.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

J.1.5 EMC EMISSION TEST AND RESULTS

SL.NO	Name of the Test	Standard	AC/DC/Enclosure/ Signal Port	Specification	Result
1	Conducted Emission	IEC 60601-1-2/ CISPR 11, Class B	Single Phase AC Power port, 240V/50Hz	Quasi Peak: 0.15MHz - 0.50MHz: 79 dB (uV) 0.50MHz-30MHz: 73 dB (uV) Average: 0.15MHz - 0.50MHz: 66 dB (uV) 0.50MHz-30MHz: 60 dB (uV)	Within the limit
2	Harmonic Emission	IEC 60601-1-2/ IEC 61000-3-2	Single phase AC power port 240V/50Hz	Class A	Within the limit
3	Flicker Emission [Short term (10 min) & Long term (120min)]	IEC 60601-1-2/ IEC 61000-3-3	Single phase AC power port 240V/50Hz	PST: 0.112, PLT: 0.111, dc [%]: 0.030, dmax [%]: 0.225, dt [s]: 0	Within the limit
4	Radiated Emission	IEC 60601-1-2/ CISPR 11, Class A	Enclosure	Quasi Peak: 30-230 MHz: 40dB (uV/m) 230-1000MHz: 47dB (uV/m)	Within the limit

SL. NO	Name of the Test	Product Standard/ Basic Standard	AC/DC/Enclosure/ Signal Port	Specification	*Performance Criteria met by EUT
1	Radiated RF immunity	IEC 60601-1-2/ IEC 61000-4-3	Enclosure	80 MHz - 2.5 GHz, 3V/m	Criteria -A
2	High Energy Surge	IEC 60601-1-2/ IEC 61000-4-5	Power Port: 240V/50Hz and 100V/50Hz	1.2/50us, ±1kV for Differential mode ± 2kV for Common mode	Criteria -A Criteria -A
3	Conducted RF Immunity	IEC 60601-1-2/ IEC 61000-4-6	Power line: 240V/50Hz Signal Line: Ethernet line	Power Line: 0.15-80MHz, 80% AM 1kHz sine wave, 3vrms Signal Line: 0.15-80MHz, 80% AM 1kHz sine wave, 3vrms	Criteria -A Criteria -A
4	Power Frequency Magnetic Field	IEC 60601-1-2/ IEC 61000-4-8	Enclosure	Power Frequency 50Hz, 60Hz Magnetic Field strength: 3A/m	Criteria -A
5	Voltage dips and interruption	IEC 60601-1-2/ IEC 61000-4-11	Power port: 240v/50Hz and 100v/50Hz	Short interruption: 0% for 250 Cycles Voltage dips: 0% of AC main voltage for 0.5 cycles 40% dipd for 5 cycles 70% dips for 25 cycles	Criteria -A
6	Electrostatic Transient	IEC 60601-1-2/ IEC 61000-4-4	Power line: 240V/50Hz and 100v/50Hz. Signal Line: Ethernet line	5/50ns, ± 2kV for power line ± 1kV for signal line	Criteria -A

7	Electrostatic discharge	IEC 60601-1-2/ IEC 61000-4-2	Enclosure	Contact discharge: ± 6kV Air discharge: ± 8kV	Criteria -A

J.2 Alarm System Details

J.2.1 Alarm System Overview

MAXIO incorporates an ALARM SYSTEM to provide visual and, where applicable, auditory indications of conditions requiring OPERATOR attention. All ALARM CONDITIONS generated by the MAXIO system are classified as TECHNICAL ALARM CONDITIONS.

Software-generated alarm indications are classified as Low Priority and are displayed visually in the MAXIO application user interface. The software does not generate auditory alarm signals.

Controller-generated technical alarms may be classified as High, Medium, or Low Priority and are indicated visually in the MAXIO application user interface and, where applicable, audibly through the external speaker.

The OPERATOR may operate the system from different positions during normal use. The monitor shall be positioned to allow the OPERATOR to view visual alarm indications. Where provided, auditory alarm signals are intended to alert the OPERATOR within the normal operating area.

J.2.2 Alarm condition

The priority-based alarm conditions are provided in the Appendix C.

J.2.3 Alarm system log

The MAXIO application maintains a log of alarm conditions. Each log entry records the alarm condition with the date and time of its occurrence.

No separate storage capacity is allocated for the alarm log; entries are stored on the system's internal storage of 1 TB, shared with all other application data. When the internal storage reaches 90 % of its capacity, the application alerts the user to free storage space. If the storage becomes completely full, the application will not run until storage space is freed; stored alarm log entries are not overwritten or lost.

The alarm system log is stored in the system's internal storage and is maintained when the system is powered down. The time of powering down is captured in the log.

The contents of the alarm system log are not affected by a total loss of power (supply mains and/or internal electrical power source) for any duration. On restoration of power and system start-up, all previously stored log entries remain available.

J.2.4 Sound pressure level of auditory alarm signals

The sound pressure level of the auditory alarm signals of the MAXIO has been measured in accordance with IEC 60601-1-8, subclause 6.3.3.2, using the hemispherical measurement method of ISO 3744:2010, with the equipment standing on the floor and at a measurement radius of 2.0 m from the geometric centre of the equipment.

HIGH PRIORITY, MEDIUM PRIORITY and LOW PRIORITY auditory alarm signals: 50 ± 3 dB(A) at a measurement radius of 2.0 m.

The sound pressure level of the auditory alarm signals is fixed and cannot be adjusted by the OPERATOR.

Appendix K: Accessories Manuals

K.1 Medspira Breath Hold Quick Reference Guide

Breath Hold

Quick Reference Guide



Figure 1

A Physician's remote display B Patient's remote display



Figure 2



Figure 3A



Figure 3B



Figure 3C



Figure 4

Education Video

Prior to setup and use of the Breath Hold System, ALL physicians, technicians and patients should view the short Medspira Breath Hold System Physician and Patient Education Video.

Set up Breath Hold system before the patient enters the CT suite

1. Turn on the docking station/base power unit (left side of base) and all remote displays (right side of displays).
2. Press the reference button located on the top of the docking station/base unit to start the LED light movement that corresponds with the movement of the bellows belt.
3. Place docking station/base power unit (with bellows belt and tubing attached) at the head of the CT table.
4. Place remote displays where best visualized by physician, patient and technicians. ALL remote displays are interchangeable.

- ✔ Radiologist remote display: Place on CT gantry or CT fluoroscopy in-room display monitor (if available). Figure 1A
- ✔ Patient remote display: Connect to gooseneck arm and place base of gooseneck under the CT table pad on the bed in the region of the patient's head and pillow. Make sure the patient can easily view the remote display and that it clears the CT gantry. Figure 1B
- ✔ CT technologist remote display: Place by CT operating console. Figure 2

Belt Placement

1. Determine if patient is a chest or abdominal breather. Once determined, place belt (with blue thermal insulators wrapped in place around rubber bellows) on patient's BARE SKIN over lower chest or upper abdomen (near diaphragm) depending on which area expands and contracts the most during respiration. Confirm with bellows belt will not interfere with planed needle entry site. Figures 3A, 3B, 3C
2. The belt should be pulled tight enough (but not so tight that the bellows cannot expand and contract while breathing) around the patient so that the belt DOES NOT MOVE during the procedure. Figure 4
3. Have the CT nurses and/or procedure assistants place all equipment (blood pressure cuff, IV fluids, pulse oximeter, etc) on patient prior to referencing the patient's breath-hold level. It is important not to have any patient movement once the reference breath-hold level has been established.
4. Make sure the bellows belt and rubber tubing are not pinched or lying underneath the patient. DO NOT place the patient's gown or blanket over the belt. Covering may cause system to function improperly. We suggest place the excess rubber tubing on the CT table at the head or foot of the patient so it is not obstructed in any way. Figure 5 (SEE REVERSE SIDE)

INSTRUCTIONS CONTINUED ON BACK

MEDSPIRA 800.383.4592 TOLL-FREE WWW.MEDSPIRA.COM



Figure 5



Figure 6



Figure 7

Patient is lighting the center red light (see arrow above)

Breath Hold System Use

1. Have patient watch the remote display while he or she breathes in and out (show the patient how the lights move to the right as the patient breaths in and to the left as the patient breaths out).

2. Instruct patient to take in desired breath that you want to be reproduced during the procedure and tell the patient to "hold it". Press the reference button on the remote display to capture the breath-hold on the center red light. Wait until only the center red light is lit before instructing the patient to breathe again. Figure 6

Performing CT Scan

1. Take the automatic voice off the CT system.

2. Manually instruct the patient to take in the same breath-hold and the light the center red light. When the patient lights up the center red light, tell the patient to hold his or her breath. Begin scanning.

3. Perform all localization markings and needle manipulations at the SAME breath-hold when the patient is lighting the center red light. Figure 7

4. Repeat each of these steps anytime pictures are being taken.

Disassemble and store the Breath Hold System on completion of procedure

1. Clean and disinfect the bellows belt prior to storage or use on another patient.

2. Turn off the docking station/base power unit and all remote displays. Store all remote displays in the docking station/base power unit.

3. At the end of the day, the Breath Hold system remote displays and docking station/base power unit should be in the OFF position and plugged in and charging.

Key Points:

- ✓ Confirm patient has watched the Breath Hold video and the Breath Hold System is set up prior to bringing the patient to the CT suite.
- ✓ The position of the bellows belt cannot move on the patient once the reference breath-hold has been established.
- ✓ During the procedure, make sure the patient lies as still as possible and the bellows belt and rubber tubing are not covered or obstructed in any way.
- ✓ Take off the automatic voice during scanning. Manually instruct the patient to light the center red light. Start scanning only when the patient has done so.
- ✓ Preform all localization markings and needle manipulations at the SAME breath-hold when the patient is lighting the center red light.
- ✓ During setup, confirm that the gooseneck holding the patient remote display clears the CT gantry.
- ✓ Clean and disinfect the bellows belt after every use.
- ✓ At the end of the day, make sure the Breath Hold system remote displays and docking station/base power unit are in the OFF position and plugged in and charging.

Medspira, LLC 1313 5th Street SE Minneapolis, MN SALE5010-001

K.2 Breath Hold Operator Manual

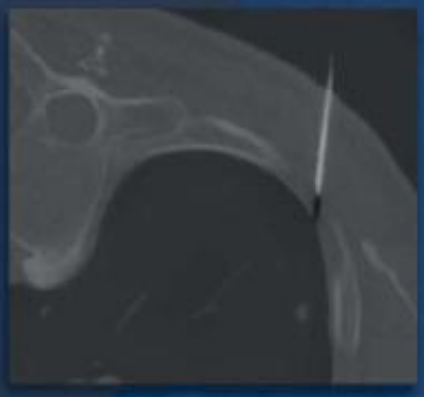
Medspira

Operators Manual

Breath Hold™ ES
(Interactive Breath-Hold Control System)







Product:
Breath Hold ES(Interactive Breath-Hold System)
Operators Manual: Number C01H048 - Revision 003

Manufacturer:
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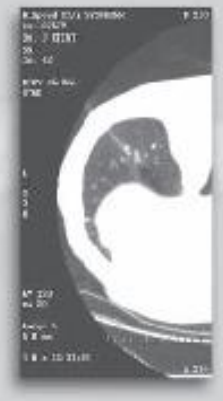
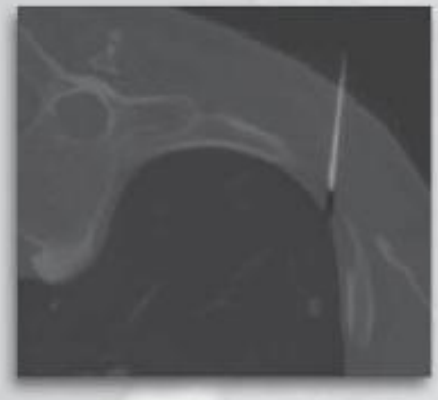
Operators Manual

Breath Hold™ ES
(Interactive Breath-Hold Control System)







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NOTE:
REBOOT SYSTEM BEFORE EVERY USE BY TURNING POWER OFF. WHILE IN THE OFF POSITION THE POWER CORD MUST BE REMOVED FROM THE DOCKING STATION AND RE-PLUGGED IN. POWER MAY BE TURNED BACK ON ONCE THIS ACTION IS COMPLETE.

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Section 1 - Introduction

This manual describes the safety precautions, features, use, and care of the Medspira Breath Hold™ ES (interactive Breath-Hold Control System). Please Reveiw this manual thoroughly before using the system.

If you have any questions or comments on this manual, or need any assistance with the use of the product, please contact a Medspira service representative at 1-800-345-4502 or visit the Web site at *http://www.medspira.com.*

This device is covered by one or more of the following US patents: Patent 7,678,063 and Patent 5,363,844.

1-1 Operators Guide Information

The operators guide provides information on how to use the Medspira Breath Hold™ ES System. The user should read this guide before using the system.

1-2 Use of Symbols

Operators should understand the following symbols used for caution and warning explanations:

Battery

Bellows

ON **On**

OFF **Off**

Wireless Transmitter that applies electromatic energy

⚠ WARNING **A hazard exists that will or could cause a minor injury**

⚠ CAUTION	A hazard exists that could cause a serious injury
	Attention: Consult accompanying documents
	Type BF applied part
	Class II equipment
	WEEE (Waste Electrical and Electronic Equipment)
⎓	Direct current
CE	Conformite Europene: Compliance to EMC
Intertek	Compliance with Intertek Testing for general product safety and emissions
	Manufactured by
MR	MR Conditional. Item has been demonstrated to pose no known hazards in a specified MRI environmnet with specified conditions of use.
FC	Federal Communicators Commission Notice (USA
	Warning or caution: This symbol alerts you to important operating considerations or potential operating condition that can be a risk for improper function or use of equipment.
EC REP	Authorized Representative in the European Community,
	Used to advise operator to consult the accompanying documents.
REF	Symbol for the catalog, reorder or reference part number
	Symbol for keep dry

1-3 AAMI 60601-1, IEC 60601-1, IEC 60601-1-2, and CSA Classification



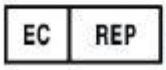
Class II equipment and internally powered equipment



Type BF applied parts

Suitable for continuous operation

This product conforms to the requirements of AAMI STD ES60601-1; IEC STD 60601-1 Ed: 3; IEC STD 60601-1-2 Ed: 3; Certified to CSA STD C22.2 #60601-1.



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1-4 Quality Assurance

Prior to using the Breath Hold™ ES System on an individual, fully charged the base unit and remote displays per 2-1-9 and 2-1-10. Power up the system and plug the bellows into the base unit side port. Expand and contract the bellows to verify that all remote displays are working properly and in sync with the expansion and contraction of bellows. Place the bellows belt on the individual to ensure the readouts on all displays are synchronized.

1-5 Safety

This manual contains detailed information on the setup, positioning, and use of the Medspira Breath Hold™ ES System. The instructions should be readcarefully and thoroughly before using the system.

1-5-1 System Operating Safety

Individual safety and comfort should be the primary concern during use. Always follow proper safety, operating, and maintenance procedures to prevent exposure to electrical or mechanical hazards that may cause injury.

1-5-2 Individual Safety

Ensure that the individual is comfortably positioned.

1-5-3 Emergency Procedures



In the unlikely event that the system creates smoke, sparks, or makes an unusually loud noise, or if the individual requires emergency assistance:

- Stop the procedure if one is in progress.
- Remove the individual from the scan room if medical treatment is needed.

1-5-4 Indications

The Medspira Breath Hold™ ES System will be used to help individuals control their breathing and achieve consistent breath-hold motion.

1-5-5 Equipment Safety

All personnel using the system should be instructed in the proper connection and handling of the system.

- Personnel should observe all warnings and cautions that appear in the guide.
- The system is not suitable for use in the presence of flammable anesthetics in combination with air, oxygen, or nitrous oxide.
- This equipment is not protected against ingress of water.

NOTE:
This equipment is rated for continuous operation.

NOTE:
For the disposal of this system at the end of its useful life, please contact a Medspira service representative at 1-800-345-4502.

1-5-6 Electrical and Mechanical Safety

- The system consists of both electrical and mechanical components. Service personnel must have specialized training to ensure the safe operating condition of the system. Therefore, only properly trained and qualified personnel should be authorized to service the system.
- The electrical and mechanical assemblies and parts of the system must be used with care and should be routinely inspected.
- Before using the system, visually check it for any external damage. Do not use the system if the housing or cable is broken.
- The system batteries are not field replaceable. Only Medspira personnel are authorized to service the system.
  If eternal equipment is connected to Breath Hold™ ES System when in use with patient, external equipment requires medical grade power supply.
- WARNING: To avoid the risk of electrical shock, this equipment must be connected to supply mains with protective earth.
- I/O port and USB port for Medspira use only.

1-5-7 Modifications

Any changes or modifications to the system must be approved by Medspira prior to installation. Do not use any components not supplied with the Breath Hold™ ES System.

1-5-8 Reporting of Incidents

- Users should contact their local field representative immeditaely to report an incident and/or injury to an individual, operator, or maintenance employee that occurred as a result of system operation
- If an accident occurs as a result of system operation, do not operate the equipment until an authorized investigation is conducted.

1-6 Shipping Contents

Description - Breath Hold™ ES System	Quantity
Base Unit/Docking Station	1
Bellows Belt - One (1) 10ft, one (1) 25ft	2
Remote Displays	3
Bellows Pad Set - Set of three (3)	1
Operators Manual - Breath Hold	1
Table-mounting Base	1
Mounting Hardware for Remote Displays	5
Education Video	1
Wireless Extender Kit	1

1-7 System Description

The Medspira Breath Hold™ ES System is a system that will help individuals in whom breathing and breath-hold motion is a problem. The system consists of a strap that wraps around the individuals cheast and is connected to a base unit and series of displays. The display indicates how deeply each breath is taken. While the Medspira Breath Hold™ ES System may be used in conjunction with imaging systems, it is not connected to and does not control the imaging system in any way. The Breath Hold™ ES System indicates the breathing level of an individual using a simple light display.

1-8 Environmental Requirements

Store the system in an air-conditioned scan room or equipment room.

1-8-1 Operating temperature range:

0 to 3,000 ft (914.m): 10 to 35 C (50 to 95F): 101kPa to 91 kPa
3,000 to 7,000 ft (2,134 m): 10 to 32 C (50 to 89.6 F): 91kPa to 78 kPa
Operating and non-operating humidity range: 10% to 80% RH, non-condensing
Shipping/storage/non-operating temperature range: 0 to 50 C (32 to 122 F)
Shipping/storage humidity range: 10% to 90% RH, non-condensing

1-9 System Installation and Service

System installation and configuration require the services of your trained service representative. Please refer to the appropriate sections for system installation and configuration information. See section 2-2-1 about proper positioning of the system.

1-9-1 Mounting Brackets

The mounting brackets for the remote displays must be installed by a technical representative of the user. The attachment must be made to provide a permanent anchor for the remote display. Note that the remote display

mates with the mounting bracket in a manner that locks the remote display into place on the mounting bracket. Insert the bottom of the mounting bracket first, pressing down against the spring-loaded edge. Rotate the remote display forward to allow the spring assembly to lift the bracket and hold it in place. Removal is accomplished by reversing the above steps.

1-9-2 Power Supply

The power supply is part of the Breath Hold™ ES System. Only use supplied power supply Astec Model DPS53-M, AC input 100-240V, 2A, 50/60Hz,DC output 12V====, 5A, 60W.

1-9-3 EMF or Other Interference

The base unit and remote displays are not affected by the electrical signals routinely found in any environment. The Breath Hold™ ES System's wireless emissions are within the unlicensed 2.4Ghz band.

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2, Edition 3.0. This testing shows the device provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular situation. If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the devices.
- Increase the separation between devices
- Connect the equipment to an outlet on a different electrical circuit.
- Consult the manufacturer for help.

1-9-4 Wireless Extender Kit

Refer to wireless extender kit installation guide/instructions for use C01H053 for installation adn service instructions.

ENGLISH

Section 2 - Setup & Instructions for Use

2-1 Introductory Instructions for Setup and System Use

2-1-1 Charging Base and Remote Units

Before each use ensure that the battery lights on the base unit and remote displays indicate an acceptable battery level (see section 2-1-9 and 2-1-10). Batteries should be charged before the initial use (charge battery stickers will cover power switches on base and remote displays).

2-1-2 Switching On the Base Unit Power

When the base unit power is turned on, all LEDs on the base unit will be switched on for approximately two seconds, the LEDs will flash ON and OFF if no errors are detected by the system. When an error is detected, alternating LEDs will be on, indicating an error. In this case, the docking station power should be turned off and the power cord unplugged from the docking station. Once these steps have been taken, plug in the power cord to the docking station and turn the power to the docking station back on. If the error persists, the base unit in unusable and must be replaced.

2-1-3 Switching On the Remote Display Unit Power

When the remote display unit is power is turned on, all LEDs on the remote display unit will be on for approximately two seconds. This action provides a check of the LEDs. After approximately two seconds, only the LEDs will flash ON and OFF if no errors are detected by the system. When an error is detected, alternating LEDs will be on indicating an error. In this case, power should be turned off then on again. If the error code persists, the remote display is unusable and must be replaced.

2-1-4 Wireless Communication Pairing to Base Unit

Before use, remote display units must be "paired" with a base unit. Pairing provides the ability to have multiple base units within wireless proximity. Pairing associates a given remote display unit to a given base unit. Pairing is achieved by plugging a remote display unit into a base unit and turning the power on to both the base unit and the remote display unit. Pairing is achieved with the remote display unit Wireless Lock LED is on.

2-1-5 Operational Use

Breath Hold™ES System operational use is achieved by pushing the reference button on either the base unit or a remote display unit. Pushing any reference button will open the solenoid and equalize the air pressure within the unit to identify a new reference level. Releasing a reference button will close the solenoid. All base unit LEDs will be on while the reference button on the base unit is pushed. All LEDs will be on for approximately one second when the reference button on the remote display unit is released. Following the release of the reference button, the center LED on both the base unit and the remote display unit will be on. Following this operation, the LEDs reflect the respiratory level communicated by the bellows indicating the new reference level at the display center.

2-1-6 System Status Indicators



2-1-7 Wireless Lock LED

The Wireless Lock LED has the same operation on both the base unit and the remote display unit. The Wireless Lock LED is on for approximately two seconds after the power switch is turned on. This action provides a check of the LED. The Wireless Lock LED on the base unit is on when the base unit is communicating. Likewise, the Wireless Lock LED on the remote display unit is on when the remote display unit is communicating.



2-1-8 Low Battery Indicator LED

The Low Battery Indicator LED has the same operation on both the base unit and the remote display unit. Do not use the system when the Low Battery Indicator is amber and blinking while the unit is unplugged. The Low Battery Indicator LED is on when the batteries are charged or charging when connected to the power supply. If the batteries are charged, but not connected to the power supply, then the Low Battery Indicator LED turns on for two seconds after the power switch is turned on, then it turns off. This action provides a check of the LED.

2-1-9 Battery Charging for Base Unit

The Breath Hold power supply charges the base unit battery when it is connected to both the base unit and the wall outlet. Once plugged in, all the display LEDs will remain on for approximately two seconds. After two seconds, the center, red LED remains on, and various green LEDs will continue to flash. The base unit switch may be either in the on or off position to charge the unit. The base unit is charged when the Low Battery LED is no longer on and flashing when the unit is disconnected from the power supply.

2-1-10 Battery Charging for Remote Display Unit

Plug the remote display into the base unit to charge it. The Breath Hold power supply charges the remote display battery when it is connected to both the base unit and the wall outlet. Once plugged in, all the display LEDs will remain on for approximately two seconds. After two seconds, the center, red LED remains on, and various green LEDs will continue to flash. The Base unit switch may be either in the on or off position to charge the unit. The remote display unit is charged when the Low Battery LED is no longer on, flashing, and is disconnected from the power supply.

2-1-11 Sensitivity Switch

The base unit has a sensitivity switch located on the bottom of the unit. LED sensitivity based on patient movement can be adjusted by turning the sensitivity switch to positions 1-7, position 8 is not in use. Please use the table below to understand LED indicator meaning for each setting. NOTE: The 25' bellows tubing can only be used with switch settings 6 and 7.

Breath Hold Sensitivity Chart

Levels	Multiplier
1	Legacy
2	1x
3	2x
4*	3x
5*	4x
6**	1x MRI
7**	2x MRI
8	Not in Use



*Level 8 – Not in Use

* To change the sensitivity adjust the dial on the bottom of the base unit. Unit must be turned off when adjusting the dial.

** Note: The use of sensitivity level 4 and 5 could lead to light drifting due to the extreme sensitivity tolerance. This drifting does not signify that the unit is malfunctioning.

*** For MR use

2-2 Positioning the System

2-2-1 Prior to using the system on an individual:

- Have individual view the patient education video.
- Assemble the Breath Hold™ ES System:

1. Place the bellows belt and base unit on the table, make sure to place base unit in a location where easy access to the power supply coupler is available. Do not block power supply coupler.
2. Place the bed mount display on the table, under the individual's pillow and table pad.
3. Place remote displays where they can be viewed by any third party who may need to monitor or help the individual achieve consistent breathing and breath-holding.
4. Connect bellows belt to base unit side port.
5. Turn on the power for the base unit and all remote displays

2-3 Positioning the Individual

2-3-1 When the individual arrives:

- Place the bellows belt on the individual immediately upon his or her entering the monitoring suite so that the belt has time to acclimate to the individual's body temperature. The belt's position can be adjusted later if necessary to ensure proper monitoring.
- Press the reference button on any remote display or the base unit to begin the monitor function.
- Familiarize the individual with the Breath Hold™ ES System and how the remote display changes as the individual breathes.

2-4 Positioning the Breath Hold™ and Usage

2-4-1 Positioning of the bellows belt portion of the system within the patient environment

- Ensure that the bellows belt with the three bellow pads is positioned on the individual's bare skin around the lower chest over the bottom of the ribs near the diaphragm (The bellow belt is the only portion of the system that are suitable for the patient environment

2-4-2 Key Points:

- The bellows belt should be moderately stretched and secured tightly enough so that it does not move in position on the individual during monitoring.
- Bellows pads should be installed over the bellows belt to keep bellows from having direct skin contact. See Figure 4 on Quick Reference Guide.
- The bellows belt should be able to expand and contract as the individual breathes (watch for movement of the bellows as the individual breathes).
- Verify that the bellows belt is able to expand. Make sure the individual is not lying on any portion of the bellows belt or the connecting rubber tubing.
- Verify that the rubber tubing connected to the bellows belt is positioned off the floor and free of kinks or other obstructions to airflow.
- Explain to the individual that it is very important to lie still and to keep the bellows belt in place.

2-4-3 Practicing with the Breath Hold™ ES System:

- Instruct the individual to view the remote display as he or she breathes. Green and red LEDs will light up as the bellows belt expands and contracts with respiration.
- Communicate to the individual that small, comfortable inspirations in which the individual can hold his or her breath for an extended period of time are ideal. During the breath-hold, the goal is to keep the center red diode lit. Have the individual take a comfortable inspiration and hold it. Center the system and remote displays by pushing and releasing the reference button on the base unit or any remote display. This will establish the reference breath-hold position that the individual will return to. Have the individual practice this technique a few times.
- After the individual is comfortable with the system, tell him or her to continue returning to the breath-hold position in which the center diode is lit whenever he or she is instructed to take a breath and hold it.

2-5 Session Completion

2-5-1 After the session is complete:

- When turning the base unit power switch off, all base unit LEDs will be off, except the center LED when the battery is charging. When turning the remote display unit power switch off, all remote display unit LEDs will be off, except the center LED when the battery is charging.
- Remove the bellows belt from the individual.
- Remember to clean and disinfect the bellows belt before returning it to its storage place. Refer to 3-1-1 for cleaning instructions.
- Remove the base unit and remote displays; recharge each if necessary prior to storage.

2-6 General Troubleshooting

2-6-1 How do I begin?

Position and connect the Breath Hold™ES System as shown in the Operators Manual and video. Ensure that the bellows belt fits around the individual snugly, but comfortably. Turn on power to the base and remote display units; push the reference button on the base unit or any remote display.

2-6-2 How can I tell if the remote displays are charging properly?
When turned off and positioned properly within the base unit, an amber indicator light on the side of the remote display should be blinking. If the unit is adequately charged, this light will not be on for longer than two seconds when plugged in.

2-6-3 What if the unit will not turn on?
It is possible the batteries are not charged. Ensure all units are plugged in during battery charging



2-6-4 Where should the belt be positioned on the individual?
Reliable breath control can be achieved with the belt positioned around the ribs in the lower chest at or near the level of the diaphragm. The exact position can be adjusted.

2-6-5 What does it mean when the lights display only a sequence of on/off?
The hardware self-test has detected an internal error that must be corrected before use. Reboot system per 2-6-8. If the error is not corrected, contact Medspira support before using system.

2-6-6 Why doesn't the reference button work with the base unit attached to AC power?
If you are recharging the batteries with the base unit main power in the off position, the system software considers the system not in use. With the base unit turned off, the reference button will have no effect on the system. To use the system when plugged in, the base unit power must be in the on position.

2-6-7 What does it mean when the two center red lights blink?
The remote display has temporarily lost the wireless connection. Reposition the display on base unit until the system reconnects.

2-6-8 How do I reset the system between procedures?
To reboot the system before every use, turn the docking station power off. While in the off position, remove the power cord from the docking station then plug it back in. Power may be turned back on once this action is complete.



2-6-9 The bellows belt is moving but the motion is not registered or it returns to the center LED too quickly.
You may not have pressed the initial reference button to start the procedure. Press the reference button. If the system begins to work properly, continue the procedure. If it does not, contact Medspira support or your service representative.

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Section 3 - Maintenance

3-1 System Care

Detach the system from AC power before attempting to clean it. Do not reattach after cleaning until the system has dried completely. Having the system attached to the AC power during cleaning or when it is wet may result in electrical shock. No other preventive maintenance is required.

3-1-1 Cleaning Instructions



- The recommended approach to clean the latex rubber bellows belt is as follows:

1. Wipe down with mild soap and water.
2. Wipe with a clean dry cloth.
3. Follow up with wipe down of 70% isopropyl alcohol (IPA) and 30% water to expedite drying time.
4. Allow five minutes to air-dry.

- The recommended approach to clean the Breath Hold electronic enclosures is as follows:

1. Cleaning via a clean damp cloth (not immersion) using any of the following solutions and then allowing components to air dry:
   10% bleach mixed in 90% tap water
   30% isopropyl alcohol (IPA) in 70% tap water
   3M-brand HB Quat Disinfectant Cleaner

NOTE:
DO NOT RUB DECALS, AS THEY WILL RUB OFF OVER TIME.
Under no circumstances should the system be placed into any type of sterilizer!

3-1-2 Storage

Store the system in an air-conditioned scan room or equipment room. (Refer to page 10, section 1-8 for room environmental requirements.)

For assistance please visit us at:
www.Medspira.com
or call (800) 345-4502 or +1-612-789-0013

Medspira

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K.3 Operating Instructions for the Vacuum Cushions.

Klarity

Vacuum Cushions
For Radiation Therapy



PRODUCT DESCRIPTION

Klarity Vacuum Cushions are medical devices for patient positioning and immobilization in radiation therapy and other medical applications. Each cushion contains small polystyrene spheres surrounded by a durable polyurethane coated nylon fabric. An evacuation pump is used to evacuate air from the cushion, causing the spheres to mold into a tightly formed shape, conforming to a patient's body. Cushions will hold this shape securely until air is allowed back into the cushion through the connecting valve.

INSTRUCTIONS FOR USE

1. Check the expiration date and make certain the vacuum cushion is in good condition.
2. Flatten out the cushion to distribute the filling evenly.
3. Position the patient on the cushion, and connect the hose to the cushion and vacuum pump.
4. Start the vacuum pump and generate a slight vacuum, then stop the pump. Mold the cushion around the body to provide the desired positioning.
5. Restart the pump until the cushion becomes rigid, holding the body securely. This process may take 5 minutes or longer. Evacuate the bag till the negative pressure is 0.08MPa/24inHG. Keep evacuating for 5-10 minutes. (When the pressure value reaches 0.08MPa/24inHG, it will not increase. Another 5 to 10-minute evacuation is required to help make sure the evacuated bag will hold its shape for the duration of the treatment period.)
6. Disconnect the hose from the cushion and stop the pump.

Warnings:

1. Care should be taken to keep the cushion valve out of the radiation treatment path.
2. Check the molded vacuum cushions regularly. Keep away from sharp objects to avoid puncturing.
3. Normally a vacuum cushion will keep its shape for more than 60 days, but no patient treatment should be started until the patient positioning has been carefully checked.
4. Keep away from hot surfaces or heat sources that can damage the nylon cushion.

Care and Cleaning

1. Store in a clean ventilated environment.
2. Clean with mild soap and lukewarm water, or with a mild alcohol based disinfectant applied with a soft cloth. Avoid aerosol sprays, bleach, solvents or abrasive detergents.

To be used under the guidance of a qualified medical professional.

www.klaritymedical.com

CE

Klarity Medical Products
1987 Coffman Road
Newark, OH 43055 USA

Ph. 740-788-8107
Fax 740-788-8109
Email: info@klaritymedical.com

IFU Form: C203-00 7/02/15

K.4 Operating Instructions for the Vacuum Pump

Klarity

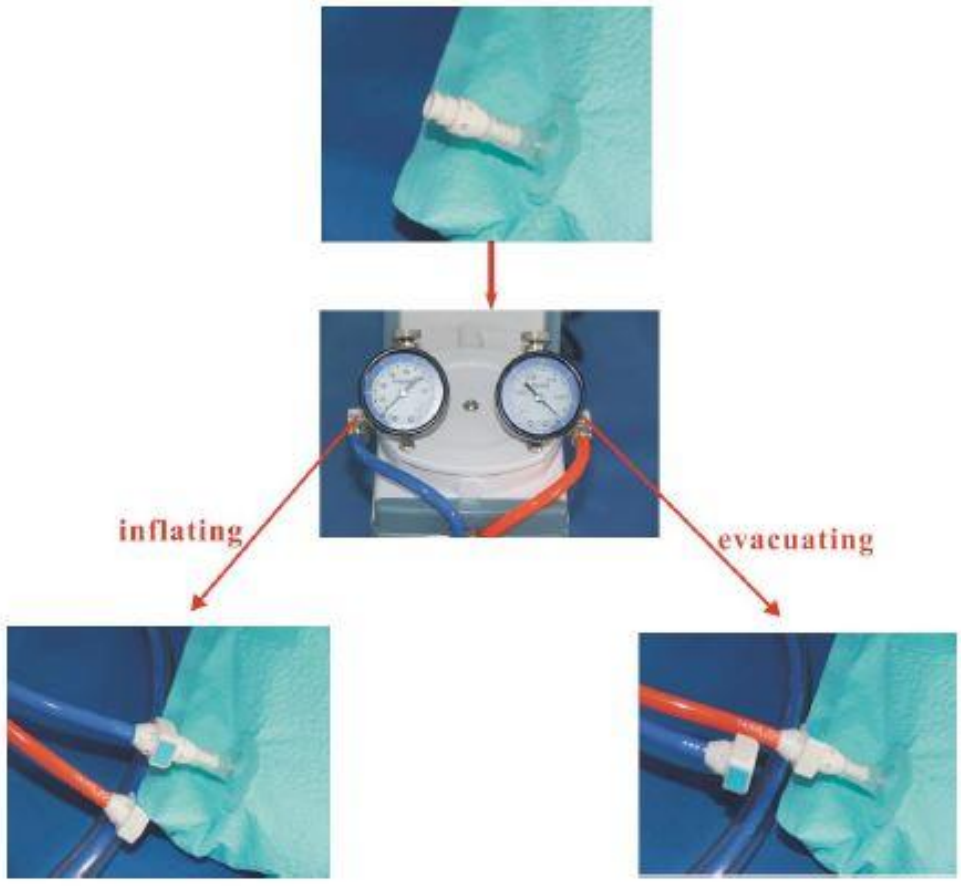
Instructions of Diaphragm Vacuum Pump
GM-05A GM-05AC

The product must only be used for the purpose of evacuating/inflating air.

PRODUCT PICTURE GM-05A



GM-05A Diaphragm Vacuum Pump



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www.klaritymedical.com

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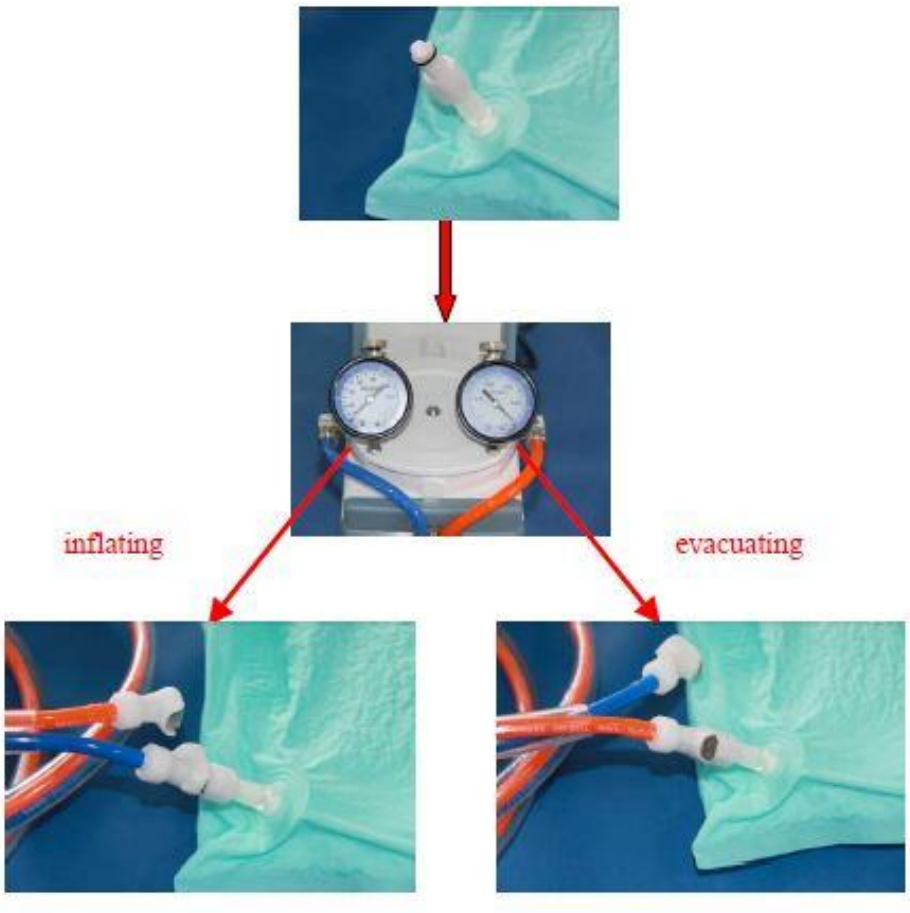
Instructions of Diaphragm Vacuum Pump
GM-05A GM-05AC

PRODUCT PICTURE GM-05AC



GM-05AC Diaphragm Vacuum Pump



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Instructions of Diaphragm Vacuum Pump
GM-05A GM-05AC

PARAMETERS

Pumping speed: (L/Min)	30	Voltage Rating	230Vac，50Hz
Ultimate Pressure Positive pressure	200mbar □30Psi	Temp of the body (□)	<55
Motor Power（w）	160	Weight(Kg)	8
Dimensions （L×B×H）(mm)	210×160×235	Diaphragm Valves	NBR
Inlet（mm） Outlet（mm）	ϕ6 ϕ6	Noise Level（dB）	<55
Working Temp（□）	7-40	Function	Vacuum&Pressure

OPERATIONS

1. Select the suitable tube:
   a. Use the red tube for evacuating.
   b. Use the blue tube for inflating.
2. Ensure the 2 metal knobs being tightened.
3. Start the vacuum pump.
4. Keep the pressure to 0.08Mpa for 1-2 minutes to make the vacuum cushion hard.
5. Turn off the vacuum pump.

CAUTIONS

1. Do not allow corrosive gases or particulate material to enter pump. Water vapor, oil-based contaminator or other liquids must be filtered out.
2. Ambient temperature should not exceed 55□.
3. Protect it against dirt and excessive moisture.

WARRANTY PERIOD

1 year

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Reporting of Serious Incidents by Hospital or Customer:

What is a Serious Incident?

A serious incident is any event related to this device that has led to, or could potentially lead to:

- Death of a patient, user, or other person
- Life-threatening condition
- Permanent injury or permanent damage to health
- A condition requiring medical or surgical intervention to prevent permanent harm
- A serious public health risk

What Should You Do?

If a serious incident occurs:

1. Stop using the device immediately, if necessary for patient safety.
2. Ensure appropriate medical care is provided to the patient.
3. Inform your hospital biomedical/technical department.
4. Report the incident immediately to:

- The Manufacturer
- The National Regulatory Authority of your country
- For users in the European Union: the competent authority of the Member State in which the user and/or patient is established

How to Report to the Manufacturer

Please provide the following information (if available):

- Device name and model
- Serial number
- Description of the event
- Date and location
- Patient outcome
- Your contact details

Cybersecurity concern

Report any suspected cybersecurity vulnerability in MAXIO to Perfint at customercare@perfinthealthcare.com or info@perfinthealthcare.com

For a confirmed critical vulnerability affecting your system, Perfint will inform you within 30 calendar days of confirmation, with any interim mitigation and the timeline for a permanent fix.

Communication Details to Manufacturer:

Perfint Healthcare Pvt. Ltd.

Address:

Plot No. 78, Annai Indira Nagar 1st Street,
Okkiyam, Thoraipakkam,
Chennai – 600097,
Tamil Nadu, India
Contact Number: +91-44-24542155

Email: customercare@perfinthealthcare.com, info@perfinthealthcare.com

E-Waste Management - Applicable to products placed in INDIA

E-Waste

Electrical and electronic equipment, including solar photo-voltaic modules or panels or cells, whole or in part discarded as waste, as well as rejects from manufacturing, refurbishment and repair processes.

Perfint Healthcare is Extended Producer Responsibility (EPR) organization as per E-Waste management rules, 2022 by the Government of India in the Ministry of Environment, Forest and Climate Change.

Perfint Healthcare is committed to collect the e-waste from the product scrapped by the customer.
Perfint request the customers to inform the Perfint Healthcare on the e-waste generated on the product to the following contact information.
Please visit http://www.perfinthealthcare.com/ to know the latest information.

Email: info@perfinthealthcare.com
Address: Plot No.78, Annai Indira Nagar 1st Street,
Okkiyam, Thoraipakkam,
Chennai – 600097,
Tamil Nadu, INDIA.
Contact #: +91-44-24542155
Website: http://www.perfinthealthcare.com/

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New Directions in Interventional Oncology