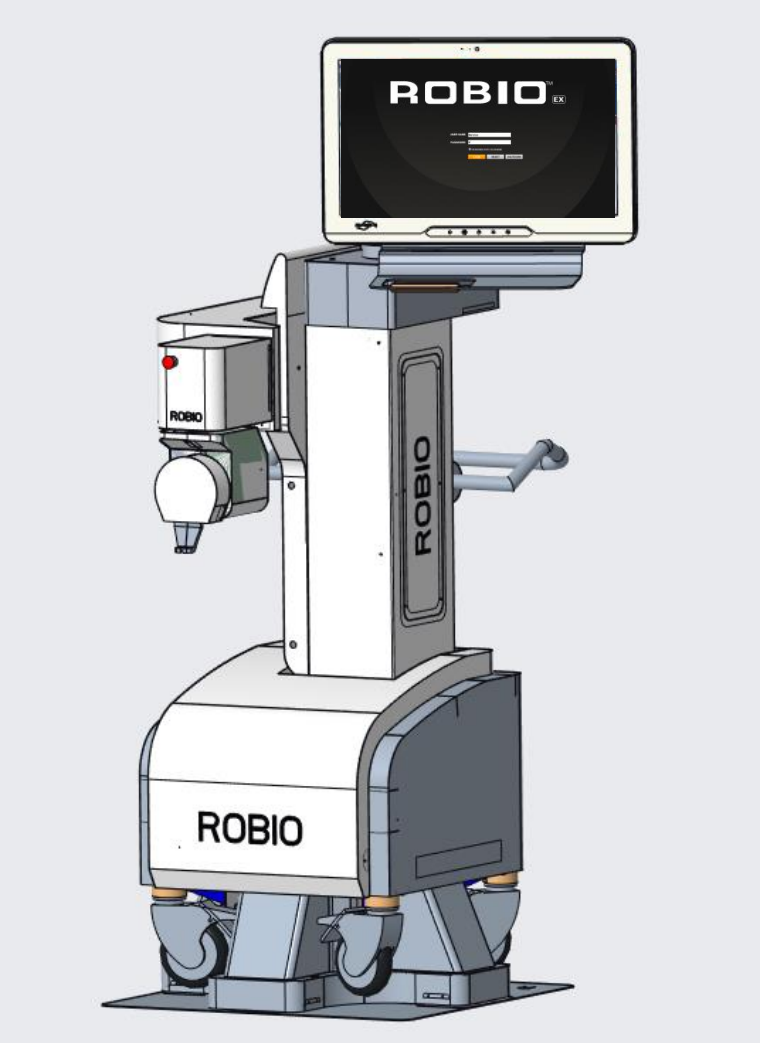
PERFINT HEALTHCARE PVT. LTD.

ROBIO™

User Manual



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

MODEL: EX / LITE

User Assistance Information

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www.perfinthealthcare.com

This user manual is intended for the use of qualified interventional clinicians. The purpose of the manual is to provide information about the ROBIO system and instructions for its use and maintenance, to enable its proper usage.

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Manufactured by Perfint Healthcare Pvt. Ltd.

General Warnings and Cautions

- Rx Only: Federal (U.S.A) law restricts this device to sale by or on the order of a physician, if sold in U.S.A.

All users associated with the usage of the device requires understanding of English language to the extent that they read and understand the user manual, label, instruction in the device and User Interface.
A hardcopy of user manual in English will be supplied with each of the equipments.
In case of any system upgrades the amendment to the user manual shall be provided.

- 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.
- 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 designated/recommended personnel.
- The device is shipped under EMI/EMC standards. Any major changes at site are to be avoided.

Disclaimer

- ROBIO has to be unpacked and set up, installed and calibrated by service and support personnel, who also will perform a field verification procedure before first use. ROBIO should be used only after proper application training from a Perfint certified Application Specialist.
- This manual is originally drafted in English. It shall be available in the local national language whenever the product is to be made available in the member states, as applicable and permitted by the national regulation requirements and only by authorized dealers.
- Do not use ROBIO for purposes other than those indicated. Perfint will not be responsible for any damage arising out of any unindicated/unspecified usage or 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 Healthcare Pvt. Ltd. will not be held responsible for any damage caused due to deviation from the above mentioned cautions and warnings.

Contraindications

The device should not be used in the following instances:

- The patient is uncooperative or dyspneic
- The procedure is required to be performed on non–soft tissue lesions
- The patient is incapable or unwilling to follow instructions

Conventions Used in This Manual

Symbols or icons are used wherever they reinforce the printed message. The following table lists and describes the icons, labels and conventions used in the manual.

Symbol	*Meaning and Use*
	**Caution/Precaution** symbol is intended to alert user to the possibility of malfunction of the device or operation associated with its use or misuse and/or special care to be exercised by a practitioner or patient for the safe and effective use of a device
	**Warning** symbol is intended to alert user to possibility of adverse reactions and potential safety hazards associated with the use or misuse of the device.
	**Do Not Reuse** symbol is an indication to prevent reusing
NOTE	**Note** is intended to alert user to related or useful information
	**Ramp** symbol is intended to alert user to the requirement for an inclined plane to move the equipment

Table 1: Manual Conventions

About this manual

This user manual is intended as an instructional booklet for the proper use, handling, and maintenance of the ROBIO device by its users.

The user manual is designed to cover aspects of its intended application, components and features, requisites for use, operation, safety, maintenance, and relevant device-related data. The information is presented in seven chapters, each covering a specific aspect or area of device information.

Chapter 1 provides a general overview of ROBIO outlining the intended application of the device, its general functionality and usage, its components, and the requisites for use of associated tools.

Chapter 2 outlines the various safety considerations to be taken into account before installing and operating the device. This chapter also lists and describes the device symbols that the user may encounter.

Chapter 3 describes the various site requirements and physical and device specifications that need to be met in order to install and operate the device. The steps involved in connecting and powering up the device is also detailed in this chapter.

Chapter 4 offers an overview of the ROBIO application, and the interface and controls required to navigate the application and operate the device.

Chapter 5 describes the workflow for the operation of the device. The various steps of the workflow from preparation (device and patient), device initialization and docking, procedure planning, and execution are detailed in a tabular form with relevant illustrative guides.

Chapter 6 takes the user through the requirements and steps for transporting and parking the device between procedural use.

Chapter 7 provides technical data and other information pertinent to the proper handling and maintenance of the device.

The Appendix constitutes the final section of the manual that tabulates other relevant user information such as application pop-up messages, message windows, control panel messages, warranty information, and a checklist post delivery.

Every chapter has notes, cautions/warnings or both where applicable. The notes and cautions are critical to the proper and intended use and operation of the ROBIO device and system and therefore must be given due attention.

Perusal of the ROBIO manual before installation and use is expected to provide the user with robust guidelines and information to optimally and effectively operate the ROBIO device to perform the specified CT/PET-CT-guided interventional procedures.

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Chapter 1

1. Introduction

This chapter describes and explains the features, functions, working and operation of ROBIO.

2. Device Overview

The ROBIO is a CT/PET-CT guided robotic positioning system designed to assist interventional radiologists & Nuclear Medicine Physicians in performing procedures that requires precise tool positioning. It was designed and developed to solve the issues with the conventional method of performing needle based interventional procedures. ROBIO is a standalone positioning device, which can be moved to the desired position along the patient table of the CT/PET-CT system. This device has 2 linear motions to position the guide to the point of interest and 2 angular motions to facilitate angular entry of the needle.

The system offers several features to help clinicians target the tumor and plan for accurate tool placement. It facilitates targeting and tool placement in deep seated lesions requiring orbital, caudocranial or craniocaudal angulations or a combination of both for thoracic, abdominal and pelvic interventional procedures.

1.1.1 Intended Use

Intended Use

ROBIO is a stereotactic accessory for Computed Tomography (CT) and PET-CT imaging systems intended for the spatial positioning and orientation of an instrument guide through which a clinician advances an instrument to reach a target.

ROBIO is also intended to provide the clinician a visual representation of the targeted path and position of the manually advanced instrument on the CT image, prior to clinician advancing the instrument as mentioned above.

Indications of Use:

ROBIO is intended to be used in CT guided, straight needle, percutaneous procedures of Interventional Oncology like Biopsy, Ablation, FNAC, pain management, drainage etc for the soft tissue in the thorax, abdomen and pelvic regions.

1.1.2 Key Features

ROBIO offers several features to help clinicians target the tumor and plan for accurate tool placement for diagnosis or therapy.

- Four Degrees of Freedom (DOF) – for targeted CT/PET-CT guided intervention such as biopsy, FNAC, pain management/drug delivery, drainage, and tumor ablation.
- 3D Positioning – for deep seated targets requiring orbital, caudo cranial or cranio caudal angulations or a combination of both.
- Integrated planning console for planning of procedure, validating plan, and generating report
- Patient immobilizer bed – for minimizing patient movement to aid in achieving the stated accuracy.
-

1.2 System Description

1.2.1 System Architecture

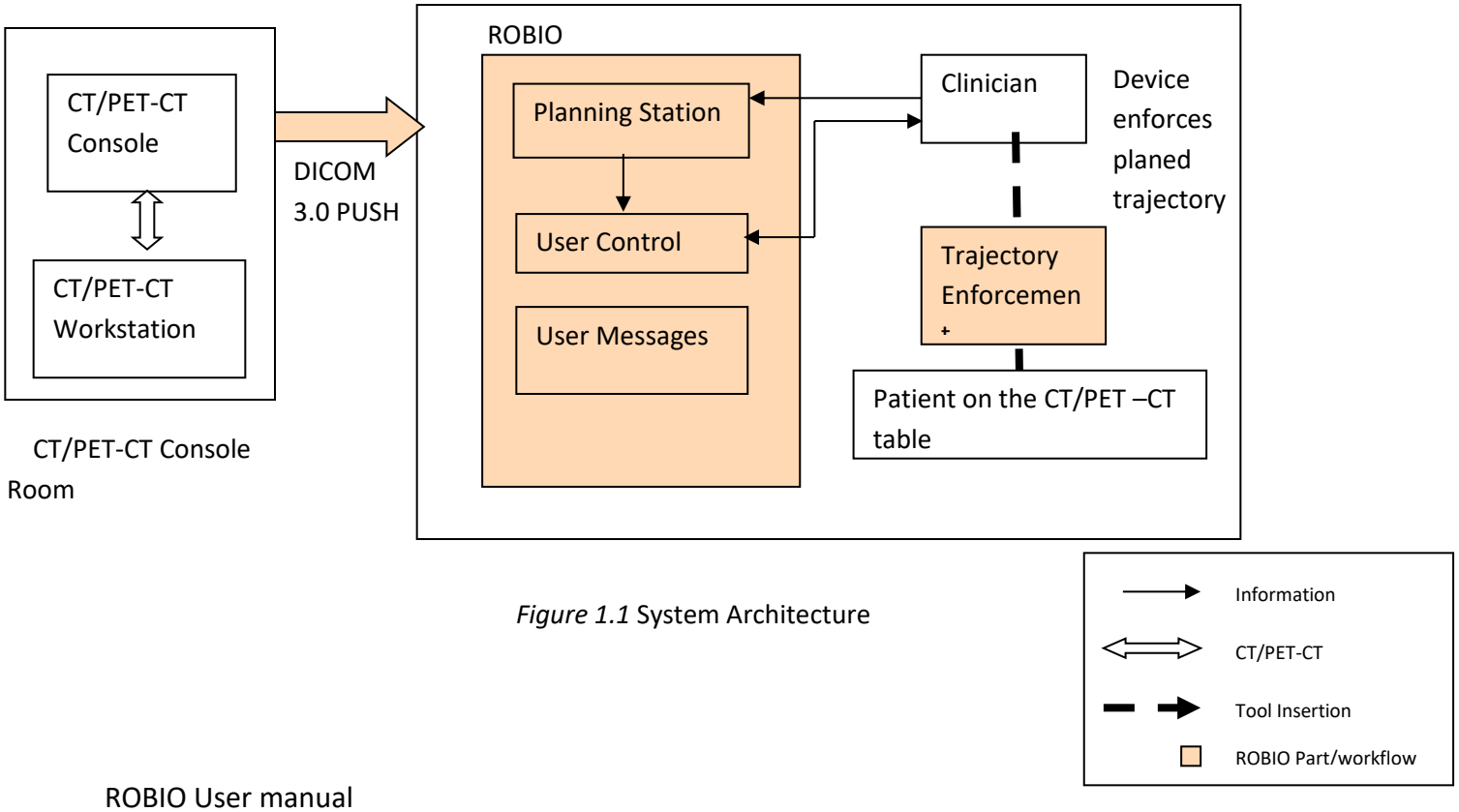


Figure 1.1 System Architecture

1.2.2 ROBIO Device Description

The robotic arm is a 4 DOF (degree of freedom) system with 2 linear axes and 2 angular axes. The device is docked to the left or right side of CT/PET-CT on the thin plate (floor mat) installed on the floor.

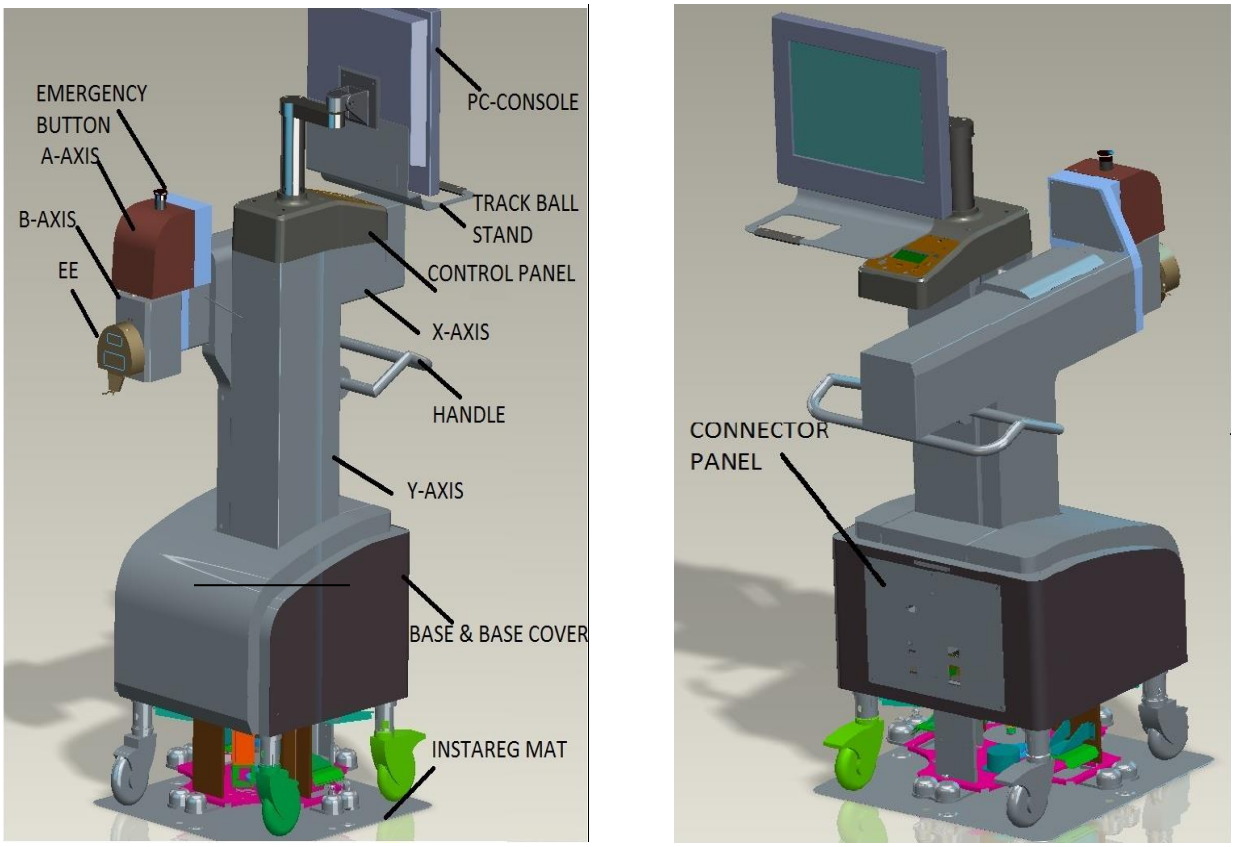


Figure 1.2 *The ROBIO device*

The device consists of the following key components:

A. *Integrated Planning Console:* Consists of a screen and a trackball / Mouse for viewing scan and planning procedure on the scan.

B. *Device Handle:* This is used for maneuvering the device during its transportation and parking.

C. *Y-axis:* This is the vertical movement axis.

D. *Device Base:* The base supports the axes and moving components. It contains the battery pack, the body, transportation wheels, docking stand, and the docking pedal.

E. *Docking Plate:* The InstaReg mat is used for calibration and registration of the device with the CT/PET-CT Unit. It is used to define the docking position of the device for subsequent docking.

F. *End Effector:* This is attached to the rotary axis found at the end of the Y axis. The End effector serves to grip the sterile clamp (needle holder) firmly. The clamping operation can be achieved either with the help of foot switch or through the EE clamp/release key on the

Control panel. The image that follows shows how the needle clamp appears and how it is gripped by the End effector arm.

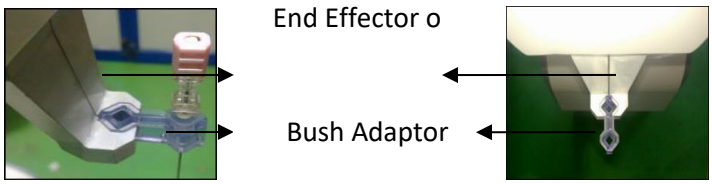


Figure 1.3 *Views of the clamp in the end-effector arm*

G. *Emergency Button:* The emergency key located on top of X- axis can be used to stop all the axes movements and release the end effector in case of an emergency situation. See figure below:



Figure 1.4 *Emergency push key*

For activating the emergency key, push the emergency switch down.

For emergency recovery, Rotate and release the emergency key.

Undock, Switch Off/On and initialise to use the equipment.

H. *X-Axis:* This is the horizontal axis along with the End effector arm moves.

I. *TrackBall Stand-RW:* Provided for the placement of trackball / Mouse and handle for rotating the monitor

J. Control Panel: This is located on a platform on the X axis. The control panel consists of a console with an LC display and a set of user controls. The control panel serves as the user-operated interface between the device application (on the integrated planning console) and the device. See below for a representation of the control panel as it appears on ROBIO.

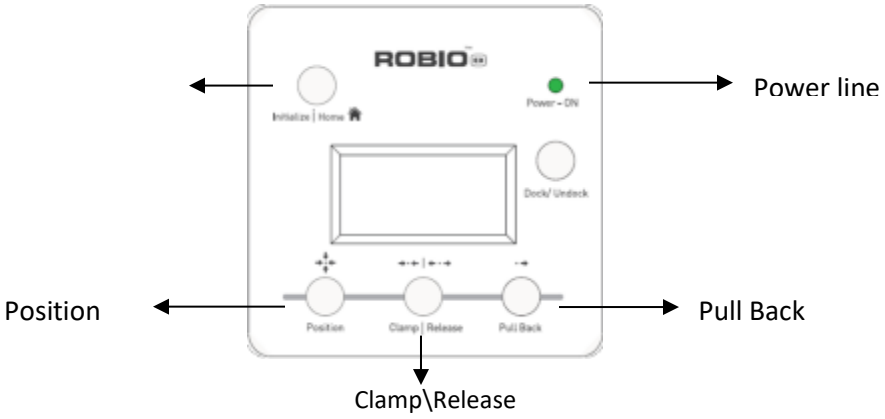


Figure 1.5 *Control panel*

The table below describes the functions of the controls/buttons on the control panel

	Power line indication. Green LED indicates power supply to the device.
	Takes the device axis to safe parking position. Also works as key to switch between Position and Anesthesia.
	Positions the device over the patient as per the plan.
	Docking button
	Closes and opens the End effector to clamp/release the bush
	Takes the device or arm up or away and giving clearance for the doctors

Table 1.1 *Functions of controls/buttons*

Along with the device is provided a foot switch pedal. The foot switch pedal is designed to enable the user to perform positioning, clamp and pullback operations by foot. See picture below for positions and functions of the pedals in the foot switch.



Figure 1.6 Pedals in the foot switch

1.2.3 Needle Bushes

The needle bushes are plastic split bushes that can be selected based on the thickness of the needle being used for the procedure. The needle bush facilitates the use of needles of different gauges and types. It ensures that the needle is tightly clamped by the End effector.

11G to 25G bushes are available for the user. User should sterile the bushes before using for any procedure. The needle bush is typically used with the device and its handling is shown in the figure below.



Figure 1.7 *The needle bush: A— Gauge Marking; B— Insertion of needle through the bush; C—Splitting of the bush (if required)*

Notes and Cautions

NOTE	*Ensure that device should be operated only inside the CT/PET-CT room.*
NOTE	*Software has a unique version number which will be displayed in the monitor*
NOTE	*Only sterile needle comes in contact with patient.*
	*Do not reuse the bush.. All used bushes have to be disposed in red disposal baskets (needs disinfection before disposal) please check the sterilized pouch is not damaged.* *Reusing the bush can result in infection and may cause serious illness to patient due to contaminants from previous usage*
	*Ensure that needle bushes are chosen such that they have same gauge marking on both sides Incorrect use of*

	needle bushes would result in inaccurate results.
⚠	*Same gauge needle of different makes vary in needle outer diameter. Never use tight bushes. Also ensure that bush is not too loose.*
⚠	*Caution: Before pull back, Please push down and rotate the adaptor away from end-effector*
NOTE	*Ensure a unique IP address is assigned to the ROBIO System. The same IP address should not be used for any other device within the network.*

1.3 Operation Overview

ROBIO allows you to plan, validate and execute precise tool placement on target areas using DICOM 3.0 images obtained from the CT or PET-CT scan system.

Planning consists of plotting the entry, target and the trajectory. Upon your confirmation of the plan, the robotic arm will position the specified tool guide above the patient's body.

The next step involves manually advancing the appropriate tool (needle), such that it reaches the target through the planned entry point.

The ROBIO system is designed to minimize human errors by supplanting free-hand tool placement and positioning with precisely computed CT/PET-CT-guided tool placement. Once the requisite inputs for planning the entry and trajectory are provided to the ROBIO application, it calculates the coordinate values for needle positioning and delivery, and communicates them to the ROBIO device. The device will then move its robotic arm to the desired location on the patient body (see below figure).
The system therefore allows for precise planning, analysis, re-planning if necessary, and execution, diminishing the margin of placement error and the number of punctures.



Figure 1.8 *Needle insertion*

1.4 Usage Specifications

- ROBIO should only be operated by personnel qualified to perform CT or PET-CT-guided interventions. All operators must be properly trained in the use of ROBIO by Perfint certified training personnel.

- The ROBIO needle guide (bush) is designed to guide/assist a clinician to manually advance straight needles and is necessary for use.
- Procedure planning and execution is to be done by qualified personnel.
- ROBIO is only intended for use with a CT and PET-CT unit.
- Patient movement should be taken care of during planning and procedure. Proper breath instruction and proper anesthesia need to be given for optimal results.

1.5 Auxiliary Device/Tool Requisites

ROBIO is fully operative and procedurally ready only if the CT or PET-CT units and needles meet certain specifications.

1.5.1 CT/PET-CT Unit Specifications

- ROBIO can be used with virtually any DICOM 3.0 compatible CT/PET-CT unit. The gantry and the table- and cradle- top position displayed by the CT/PET-CT unit should be correct relative to the vertical

  axis. Furthermore, the longitudinal axis of the CT/PET-CT table must be 90° to the scan plane (when the gantry is not tilted).

- The CT/PET-CT unit must be able to display scanned and reconstructed images in the radiology view for all scan protocols.
- The CT/PET-CT unit must be able to transfer scanned and reconstructed images to ROBIO console in the radiology view for all scan protocols

Notes

NOTE	Refer to the user manual of the ROBIO console for specific instructions related to the console monitor.

1.5.2 Needle Use Specifications

- Virtually any type of straight needles with thickness between 11G and 25G can be used. Correct needle length should be entered for accuracy.
- The needle should not bend during insertion as this could cause the needle to be inserted at a wrong angle.

Notes and Cautions

	*Enter correct length of the needle for calculation. Needle length displayed by manufacturer may not be correct. Use metallic scale to measure the length of the usable part of needle excluding the white depth marker bush space if any.*
NOTE	*Refer to any use instructions provided by needle manufacturer for specific instructions related to the needle.*

Chapter 2

2. Safety

This chapter describes and explains the critical safety features that need to be ensured prior to, during, and between uses for the effective operation of ROBIO.

2.1 Important Safety Considerations

All of the following conditions are to be stringently observed by users of the ROBIO system.

— **Trained personnel**: The user must be trained in the operational procedure and should be fully aware of potential hazards before using the device.

— **Device connection**: Always use device on line power. Use battery only for purposes of emergency. Check battery status before using the device. Do not plug in/out cables when device is ON.

— **Pressure on the End Effector**: The End effector may be deflected, if more pressure than intended is applied. Do not apply excess pressure on the End effector to ensure accurate needle placement and do not use tight bushes during needle insertion.

— **Needle handling**: The needle should not be bent during insertion as this could cause the needle to be inserted at a wrong angle (see the figure below). The risk of bending the needle increases with the use of long and thin needles and has also been noticed in some single-use biopsy guns. If a biopsy gun is used, it is advisable to use an introducer needle. See instructions for use in section 4.9.



Figure 2.1 *User bending the needle head away from him as he inserts*

— Non-encumbrance of device arms: Ensure that the device arms are used only for the purpose(s) indicated. The arms must not be used at any time for placing objects on or hanging objects from/over.
— Care during device transportation: Special care must be taken to secure the safety of the End effector during the transport of the ROBIO. Ensure that the device is always in home position during its transportation, movement or parking. Device docking: ROBIO must be properly docked. Follow instructions in section for 5.5 for smoother and safer docking.

Cautions and Warnings

	*Do not use device below 50% of battery level as shown in the LCD. Always use device with battery status of "-+++" or "++++" in the LCD*
	*Do not use ROBIO for purposes other than those intended. Perfint will not be responsible for any damage arising out of such unintended use.*
	*Do not bend the needle during insertion.*
	*Ensure monitor is in parking position during moving.*
	*Protect the device from liquid spillage.*

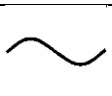
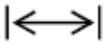
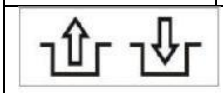
— **Clearance from surface above/near vital organs**: Always plan your procedure such that there is sufficient clearance from the vital structures to avoid inadvertent damage. Other factors such as involuntary patient movement can also result in needle mis-positioning. Such factors need to be taken into account while positioning needle for clearance. It is advisable to perform a check scan to ensure safety.

Notes and Cautions

	*Do not plan close to vital structures. Always plan giving enough clearance to avoid any harm to patient.*
NOTE	*Provide enough clearance from vital organs while planning for deep seated lesions with 3D angulations of more than 45deg.*

2.2 Device Symbols

The basic machine operations and inputs for ROBIO are indicated to the user by a collection of symbols, diagrams, notations, and buttons. These are listed and described in the table below:

	Indicates the power “OFF” position on device power switch
	Indicates the power “ON” position on device power switch
O	Indicates “ON” position of line main power switch.
|	Indicates “OFF” position of line main power switch.
	Indicates emergency switch. Press the emergency switch to stop all axes movement in case of any emergency.
	Indicates alternating current (AC). Device should be operated only by connecting to 100 - 240V, 50/60Hz line power.
	Indicates line power.
	Indicates the rotational axes of the device. (Orbital and Craniocaudal or Caudocranial).
	Indicates linear axis of the device(X,Y)
	Indicates the undocking and docking of the device respectively.
	Foot Switch: To identify a foot switch or a connection for a foot switch.
	Indicates the switch to position all axis 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.

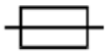
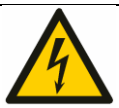
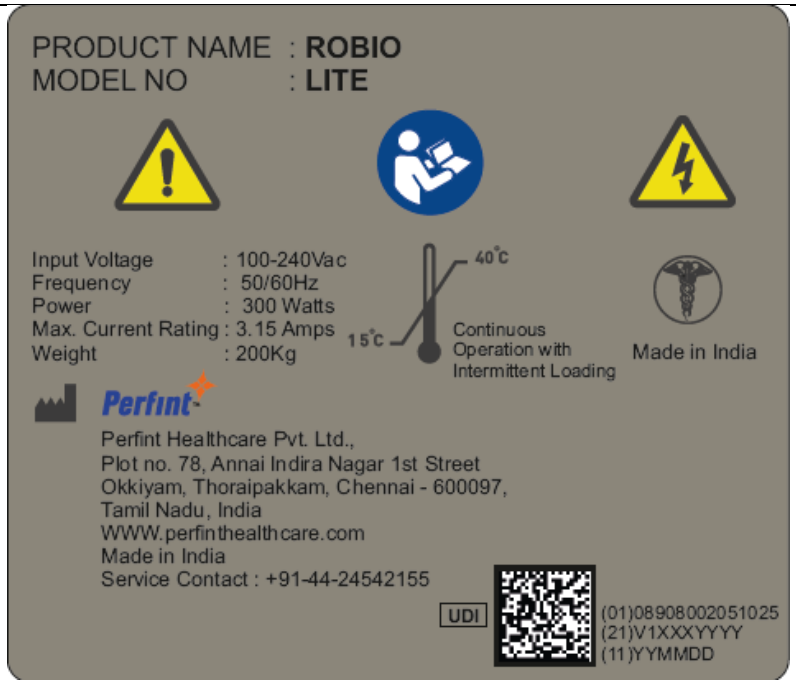
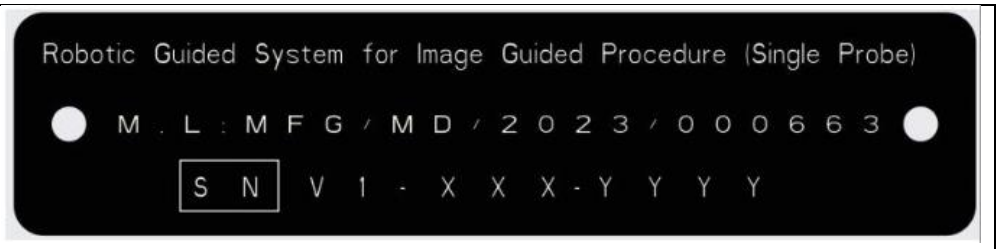
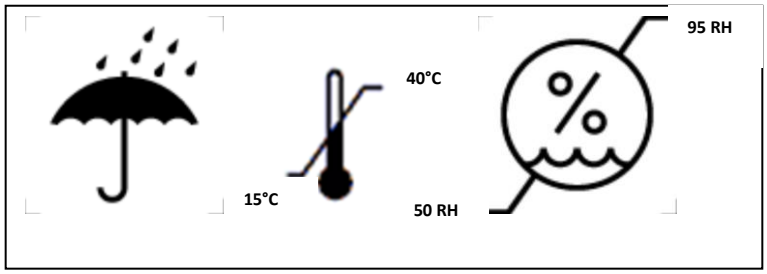
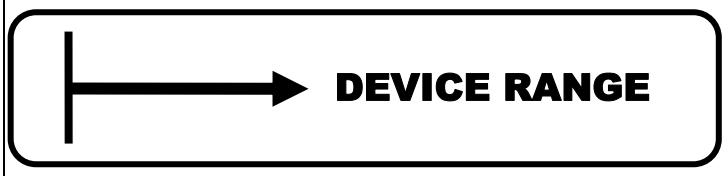
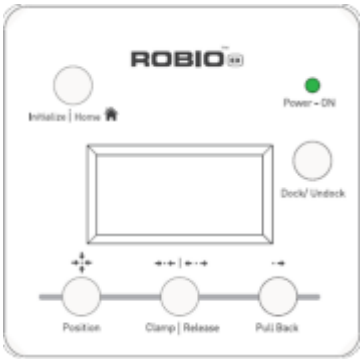
	
	Indicates the switch to position the device to its HOME/INIT position & to Toggle between anesthesia and position.
	Indicates the switch to clamp the EE
	Indicates the switch to release the End effector
	To identify fuse boxes and their location.
	General Warning
	Follow instructions for use in the User Manual to operate the machine.
	Warning: Dangerous Voltage, take care while plugging power cord to the device.
	Plot no. 78, Annai Indira Nagar 1st Street, Okkiyam, Thoraipakkam, Chennai – 600097,Tamil Nadu, India
	The device should be operated in between 15 to 40 deg. Celsius

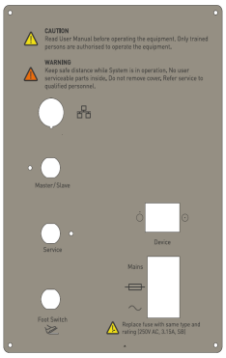
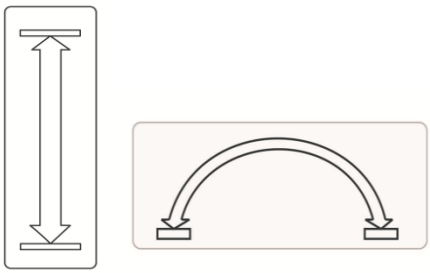
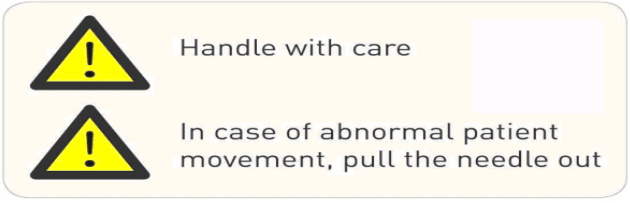
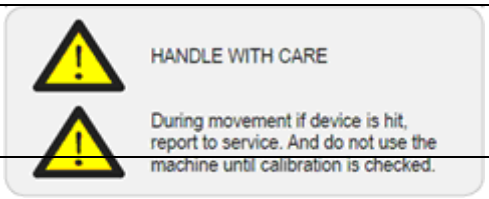
Table 2.1 *Device symbols and conventions for ROBIO*

2.3 Device Labels

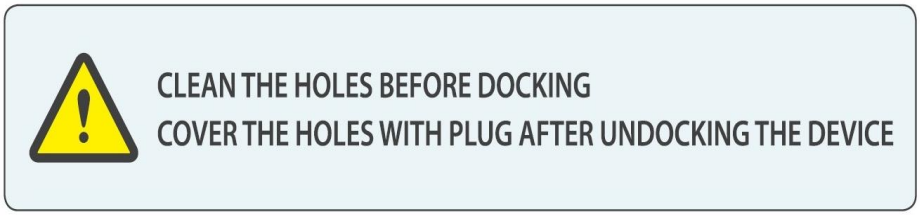
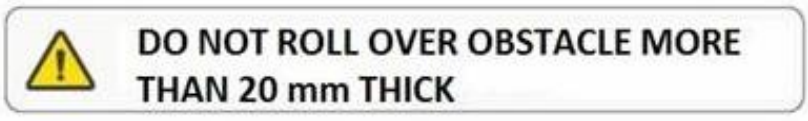
Labels are written, printed or graphic matter affixed to a medical device or any of its containers or wrappers, or, accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents. The following table contains a list and description of the labels found on the device, accessories, and immediate packaging:

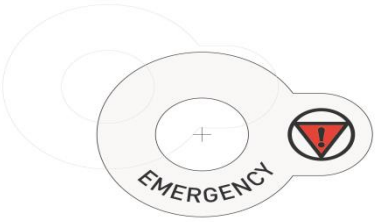
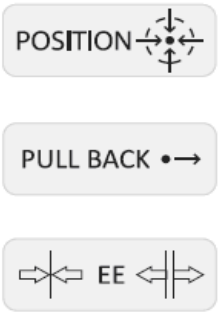
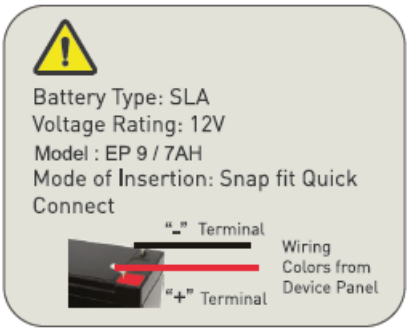
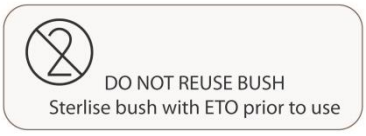
Manufacturer Label – ROBIO EX	
Manufacturer Label – ROBIO LITE	

Site registration number- IMDR (India)	 Where V1 stands for model/version number XXX stands for continuous Serial number YYYY stands for Year of manufacture
Packaging Label	
ROBIO Range of Operation Sticker for CT/PET-CT Table	
Control Panel Label Indicates the position of control switches. 16x4 display shows the device status	

Connector Panel	
Linear Movement and Angular Movement **<u>Movement limited in both directions</u>**: To indicate that a linear movement is possible in both the indicated directions within predetermined limits	
EE Warning Sticker Cautions user for patient movement during procedure	
Device Movement Warning	

Contingency Measures Indication	
Hand Crush Warning Cautions user against placing hands between moving parts	
Docking Location Indicates docking of the device on the left side of CT/PET-CT gantry Indicates docking of the device on the right side of CT/PET -CT gantry	 
Pump Outlets Sticker Caution for when pump is used for inflating/deflating the immobilizer bed **Patient Immobilizer**	 

Bed and CT/PET-CT Console Sticker Caution for when pump is used for inflating/deflating the immobilizer bed	
Device Handle Sticker Caution for when the device is moved from its parking condition and after procedure.	
On docking InstaReg plate InstaReg cleaning instruction	
On-X-axis cover Do not lean on the device	
Near Handle When the device is moved from its parking condition	

and after procedure	
Emergency Switch Emergency OFF	
Foot Switch Stickers (When foot switch is used for controlling the device during procedure) Indicates the position of the pedals	
Battery Label Battery type and mode of insertion	
Needle guide (bush) Label Outside the package containing the needle bushes	

Labels to be used when the optional accessories are used:

Pump Outlets When the pump is used for inflating/deflating the immobilizer bed	
On the patient immobilizer bed and CT/PET -CT console When the pump is used for inflating/deflating the immobilizer bed	

Table 2.2 *Device labels for ROBIO*

Chapter 3

3. Preparing the System for Use

This chapter describes: (a) Preparations that are critical to for ensuring that suitable storage, operation, and procedural conditions are met; (b) Setting up of the device and system

3.1 Site Requirements

It is necessary to ensure that pre installation work is complete and that they satisfy the requirements listed in this manual before delivery/ installation of the system and device.

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

- Evaluating the room size.
- Positioning system components (relative to the system position) within the room.
- Ensuring accessibility for the equipment at its points of loading, storage and transportation.
- Carrying out floor loading, floor leveling or any other building modifications necessary.
- Installing air conditioners, if necessary.
- Installing or changing the electrical conduit(s), junction boxes, ducts and earth reference terminal (ERT) if necessary.
- Checking for compatibility of network configuration and hardware and changing them if required.
- Procuring the materials to carry out renovation and construction work.
- Covering alteration and modification costs when not specifically provided for in the Perfint Sales Contract.
- Providing storage for the system, if necessary prior to installation.

3.1.1 Room Layout

ROBIO Room Layout depends on the CT/PET-CT room layout and hence may vary accordingly.

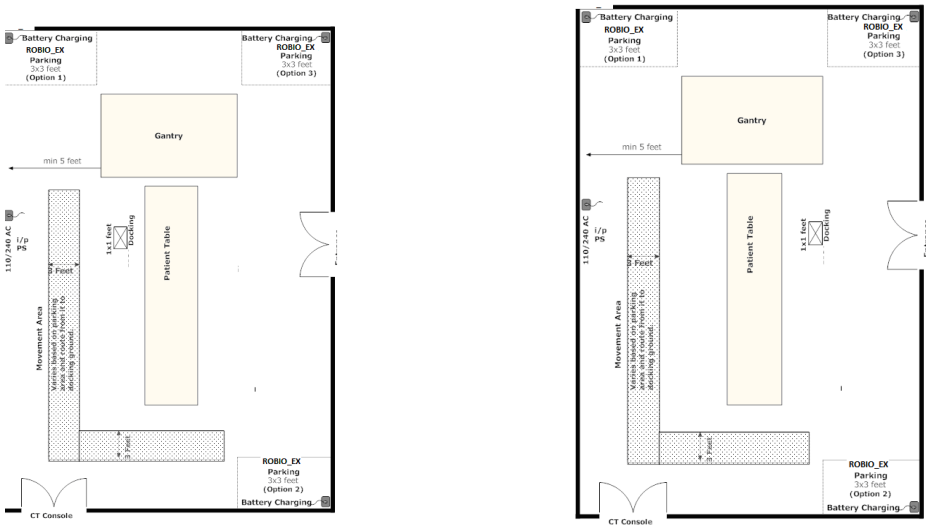


Figure 3.1 *Possible CT/PET-CT room plans*

The choice of parking area rests with the hospital and/or user, but has to be defined in the pre installation site documentation.

ROBIO movement area depends on the route from the parking area to the docking station.

3.1.2 Environmental Requirements

The system should be operated, stored and transported within the parameters outlined below. Either its operational environment must be constantly maintained or the unit must be turned off and store the device accessories, Disposables and consumables in Dark, Cool, Dry place and temperature of 0°c to 50°c and closed place.

	Operational	**Storage**	**Transport**
Temperature	15 to 40˚C	0 to 50˚C	0 to 50˚C
Humidity	50 to 95 % RH	50 to 95 % RH	50 to 95 % RH
Pressure	700 to 1060hPa	700 to 1060hPa	700 to 1060hPa

Table 3.1 *Operating environmental conditions for ROBIO*

3.1.3 Electrical Requirements

The electrical and wiring requirements for the system is as outlined below.

- 100 - 240V, 50/60 Hz Single phase
- Wiring duct for a cable length of min 5m.

3.1.5 DICOM Connectivity Requirements

DICOM Standard	**DICOM 3.0**

3.2 Getting Started

This stage of preparation consists of preparing the system for use, and launching the system application for its subsequent use in the procedure.

3.2.1 Physical Setup

Connecting Power

Plug to the system AC input port located on the system's rear panel and plug the power cord into a grounded, protective earth outlet. **Switch on the Main switch.** The panel and EMI switch appear as in the figures shown.

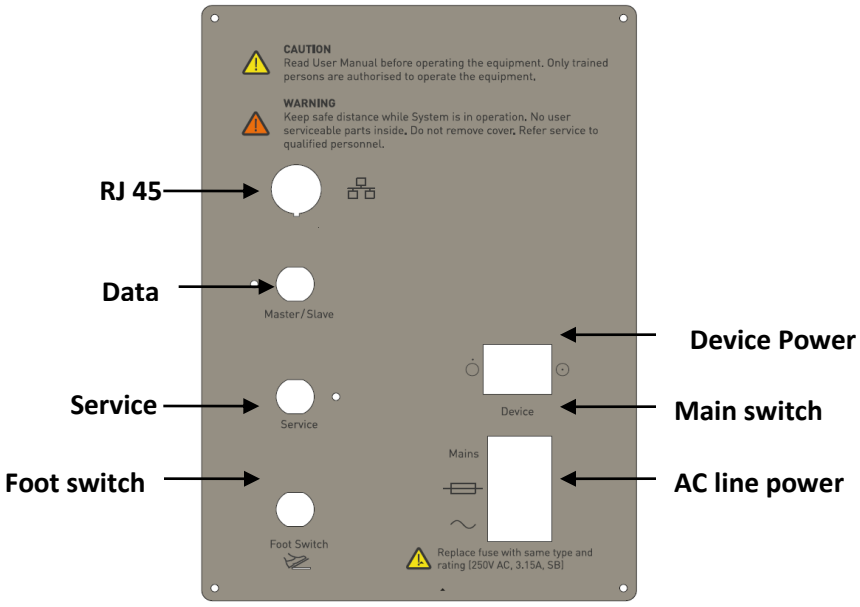




Figure 3.2 *Back panel containing the input ports, dust cover, indicators and Main switch*

Cautions

⚠	*Use power supply cords meeting national requirements of the respective country in which the equipment is used.*
⚠	*Please connect the data cable to the slot provided, with an interlocking data connector*
⚠	*In case of any accident, detach the power cord from the device to isolate from the mains supply.*
⚠	*Dust cover is only for service use. Please ensure user should not try to open it*

Connecting Foot Switch

The foot switch is connected to the device through the interlocking connector provided at the rear end of the device. See figure below for precise instructions:



Figure 3.3 *connect the connector aligning the cut and rotate to lock.*

ROBIO Network Connectivity

ROBIO is connected to a CT/PET-CT scanner using Ethernet for receiving CT/PET DICOM 3.0 images.

Caution

	*During device setup ensure that only the components and devices supplied as part of the ROBIO system are used.*

3.2.2 Powering On the Machine

Press the *Power On/Off* Switch at the rear end of the machine.

When the On/Off Switch is pressed the machine is powered on with a greeting on the LCD panel, as appears in the figure below.

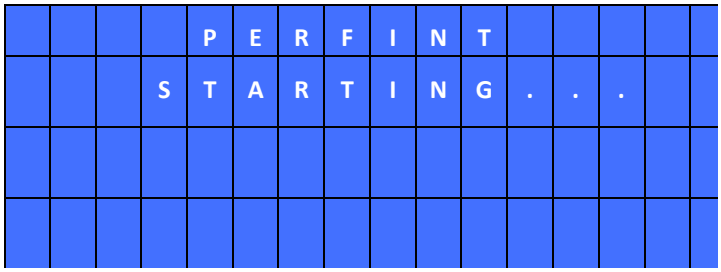


Figure 3.4 Device starting notification

System Power On Self Test (POST)

The device runs a series of startup self-checks that test the status of the tests motors, encoder, and sensors. The results of the self-checks are communicated to the application. These communications appear on the LCD screen as shown in the figures below.

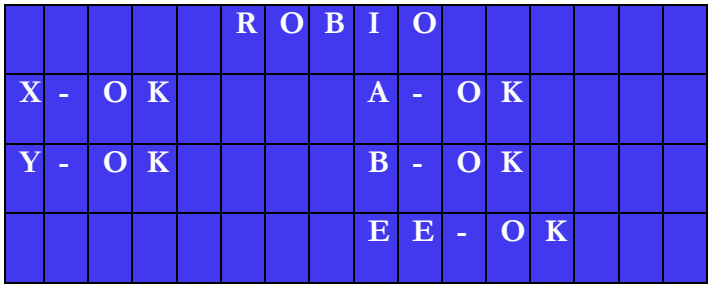


Figure 3.5 (A) Notification for successful completion of POST

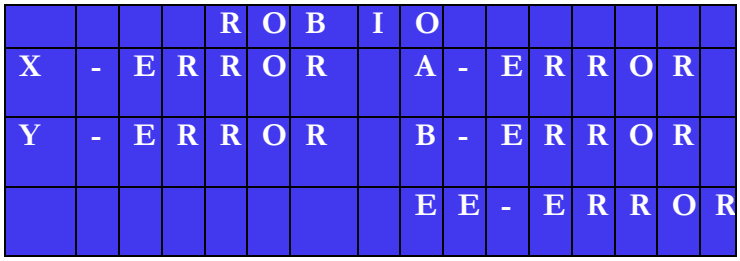


Figure 3.5 (B) Notification of errors on all exes after POST

Caution

⚠	*Call Perfint Service Centre in case of any such technical errors*

System Initialization

System initialization is the start-up procedure after successfully powering on ROBIO. Every switching ON of the machine should be followed by a half initialization. Press INITIALIZE key for device initialization. The process places each machine axis at zero position. ROBIO cannot be used without successful initialization.

Cautions

⚠	*Call Perfint Service Centre in case of repeated initialize errors.*
⚠	*Make sure the device and operator are at a safe distance to avoid accidental hit or injury during device movement for INIT/HOME*

4. User Interface and Application Overview

This chapter briefly describes the user input interfaces and the application that control the working of the device.

User Interfaces

The operation of the device is controlled by the ROBIO application installed in the integrated planning station (console). The visual outputs of the application appear on the monitor of the station upon which scan loading, planning, validating of the interventional procedure is performed by the user. Visual outputs also appear on the LCD display of the control panel, which serves as a communication bridge between the application and the device. The control panel allows the user to view and manually push the commands received by the application to the device.

It is critical to familiarize yourself with both interfaces, therefore, to be able to use the device for its intended purpose.

4.1 Control Panel LCD Screen

The screen displays commands issued by the ROBIO application. The LCD screen showing the display elements that may appear at any time of operation appears as in the below figure.

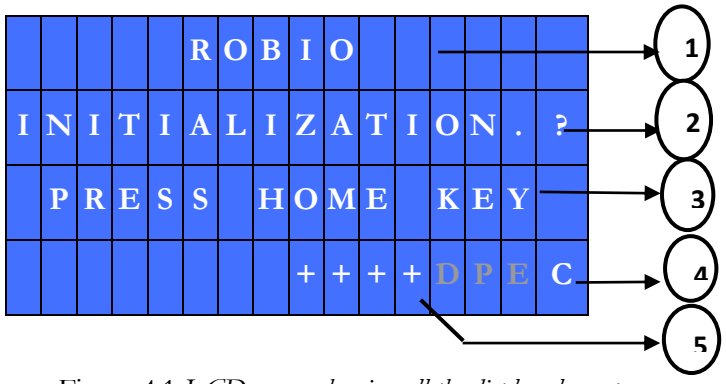


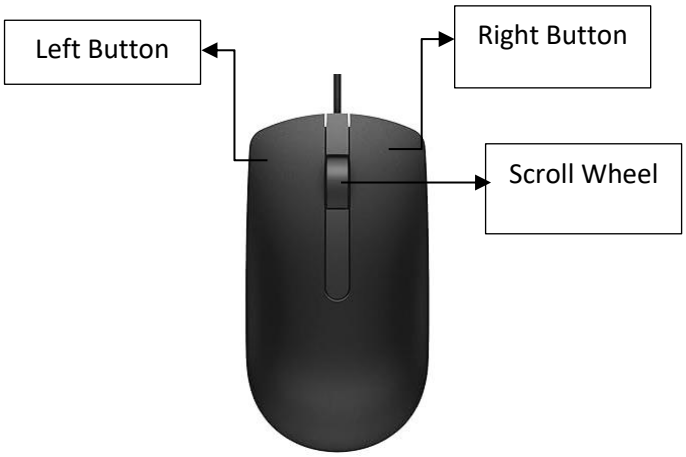
Figure 4.1 *LCD screen showing all the display elements*

The elements that may appear on the display during the operations are, in correspondence with their numbering in fig.4.1, the following:

1. ROBIO display
2. Device action.
3. Device action status/Error code.
4. Device status- Communication-C, Emergency-E, Docking-D.
5. Battery indication – 4 '+' shows battery full condition.

4.1.1 COMPONENTS OF OPTICAL MOUSE:

- Left Button: For selecting and clicking items.
- Right Button: For context menus and additional options.
- Scroll Wheel: For vertical scrolling or zoom in/ zoom out.



4.2 Application Interface

The ROBIO application interface is displayed on the monitor of the integrated planning station (console). The interface enables and guides the planning and execution of the procedure by prompting user inputs and commands. Onscreen navigation is enabled by a trackball / Mouse on the integrated procedure planning station, as well as an onscreen keyboard for user inputs.

The user may log in to the application either as a User or as an Administrator. The administrator, while also a user, holds administrative rights/privileges that are reflected on the interface as additional functionalities and features. Differences in the interface for the administrator will be indicated separately.

The screens and functional elements are illustrated and described in the sequence they appear as you go through the procedure using the application.

4.2.1 Landing Screen

The landing screen contains login fields for User, Admin, and Service. It appears as shown in the figure below.



Figure 4.2 *ROBIO application landing/login screen*

4.2.2 Procedure and Modality Selection Screen

This screen allows you (User, Admin) to select procedure type and modality, and choose the desired docking option. The modality/procedure screen appears as in the figure below.



Figure 4.3 *Procedure/Modality/Docking selection screen*

A confirmation prompt or pop-up window appears after every completed step allowing you to CONFIRM or CANCEL the previous transaction. The confirmation pop-up window appears as in the figure below.

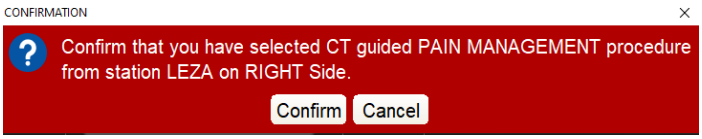


Figure 4.4 *Transaction confirmation window*

Note

NOTE	*Confirmation prompts will appear at the end of most transactions. They will, therefore, not be illustrated in this manual at every instance of their occurrence.*

4.2.3 Application Main Screen—Image Loading Screen

MAIN MENU:

The main 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. It's gross structure remains the same throughout the procedure. Changes in procedural steps are accompanied by changes in functionality and functional elements.

The gross structure of the landing screen of the application interface may be divided into 3 general areas: the task pane; the task bar; and the image area with the tool bar. The elements of the interface that you will be working with are indicated in the figure below.

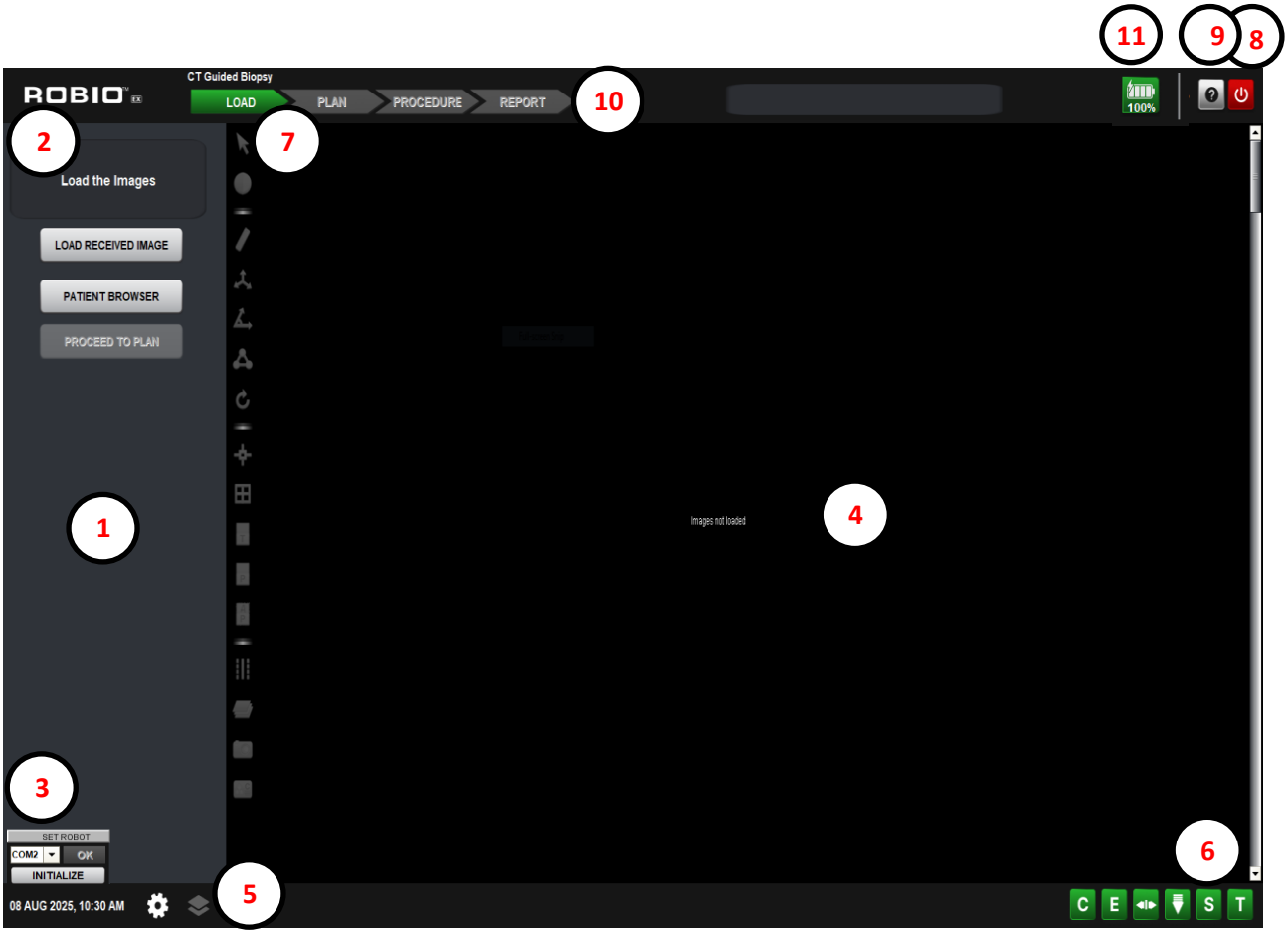


Figure 4.5 *Main application interface screen*

1. Task pane

2. Procedure status/prompt display

3. Set Robot button

4. Image window

5. Access icon; CT and PET-CT preset icon (Task bar)

6. Device Communication Status icons (Task bar)

7. Tool bar

8. Help buttons

9. Application shut down button

10. Procedure progression bar

11. Battery status

The functionalities provided by the elements of the task bar, while of operative or indicative natures, remain the same throughout the procedure. These features are briefly described below:

SET ROBOT: The operability varies for User and Admin as described below.

User: The device port is preset by the administrator. Port options are deactivated for user.
Admin: The administrator can choose and set the device port to be activated

ACCESS MENU: The functionality differs for User and Admin as shown below

User: Clicking on the Access icon opens a "Release EE Values" window with user entry fields for X and Y axes. This window appears as in the below figure.

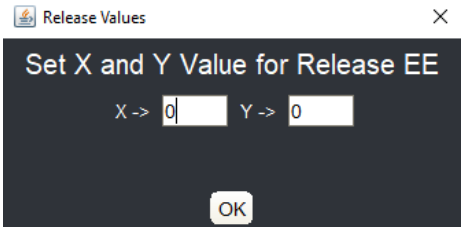


Figure 4.6 *Release Values user input window*

Admin: Clicking on the Access icon invokes an Admin Options menu in the process and settings pane. The menu that appears allows Admin to set and change user logins and access, window length and width values, communication settings and procedure comments for the preset procedures. It also contains an option for viewing the procedure status on the console. It also contains the User functionality of setting EE release values. The figure below shows how the Admin Options menu appears.

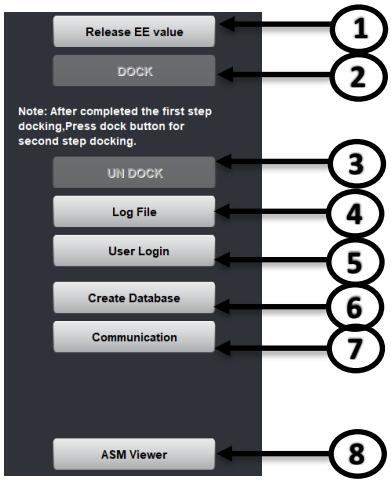


Figure 4.7 *Admin Options menu in Process/Input pane*

1. Allows admin to input X and Y values for EE release.

2. Allows admin to DOCK the device

3. Allows admin to UNDOCK the device

4. Allows admin to view the log details.

5. Allows admin to add and delete users; view user details; assign authorization rights.

6. Allows admin to update all the data series in the existing database.

7. Allows admin to view and select communication settings.

8. Allows admin to choose to view the procedure status on the console.

CT/PET-CT PRESETS: The functionality is common to both User and Admin. The presets present various preset modes for image viewing depending on the tissue or region being addressed. The invoked list appears as in the below figure.

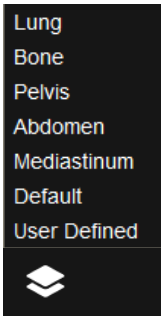


Figure 4.8 *List of CT/PET-CT presets*

IMAGE LOADING PANE

The primary functionality of the elements of the image loading pane is the loading of the scanned image for procedure planning. The image loading pane appears as in the figure below.

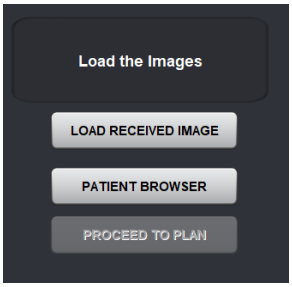


Figure 4.9 *Load Image task pane*

If the scanned image has been pushed prior to login, the image will appear on the image display screen after login. If the image is pushed after login, the "Load Received Message" button will appear on the task pane, which will enable the user to load recently scanned images received by ROBIO. The 'Patient Browser" button allows the user to load a list of images loaded and transferred to ROBIO by the administrator.

Clicking the "Patient Browser" button in the task pane will open a patient browser window containing panes that will list patient data, image series of the patient, and image tags from a selected series.

MACHINE COMMUNICATION STATUS

The machine communication status is indicated by a set of icons at the bottom right of the screen. These icons may get highlighted at various points of the procedure to call attention to and indicate the status of communication. The icons on the task bar appear as in the below figure.



Figure 4.10 *Machine communication status bar*

1. Communication status

2 Emergency status

3 End effector status

4 Docking status

5 Tracker status

6 Tilt sensor status

IMAGE DISPLAY

Clicking on the "Patient Browser" button invokes a patient browser window containing patient stats and the most recent image series of the patient. The patient browser window appear as in the figure below.

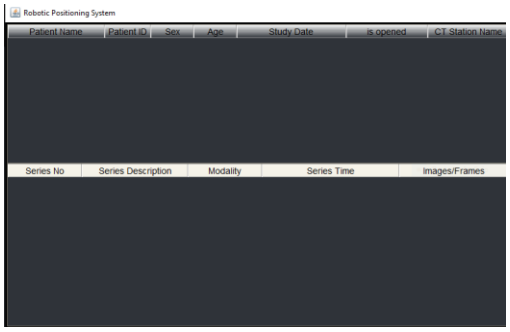


Figure 4.11 *Patient Browser window*

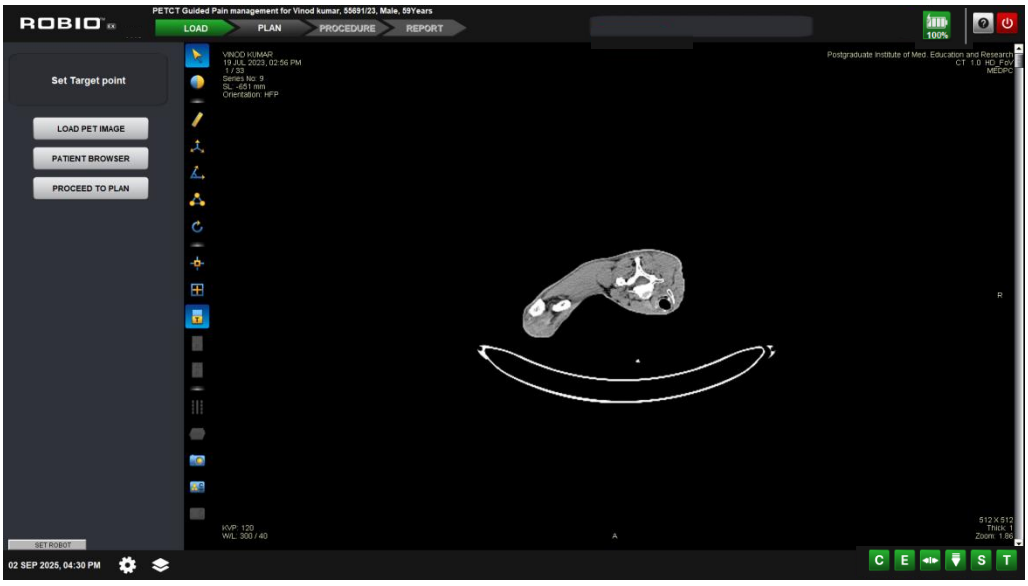
Once the image series is loaded, clicking on the desired series row will load the series onto the display window. The image that will appear on the window will be the first image of the series. The other images of the series can be viewed either my mosue scrolling or by using the scroll bar on the right edge.The display window appears as in the figure below.



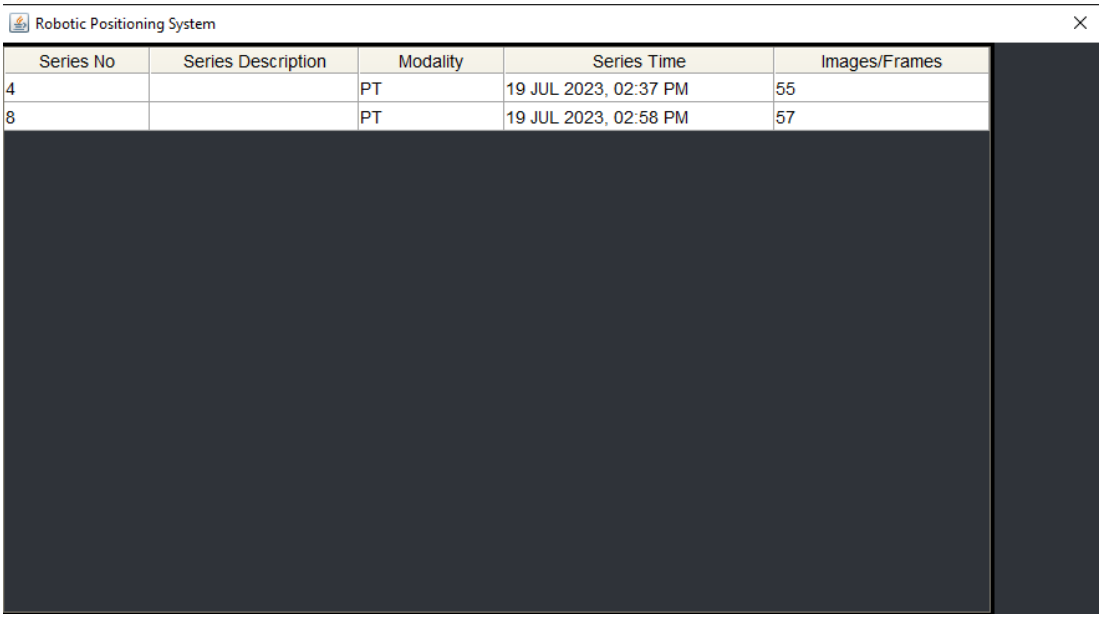
Figure 4.12 *Image display window*

The display window contains the image (which can be viewed from any level along the plane by scrolling) and the sliding tool bar (which will be addressed in the next section) Also displayed on the screen are the patient name, date and time of imaging, image number in series, the number of the series, the slice location (SL), the window length and width, the KiloVolt peak (KVp) the institution name, series description, station name, dimensions, slice thickness, and zoom.

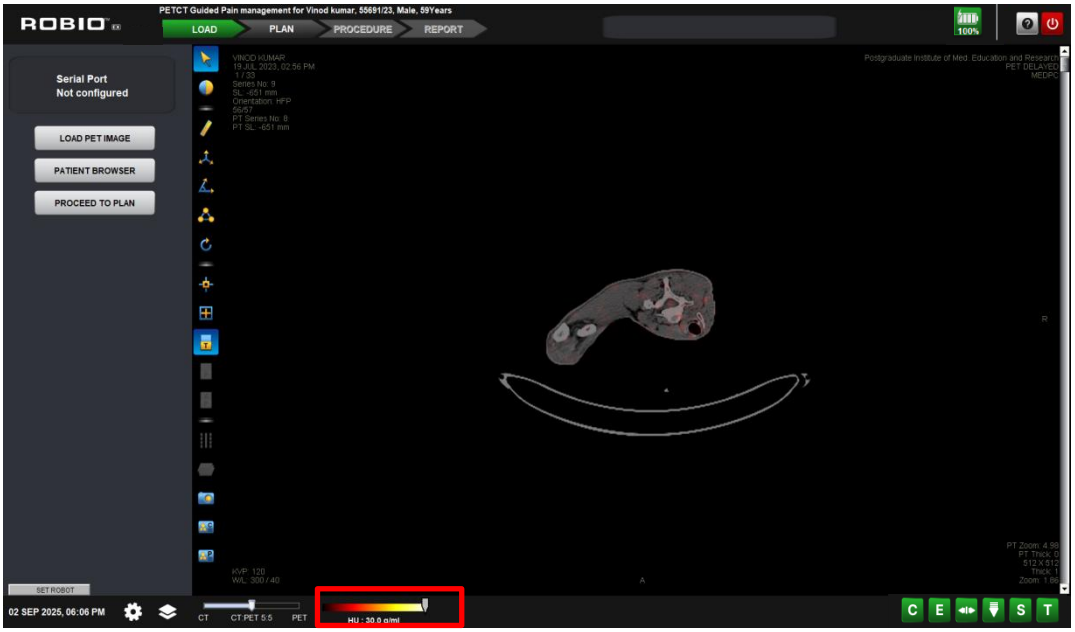
IMAGE DISPLAY PET-CT



To load PET image →Click LOAD PET IMAGE button.



Application will open a list of the entire PET image.



To modify the opacity of the PET image and adjust the window level, utilize the “PET Opacity" option located in the toolbar. Then, simply manipulate the associated slider to achieve the desired effect.

4.2.4 Trajectory Planning Screen

Clicking on the "Proceed to Plan" button followed a confirmation will lead to opening of the trajectory planning screen. The trajectory planning screen differs from the landing screen only in the menu options and buttons in the task pane. The task pane of the planning screen appears as in the figure below.

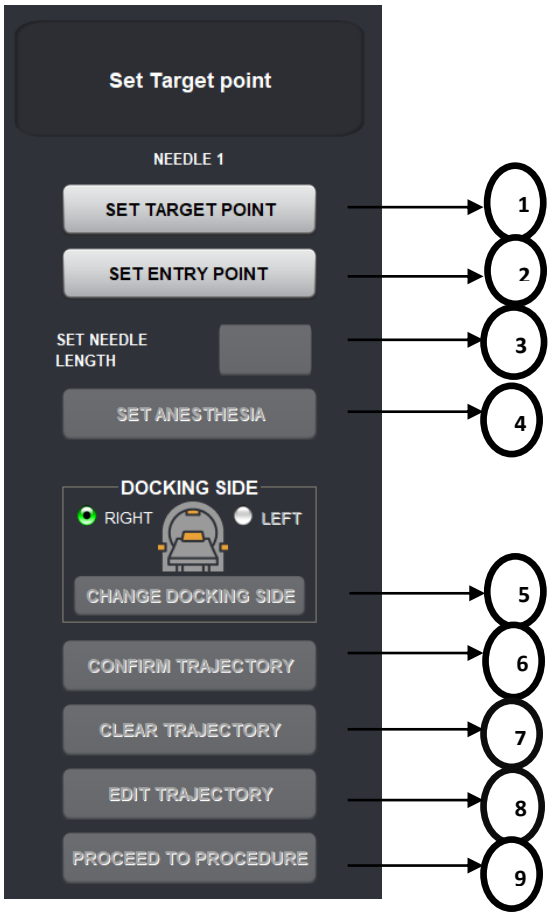


Figure 4.13a *Procedure planning pane*

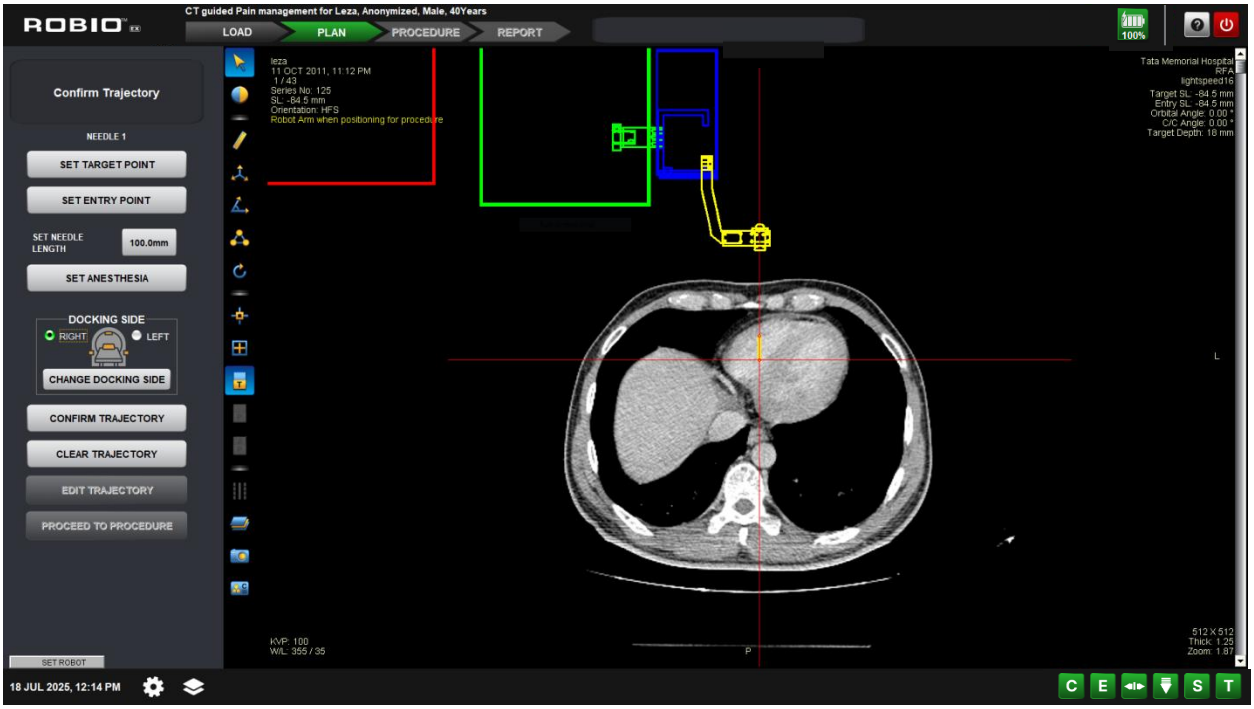


Figure 4.13b *Setting target and entry points on the scan image*

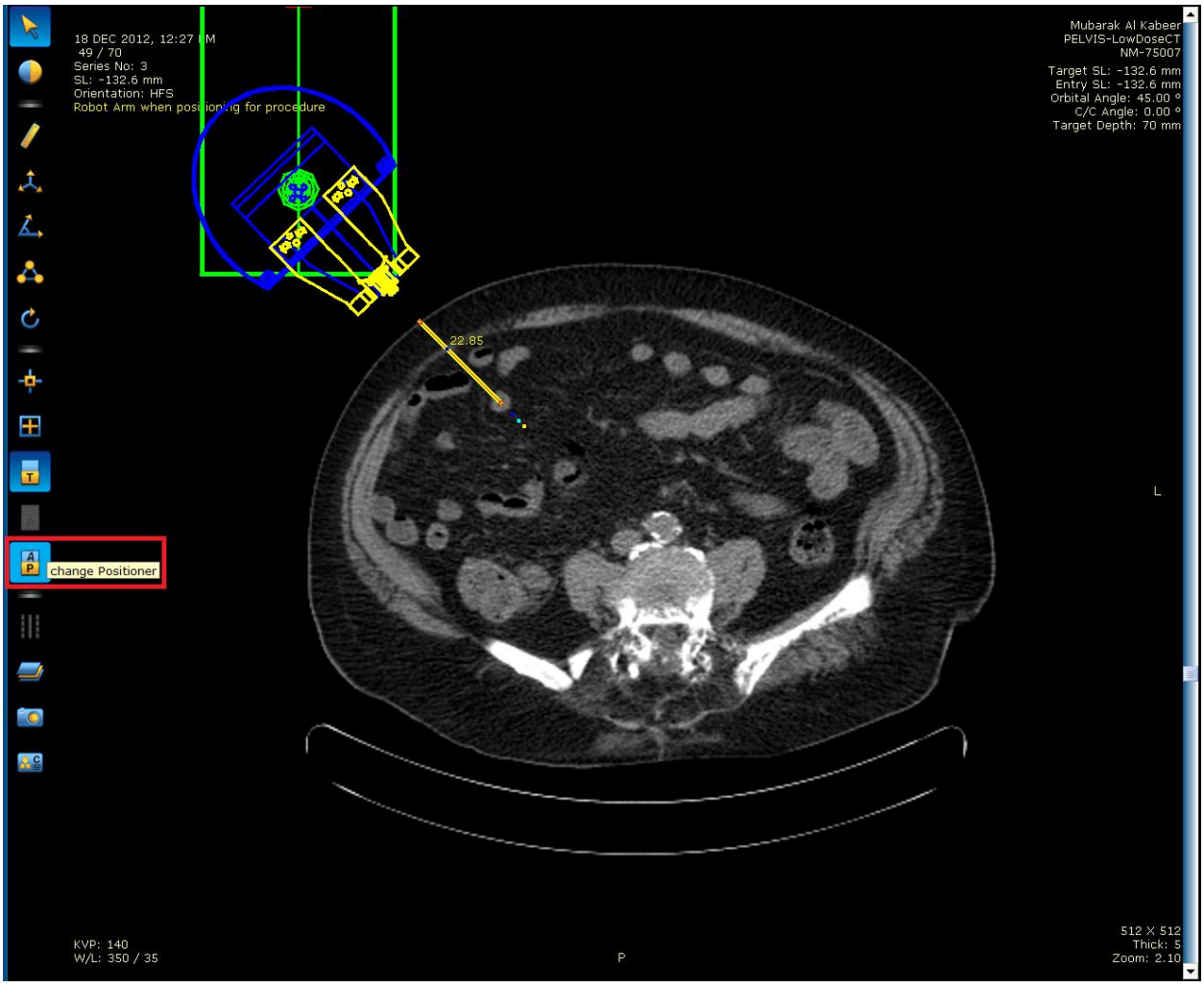


Figure 4.13c *Show positioner toggle button for anesthesia plan and procedure plan on the scan image*

The planning panel consists of the following elements in the order that they have been numbered:

1. Set Target Point button: Allows the user (by clicking on the button) to mark the desired target point for the needle on the scan image(in the image window).

2. Set Entry Point button: Allows the user (by clicking on the button) to mark the desired entry point for the needle on the scan image. Completion of this step will activate the "Set Needle Length" button.

3. Set Needle Length: Allows user to specify needle length above the stated minimum, example ">65mm". Clicking the needle length button opens a window of presets length options and an entry option and field. It window appears as below:



Figure 4.14 *Needle length window*

4. Set Anesthesia window: Allows the user (by clicking the button) to mark the point on the trajectory created, and activates the "Set Anesthesia Needle Length" field. The button, which displays the minimum length, example ">34mm", when clicked opens a length selection/entry box similar to that of the needle length selection box described previously.

5. Confirm Trajectory button: Allows user to confirm or reject the trajectory that has been set by the user.

6. Clear Trajectory button: Allows the user to clear the trajectory so far set. By clicking this button the the previously selected points and values are cleared, allowing the user to set the trajectory afresh.

7. Docking side selection buttons: This allows the user to select the docking side by clicking either of the radio buttons. To change the device docking orientation to suit the trajectory plan, the user may click on the "Change Docking Side" button.

8. Edit Trajectory: Allows the user (by clicking on the button) to change some or all of the trajectory points and values without having to reset all of them.

9. Proceed to Procedure button: Allows the user (by clicking on it) to begin the procedure, the trajectory and other data having been communicated to the device upon the completion of this step.

10.Show positioner toggle button helps to toggle between anaethsia and procedure planning,(ref: Figure 4.13c *Show positioner toggle button for anesthesia plan and procedure plan on the scan image)*

The buttons are sequentially activated in order for the planning to be performed in the set order. During the planning, the user may wish to evaluate certain other parameters on the scanned image. The scrolling tool bar on the image window contains tools that enable the user to make the requisite calculations and evaluations relevant to the case and procedure. The tools in the tool bar are indexed in the image below. The image also shows the computed trajectory as it appears on the image screen.

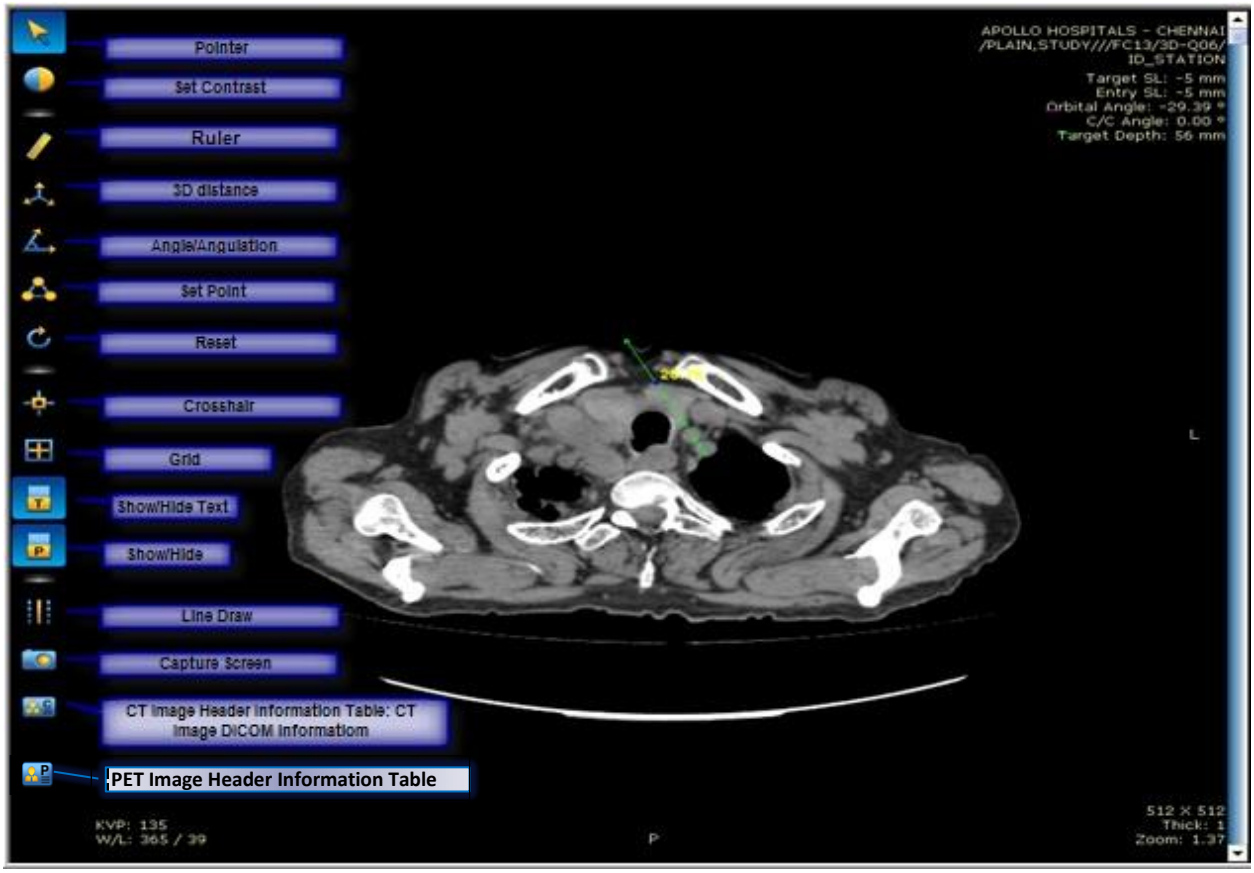


Figure 4.15 *Tool bar icons and their functions*

1. Pointer: Pointer tool can be used for the selection of objects and tool by clicking on.

2. Window Level for CT image: Select tool and left click in the Trackball/ Mouse and scroll up and down, left and right sides in the 2D views to adjust the required brightness.

3. Ruler: Select the tool, right click in the Trackball / Mouse and move the cursor to the desired point to measure the distance.

4. 3D Distance: 3D Distance tool to measure the distance between two points in three-dimensional space.

5. Angle: Select the tool, right click in the Trackball / Mouse and move the cursor to the desired point to measure the angle.

6. Set Point: 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.

7. Reset: Select the tool to revert the last step.

8. Crosshair: Marker used to show an exact point.

9. Grid: The grid is used as a reference to measure and align structures in the image.

10. Show/Hide Text: Select the tool to show or hide the text of the patient details in image area.

11. Show/Hide: Select the tool to show or hide the robot arm in image area.

12. Line Draw: Draw a line parallel to the length of the needle

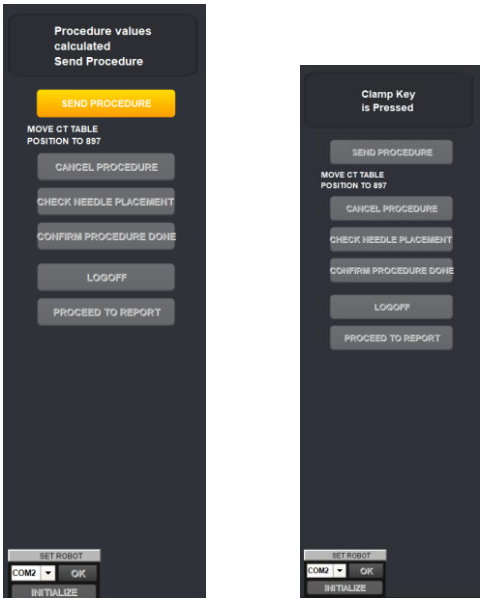
13. Capture Screen: Select the tool to capture the screen. The captured screen is saved in the root folder under the name "Captured Images".

14. CT Image Header Information Table: DICOM header information of the loaded and selected CT image series.

15. PET Image Header Information Table: DICOM header information of the loaded and selected PET image series.

4.2.5 Procedure Execution Screen

Clicking the "Proceed to Procedure" opens the Procedure Execution screen. The procedure execution screen contains all of the components of the main screen, differing only in the task pane elements. The procedure execution task pane contains functions that enable the planned procedure in terms of the plotted points of the trajectory to be communicated to the device in order to position the device arm for marking and insertion of needle. The figure that follows shows the task pane as it appears on the screen during two distinct steps for which indications and prompts will be provided. These panels are shown as it appears during the positioning and clamping stages.



A **B**

Figures 4.16 *Procedure execution panel during (A) CT/PET-CT table positioning and (B) Needle clamping*

The functions of the keys are indicated within the application and are self-explanatory. The applicable buttons or elements may be highlighted during the relevant steps of the procedure to indicate user input or step status. For verification of needle placement, the "Check Needle Placement" button will enable the user to implement a scan of the needle position within the patient.

Once the procedure is satisfactorily completed, the user may click on the "Confirm Procedure Done" button which will be activated for use. To proceed to create and generate a report, the user must click on the "Proceed to Report" button.

4.2.6 Report Generation Screen

Clicking on the "Proceed to Report" button invokes the report generation window which displays user-entry form. The form appears as in figure below.

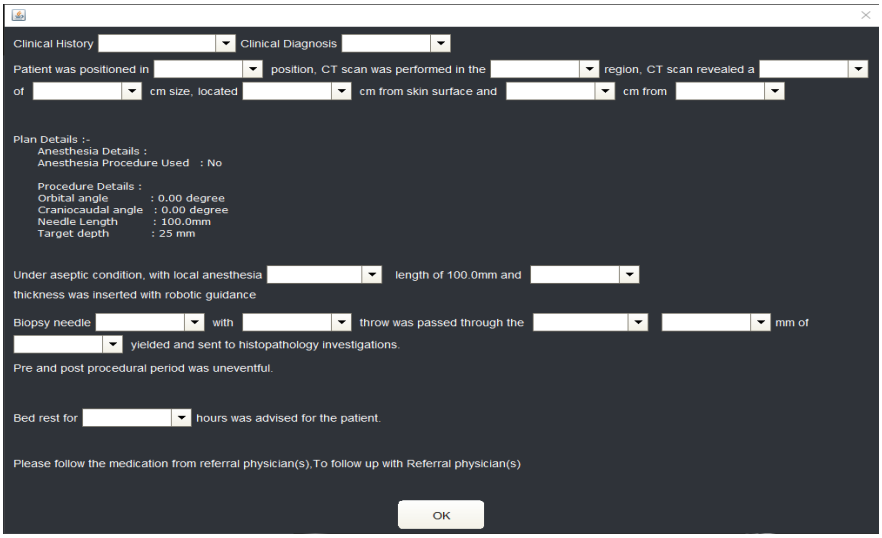


Figure 4.17 *Report generation form with user input fields with drop-down presets.*

Once the input fields are filled, the "OK" button is clicked on to invoke generate report functionality in the task pane. The "Generate Report" pane appears as in the below figure.

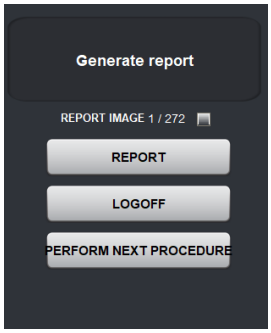


Figure 4.18 *Generate Report pane*

The final step of the procedure is the generation of the report. The "Generate Report" pane allows the user to select the image for which the report is to be generated, click the "Report" button to view and save the report output, to "Logoff" or to "Perform Next Procedure" by clicking on the respective buttons. The generated report appears as in the figure below. However, the user cannot perform the "Save" and "Print" options in the report window.

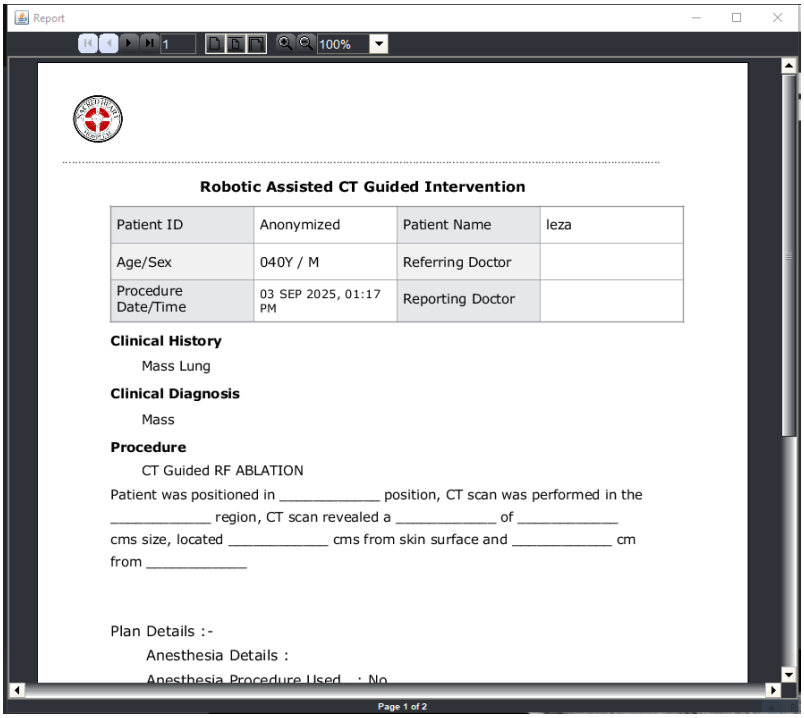
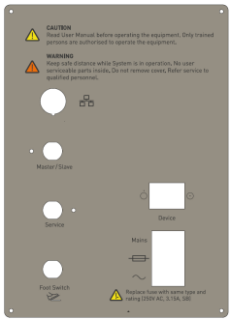


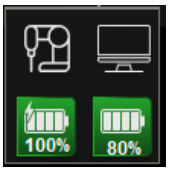
Figure 4.19 *Report of procedure and procedure findings*

5. Procedure Workflow

This chapter describes the procedural workflow for the various interventional procedures indicated for the use of the machine.

5.1 Setting up ROBIO

1.	Wipe the EE using spirit and Povidone-Iodine before every procedure.	Figure 5.1 
2.	(a) Connect the line power, data cable and foot switch. Switch on the line power. Check for line power indication. (b) Connect the connector aligning the cut and rotate to lock.	Figure 5.2a  Figure 5.2b 
3.	(a) Switch on the device. Look for the device ready status displayed in LCD. (b) The line power LED glows green in case of input power else no LED indication	Figure 5.3 

4.	Displays the battery icon indicating the current charge level of the batteries. Two battery indicators are shown: • Device Battery • PC Battery	 Figure 5.3a
5.	Open ROBIO application in integrated console. Login the application from user name and password Confirm availability of communication with the device and CT/PET-CT system.	Figure 5.4 
6.	Fill all the desired details required for Procedure type, CT/PET-CT station, and CT/PET-CT side. Check for calibrated pattern image in the application.	 Figure 5.4a

5.2 ROBIO Initialization

ROBIO system needs to be initialized after every switch ON. Device initialization can be done from the control key or application. Initialization is a onetime process. Any number of procedures can be performed after successful device initialization

Press Initialize/Home key in the control panel to initialize the device. Initialization can be also done from the "Initialize" button in console.



Figure 5.5 *LCD display after device initialization*

Note : *Always connect ROBIO with the hospital power supply. (UPS)*

5.3 Patient Preparation

Prepare the patient using Immobilizer Bed as follows:

Patient Immobilizer Bed setup:

1. Keep the Immobilizer Bed on the CT/PET-CT table at the appropriate location with the air inlet valve of the bed located at the left side of the CT/PET-CT gantry near the end of the CT/PET-CT table.
2. Connect one end of the air hose with bed and the other end with the compressor port of the pump.
3. Connect the immobilizer bed pump to power and switch on.
4. Inflate the bed using the pump in such a way that the beads are loose and free flowing.
5. Switch off the pump and remove the air hose from bed.
6. Connect the air hose, one end with bed and the other end with the vacuum port of the pump.
7. Hold the bed around the patient and tie with the provided straps, in such a way it embraces the patient around the sides.
8. Switch on the pump; wait till the bed becomes rigidly 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.

5.4 Patient Positioning

ROBIO system supports all patient positioning protocols for Head first. Please refer to Quick Reference Card for details. Use Patient Immobilizer bed to avoid patient movement during the entire procedure.

While positioning the patient following care must be taken to:

- Always position the patient region of interest within the ROBIO range as indicated by the ROBIO range sticker on the CT/PET -CT table.
- Use the Patient Immobilizer Bed to avoid patient movement during the entire procedure; and make sure that the bed does not interfere with the region of interest on the patient's body.

Notes and Cautions

NOTE	*In case of bulky patients, keep the table height at lower position to a position within the device height.*
NOTE	*Always position the patient's region of interest below the ROBIO range sticker on the CT/PET-CT cradle.*
	*Patient movement may necessitate re-scanning. The clinician should monitor patient movement more closely when performing any procedure close to vital organs.*

5.5 Device Docking

Docking is the positioning and locking of the ROBIO device on a predetermined side of the CT/PET gantry. Docking involves device registration and position fixing. Calibration will be performed for a device and its associated CT or PET-CT station by the service personnel. For subsequent device positioning and fixing, the following steps have to be followed:

- Before docking, ensure that the rubber plug is removed from the InstaReg Plate.
- Wheel the device on to the InstaReg plate.
- Look for the IntaReg pattern in the application (calibrated pattern).
- The device has four pairs of housing on the InstaReg plate. Each housing holds a docking sphere.
- Position the device such that all the guide marks on the Instareg plate are aligned with the housing holder of the device.
- Docking is a two-step process. Press the "Dock" button on the control panel. As the docking progresses gently guide the machine to more closely align with the guide marks. Machine docks at first step. Please do minor adjustment if necessary. Press "dock" button again to complete the docking. If the device is positioned and guided correctly it will rest smoothly on the locating holes without any sound or jerk. If any jerk found, re-dock again without moving the unit.
- Look for live InstaReg pattern, which will merge with calibrated pattern.
- Check for all indicators status on bottom right corner turns green.
- If the device docks with a jerk undock the device and dock again.

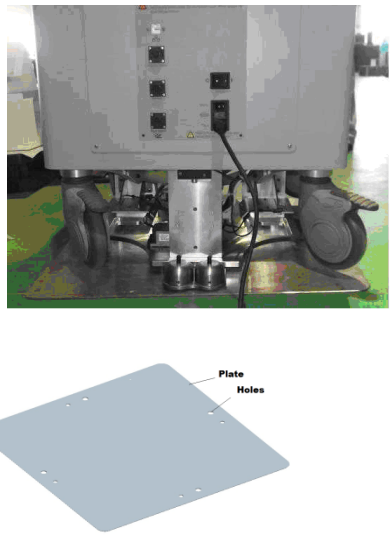


Figure 5.6 *Docking using Instareg plate*

Cautions and Warnings

⚠	*During device docking check if the InstaReg plate is firm. Do not perform procedure in case of loose docking. Call Perfint service centre for repair.*
⚠	*Proper device docking is necessary for system accuracy. Refer to the feedback mechanism to confirm proper docking.*
⚠	*Do not move or place any other device on or over the plate.*
⚠	*Keep the holes in the plate clean*

5.6 Patient Scan and Image Transfer

Scan the patient as per the CT/PET-CT scan manufactures instruction. Ensure that the patient does not move during and after the scan, if required using commercially available patient immobilizer bed. Always set the image view to radiology view before scan.

Imaging protocol for CT and PET-CT

Use the following imaging protocol when scanning the patients for ROBIO

Slice Thickness: 1mm – 5mm

- Scan using the thinnest possible slice thickness. A one millimeter (1mm) slice provides the best spatial accuracy.
- Scan using the same slice thickness throughout.

Slice Spacing: Contiguous

- No overlapping slices
- 1 mm interval

Patient Positioning: HFS, HFP, FFS and FFP for SIEMENS, GE and TOSHIBA

HFS only for PHILIPS

Scan Plan: Helical / spiral

Acquisition: Helical only, no Axial.

Gantry Tilt: None (must be zero)

Algorithm: Standard

Matrix: 512x512 (Must be a Square Matrix)

Field of View: Large enough to include the entire Organ of Interest (transverse and spinous process without off centering the patient in the gantry)

Maintain the same FOV for the entire scan

Recon Do the recon with X=0 and Y=0, for GE, PHILIPS and SIEMENS

X=256 and Y=256 for Toshiba (no offset images)

PET image parameters

Matrix 128x128 for GE(whole body protocol)

128x128 for SIEMENS(regional protocol-Abdomen/Chest)

Default settings for PHILIPS (144x144)

FOV Maximum possible FOV

Note First send the CT series and load it, then transfer PET series and Load

Scroll the images up and down to check image fusion before proceed for planning

-- 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.

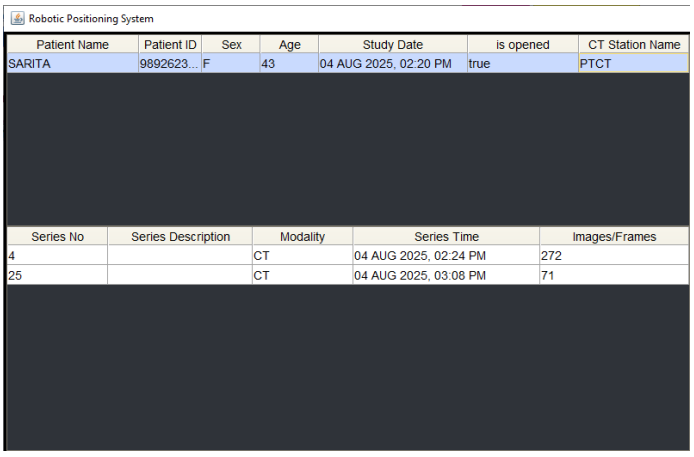
NOTE: It is the responsibility of the ordering physician to discuss the scan requirements with the radiologist on duty. It is the radiologist's final decision as to the actual scan parameters for each individual patient

Cautions and Warnings

⚠	*Undetected image centering offset may result in wrong device positioning.*
⚠	*Scan only the required area. Large number of images takes longer transfer time.*
⚠	*No gantry tilt scanning is allowed.*
⚠	*Thinner the slices better the accuracy. Recon at 1mm is recommended.*
⚠	*CT/PET view to radiology view.*
⚠	*Please do not use BIOPSY RX mode*

5.7 Image Loading

The scanned image can be pushed to the device either before logging in or after. If before, the transferred image series will be loaded automatically into the viewing screen immediately after login. If not, depending on the images required, the user may either click on the "Load Image" button or "Patient Browser" button to invoke the "Patient Browser" window (see Ch.4).
From the browser window, the required image series has to be loaded manually through a series of steps.

1.	From the patient list, if there are multiple patients, click on the patient for whom the procedure is required. This will open a list of all the image series of the selected patient.	Figure 5.7 
2.	From the patient scan series listed, double-click on the line containing the desired image series. This will load the desired image series on the image display screen.	

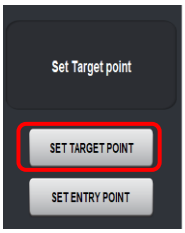
3.	Confirm the (R0, A0) or X-Y centering values for the series loaded from the CT/PET. (Confirmation window will not be displayed if the values are as per the protocol.)

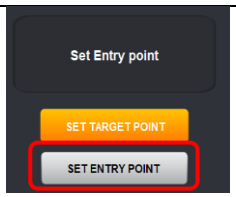
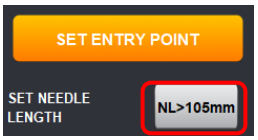
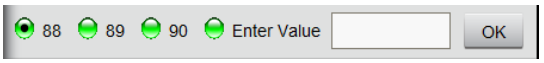
Notes

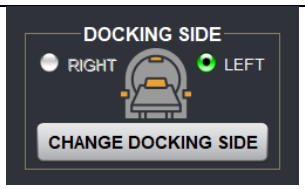
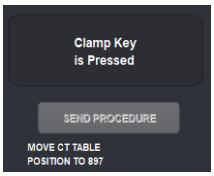
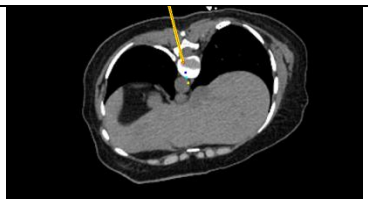
NOTE	*If the modality selected for the procedure is CT/PET or if there are preexisting PET images, the "Load PET Images button" will appear on the task panel. Clicking on the button will similarly invoke the browser window.*
NOTE	*If there is only a single series for a given patient, double-clicking on the patient line will load the associated image series on the screen.*

5.8 Procedure Planning

5.8.1 BIOPSY, FNAC & ABLATION

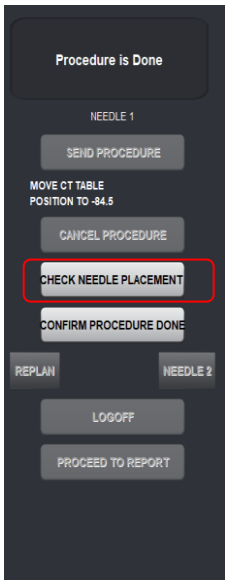
1.	(a)Click on the "Set Target Point" button in the task bar. (b)Click on the "Point" tool from the tool bar and mark the target point on the image on the image display screen. (Always mark the target point at the centre of the lesion/region of interest. Use the 1cm, 1.5cm, 2cm biopsy gun throw points as reference to mark the target points for biopsy.)	Figure 5.8a  Figure 5.8b 
2.	(a)Click on the "Set Entry Point" button on the task bar. **For ablation**, entry point can	Figure 5.9

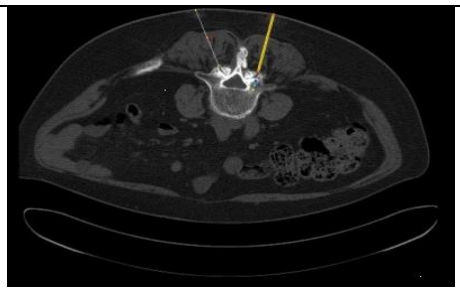
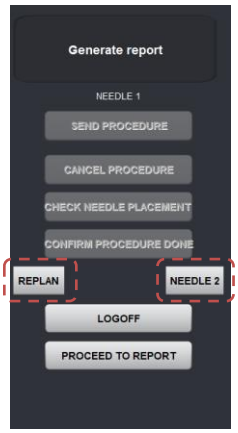
	be below target point. (b)Click on the "Point" tool (Refer fig 5.7b) from the tool bar and mark the entry point (skin surface) on the image on the image display screen.	
3.	(a) Click on minimum-needle-length button to "Set Needle Length". (b)Choose and set length by clicking on the appropriate radio button.	Figure 5.10a  Figure 5.10b 
4.	(a)Click on "Set Anesthesia" button to set the point on the image. (b) Click on minimum-needle-length button to the "Set Anesthesia Needle Length". (c) Set length by clicking on the appropriate radio button.	Figure 5.11a  Figure 5.11b 
5.	Click on "Confirm Trajectory" to confirm the needle length values; Click on "Clear Trajectory" to clear all values and points for the trajectory and re-plan, or Click on "Edit Trajectory" to change some values or points for the trajectory.	Figure 5.12a  Figure 5.12b 
6.	Click on radio button for docking side selection based on planning. Click on "Change Docking Side", if the procedure requires change in docking side.	Figure 5.13

		
7.	Click on "Proceed to Procedure" to send values to the device and commence procedure.	Figure 5.14 
8.	Set CT/PET-CT cradle to the specified position before starting the procedure	Figure 5.15 
9	Click on the "Check Needle Placement" button in the procedure task pane.	 Figure 5.30
10	User can see the previous plan and check scan on the transferred images.(CT/PET-CT Workflow)	 Figure 5.31

Notes and Cautions

NOTE	*ROBIO reach depends on the CT/PET-CT and patient profile. Extreme end for bulky patient may not be within range for all sites.*
NOTE	*Ensure selection of appropriate docking location in the application by looking at the label provided on the CT/PET-CT, L and R.*
⚠	*Do not plan ablation procedures close to vital structures. Always plan giving enough clearance to avoid any harm.*

PAIN MANAGEMENT		
If more than one needle has to be placed for the pain management procedure, the user should plan the new procedure on the check scan image obtained after the first needle placement. Care should be taken to make sure that the second needle trajectory does not collide with the needle already placed on the patient. Also, care should be taken to make sure the robotic arm does not collide with the already placed needle. This can be verified by observing the "Show Positioner" (schematic of the robotic arm) obtained upon confirming the second needle trajectory.		
Plan for Needle One **Follow the instructions provided for trajectory planning and positioning in section 5.8.1 above.**		
⚠	*Please check the trajectory for first needle after executing and before planning for the second needle.*	
Plan for Needle Two		
1.	Click on the "Check Needle Placement" button in the procedure task pane.	Figure 5.16 
2.	Transfer the scanned image to ROBIO console by following the instructions provided in sections 5.6 and 5.7 for transferring and loading the series.	
3.	User can see his/her previous plan and check scan on the transferred images. Now the user can plan for the second needle on that selected series	Figure 5.17

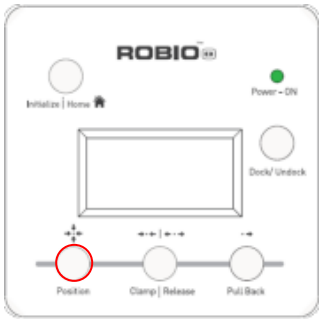
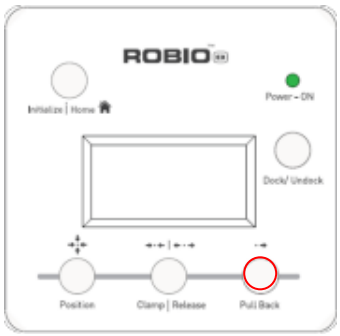
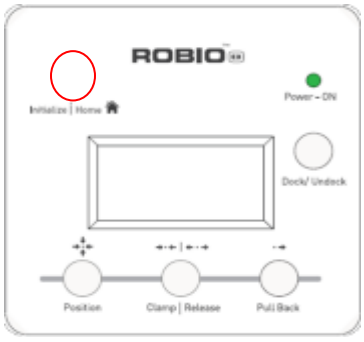
	of images	
4.	Select needle 2 to plan for second needle or needle 1 to re-plan for first needle, follow same procedure and instructions used for first needle.	Figure 5.18 

Note

NOTE	*Perfint recommends the use of ROBIO as a guidance/assistance tool to deliver anesthesia precisely in the planned trajectory. However, the user is free to deliver anesthesia manually as well.*

5.9 Positioning for Procedure

1.	Move cradle to the table top position displayed on the LCD and ROBIO planning station.	Figure 5.19 

2.	Prepare the patient's skin for the procedure.	
3.	Press Position key to position for anesthesia.	Figure 5.20 
4.	Insert the bush and press EE key to clamp the bush. (See Fig 1.2)	
5.	Insert needle for anesthesia. Ensure that the patient is asked to hold breath before needle insertion.	
6.	Press EE key to release the needle from ROBIO after full needle insertion. Push the bush and bush adapter down after releasing the EE and prior to pulling the device back. Press Pull back key for X and Y release **The release avoids inadvertent pulling out of needle during device pull back and gives clearance for the physician to perform post needle placement activities and avoids any accidental patient hit during cradle movement.**	Figure 5.21 
7.	Press Home key to Switch to procedure(Needle position)	Figure 5.22 
8.	Repeat all the above steps for the procedure.	

	Ensure the table is moved to the cradle value displayed for the procedure (needle positioning).

Notes and Cautions

NOTE	*In case of abnormal patient movement when the needle is held by the End effector pull out the needle to avoid any injury.*
⚠	*Cradle should be moved to the value displayed on the LCD every time device is positioned. Wrong cradle positioning will lead to wrong positioning of the needle.*
⚠	*Keep hand away from CT/PET gantry controls. Accidental pressing of gantry controls may lead to wrong positioning.*
⚠	*Crosscheck the cradle value in LCD with the display in ROBIO planning console.*
⚠	*Do not change the table height during the procedure. Be cautious while moving the cradle.*
⚠	*Ensure the bush is clamped tightly by the End effector before inserting the needle.*
⚠	*Insert the needle to full length.*
⚠	*Ensure that the needle does not sag and is not pulled out during X release and device pull back.*

5.10 Needle Insertion with ROBIO

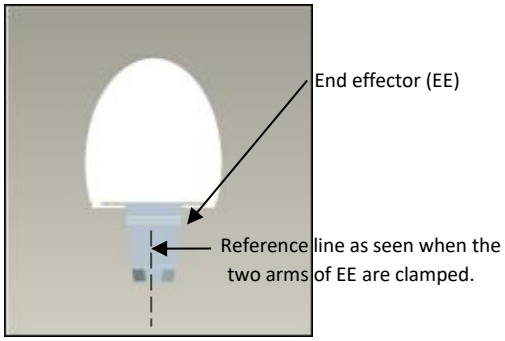
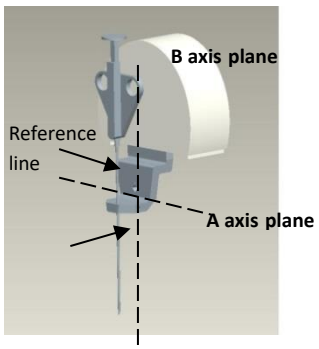
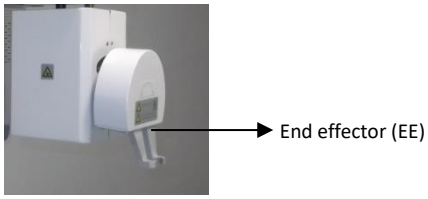
The robotic arm positions the needle guide (Bush) above the patient body as per the clinician plan.		
1.	Instruct the patient not to move or fasten the patient using the immobilizer, before start of the procedure. Place the appropriate bush with bush holder and press "EE" button to close the End Effector	
2.	Advance the anesthesia needle manually through the needle guide (Bush) such that it stops short of the skin surface, to help clinician determine the entry point.	Figure 5.23a 

		Figure 5.23b  Figure 5.23c 
3.	Deliver the local anesthesia manually around the point indicated by the anesthesia needle over the skin surface, in a circular fashion.	Figure 5.24 
4.	Make a knick on the skin for large bore needles	
5.	Instruct the patient to hold breath. Insert the needle manually through the bush into the skin. Ensure that the needle does not get deflected during insertion. Instruct the patient breath normal.	
6.	Press "clamp/release" button to release the needle from the end-effector	
7.	Caution: Before pull back, Please push down and rotate the adaptor away from end-effector"	

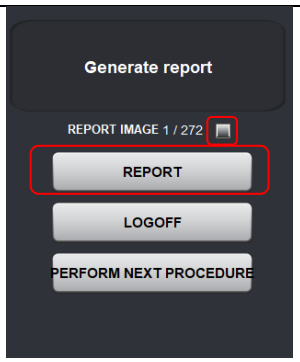
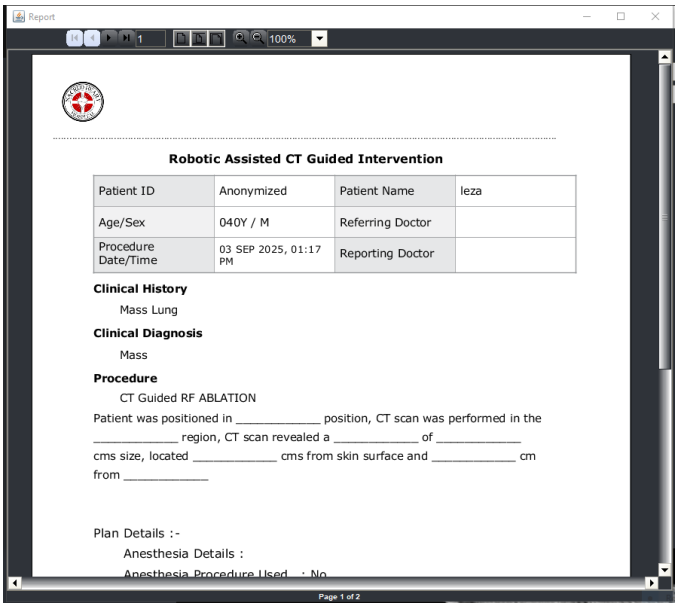
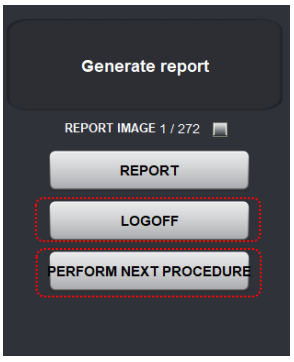
8.	Press “pull back” button to pullback the axis away from patient

Notes and Cautions

NOTE	*Always use the reference line on EE as shown in fig: 5.23b*
NOTE	*Hold the needle on top and insert such that it is parallel to the reference line.*
⚠	*Do not bend the needle during insertion.*
⚠	*Caution: Before pull back, Please push down and rotate the adaptor away from end-effector"*

5.11 Procedure Report Generation and Completion

1.	After the completion of the procedure, click on the “Proceed To Report” button on the Procedure task pane.	Figure 5.25 
2.	Enter the requisite details in the Patient Report form so invoked. Click “OK” to proceed to the next step.	Figure 5.26 
3.	On the Generate Report task pane, select the “Report Image (x/y) square radio button, and click on the “Report”	Figure 5.27

		
4.	The procedure report is generated. It contains the procedure details and observations there from.	Figure 5.28 
5.	On the Generate Report task pane, the user may choose either to "Log Off" or to "Perform Next Procedure"	Figure 5.29 

6. System Parking and Transporting

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

6.1 Moving the Device

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

Before moving the system performs the following steps:

1. If the device is in the docked condition:

   Press the "Dock/Undock" switch on the Control panel, where upon the base plates goes up and the docking wheels comes down. Move ROBIO away from CT table.
2. Press the Home key to position the device in HOME POSITION
3. Shut down the console
4. Disconnect all cables. To prevent damage to the Power Cord, DO NOT pull excessively on the cord or makes sharp bends while wrapping.
5. Unplug the power cord (if the system is plugged in).
6. After undocking, ensure that the rubber plug is placed back onto the InstaReg Plate.

Notes and Cautions

NOTE	*Equipment has to be parked and transported in the Home position for an Angle greater than 10 degree from the ground level.*
NOTE	*In case of any damage during device movement/transport, call Perfint Service Centre*
NOTE	*When moving the system, Special attention must be taken care about End effector during device movement or transport. End effector may get damaged due to accidental hits.*
	*Do not move the device on more than 10 deg inclined plane. The Device may topple.*
	*DO NOT unplug and/or transport the unit until switched off. Failure to do so may result in operational hazards.*
	• *Always use the handle to move the system.* • *Avoid scraping or collision of the device with other devices and building structures— the system weighs about 200 kg.*

	• *Limit movement to slow walk.*
	*Bring the device to the HOME Position before moving the Device*
	*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 deg.

6.2 Parking the Device

When not used, ROBIO is to be parked in the parking area defined by the customer in the CT/PET-CT room. The parking area should be a 3x3 feet free area at any corner at the CT/PET-CT room having a 5A power socket for battery charging. Also a 3 feet path from the parking to docking area must be maintained. See figure below for recommended parking of device.



Figure 6.1 *Parking position*

Steps to be followed for parking:

1. Position in the device in HOME POSITION for parking by pressing Home key
2. Move the equipment to the parking lot and properly park the equipment.
3. Lock the castor wheels.
4. Connect the machine to the 5A power socket for battery charging.

6.3 Transporting the Device

Use extra care when transporting the system using vehicles. In addition to the instructions used for moving the system also perform the following:

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 or as directed to prevent motion during transport.

7. User Maintenance

This chapter contains information about system specifications, user assistance details, and system care and maintenance.

7.1 Technical Specifications

7.1.1 Usage Specifications

S. No.	Parameter	Values
1.	Compatible Modality	CT and PET-CT
2.	Imaging Interface	DICOM 3.0
3.	Needle Positioning Accuracy	*2mm radius sphere at a needle length of 120 mm on specification-moving phantom
4.	User Interface	Integrated PC

Table 7.1 *Usage specifications listing parameters and values*

7.1.2 Physical Specifications

S. No.	Parameter	Values
1.	Height	1800mm(Max)
2.	Width	750mm(Approx)
3.	Depth	1080mm(Approx)
4.	Weight	Approx 200Kg(Approx)
5.	Max. Allowable floor incline during mobility	5 °, device in home position
6.	Positioning of the device with respect to CT/PET -CT system	Thin plate docking

7.	Device Controls	Control panel switches and foot switch for procedure functionality.

Table 7.2 *Specification of physical parameters and their values*

7.1.3 Electrical Specifications

S. No.	Parameter	Values
1.	Mains Voltage	100 - 240 V
2.	Line frequency	50 /60 Hz
3.	Length of power cable	For India: 8 Meters with Indian power plug For other countries: IEC Extension power cord of length 5M and Country Specific power cord of length between 1.5 to 3M
4.	Power usage	300W
5.	Mains Isolation External: done by the user	Power supply cord shall be plugged where both poles (L & N) are isolated simultaneously.

Table 7.3 *Specification of electrical parameters and their values*

7.1.4 ROBIO Console

Parameter	Status
Compliance to IEC standard 60601-1 & 60601-1-2	Compliant

Table 7.4 *Console certification*

7.1.5 Mechanical Specifications

S. No.	Parameter	Values
1.	Mobility	Castor wheels (4 with lock)

2.	Degrees of Freedom	4 DOF
3.	x range Max	450 ± 10mm
4.	y range Max	Min 440 ± 10mm
5.	Orbital(L-R)	Min ± 95° Required
6.	Cranio/caudal	Min ± 90 ° Required

Table 7.5 *Specification of mechanical parameters and their values*

7.1.6 PC Specifications

- **Teguar PC TM-5557-22**

S. No.	Parameter	Values
1.	Operating system	Windows 10 Pro
2.	System configuration	All-in-one PC 22" LCD Screen resolution: 1920 x 1080 (Full HD) Intel core™ i5-7300U CPU @ 2.60GHz, 8GB RAM and internal storage of 512 GB
3.	Storage temperature	-20°C to 40° C
4.	Operating temperature	0°C to 40°C

Table 7.6 *Specification of software parameters and their values*

- **Onyx PC Mate2-2210**

S. No.	Parameter	Values
1.	Operating system	Windows 10
2.	System configuration	All-in-one PC 22" LCD Screen resolution: 1920 x 1080 (Full HD) Intel core™ i5-9500U TE CPU @ 2.20GHz, 8GB RAM and internal storage of 1TB
3.	Storage temperature	-20° to 60°C
4.	Operating temperature	0°C to 35°C

- **Onyx PC Mate-2405**

S.No.	Parameter	Values
1.	Operating system	Windows 10
2.	System configuration	All-in-one PC 24" LCD Screen resolution: 1920 x 1080 (Full HD) Intel core™ i5-9500U TE @ 3.60GHz, 8GB RAM and internal storage of 512 GB
3.	Storage temperature	-20° to 60°C
4.	Operating temperature	0°C to 35°C

- **Onyx PC Mate2-2412**

S.No.	Parameter	Values
1.	Operating system	Windows 10

2.	System configuration	All-in-one PC 24" LCD Screen resolution: 1920 x 1080 (Full HD) Intel core™ i3-13100U TE @ 4.5GHz, 8GB RAM and internal storage of 512 GB
3.	Storage temperature	-20° to 60°C
4.	Operating temperature	0°C to 35°C

7.1.7 Needle Guide (Compatibility) Specifications

S. No.	Parameter	Values
1.	Gauge	22, 21, 20, 19, 18, 17, 16, 14, 13, 11
2.	Material	Polycarbonate
3.	Sterilization	ETO sterilized– single use

Table 7.7 *Specification of needle guide parameters and their values*

7.1.8 Needle Specification

S. No.	Parameter	Values
1.	Gauge(G)	22, 21, 20, 19, 18, 17, 16, 14, 13, 11
2.	Length(mm)	200(Max)
3.	Material and Manufacturer	Standard rigid needle, any make

Table 7.8 *Specification of needle parameters and their values*

7.1.9 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

Table 7.9 *Specification of environmental parameters and their values*

7.1.10 Safety

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

Table 7.10 *Specification of safety parameters*

7.1.11 Device Classification

S. No.	Classification	Description
1.	Class I & Internally powered	Type of Protection against Electric Shock
2.	Ordinary Equipment	Degree of Protection against Ingress of water
3.	Equipment not suitable for use in the presence of flammable mixtures	Degree of safety in presence of flammable anesthetic mixture with air, oxygen or nitrous oxide
4.	Continuous operation with Intermittent loading Maximum Loading Time: 2 minutes	Mode of Operation
5.	Group 1 Class A	CISPR 11 ISM Classification

Table 7.11 *Device classification and description*

7.2 System Care and Maintenance

7.2.1 Overview

There are no user serviceable / repairable parts in the device. Users are advised to call the service representative in case of any observations of non-function or damage. Contact the local Service representative for parts or for periodic maintenance inspections.

7.2.2 Inspection and Maintenance

Examine the following before every procedure:

- Connectors on cables for any mechanical defects.
- Entire length of electrical and power cables for cuts or abrasions.
- Equipment for loose hardware.
- Castor wheels for proper locking operation.

Notes and Cautions

NOTE	*The equipment must be inspected before every procedure. Preventive maintenance should be done every six months. The PM record must be kept for the same.* *For any repairs, please contact Perfint Service Centre.*
	*To avoid electrical shock hazards, do not remove panels or covers from the machine. There are no user serviceable/repairable parts inside the device.*

7.2.3 System Cleaning

Prior to cleaning any part of the system turn off the system power. If possible, disconnect the power cord.

Operator Control Panel

To clean the operator control panel:

1. Moisten a soft, non-abrasive folded cloth with a mild, general purpose, non-abrasive soap and water solution.

2. Wipe down operator control panel.

LCD Display

To clean the monitor face:

1. Use a soft, folded cloth. Gently wipe the monitor face.
2. Do NOT use a glass cleaner that has a hydrocarbon base such as Benzene, Methyl Alcohol or Methyl Ethyl Ketone on monitors with the filter (anti-glare shield).
3. Hard rubbing will also damage the filter.

PC Battery usage instruction:

1. Operating time of the battery is min 20 to 30 mins.
2. Battery to be charged before use if the device is idle for more than 2 months.

Note

NOTE	*When cleaning the screen, make sure not to scratch the LCD.*

End Effector

Clean the End effector before every procedure.

To clean the End effector, follow these steps:

1. Moisten a soft, non-abrasive folded cloth with a mild, general purpose, non-abrasive soap and water solution.

2. Wipe the external surfaces of the unit then dry with a soft, clean cloth.

3. For End effector sterilization and for at most patient care, the surfaces can be wiped with a sterilizing solution.

4. Sterile drape covers should be used in order to reduce the risk of patient infection

Cleaning the Patient Immobilizer Bed

1. Moisten a soft, non-abrasive folded cloth with mild, disinfectant/Germicidal cleaner.

2. Wipe the bed gently with this wet cloth in the areas where blood stains are present after performing the procedure.

3. Let the bed dry before the next procedure by rubbing with a dry cloth.

4. The cleaner used should be CFC free Aerosol.

Needle Bushes

Needle bushes compatible with ROBIO are supplied only by Perfint. User should sterile before using them for any procedure. Needle bushes are for single use only.

Caution

	*Use appropriate needle bushes supplied by Perfint. Failure to do so may result in erroneous positioning and risk of patient safety.*

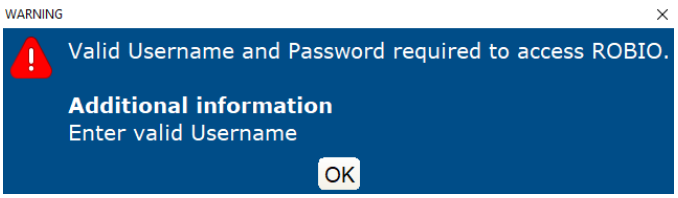
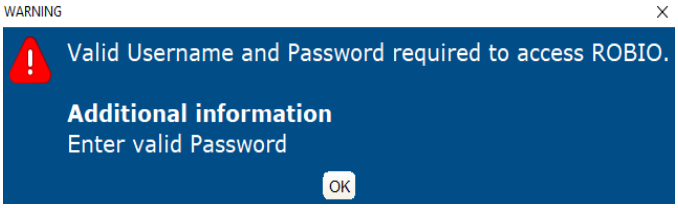
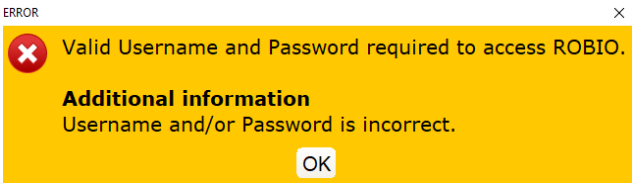
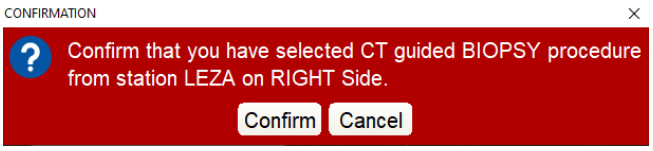
7.2.4 Disposal

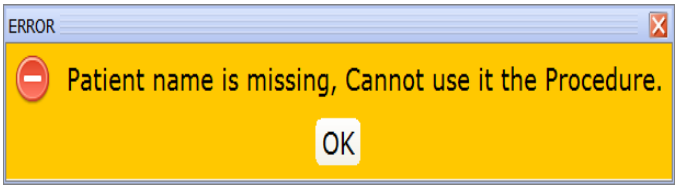
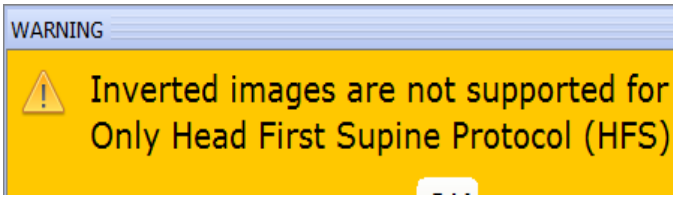
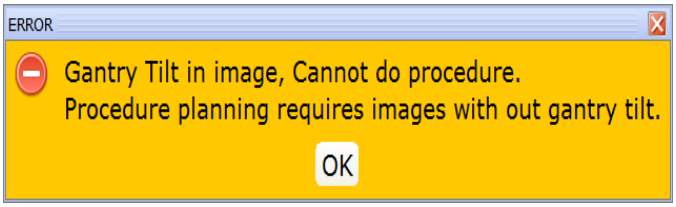
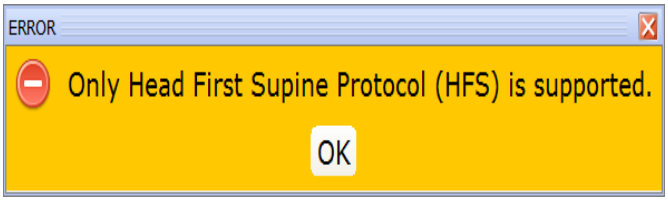
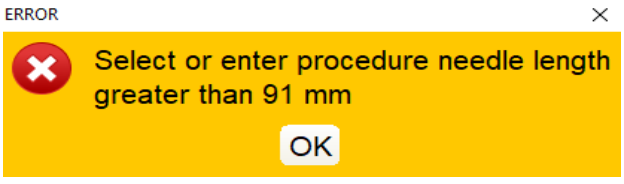
The service lifetime of the device is 7 years.For device disposals after the device has completed its lifespan, send the device back to the manufacturer. Should it not be possible to return the device, dispose of the device and its accessories as per WEEE (Waste Electrical and Electronic Equipment) guidelines (2002/96/EC).

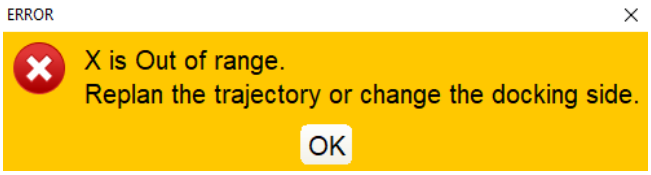
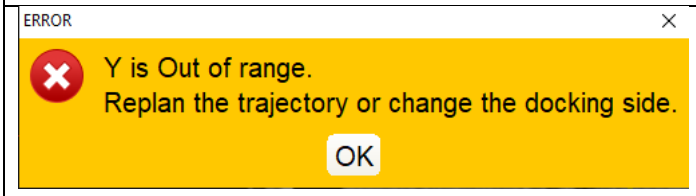
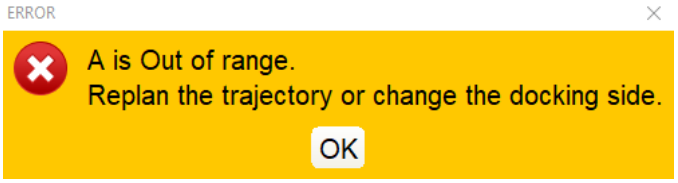
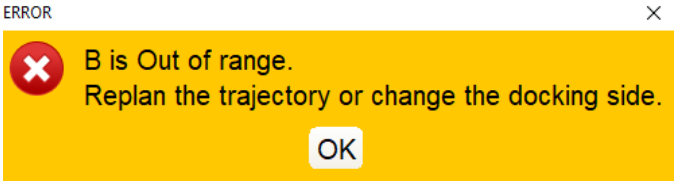
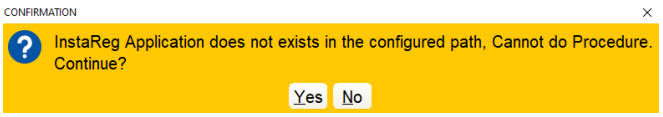
Appendix

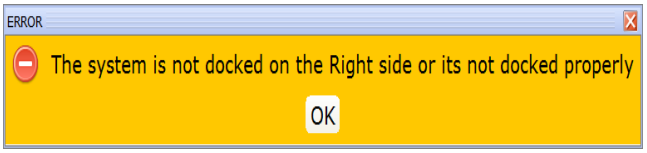
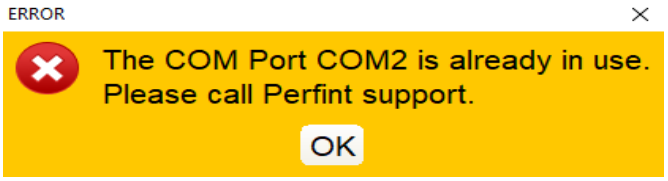
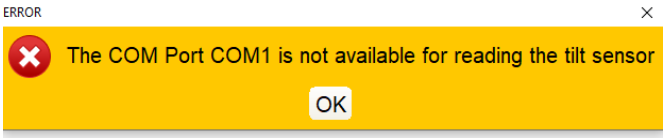
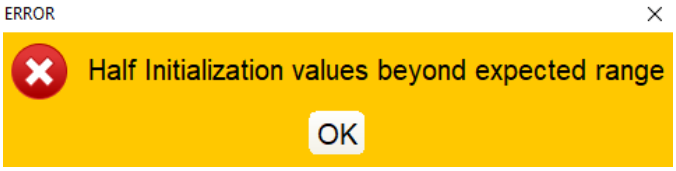
This section contains data and information that supplement the information in the chapters, to facilitate correct and proper usage of the ROBIO system.

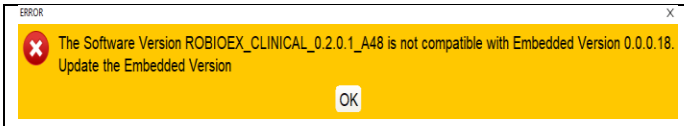
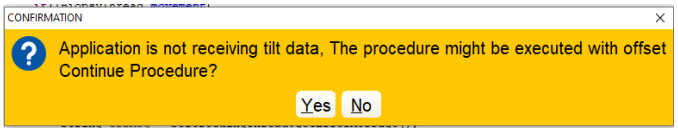
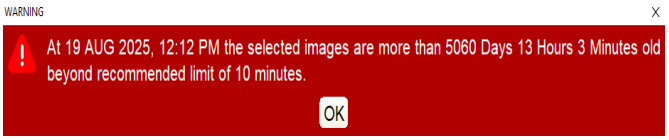
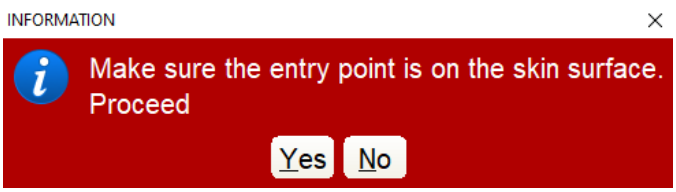
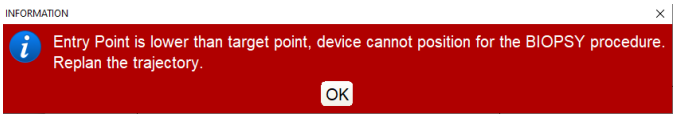
I Application Popup Messages

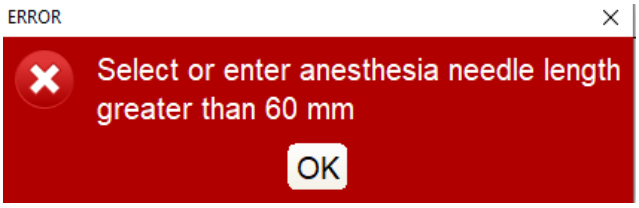
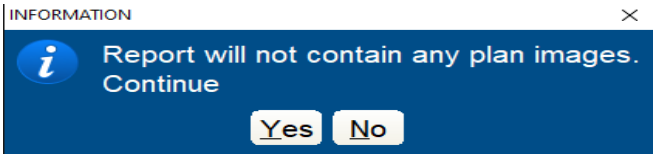
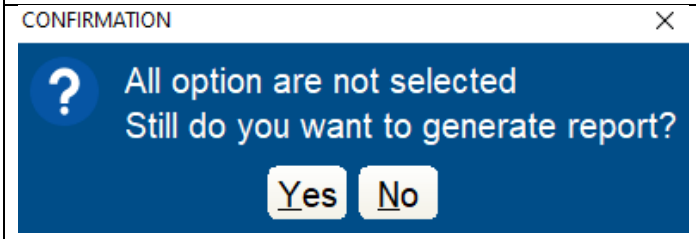
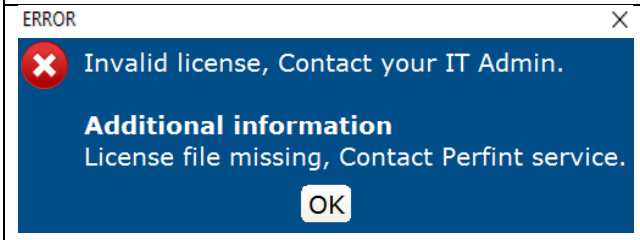
	Empty User Name
	Empty Password
	User Name/Password is invalid
	Confirmation of the selected Procedure Image Guidance, Station Name and docking side.

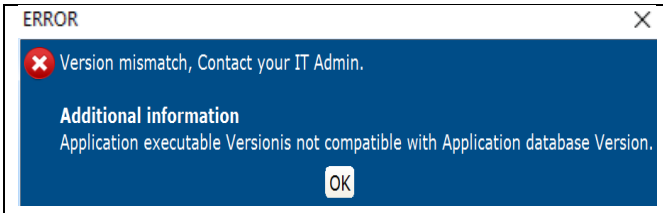
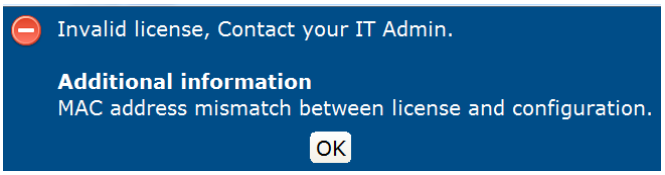
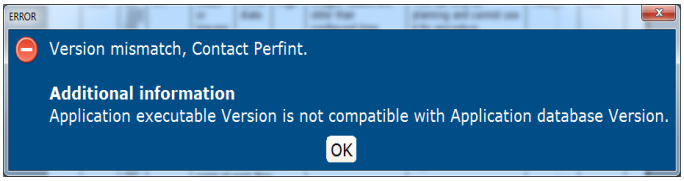
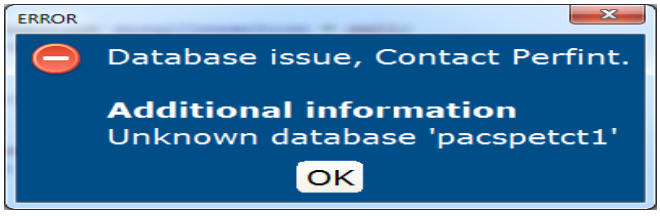
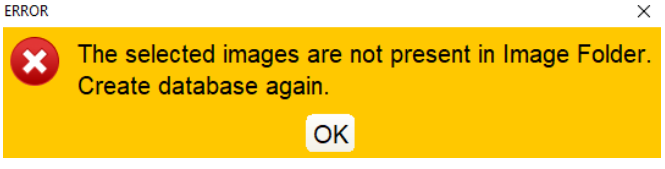
	Patient name is missing
	User tries to load inverted images.
	User tries to load images with gantry tilt.
	User tries to load image other than that are taken with HFS
	Selected applicator length not sufficient for trajectory plan.

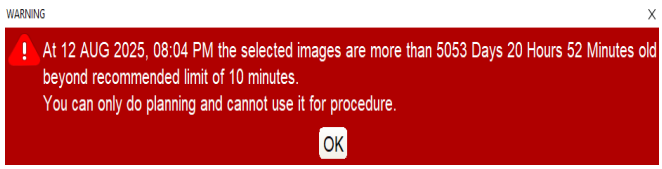
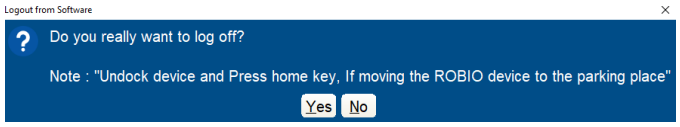
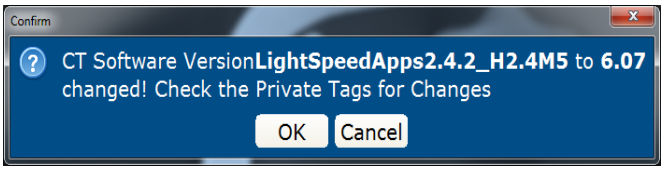
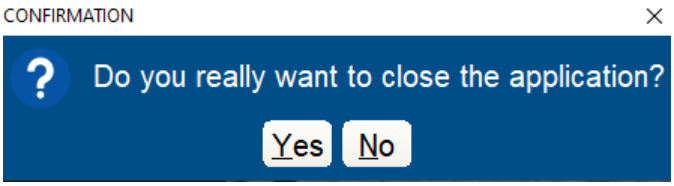
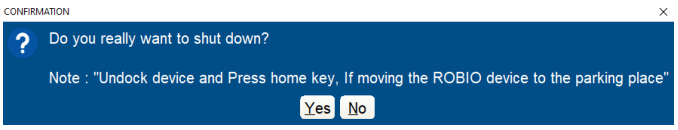
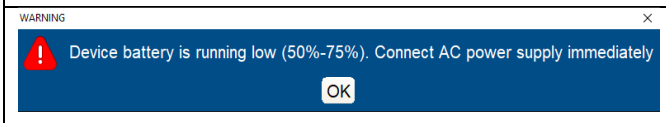
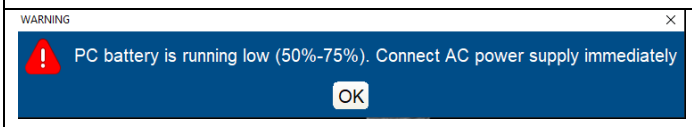
	Planned probe is X out of range
	Planned probe is Y out of range
	Planned probe is A out of range
	Planned probe is B out of range
	Docking application not present in the path defined
	Confirmation of change of docking side from Right to Left.
	Confirmation of change of docking side from Left to Right.

	I Docking offset is more
	Confirmation of station name and docking side before sending the procedure
	Application already running in the system
	Device is docked outside the docking range
	Serial Port not available
	Half initialization values beyond expected range
	Software and embedded version mismatch

	
	Tilt sensor is not working
	Image series older than the configured time is selected
	Confirmation for planning
	Intersection happen while planning
	During Planning choosing entry point below target point

	Anesthesia requires greater needle/applicator length
	The Entry and Target points are not within the check scan image range
	The Entry points are not within the check scan image range
	The Target points are not within the check scan image range
	Create report without selecting image
	Filter details in report generation
	License file not available

	License file invalid due to software version mismatch
	License file invalid due to MAC address mismatch
	Application executable version and application database version mismatch.
	Database error
	Images not available

	Images loaded are older than configured time
	Do you really want to log off
	Software version mismatch
	Close App button is clicked
	Shut down button is clicked
	Device AC Power Switch off
	PC AC Power Switch off
	Device Battery Percentage below 75%
	PC Battery Percentage below 75%

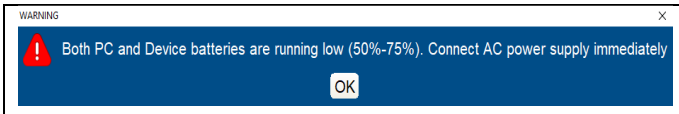
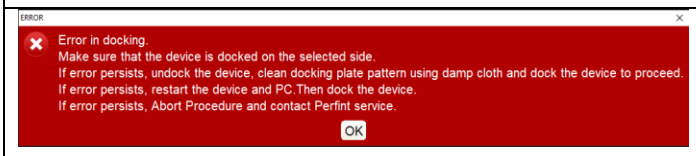
	Both Device and PC Percentage below 75%
	Device Battery Percentage below 50% and Continuous beeps
	PC Battery Percentage below 50% and Continuous beeps
	Both Device and PC Battery Percentage below 50% and Continuous beeps
	Error in Instareg while trying to Confirm the Probe.

Table A-1Pop-up messages

II Message Windows

ROBIO GUI message window shows all error conditions of the device. In the absence of any errors, it acts as a real time user guidance tool for planning and executing the procedure.

The message window messages are grouped as:

1. Error messages
2. Warning messages
3. User information

II.I Error Messages

All error messages are indicated in the Top left corner of the application, as shown in the figure below.

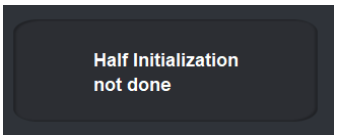


Figure A-1 Error message

II.II Warning Messages

All device-related warning is logged in the message box. The warning messages can be viewed only after clearing all the error conditions.

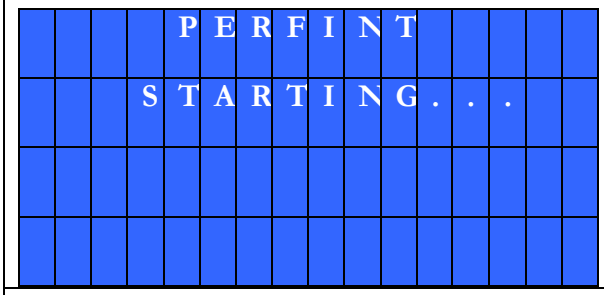
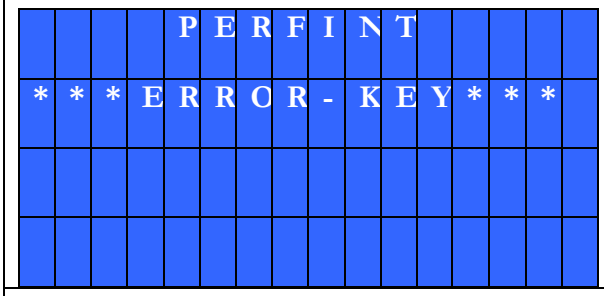
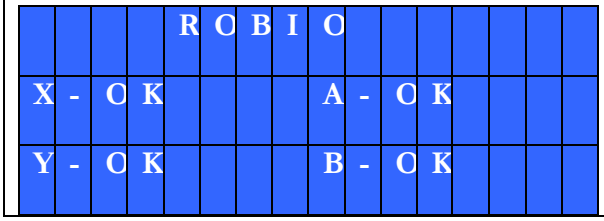
II.III User Information

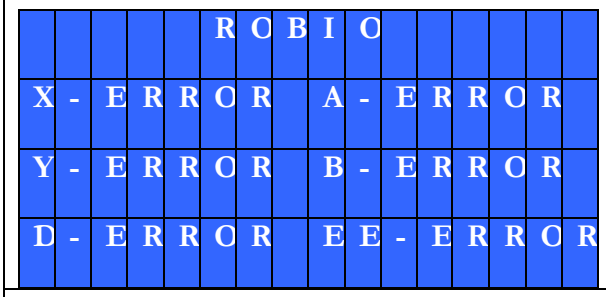
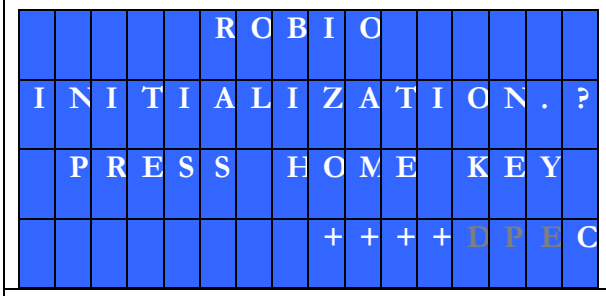
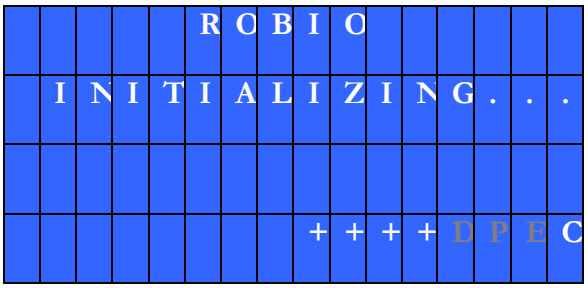
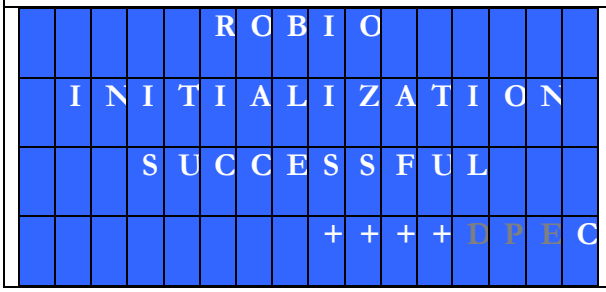
Real-time application help in the form of tool-tips provide guidance for using the application. The tool tips appear when the user rests the mouse or cursor over an active screen element, indicating its use. A tool tip appears as in the figure below.

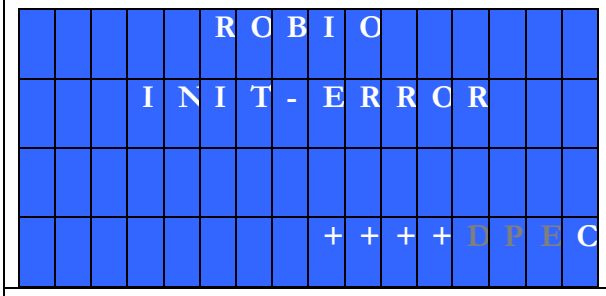
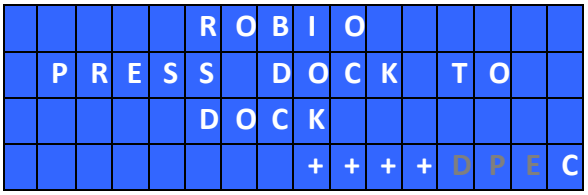
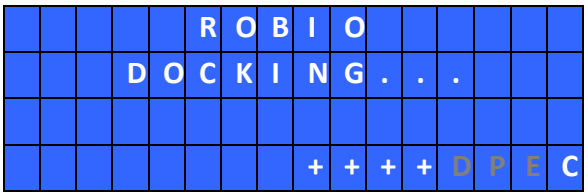
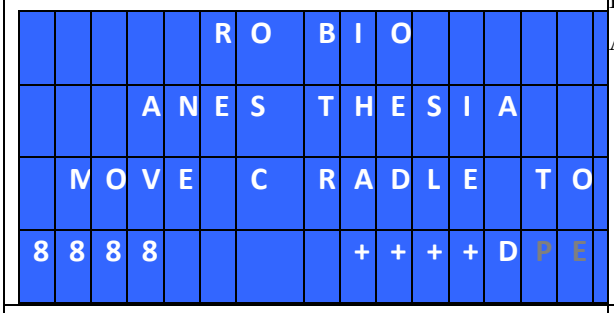
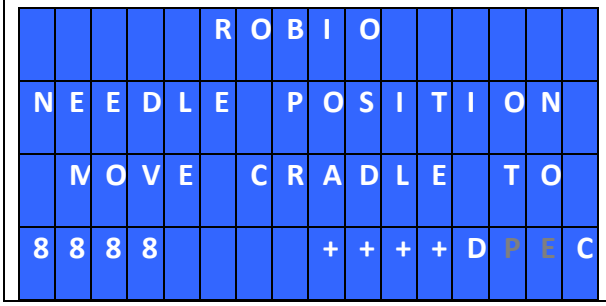


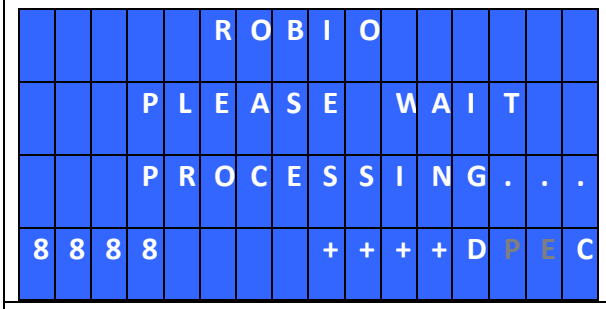
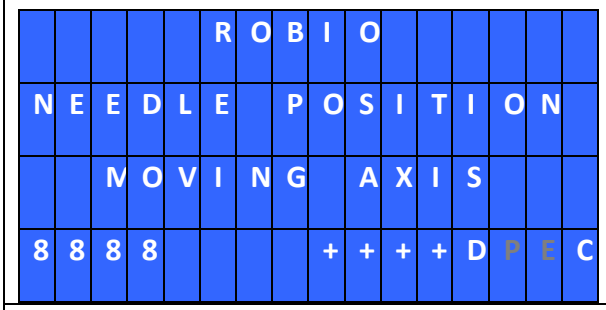
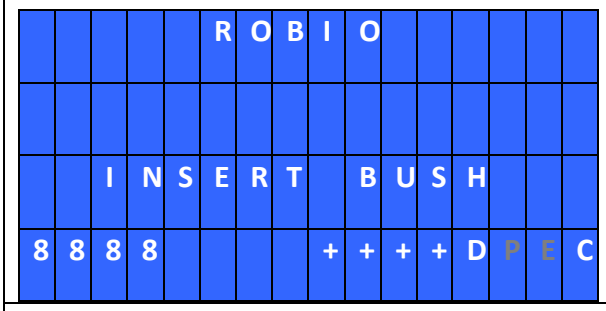
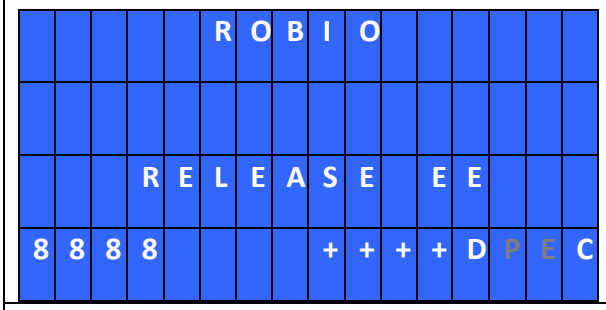
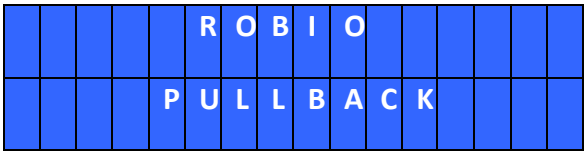
Figure A-3 Tool tip

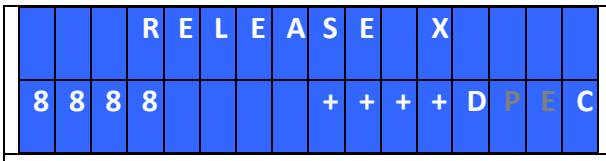
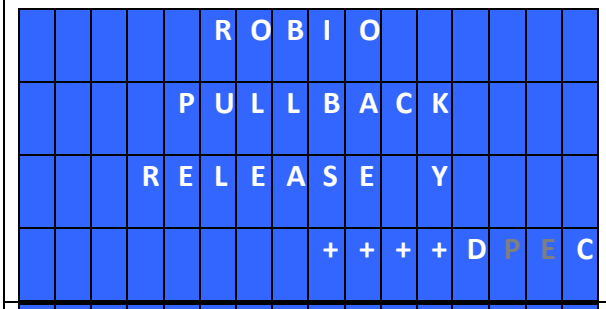
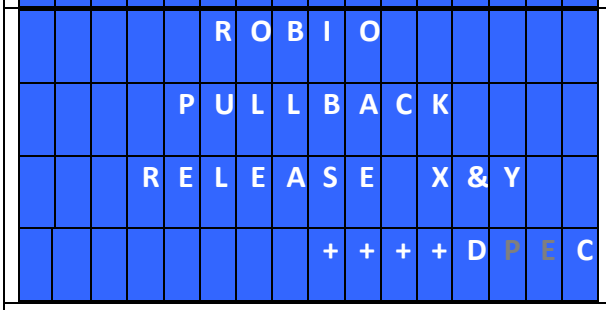
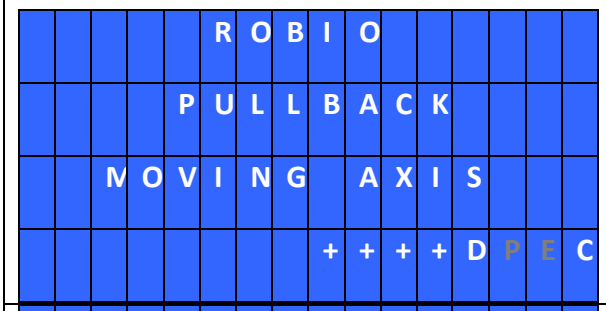
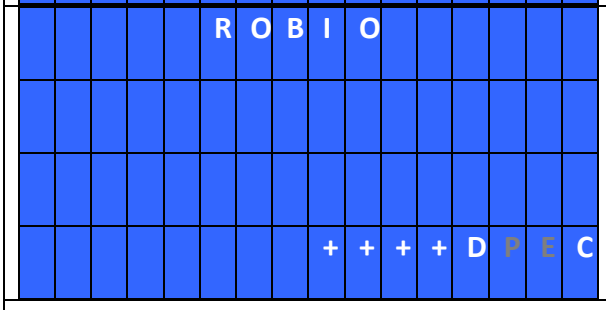
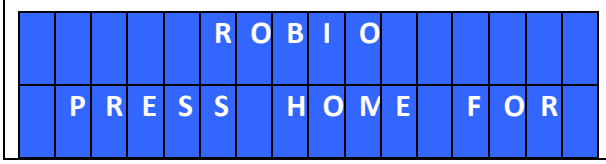
III Messages in Control Panel

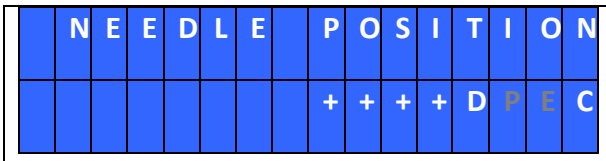
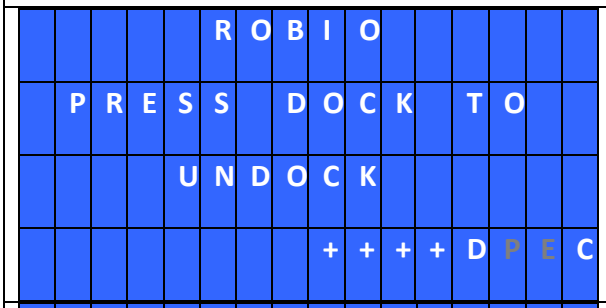
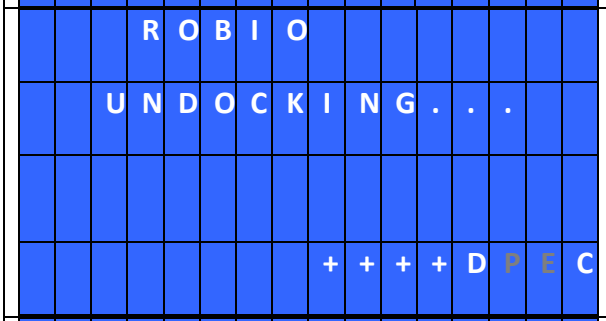
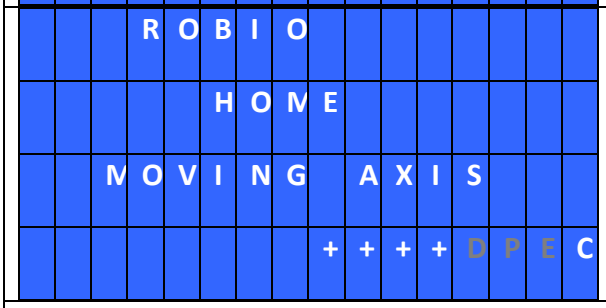
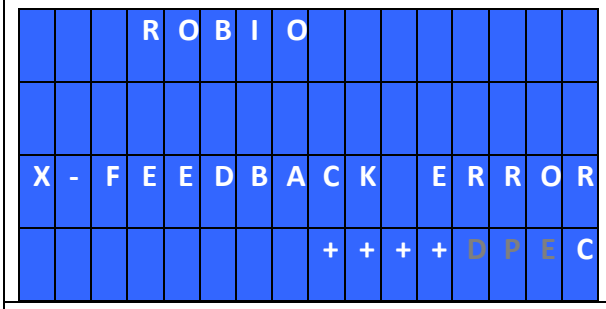
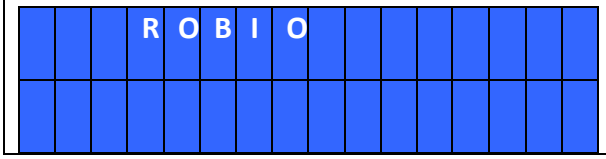
Messages/Display	Alarms		Comments
	Audio	Video	
	Beep 3 times.	—	ROBIO Start-up screen.
	High Priority Alarm	—	Indicates emergency switch is in pressed state on device power on. **Recovery Mechanism**: Release emergency switch and power off and on only device.
	—	—	Indicates successful POST status.

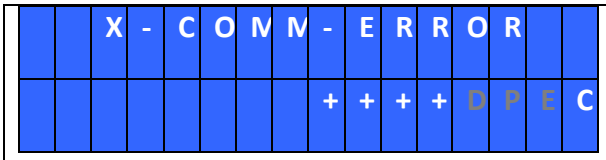
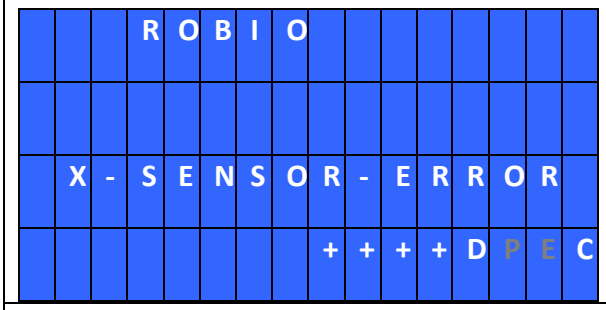
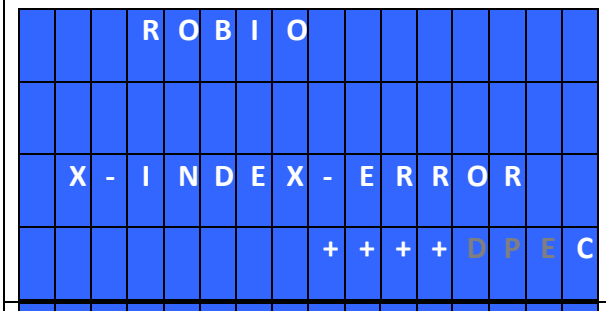
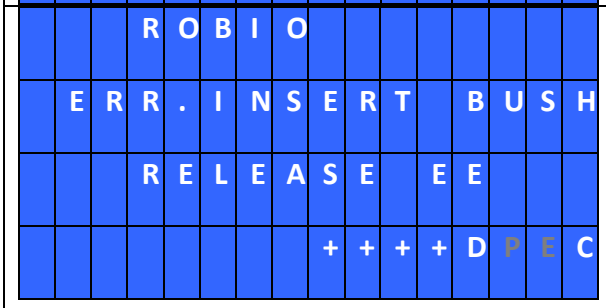
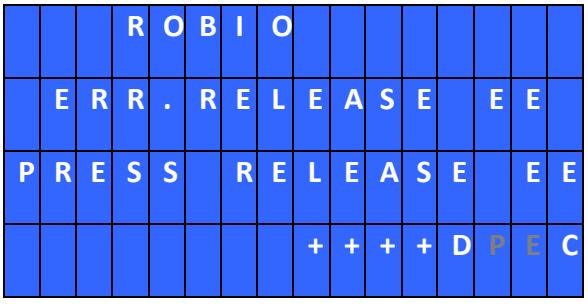
			
	Low Priority Alarm	—	Indicates POST fail of respective axis: **Recovery Mechanism:** • Restart the system. • If the error persists call Perfint Service Centre
	—	—	Indicates device is ready for Initialization.
	—	—	Indicates device is moving to reference position.
	—	—	Successful Initialization: • Indicates device is ready fo positioning..

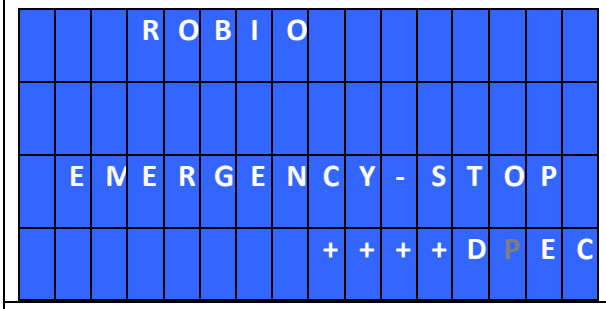
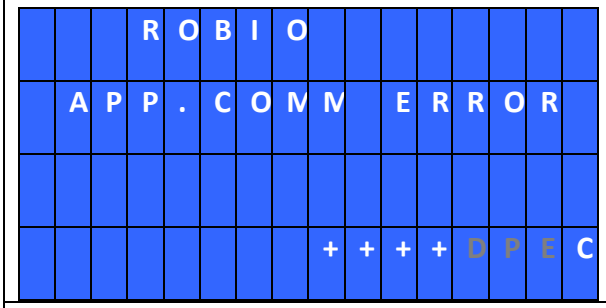
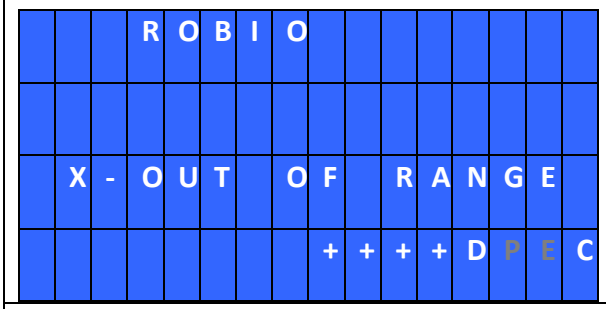
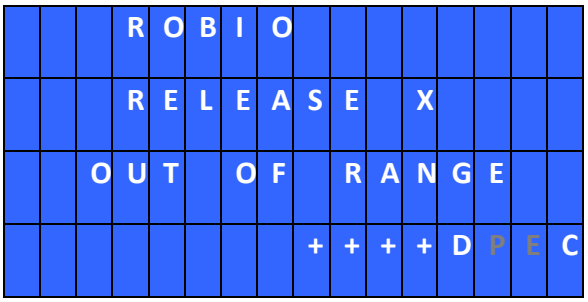
	—	—	Indicates error in moving to reference position. Reinitialize the system. • If error persists call Perfint Service Centre.
	Beeps once	-	Indicates device is ready for docking. Press Dock key to dock the device.
	-	-	Indicates device is moving to dock.
	Medium Priority Alarm	Cradle Distance for anesthesia	Indicates device received position values for the plan an informing the user to move to the defined cradle distance (sa 8888 in the beside LCD message) and press position key for moving the device to the position.
	Medium Priority Alarm	Cradle Distance for needle positioning	Indicates device received position values for the plan an informing the user to move to the defined cradle distance (sa 8888 in the beside LCD message) and press position key for moving the device to the position.

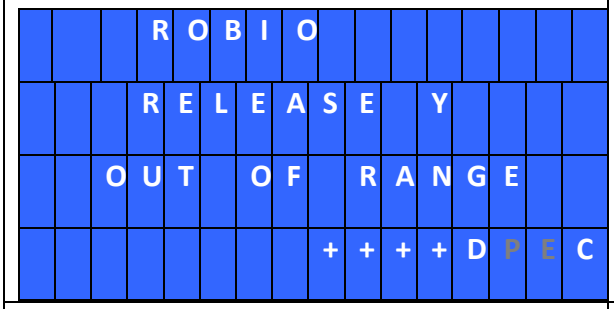
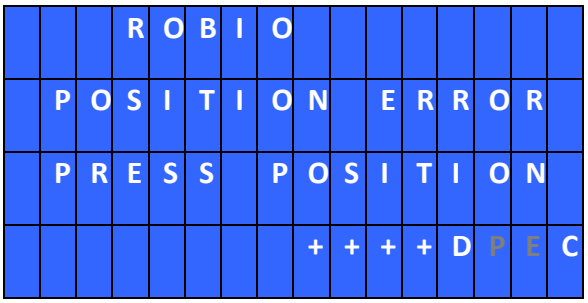
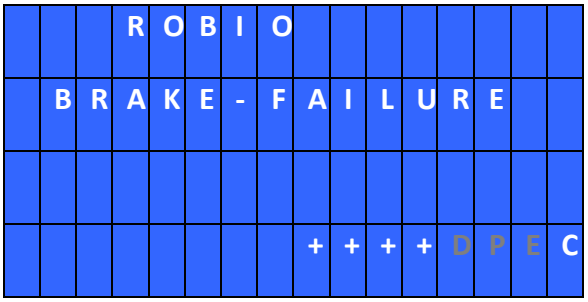
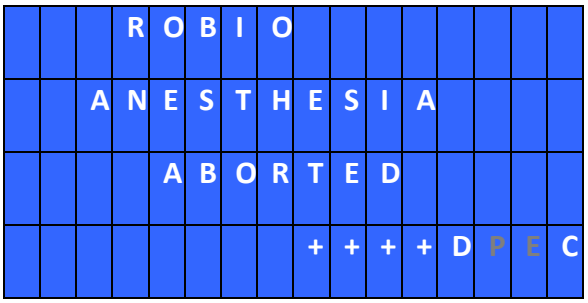
	—	—	Indicates device is cross verifying the values with the software before start of positioning.
	—	—	Indicates device is moving for the requested position values of Needle position plan.
	Beeps Once	—	Indicates to place the needle bush in the EE and press the EE clamp Key to clamp the bush. Device gives a single beep on pressing the EE key.
	Beeps Once	—	Indicates to press EE release key to release the End effector and remove needle from the bush. Device gives a single beep on pressing the EE key.
	Beeps Once	—	Indicates to press pull back key on the device or on the foot switch. X arm moves back by 30mm (default) from needle insertion position. Device gives a single beep on pressing the pullback key.

			
	Beeps Once	—	Indicates to press the pullback key to move up (40 mm by default) Y axis to intermediate Y position and clear the patier for CT/PET-CT scan. Device gives a single beep on pressing the pullback key.
	Beeps Once	—	Indicates to press the pullback key to pull X&Y to their max pullback positions. Device gives a single beep on pressing the pullback key.
	—	—	This message indicates device is moving for either of three pullback steps.
	—	—	This message is indicated in idle state of the device.
	—	—	Indicates to press Home key t switch the plan from anesthesi to needle position or vice vers

			
	Beep once	-	Indicates device is ready for undocking. Press dock key to undock the device.
	-	-	Indicates device is moving to undock.
	—	—	Indicates device is moving to home position for parking.
ERROR MESSAGES: 	Medium Priority Alarm	—	Device Error: **Recovery mechanism:** Power off and power on the device. If still error persists ca Perfint Service Centre.
	Medium Priority Alarm	—	Device Error: **Recovery mechanism:** Power off and power on the device. If still error persists ca Perfint Service Centre.

			
	High Priority Alarm	—	Device Error: **Recovery mechanism:** Power off and power on the device. If still error persists cal Perfint Service Centre.
	Medium Priority Alarm	—	Device Error: **Recovery mechanism:** Power off and power on the device. If still error persists cal Perfint Service Centre.
	Medium Priority Alarm	—	Device Error: **Recovery mechanism:** Press EE key until it shows Press pull back, Release X message and continue with pu back Y and pull back X&Y, then Power off and power on the device. If still error persist call Perfint Service Centre.
	High Priority Alarm	—	Device Error: **Recovery mechanism:** • Press EE key until it shows Press pull back, Release X message and continue with pull back Y and pull back X&Y, then Power off and power on the device. If stil error persists call Perfint Service Centre.

	High Priority Alarm	—	Emergency is triggered: Release the emergency key, press dock to undock the device and move the device away from the patient or release emergency key, perfor initialization and then continu for planning.
	Medium Priority Alarm	—	Indicates loss of communication between devic and software. Please check communication cable and if error persists call perfint service center.
	—	—	Indicating X position value is more than the device movable value. Modify and resend plan.
	—	—	Indicating pull back X is more than device movable value. Modify and resend plan.

	—	—	Indicating pull back Y is more than device movable value. Modify and resend plan.
	Medium Priority Alarm	—	Indicates error in device positioning: **Recovery Mechanism:** Press position key to move to correct position. If problem persists, call Perfint Service Centre.
	High Priority Alarm		Indicates Y brake failure: • Call Perfint Service Centre.
Other Messages: 	—	—	Indicates procedure cancelled during Anesthesia positioning.

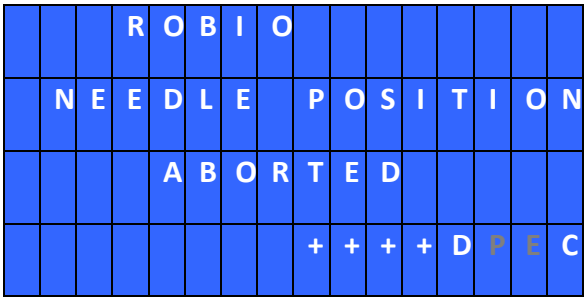
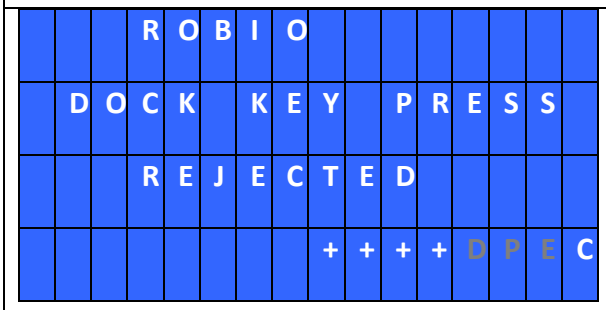
	—	—	Indicates procedure cancelled during needle positioning.
	—	—	This message informs user that device is not ready for undocking/docking as part of work flow.

Table A-2 Messages on control panel LCD screen

IV Warranty Clause

IV.I Scope and Duration of Warranties

Product Warranties

Perfint warrants that ROBIO is:

1. Free from defects in material, workmanship, and title.

2. Conforms to our published product specifications in effect on the date of shipment of the products.

The product specifications are available on request.

Patent and Copyright Warranty

Perfint warrants that when delivered, the products will not be subject to any valid patent or copyright infringement claim. The standard warranty period for all warranties, except the warranty of title, and the patent and copyright warranty, 1 year from the date of install or 15 months from the date of shipment whichever occurs the earliest. The warranty period may be subjected to changes based on the contract.

The warranty period begins Five (5) days after the date Perfint notifies you that it has completed installation and the products are operating in accordance with our published product specifications.

If installation is delayed for 30 days or more after the date of delivery for a reason beyond our reasonable control, the warranty period will begin on the thirtieth day after the date of delivery.

The warranty period for any product or part furnished to correct a warranty failure will be the unexpired term of the warranty applicable to the repaired or replaced products.

Note

NOTE	If a maintenance agreement is desired to extend coverage beyond the manufacturer's warranty, please contact the local service or sales.

IV.II Warranty Exclusions

These warranties are exclusive and in lieu of all other warranties, whether written, oral, expressed, implied, or statutory.

The warranties DO NOT cover:

1. Any defect or deficiency (including failure to conform to product specifications) which results, in whole or in part, from:
   - Any alteration, improper storage, handling, use or maintenance, or any extraordinary use of the products, by anyone other than Perfint.
   - Failure to follow any of Perfint's written recommendations or instructions.
   - Use of the product with products of others or with incompatible Perfint products.
   - Any of our designs, specifications or instructions.

   OR

   Any cause external to the products as furnished by Perfint or beyond our reasonable control.
2. The payment and reimbursement of any facility costs arising from repair or replacement of the products or parts.

Note

NOTE	*No warranty of merchantability or fitness for a particular purpose applies.* *No implied warranties of whatsoever nature for any purposes are provided by Perfint except for the express warranties provided herein.*

IV.III Exclusive Warranty Remedies

Product Warranties

If you promptly notify us of your warranty claim and make the product available for service, Perfint will at its option, repair, adjust, or replace (with new or exchange replacement parts) the non-conforming product or parts of the product. Warranty service will be performed without charge from 9:00 am to 5:00 pm, Monday through Friday, excluding holidays. This warranty shall be available for during the warranty period of one (1) year as set forth in clause IV.1 above.

Patent and Copyright Warranty

Perfint will defend or settle any suit against you to the extent it is based on an infringement claim which would be a breach of patent and copyright warranty. If the infringement claim is valid, Perfint will pay all damages and costs awarded against you, due to the breach. In addition, Perfint will obtain a license for you to continue using the infringing product, provide a non-infringing replacement, alter the product so that it is non-infringing, or remove the infringing product and refund the price (less reasonable depreciation) and any return transportation costs paid by you. The above describes your exclusive remedies and our sole liability for any warranty claims. You agree that Perfint and our representatives have no liability to you for:

1. Any penal, incidental, indirect, remote, special, or consequential damages such as lost profit or revenue even if Perfint knew or should have known of such damages.

2. Any assistance not required under our quotation.

3. Anything occurring after the warranty period ends.

4. Notwithstanding what is stated above, you agree that the maximum liability of Perfint for any and all damages, losses that may be incurred by you due to or arising out of the product shall not exceed the price at which you purchased the product.

V Post Delivery Checklist

Before shipment from the factory, this product has been thoroughly tested and visually inspected. The product is a fine tuned electronic instrument and should be treated properly during transportation.

To learn about any issues that are discovered at the reception of the package or when unpacking and installing the product, the Post Delivery Checklist has been introduced.

- Please complete the form on the back of this reminder, the Post Delivery Check List, and mail or fax it to our Customer Support Department as soon as unpacked, installed and verified the product.
- If you prefer to use email, you can report your findings in an email and send it to: customersupport@perfinttech.com
- Or, send the signed of copy through the installation engineer.

Packing Box Content

Verify the contents of the box according to the lists below:

ITEM	PARTNAME	QTY
1.	ROBIO	1
2.	DOCKING KIT(Docking mat)	2
3.	SAMPLE NEEDLE BUSHES AND BUSH ADAPTOR	1set
4.	POWER CORDS*	1
5.	DATA CORD SET(485 Cable, 485 line driver USB cable)	1
6.	FUSE	1
7.	MONITOR	1
8	TRACK BALL / MOUSE	1
9	DICOM CABLE	1
10	FOOT SWITCH	1
11	USER MANUAL in English (local language as applicable)	1

Table 3 *Device, accessories, and component check list*

Power cord details:

Hospital grade power cords and plugs supplied with country specific power cords with required regulatory approvals:

- India – ISI (Volex IS6A3)
- Europe – CEE 7 (Std.Sht. XVII), IEC 60884-1
- North America - CSA Std C22.2, UL498UL817
- UK - BS 1363/AStd.122 by A.S.T.A.

And as required for othe

VI Instructions for ETO Sterilization Process

The following are the instructions for ETO sterilization process using ETO 20%:80% CO_2 or 10:90 or 30:70.

1. Pre Humidification:

- Humidification of the material within the chamber should be done using a controlled steam injection from the steam generator through the chamber steam inlet valve.
- Humidity level of more than 30% is required in the sterilizer chamber. (RH: 30% to 70%)

Note

NOTE	Diverse effect of the excessive humidity on the product packing should be considered while setting the upper limit of the RH levels.

Diverse effect of the excessive humidity on the product packing should be considered while setting the upper limit of the RH levels.

2. Pre-Conditioning Temperature:

- Sterilization Material in the closed sterilizer-chamber should be heated up to e.g. 45°C.
- Heating should be done using hot water circulation in a closed loop using a Hot Water Circulating Pump between Hot Water Tank and Sterilizer Jacket.

3. Pre-Conditioning Phase (Hold Time):

- The sterilization Material should be kept under this condition for some time e.g. 30 Mins.

4. Pre-Vacuum Phase (Air Removal):

- The sterilizer chamber should be evacuated for e.g. -0.60 kg/cm.sq. to remove the Air.

5. Vacuum Hold Phase (leak Test):

- The sterilizer should be kept under vacuum of e.g. -0.60 kg/cm.sq. for some time e.g. 15 Min

6. Humidification – Conditioning Phase (RH injection, RH dwell)

- The sterilizer chamber humidity level will get reduced because of initial evacuation (pre-vacuum) and therefore, if required, humidification can be done once again to make up the reduced RH level.

7. Gas Injection Phase (Sterilant Injection):

- Pre heated gas mixture should be slowly injected in to the chamber.
- For the chamber volume of 12000 liter, the preheated gas mixture of 20:80 (ETO: CO_2) of 30 kg should be injected to have 500 mg/liter gas concentration in the sterilizer chamber.
- Vacuum level in the chamber rounds to 1.05 kg/cm.sq.

8. Gas Hold Time (Sterilization – Exposure) Phase:

- The material which is in the chamber with a gas pressure of about 1.05 kg/cm.sq should be kept for 360 mins. for sterilization.
- The temperature should be controlled at 50°C.
- During the sterilization the temperature range across the load should be in the range of 10 °C. (e.g. 45 – 55 °C)

9. Gas Discharge Phase (Exhaust, Vacuum):

- Gas should be discharged slowly through chamber exhaust valve up to 0.05 kg/cm.sq
- The Vacuum pump will discharge the gas from 0.05 to e.g. -0.50 kg/cm.sq.
- This gas from the sterilizer chamber is recommended to be discharged slowly in to the Gas Dilution Tank.

10. Air Break Phase (Vacuum Break):

- Fresh Atmospheric Air should be allowed to get in to the chamber through chamber Air Inlet valve e.g. from -0.50 to -0.05 kg/cm.sq. chamber pressure.

11. Air Washing Pulse – Aeration Phase (Vacuum, Air Inlet):

- To minimize the chamber and product residual gas, the sterilizer chamber should be applied with air washing pulses for e.g. 03 times with Vacuum e.g. from -0.05 to -0.50 kg/cm.sq and Air inlet e.g. from -0.50 to -0.05 kg/cm.sq.

VII EMC Information

Guidance and manufacturer's declaration – electromagnetic immunity- for Non- Life Supporting Devices- REF TEST REPORT BELOW			
The **ROBIO** is intended for use in the electromagnetic environment specified below. The customer or the user of the **ROBIO** 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	Conducted RF IEC 61000-4-6	**Criteria A**	Portable and mobile RF communications equipment should be used no closer to any part of the ROBIO , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 80 MHz to 800 MHz d = 800 MHz to 2,5 GHz where P is the maximum output
Radiated RF IEC 61000-4-3	Radiated RF IEC 61000-4-3	**Criteria A**	

			power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range ***(a)***. Interference may occur in the vicinity ***(b).***

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.

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.

(a) If the measured field strength in the location in which the ROBIO is used exceeds the applicable RF compliance level above, the ROBIO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ROBIO

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

Guidance and manufacturer's declaration – electromagnetic immunity- REF TEST REPORT BELOW

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

IMMUNITY Test	**IEC 60601** **Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**

Electrostatic discharge (ESD)	+/– 6 kV contact +/– 8 kV air	**Criteria A**	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	**Criteria A**	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	**Criteria A**	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	**Criteria A**	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ROBIO requires continued operation during power mains interruptions, it is recommended that the ROBIO be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	**Criteria A**	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions-REF TEST REPORT BELOW		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The equipment 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 ROBIO is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the ROBIO or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	

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/