GALAXY

Instructions for Use

Galaxy System™
Instructions for Use

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Customer Support

Only qualified service personnel should service or maintain hardware components. If you feel that the Galaxy System™ hardware components or associated features or functions do not perform as expected, or they provide results that are inconsistent with your established clinical and research protocols, contact Noah Medical Customer Service at +1-888-325-NOAH (6624).

any particular purpose, title, and noninfringement. Noah Medical Corp. expressly excludes and disclaims such warranties.

This IFU applies to the Galaxy System™ (GAL-001), Galaxy System™ Software version 1.0.2.0 and Galaxy Planning Software 1.0.2.0. The version number can be found in the user menu at the top right of the user interface.

Introduction

This IFU provides information specific to the Galaxy System™. The operating instructions and feature descriptions herein are specific to the software versions listed above.

Anyone who operates, services, maintains, or is otherwise associated with the Galaxy System™ must read, understand, and be thoroughly familiar with the information in this IFU, and take precautions to protect themselves, their associates, patients, and the equipment. At each step in the installation, specific warnings and cautions are given for specific actions.

Noah Medical Corp. reserves the right to revise this publication and to make changes in content from time to time without obligation on the part of Noah Medical Corp. to provide notification of such revision or change.

Intended Use/Indications for Use

The Galaxy System™ and its accessories are intended to provide bronchoscopic visualization of and access to patient airways for diagnostic and therapeutic procedures.

Contraindications

Contraindications include but are not limited to:

- Patients whose general health or respiratory function or both are compromised to the point that the patient would not tolerate flexible bronchoscopy.
- Absence of a trained bronchoscopist to perform or closely and directly supervise the procedure, as well as manage complications common to flexible bronchoscopy.
- Use of the system in patients with electrically or magnetically activated implanted medical devices.

Warnings

A thorough understanding of the technical principles, clinical applications, and risks associated with pulmonary bronchoscopy is necessary before using this device. Additional warnings are detailed throughout this document to describe actions or conditions that could result in injury or death.

Adverse Effects

Complications from bronchoscopy are rare and most often minor, but if they occur, may include bleeding, procedure delay which may result in administration of unplanned additional anesthesia, or fluid in the lungs. It is possible that a bronchoscopic procedure may be unable to be completed and provide results due to device failure. Only rarely do patients experience other more serious complications (for example, infection, collapsed lung, heart attack, and/or cardiac arrhythmia).

Notations

This IFU uses the special notations below to bring attention to important information.

Symbol Descriptions

Symbol	Description
	**WARNING:** Describes actions or conditions that could result in serious injury or death.
	**CAUTION**: Describes actions or conditions that could result in damage to the equipment or minor harm to the user or patient.
	**NOTE:** Provides more information about a subject.

Prescription Device Statement

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

Safety Precautions and Warnings

Safe operation of the Galaxy System™ requires careful attention to the serious hazards associated with use of the device and ways to avoid or minimize the hazards, and familiarity with emergency procedures. Untrained or careless operation of the Galaxy System™ can damage the system, its components, or other property; cause poor performance; or lead to serious bodily injury and possibly death.

Noah Medical Corp. strongly recommends that personnel be trained by Noah Medical on the Galaxy System™ prior to use for research or clinical purposes. Only physicians having adequate training and experience with endoscopic techniques should perform endoscopic procedures.

Users must follow all instructions for use supplied with the system, its components, instruments, and accessories including any instructions for use (IFUs) provided with instruments or accessories. The IFU provided are the primary sources for detailed safety information.

Under the conditions described in the Technical Specifications section, the system may fault in an immobilized state. Follow the directions indicated to return to normal operation.

Check that the Galaxy System™ is configured for safe use according to these instructions prior to each use. Ensure that any instruments used with the system have no unintended rough surfaces, sharp edges, or protrusions that could cause harm.

The Galaxy System™ Bronchoscope is a Type BF applied part - any applied parts of other Medical Electrical (ME) Equipment used with the Galaxy System™ should be at least F-Type applied parts. Leakage currents can be additive when other ME Equipment is used with the Galaxy System™.

Faults and System Messages

Faults, system messages and notifications are described in Appendix A. Follow the directions indicated to return to normal operation.

Disposal

When a Noah Medical reusable component reaches the end of its useful life and your facility desires to remove the device, contact Noah Medical Customer Service to uninstall and appropriately dispose of the components.

When disposing of instruments, accessories, or any of their components, follow all applicable national and local laws and guidelines.

Regulatory Compliance with Directives and Standards

The Galaxy System™ and accessories have been tested for compliance to the following standards:

Regulatory Compliance Standards

Standard Number	Standard Title
AAMI/ANSI ES60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.
IEC 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
IEC 60601-2-18	Medical electrical equipment – Part 2-18: Requirements for the basic safety and essential performance of endoscopic equipment.
IEC 62366	Medical devices -- Application of usability engineering to medical devices.
ISO 15223-1	Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements.
ISO 14971	Medical devices -- Application of risk management to medical devices.
ISO 11135	Sterilization of health-care products – Ethylene Oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices.
ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems.
ISO 11607-2	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.

ISO 10993	Biological evaluation of medical devices.
ISO 8600-1	Endoscopes -- Medical endoscopes and endotherapy devices -- Part 1: General requirements.
ISO 8600-3	Optics and optical instruments -- Medical endoscopes and endoscopic accessories -- Part 3: Determination of field of view and direction of view of endoscopes with optics.
ISO 8600-4	Endoscopes -- Medical endoscopes and endotherapy devices -- Part 4: Determination of maximum width of insertion portion.
BS EN 1041	Information supplied by a manufacturer of medical devices.
BS EN 556-1	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices".
ANSI/AAMI/ISO 14937	Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices.
CSA 22.2 NO 60601-1:14	Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance.

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Table of Contents

1 Safety Information and Technical Description

This chapter provides information that is essential for the safe operation, transport, and storage of the Galaxy System™. This chapter covers the following sections:

CAUTION: Do not modify this equipment. Modification of this equipment may result in injury to users or patients and may void product warranties.

Installation of this system is to be performed only by an authorized Noah Medical representative. There are no user serviceable components. Contact Noah Medical Customer Service to schedule installation or service.

1.1 Galaxy System™ Component Overview

These Instructions for Use refers to the Galaxy System™ and the associated components used with it. Refer to the following table for a list of products.

Table 1.1 Galaxy System™ Components

Official Product Name	Shortened Name
Galaxy System™	Galaxy
Galaxy Planning Software	Planning Software
Galaxy Planning Laptop	Planning Laptop
Galaxy Cart	Cart
Galaxy Controller	Controller
Galaxy Touchscreen	Touchscreen, Screen
Galaxy System™ Bronchoscope	Bronchoscope, Scope
Patient Side Mount	PSM
Galaxy Field Generator	Field Generator
Galaxy TiLT^{+} Board	TiLT^{+} Board
TiLT^{+} Spacer Board	Spacer Board
Galaxy System™ Accessory Kit	Accessory Kit
Scope Guide	Scope Guide, Anti-Buckling Mechanism
Bronchoscope Connector	Bronch Connector
Irrigation Aspiration Tubing	Fluidics Tubing, IA Tubing
TiLT^{+} Technology™ (Tool in Lesion Tomography)	TiLT^{+} Software, TiLT^{+}
Scope Drive Mechanism	Scope Drive

1.2 System Overview

The Galaxy System™ enables articulation and precise control of a flexible, single-use disposable Bronchoscope under continuous and direct control by a physician operator. The Galaxy System™ includes full procedure navigation that integrates a pre-operative computed tomography scan to display scope tip location relative to the scan anatomy. Additionally, Galaxy integrates tomosynthesis to update the scope and target position to overcome any changes in anatomy not reflected in the pre-operative scan.

Planning

Prior to the procedure, the Galaxy Planning Software running on the Galaxy Planning Laptop enables a physician to review a pre-procedural CT scan and plan a pathway through the airways for a physician-controlled Bronchoscope to navigate towards the target of interest. During the procedure, the software displays the plan on the Touchscreen of the Galaxy Cart.

The Galaxy Planning Software provides the following features:

- **CT image visualization:** CT viewing capabilities similar to standard CT DICOM viewer software.
- **Airway segmentation:** segmentation of the trachea and airways to aid visualization of the airways and path planning.
- **Target identification**: ability to select one or more targets of interest.
- **Automated path planning**: computer generated path to the target based on segmented airways.
- **Extend airways:** ability to extend airway segmentation based on CT.
- **Path editing:** ability to select an alternate path and adjust the throw distance and angle to finalize a pathway to the target.

Galaxy Cart

The Galaxy Cart is a maneuverable piece of reusable equipment that can be transported in and out of the bronchoscopy suite, stowed away when not in use, and positioned relative to the patient table as needed for a given procedure. It is used to transmit physician controls to the Bronchoscope (insertion, retraction, and articulation). It contains a robotic arm, Touchscreen, and the Scope Drive Mechanism, which is a robotic interface for the Bronchoscope.

The following image shows the Galaxy Cart with the robotic arm in the unstowed position:

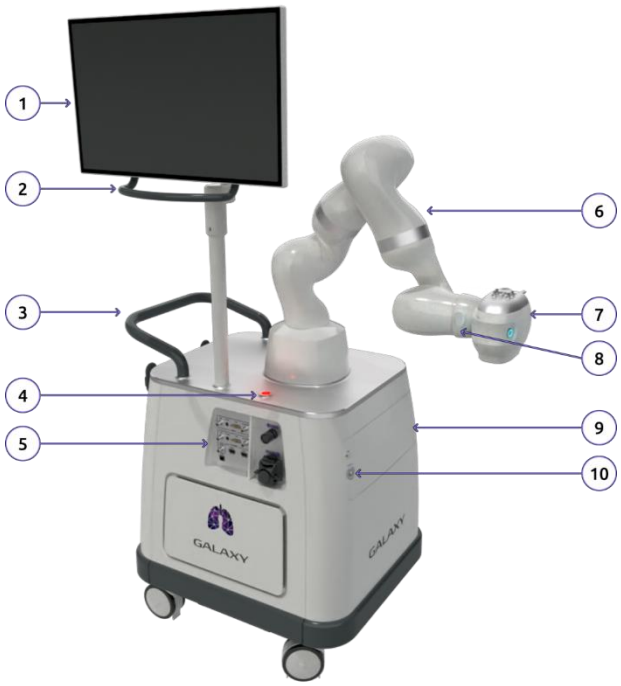

Figure 1.1 Galaxy Cart

Table 1.2 Galaxy Cart Components

No.	Description
1	Monitor
2	Monitor Handle
3	Cart Handle
4	Emergency-Stop (E-Stop) Button
5	Audio Visual (AV) and Fluidics Panels
6	Robotic Arm
7	Scope Drive
8	Fluidics Hook
9	Drawer
10	Front Panel

The Galaxy Cart contains a single robotic arm as well as the electrical and computer systems used in the procedure. The robotic arm holds the Scope Drive which uses rotary pulleys to actuate the drive cables of the Galaxy Bronchoscope. A Touchscreen on the Cart provides system setup instructions and allows user input.

Figure 1.2 Galaxy Cart (Rear)

Table 1.3 Galaxy Cart (Rear) Components

No.	Description
1	Cart Handle
2	Cable Hooks
3	Saline Bag Hook
4	Accessory Connection Panel
5	Power Control Switch
6	Power Inlet
7	Brake Pedal

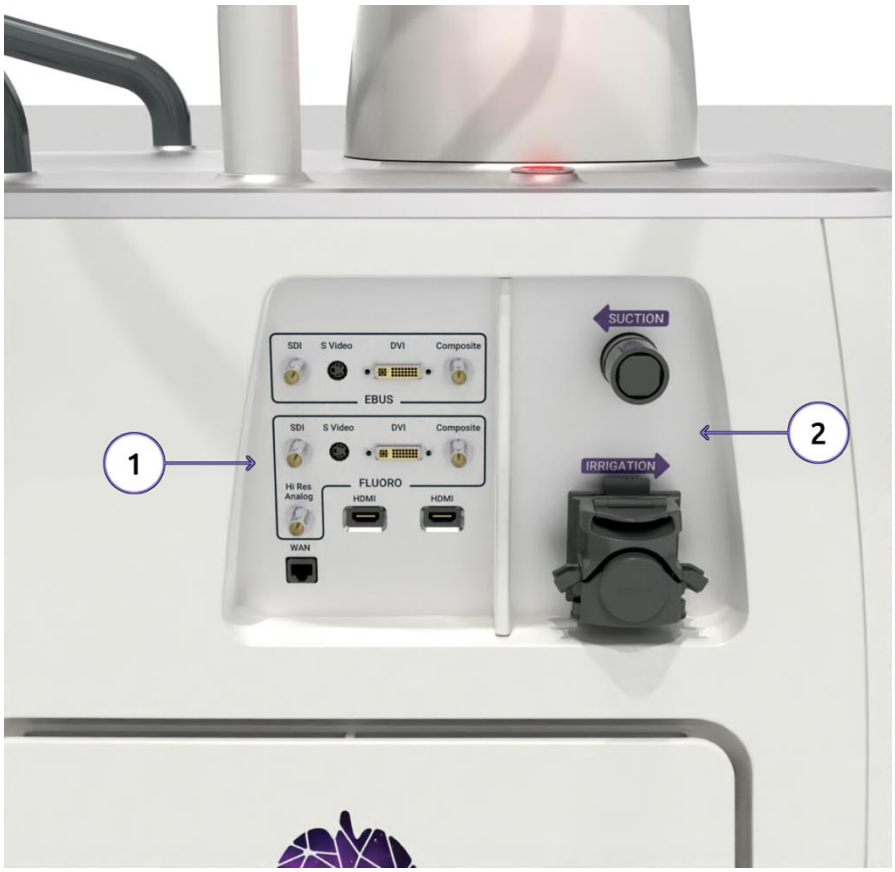

Figure 1.3 Audio Visual (AV) and Fluidics Panel

Table 1.4 Audio Visual (AV) and Fluidics Panels

No.	Description
1	Audio Visual (AV) Connection Panel
2	Fluidics Panel

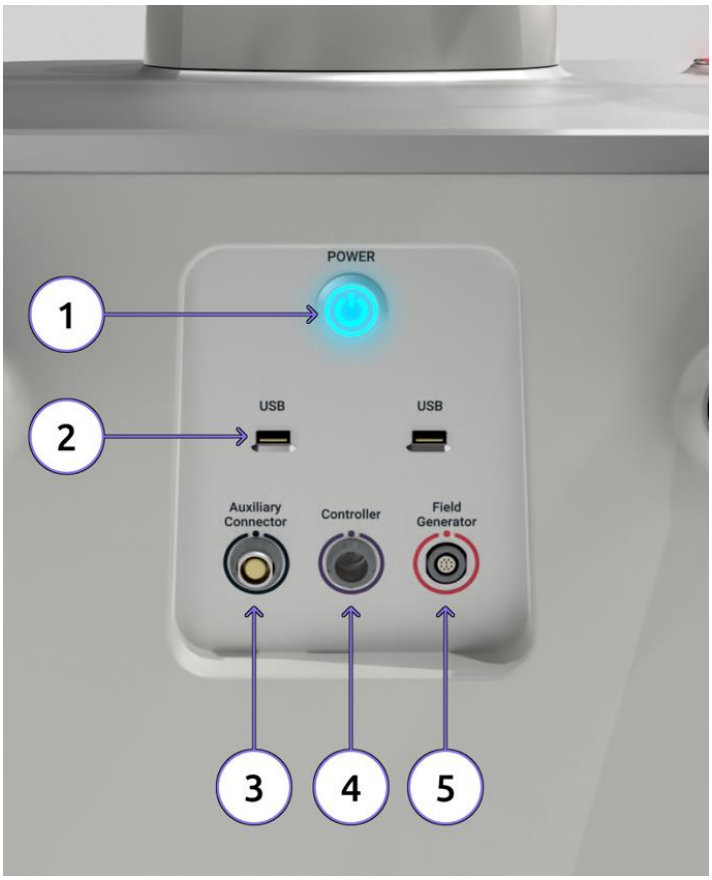

Figure 1.4 Galaxy Back Panel

Table 1.5 Galaxy Back Panel Components

No.	Description
1	Power Button
2	USB Ports
3	Auxiliary Connector Port
4	Controller Port
5	Field Generator Port

Figure 1.5 Galaxy Front Panel

Table 1.6 Galaxy Front Panel Components

No.	Description
1	USB Port
2	Controller Port

NOTE: The Galaxy Cart incorporates an uninterruptible power supply (UPS) backup. In the event of a power outage, the backup supply provides a five-minute operating window, which allows the operator to safely remove the Galaxy Bronchoscope and shut down the Galaxy Cart.

Galaxy System™ Bronchoscope

The Galaxy System™ Bronchoscope is single-use, disposable, and has 180˚ steering capability in all 360˚ of articulation.

The following image shows the Galaxy System™ Bronchoscope handle:

Figure 1.6 Galaxy System™ Bronchoscope Handle

The Bronchoscope has an integrated camera and light source at the tip. There is a 2.1 mm diameter working channel for the passing of manually controlled tools.

The Bronchoscope has a distal section capable of achieving articulation in any direction to enable precision even in the most peripheral airways.

The dimensions are as follows:

Figure 1.7 Bronchoscope Dimensions

Table 1.7 Bronchoscope Dimension Table

Item	Description
Tip Outer Diameter	4.0 mm [1]
Working Channel Diameter	2.1mm
Working Channel Length	1020 mm [2]

[1] Diameter measured at the Bronchoscope tip.

[2] Includes Bronchoscope valve attached to the Bronchoscope handle.

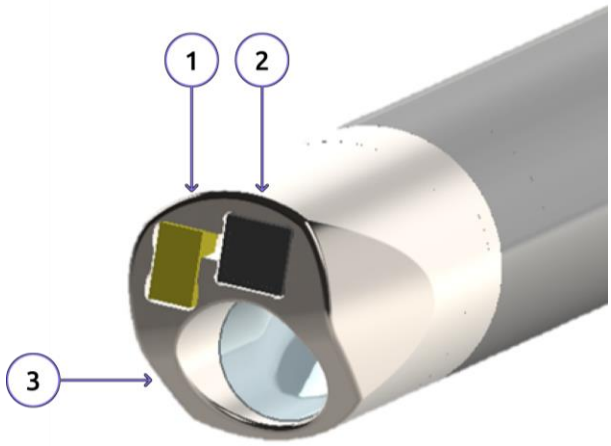

Figure 1.8 Scope Tip

Table 1.8 Scope Tip Components

No.	Description
1	Light Source
2	Camera
3	Working Channel

CAUTION: The temperature of the distal end of the Bronchoscope may exceed 41°C (106°F) and reach 50°C (122°F) due to intense illumination. Surface temperatures over 41°C (106°F) may cause mucosal burns. Always maintain a suitable distance necessary for adequate viewing. Do not leave the distal end of the scope close to the mucous membrane for a long time without necessity. Whenever possible, do not leave the scope illuminated before and/or after an examination. Continued illumination will cause the distal end of the scope to become hot and could cause operator and/or patient burns.

Device Sterility

Contents supplied sterile using an ethylene oxide (EO) process.

WARNING: Contents supplied sterile using an ethylene oxide (EO) process. Do not use if the sterile barrier has been damaged. For single use only. Do not reuse, reprocess, or re-sterilize single-use products. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness, or death. Reuse, reprocessing, or re-sterilization may also increase the risk of contamination of the device and/or cause patient infection or cross-infection, including but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Compatible Equipment

Below is information regarding tools/instruments, surgical tables, and imaging systems tested and approved to be used with the Galaxy System™. Noah Medical is not responsible for system error if used with non-approved devices. Please consult Noah Medical prior to using any devices not included in the list.

Working Channel Tools/Instruments

The Galaxy System™ is compatible with flexible working channel instruments with lengths greater or equal to 1100 mm that are designed to fit within a working channel with a 2.1 mm inner diameter.

Devices that are compatible include the following instruments:

- Olympus PeriView FLEX TBNA Needle
- Medtronic Arcpoint™ Pulmonary Needle
- Boston Scientific Acquire™ Pulmonary Endobronchial Ultrasound Fine Needle Biopsy Device
- Boston Scientific CoreDx™ Pulmonary Mini-Forceps
- Cook Medical Captura® Mini Biopsy Forceps
- Medtronic superDimension™ Biopsy Forceps
- Olympus EndoJaw Disposable Biopsy Forceps
- Olympus Bronchial Cytology Brush
- Boston Scientific Celebrity™ Single-Use Cytology Brush
- Medtronic superDimension™ Cytology Brush
- Erbe Flexible Cryoprobe, Single-Use (ø 1.1mm, 1.7 mm)

- Olympus Endoscopic Radial Probe UM-S20-17S
- Medtronic superDimension™ Marker Delivery Kit
- Medtronic SuperLock™ Nitinol Coil Fiducial Marker
- Medtronic superDimension™ Band Fiducial Marker

Surgical Tables

The Galaxy System™ is compatible with surgical tables with the following dimensions and features:

Table 1.9 Patient Table Compatibility Parameters

Feature		**Dimensions of Features**		
Surgical/ Fluoroscopy Tables	Thickness	39mm – 45mm		
	Width	535mm – 610 mm		
	Corner Angle	60deg – 90deg	OR	Includes a positive engagement feature (see figure 1.9a)
CBCT Tables	Thickness	5mm – 10mm	OR	Includes a positive engagement feature (see image 1.9b)
	Width	495mm – 610mm		

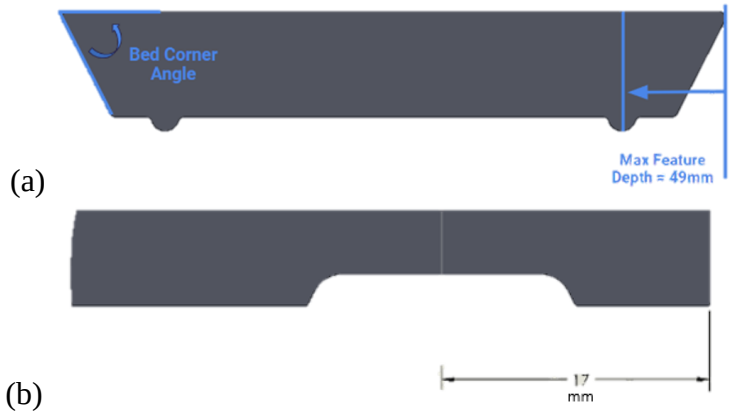

Figure 1.9 Patient Table Compatibility for (a) Surgical/Fluoroscopy Tables and (b) CBCT Tables

Examples of compatible surgical tables include the following:

- Steris 36 in. Carbon Fiber Fluoroscope Extension for STERIS 5085, STERIS 4085, Cmax, AMSCO® 3085, AMSCO® 3080 and AMSCO® 3080-R Surgical Tables

Imaging Systems

To date, the Galaxy System™ is compatible with Fluoroscopes/C-arms with the any combination of the following features and parameters:

Table 1.10 Imaging System Compatibility Parameters

Features	Details
Detector Technology	Image Intensifier
	Flat Panel
Detector Size	9 in – 12 in
Video Interface	High resolution analog
	NTSC (analog)
	DVI (digital)
Isocenter	No
	Yes

Examples of compatible C-arms include the following:

- GE OEC 9800
- GE OEC 9900
- Siemens Cios Spin

Accessories

Single Use Accessories

The system features sterilized single-use accessories necessary to perform bronchoscopic procedures. These accessories are packaged in the Accessory Kit:

- Bronchoscope Connector: A connector that attaches to the endotracheal tube to allow passage of a bronchoscope while maintaining ventilation pressure. It connects to the Patient Side Mount.

Figure 1.10 Bronchoscope Connector

- Irrigation Aspiration Tubing: Separate tubing lines for irrigation and vacuum aspiration which converge at a valve that attaches to the Bronchoscope. Irrigation and aspiration lines connect to the Cart. A side port on the tubing allows for manual irrigation.

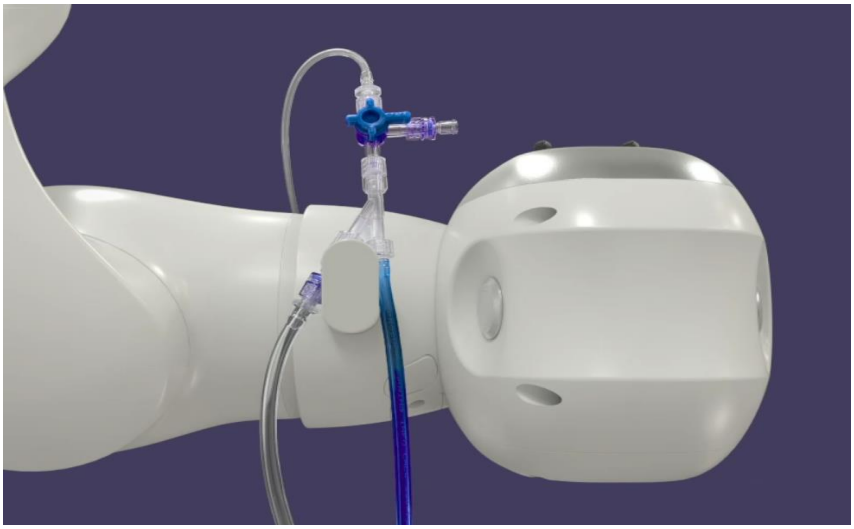

Figure 1.11 Irrigation Aspiration Tubing

The Irrigation Aspiration Tubing valve at end of the tubing facilitates the insertion and sealing of various ancillary devices, such as the biopsy needles.

Additionally, the proximal section routes irrigation and aspiration to the shared working channel.

Figure 1.12 Irrigation Aspiration Tubing Valve

- Scope Guide: An accessory that guides the Bronchoscope from the Scope Drive through the Bronchoscope Connector and into the endotracheal tube. The Scope Guide provides gentle rigidity at the sides of the Bronchoscope to direct force in a forward direction.

Figure 1.13 Scope Guide

Reusable Accessories

The following reusable accessories are included:

- **Galaxy Controller**: The Galaxy Controller allows the clinician to control the system during a procedure. Two joysticks are used to drive and articulate the Bronchoscope while buttons are used to control irrigation, aspiration, light levels, scope relaxation, open the driving screen menu, and capture images and video.

Figure 1.14 Galaxy Controller

- **Patient Side Mount**: Adjustable mount that attaches to a bed and holds the Bronchoscope Connector.

Figure 1.15 Patient Side Mount

- Galaxy Field Generator: Provides an electromagnetic field to be sensed by the Bronchoscope to provide location information. The Galaxy Field Generator plugs into the Galaxy Cart and comes with an adjustable mount that attaches to the bed, either the Expanding Mount or the Velcro Mount.

Figure 1.16 Galaxy Field Generator with Expanding Mount (left) and Velcro Mount (right)

- Galaxy TiLT^{+} Board: Provides reference points on fluoroscopy images, enabling TiLT^{+}.

Figure 1.17 Galaxy TiLT+ Board

CAUTION: Dropping the Field generator or TiLT^{+} Board could result in damage to the components. Do not use if dropped.

- Galaxy Spacer Board: Provides a flat surface for the TiLT^{+} Board to reside on. (Only required for certain beds)

1.3 Classifications

According to Directive 2017/745, this product is a Class IIa Medical Device.

According to CISPR 11 (a publication of the IEC committee on radio interference), this product is Class A, Group 1 ISM Equipment.

The Galaxy System™ is classified by the following:

- Protection against electric shock: Class 1 (grounded equipment).
- Applied part(s): The Galaxy Robotic Bronchoscope™ is a Type BF Applied Part.
- Protection against harmful ingress of water: Rated IPX0 (ordinary equipment, not specially protected).
- Methods of sterilization or disinfection of single-use components: Ethylene oxide processing.
- Mode of operation: The Galaxy System™ is considered Continuous equipment as defined by IEC 60601-1.

1.4 Galaxy System™ Labels

Symbols

Table 1.11 Galaxy System™ Label Symbols

Symbol	Name	Meaning
	Type BF applied part symbol is in accordance with IEC 60601-1.	Used to indicate Type BF certified components.
	ON/OFF	This indicates the power on state of the system. This power switch does not isolate the mains supply.
	Protective Earth	This indicates a protective earth (grounding) terminal.
	Manufacturer’s Serial Number	This symbol appears adjacent to the manufacturer’s serial number.
	Manufacturer’s Lot Number	This symbol appears adjacent to the

		manufacturer's lot number.
	Date of Manufacture	This symbol appears adjacent to the date of manufacture.
	Equipment Manufacturer	This symbol appears adjacent to the name and address of the equipment manufacturer.
	Waste Electrical and Electrical Equipment	This symbol indicates that this equipment has been designed as electrical and electronic equipment that is not to be disposed of as unsorted municipal waste. EEE contains substances that may present hazards to human and to the environment. It must be recovered, reused, recycled, or otherwise treated, and properly disposed of.
	Emergency Stop	This symbol indicates an emergency stop control device.
	Read instructions prior to use	This symbol is used to alert the user to refer to the Instructions for Use or other instructions when complete information cannot be provided on the label.
	Reference Number	This symbol appears adjacent to Catalog or Assembly Number.
	Alternating Current	This symbol indicates that the equipment is suitable for alternating current only.
	ON	This symbol indicates connection to the mains.
	Keep dry	This symbol indicates to store in a dry place.

EC REP	Authorized EU Representative	This symbol indicates the name and address of authorized EU representative.
IPX0	No special protection against water	This symbol indicates the degree of protection the device has against the ingress of water.
	Single-use only	Used to warn the user that the piece of equipment with this label is for single-use only and it must not be used more than once.
	Use by date	This symbol indicates that the device should not be used after the date accompanying the symbol.
STERILE EO	Sterilized using ethylene oxide	This symbol indicates that the device is provided sterile and has been sterilized using ethylene oxide.
℞ Only	Rx only	Federal (USA) law restricts this device to sale by or on the order of a physician.
	Do not resterilize	This symbol indicates that the device should not be re-sterilized after it once has been sterilized.
	Do not use if package is damaged	This symbol indicates that the device must not be used if the package holding the device is damaged.
	Keep away from sunlight	This symbol indicates to keep the device away from sunlight.
	Mass of mounted part	This symbol is adjacent to the mass of the mounted part.
	TUV Rheinland of North America certification	This symbol is proof of compliance with Canadian and U.S. National Standards. It demonstrates an electrical product has been successfully tested and certified.

Label Locations

The following figures show the system label locations. The Galaxy System™ UDI is located on the Cart.

Figure 1.18 Label Location

1.5 Technical Specifications

Physical Dimensions, Weight, and Power Requirements

Table 1.12 Physical Dimensions, Weight, and Power Requirements

Category	Measurement
Height (to top of arm at max extension)	90” / 228.6 cm
Height (to top of stowed arm)	70.9” / 180.0 cm
Height (to top plate)	33.00” / 83.7 cm
Width	26.8” / 68.0 cm
Depth	34.8” / 88.5 cm
Weight	463 lbs. / 210 kg
Max weight in drawers	20 lbs. / 9.07 kg
Power Requirement	100-240V~ 50/60Hz 1440W*

*Recommended to use separate dedicated branch circuits.

The following environmental conditions are recommended for transportation, storage, and usage of the Galaxy System™:

Table 1.13 Environmental Condition Parameter Recommendations

Galaxy System™	Operating	Non-Operating (Shipping and Storage)
Temperature	10° C to 30° C	0° C to 40° C
Humidity	30% to 60% Non-condensing	10% to 85% Non-condensing
Altitude	Up to 3000 meters	N/A

The noise generated during operation may be up to 63 dB @ 1 meter & 20°C.

1.6 Electromagnetic Compatibility (EMC) and Associated Risks

Please reference Appendix B for details on Electromagnetic Compatibility (EMC) and Associated Risks.

1.7 Original Documentation

This IFU is originally written in English.

2 Planning a Procedure

This chapter covers procedure planning using the Galaxy Planning Laptop. The planning laptop utilizes CT scans to create procedural plans. Plans are later imported onto the Galaxy Cart. The following sections are covered in this chapter:

2.1 Recommended CT Scan and Reconstruction Parameters

To produce CT images suitable for use with the Galaxy Planning Laptop and the Galaxy System™, the following conditions should be met while scanning patient:

- **Patient position**:
  - Supine
  - Immobile
  - Full inspiration breath hold
  - Arms at sides
- **Scanner type**:
  - Multi-slice
  - 4 detector or greater (16 detector or greater preferred)
- **Scan type**:
  - Chest
  - Lung, or pulmonary embolism.
- **Scan area**:
  - Entire chest.
- **Scan duration**:
  - Within the breath-hold duration of patient.
- **Image noise**:
  - Minimize noise standard deviation.

Parameters

3D Map generation has been optimized for use with the reconstruction parameters listed below. 3D Map generation and quality has not been optimized with other reconstruction parameters, so it is strongly recommended that these parameters be used.

- **Image resolution :** 512 x 512.
- **Slice Thickness:** ≤ 1.0 mm
- **Overlap**: 0% – 50%.
- **Field of view**: Minimal field required to cover at least 6 cm of trachea and entire lung volume.

The following table lists the kernel and filter to use for each scanner manufacturer:

Table 2.1 Kernel and Filter with Associated Manufacturer

Scanner Manufacturer	Kernel and Filter	
GE™	Kernel Filter	Standard Body
Philips™	Kernel Enhancement	C 0
Siemens™	Kernel	B31f
Toshiba™	Kernel	FC05

NOTE: To avoid excess CT noise, patient should be immobile for the duration of the scan. For the best 3D Map results, ensure the CT scan is taken with patient's breath held on inspiration.

NOTE: CT scans must be in DICOM format. If using a DVD, the format must be UDF version 1.02 to 2.60. If using a CD, the format must have a CDFS file system. Verify the disk content when the CD or DVD is created to ensure the disk is valid before attempting to use the disk with the Galaxy Pre-Op Planning Application.

The Galaxy Planning Software will not load the PET portion of a PET/CT scan.

2.2 Galaxy Planning Laptop User Interface

Home Screen Overview

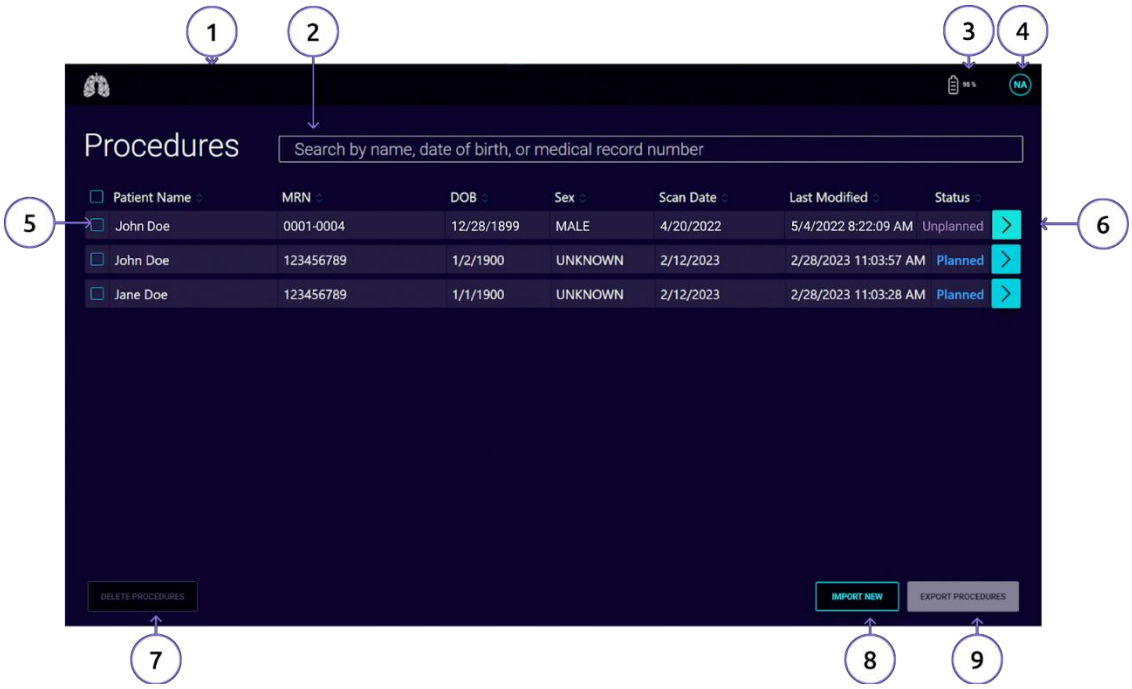

Figure 2.1 Home Screen Overview

Home Screen Elements

Table 2.2 Home Screen Elements

No.	Item	Description
1	**Sort**	Select to sort by selected column.
2	**Search**	Search for a procedure.
3	**Battery**	Indicates laptop battery level.
4	**User Menu**	Select to open the menu to log out or update user password.
5	**Select Procedure**	Select checkbox(es) to select procedure(s).
6	**Edit Procedure**	Select to edit a procedure.
7	**Delete Procedure(s)**	Select to delete selected procedure(s).
8	**Import Scans**	Select to import the patient's CT images.

9	**Export Procedure(s)**	Select to export selected procedure(s)

Procedure Information

The Procedure List displays the following general information:

Table 2.3 Procedure List

Item	Description
Name	Patient’s name.
MRN	Patient’s MRN/ID.
Date of Birth	Patient’s date of birth.
Gender	Patient’s gender.
Scan Date	Date of CT scan.
Last Modified	Last modified time of plan.
Status	Procedure status (unplanned, planned, or exported).

Scan Import Screen

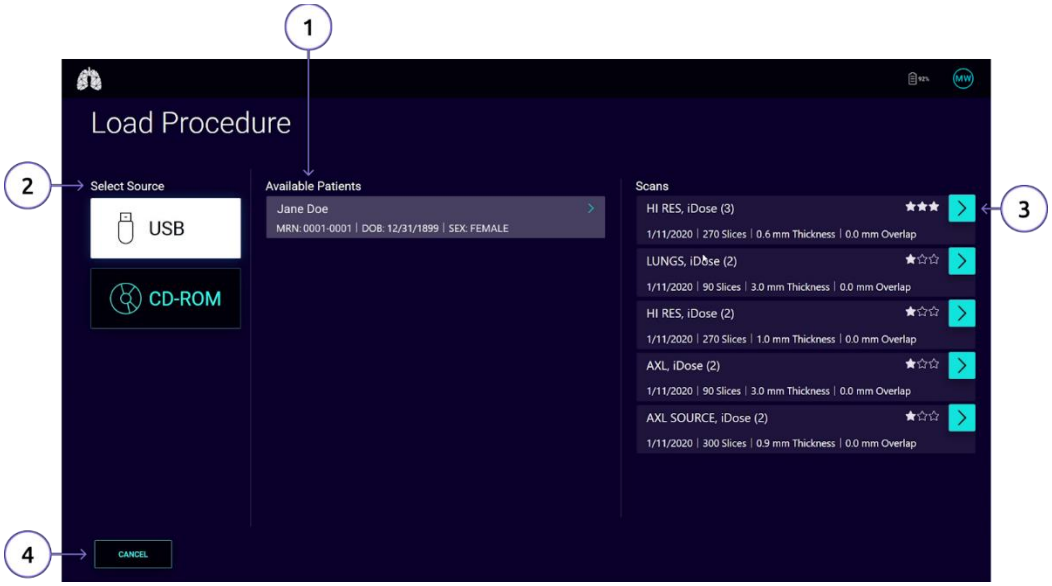

Figure 2.2 Scan Import Screen

Scan Import Elements

Table 2.4 Scan Import Elements

No.	Item	Description
1	**Patient Selection**	Select a patient from the list.
2	**Source Selection**	Select a source from the list.
3	**Import**	Select a scan from the list for import.
4	**Cancel**	Select to return to home screen.

Scan Information

The Scan List displays the following general information:

Table 2.5 Scan Information

Item	Description
Name	Patient's name.
Date of Birth	Patient's date of birth.
MRN	Patient's MRN/ID.
Scan Date	Date of CT scan.
Number of Slices	Number of CT slices in scan.
Slice Thickness	Thickness of CT slices.
Slice Overlap	Overlap between CT slices.
Scan Rating	Suitability rating of CT scan parameters.
	★ ★ ★ Slice thickness < 2 mm, number of slices > 300, consistency in slice interval
	★ ★ ☆ Slice thickness < 2 mm, number of slices > 300, inconsistency in slice interval detected
	★ ☆ ☆ Slice thickness > 2mm and/or number of slices < 300

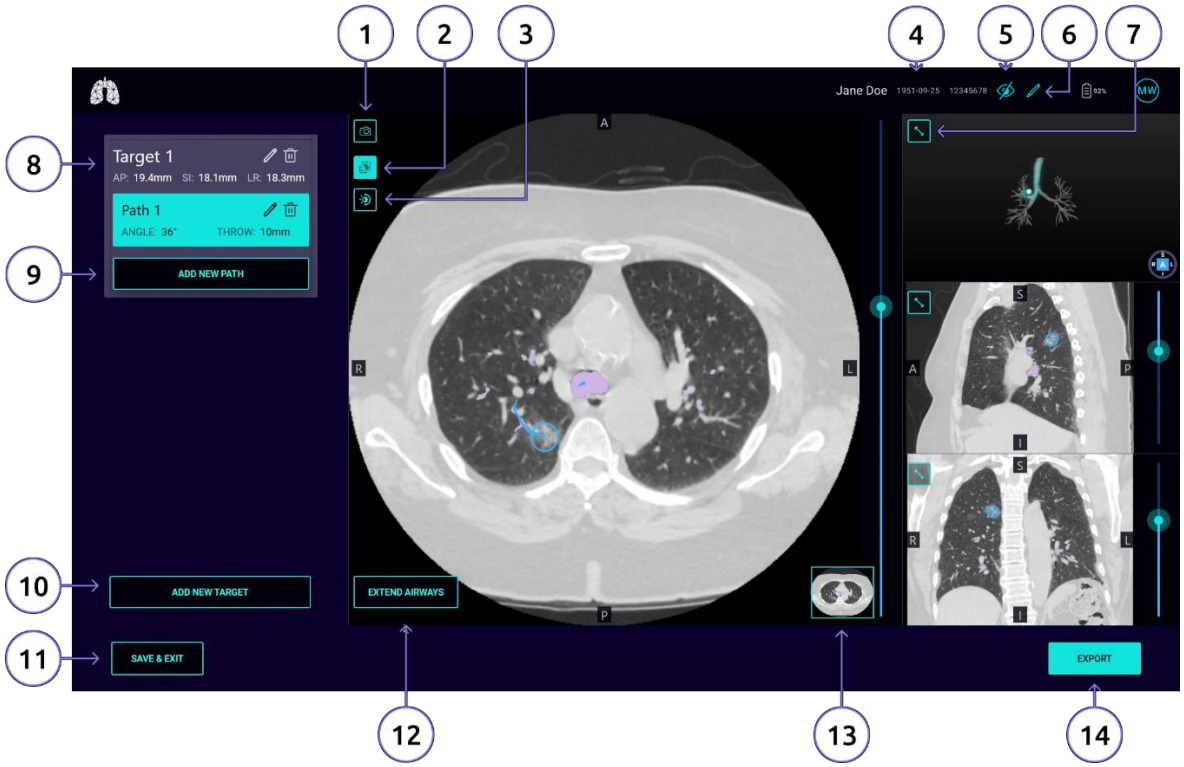

Figure 2.3 Planning Screen

Planning Screen Elements

Table 2.6 Planning Screen Elements

No.	Item	Description
1	**Snapshot**	Select to take a snapshot.
2	**Overlay**	Select to toggle on/off segmentation overlay.
3	**Windowing**	Select to adjust CT windowing.
4	**Patient Information**	Displays the patient's name, date of birth, and MRN.
5	**Hide/Show**	Select to hide/show the patient information.
6	**Edit Patient**	Select to edit the patient information.
7	**Enlarge**	Select to enlarge secondary view to primary view.
8	**Target and Path Panel**	Displays information on planned targets and paths and contains edit and deletion functionalities.
9	**New Path**	Select to add a new path.

10	**New Target**	Select to add a new target.
11	**Save & Exit**	Select to save and return to home screen.
12	**Extend Airways**	Select to extend airways.
13	**Zoom location**	Displays magnified location.
14	**Export**	Select to export plan.

Target and Path Information

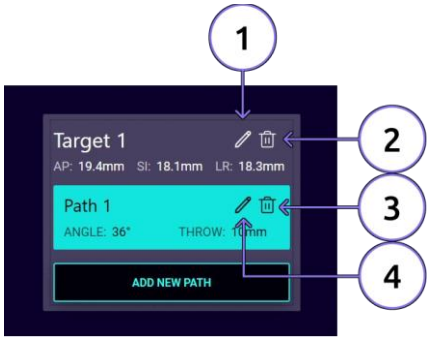

Figure 2.4 Target and Path Information

Table 2.7 Target and Path Information Interactions

No.	Interaction	Description
1	**Edit Target**	Select to edit target.
2	**Delete Target**	Select to delete target. Deleting a target also deletes the associated paths.
3	**Delete Path**	Select to delete path.
4	**Edit Path**	Select to edit path.

Planning Views and Interactions

CT Views (Axial, Sagittal, Coronal)

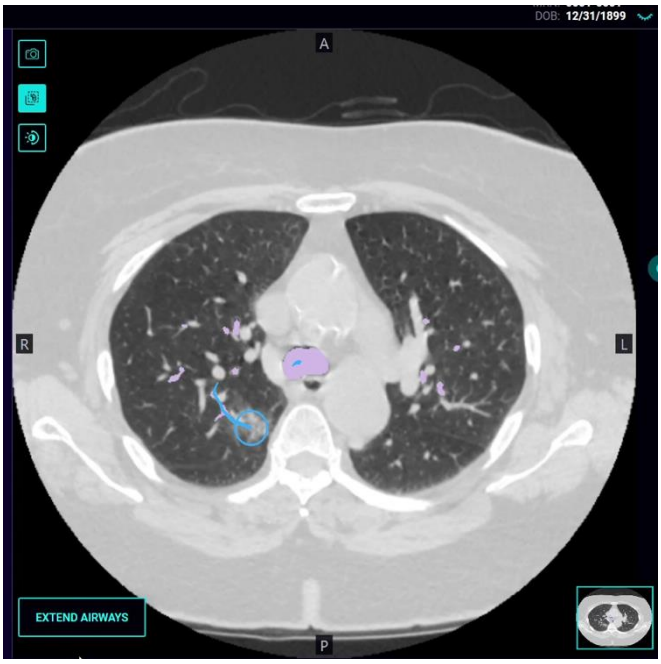

Figure 2.5 CT Views (Axial, Sagittal, and Coronal)

Table 2.8 CT View Interactions

Interaction	Description
Scroll	Select and drag the slider bar. OR Use scroll wheel.
Zoom	Right click and drag.
Pan	Scroll button click and drag.

3D Map

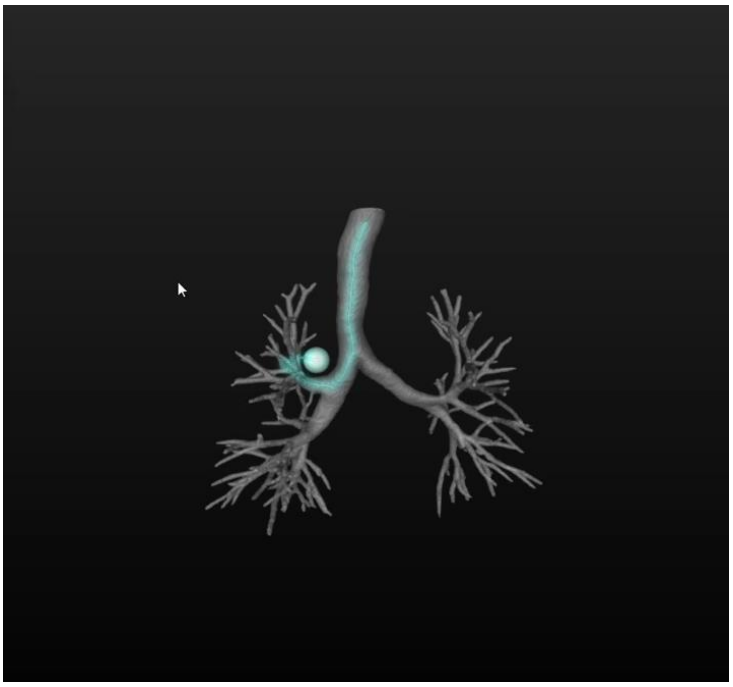

Figure 2.6 3D Map

Table 2.9 3D Map Interactions

Interaction	Description
Rotate	Left click and drag.
Zoom	Right click and drag.
Pan	Scroll button click and drag.
Reset View	Select the orientation indicator in the bottom right corner.

2.3 Creating a Plan

Scan Patient

1. Patient must have a CT scan conducted prior to creating a plan with the Galaxy Planning Laptop. Refer to the Recommended CT Scan and Reconstruction Parameters for optimal results.
2. Save CT scan to a CD-ROM or USB.

Login and Import Scan

1. Log in to the Galaxy Planning Laptop.
2. Select **LOAD NEW** in the upper-right hand corner of the screen.
3. Load scans by selecting the appropriate media (CD-ROM or USB). The system will load the files onto the selected media.
4. Select the desired patient. The scan(s) associated with that patient will appear.
5. Select the desired scan. The scan will be imported, and the planning screen will appear.
    a. Segmentation will automatically begin, and the progress will be indicated in the 3D Map view. Target placement can occur prior to completion of segmentation, but paths cannot be added until segmentation is complete.

CAUTION: Selecting scans with parameters different than those recommended can negatively impact planning, and subsequently navigation to the lesion.

Identify a Target and Path

1. Select **ADD NEW TARGET** and select your target in any of the CT views. The target shape is automatically generated as a sphere.
    a. Edit the target size and shape to match the nodule in any of the CT views.
2. Select **ADD NEW PATH** to map out a path to the target. This path will automatically map the path through the segmented airways that has the shortest throw distance to the lesion.
    a. Edit your path on the airway tree to match your intended navigation path through the lung.

CAUTION: Navigation paths provides supplemental information to navigate to a nodule. Failure to exercise clinical judgment to determine appropriate navigation and biopsy plan may result in biopsy of unintended location.

Edit Target

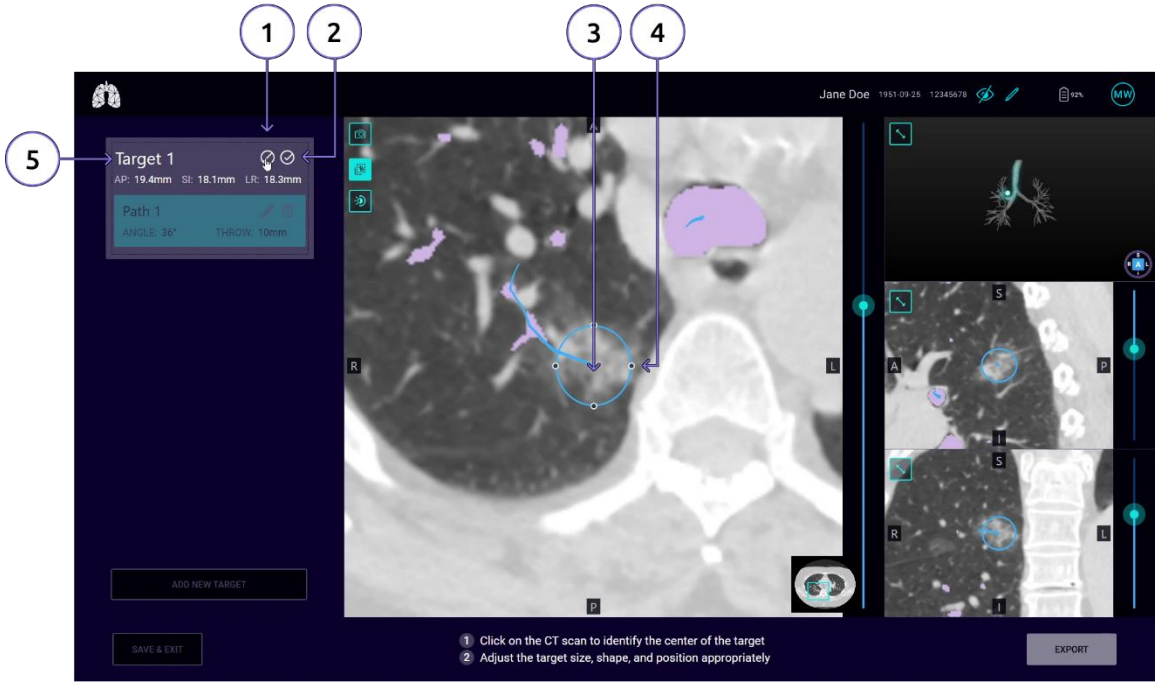

Figure 2.7 Edit Target

Table 2.10 Edit Target Interactions

No.	Interaction	Description
1	**Cancel**	Select to cancel edits.
2	**Confirm**	Select to confirm edits.
3	**Target Location**	To edit target location, select position on CT in which to place the center of the target.
4	**Target Size and shape**	To edit target size/shape, click and drag anchors.
5	**Rename target**	Select the target name and type desired name.

Edit Path

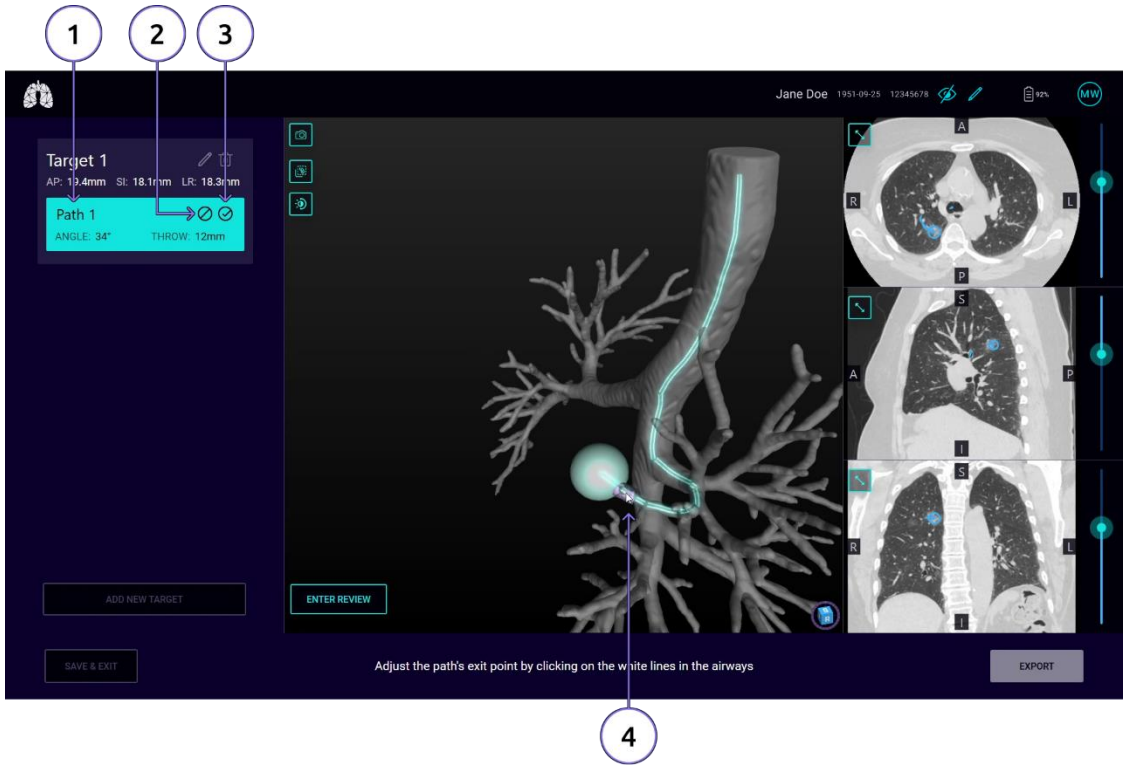

Figure 2.8 Edit Path

Table 2.11 Edit Path Interactions

No.	Interaction	Description
1	**Rename path**	Select the target name and type desired name.
2	**Cancel**	Select to cancel edits.
3	**Confirm**	Select to confirm edits.
4	**Adjust path**	Hover over path and scroll to adjust exit point along airway. Select another airway to change airway path.

CAUTION: Modification of the automatically generated path can result in paths that transect critical anatomy. Ensure that paths are reviewed before export.

Extend Airways

1. To extend segmented airways, select **EXTEND AIRWAY** while any of the CT views are in the large viewport.
2. Draw in the airway starting from a segmented airway by selecting and dragging to paint over desired airway.
    - The extended airway will be reflected in the 3D map in purple prior to airway confirmation.
    - This can only be performed in the CT views.

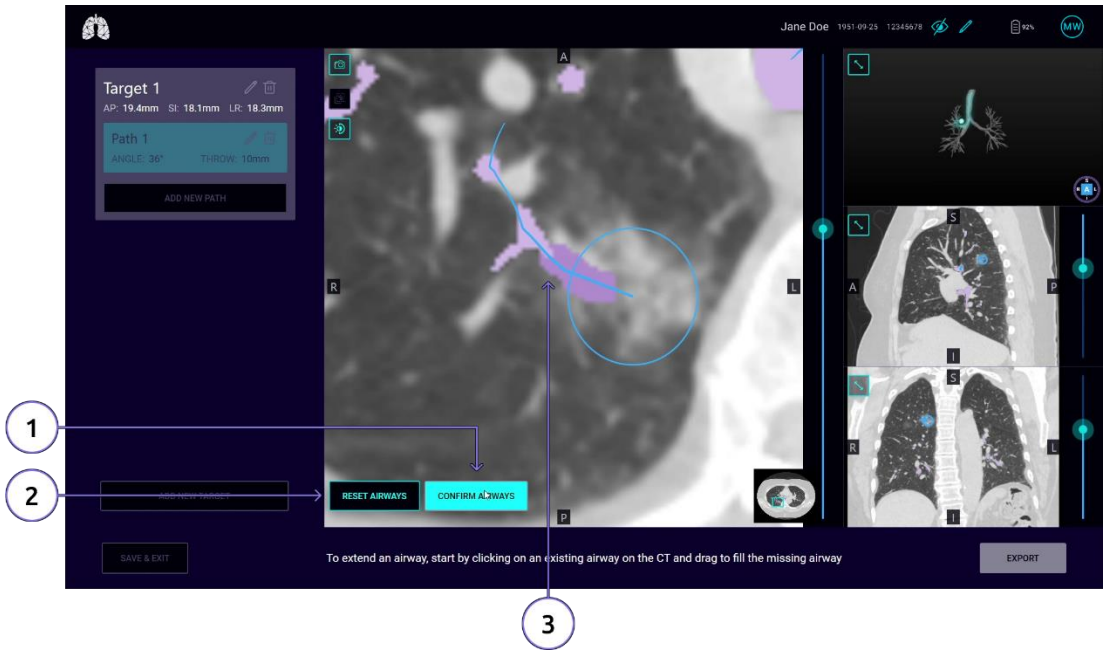

Figure 2.9 Extend Airways

Table 2.12 Extend Airways Interactions

No.	Interaction	Description
1	**Confirm Airways**	Select to confirm and save manually segmented airways.
2	**Reset Airways**	Select to reset segmentation to default auto-generated segmentation.
3	**Extend Airways**	Starting at a segmented airway, click and drag to extend airway.

Review Path

Figure 2.10 Review Path

Table 2.13 Review Path Interactions

No.	Interaction	Description
1	**Reset Review**	Select to reset the review.
2	**Play/Pause**	Select to play/pause the review.
3	**Scroll Through Review**	Select and drag slider to manually scroll through review.
4	**Exit Review**	Select to exit path review.

Export a Procedure

1. Insert USB into the planning laptop.
2. Select **EXPORT**.
3. Disconnect USB from planning laptop.
4. Log out of the account or go back to dashboard to plan another procedure.

3 System Setup

The Galaxy System™ provides step-by-step guidance to ensure that the Galaxy Cart and related components are ready for use. The following sections are covered in this chapter:

3.1 Room Preparation

1. Bring the Accessory Kit and Bronchoscope into the room. The Accessory Kit contains the following items:
   - Bronchoscope Connector
   - Fluidics Tubing
   - Scope Guide
2. Bring the Cart into the room and place it in the desired location in the procedure room.
3. Ensure the reusable accessories are in the room, which include the following:
   - Galaxy Controller
   - Patient Side Mount
   - Galaxy Field Generator
   - Galaxy TiLT^{+} Board
   - TiLT^{+} Spacer Board (if necessary)

WARNING: The Bronchoscope and accessories in the Accessory Kit are provided sterile. Ensure that the components used are in-date and intended for clinical use. Failure to use sterile devices may result in patient harm. Do not use if sterile barrier has been compromised.

3.2 Galaxy System Startup

Moving the Cart

Utilize the following steps to move Cart:

1. Unlock the brakes by lifting the brake pedal up with top of foot.
2. Use the handle to push the Cart.

Connecting the System

Power

1. Connect the power cable to the wall outlet and ensure the power cord is securely latched to the Cart's power inlet. It is recommended to use an outlet that is connected to emergency backup power.
2. Ensure the power control switch is switched on.

Audio Visual (AV) Connections

Figure 3.2 Audio Visual (AV) Connection Panel

- Video streams from the Cart monitor can be viewed on external monitors or recording devices at 1920 x 1080 resolution through two HDMI output ports.
- Fluoroscopy C-arm and EBUS can be connected to the Cart. Only one input type should be used in each group:
    - DVI

- Composite
- S-Video
- SDI
- Hi Res Analog (for Fluoroscopy only)

Startup

Start Up the System

Utilize the following steps to start-up the system:

1. Press the Power button on the Cart.
2. Run the robotic arm brake test by pressing **RUN**.
3. Run sensor referencing by pressing **RUN** to unstow the arm.
    - Ensure that the monitor is positioned appropriately to provide clearance for the robotic arm.
    - The robotic arm ends up in the unstowed configuration as part of the completion of this step.

CAUTION: Ensure the monitor is moved out of the way and maintain a clearance of one to two feet between the Galaxy Cart and patient, staff, and other equipment to unstow the arm safely. Use the Emergency Stop button on the cart to stop robotic motion, if necessary.

CAUTION: Forcing the monitor beyond adjustable range could result in damage to the monitor and/or associated components.

3.3 Room Setup

The following is a suggested configuration of where to place the system in the bronchoscopy suite. The system can be placed anywhere in the blue region following the guidelines below:

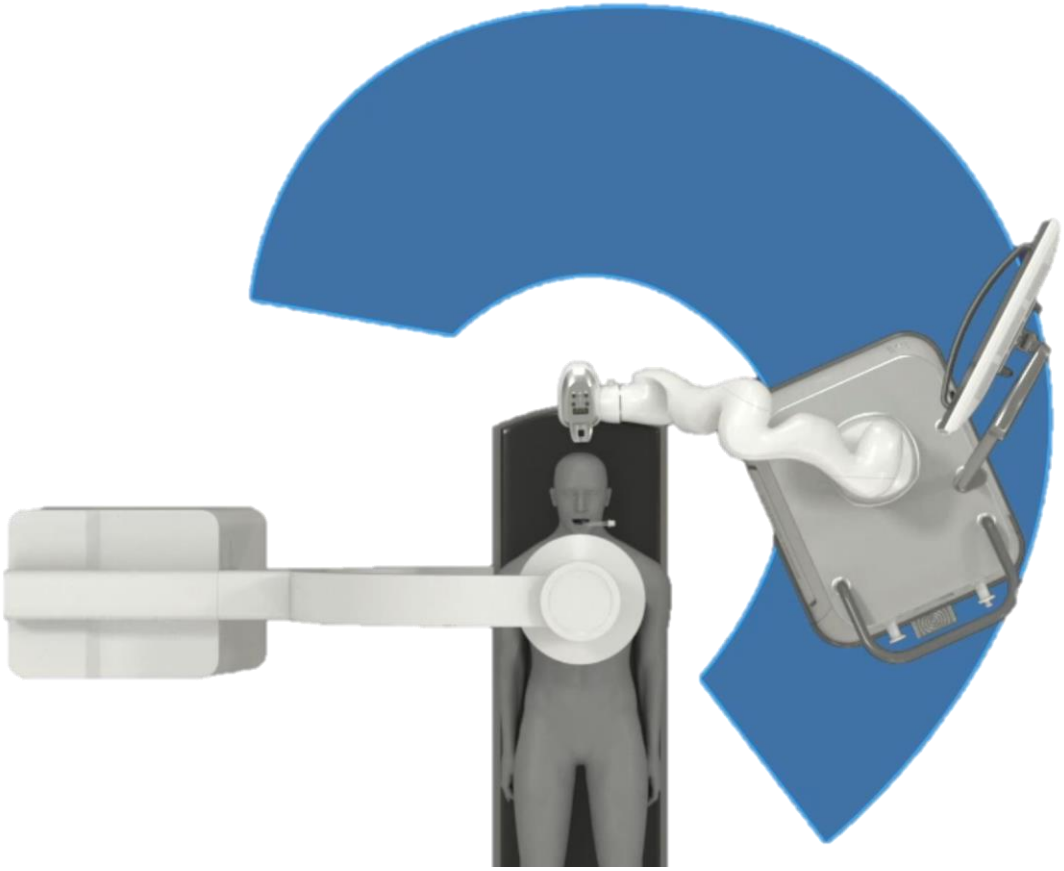

Figure 3.1 Recommended Room Set-Up Configuration

Positioning the Cart

1. Move the cart to the desired position within the recommended room set-up configuration.
2. Lock brakes by stepping on brake pedal until you receive audible and tactile feedback from the brake pedal indicating brakes have been engaged.

WARNING: Ensure that the Cart brakes are locked when the Cart is in the final operating position. Failure to do so will result in the need to repeat alignment. Failure to do so may also result in patient harm.

Guidelines for Positioning the Cart in the Procedure Room

- Ensure the Cart power cable can reach a power outlet.
- Ensure that the front left corner of the Cart is within 1-2 feet from the edge of patient bed.
- Ensure there is enough room for the Fluoroscopy C-arm to be placed perpendicular to the bed and rotate between 30° LAO and 30° RAO.
- Ensure the Cart does not interfere with other equipment in the room.
- Ensure that there are no obstructions around the Cart.
- Ensure the physician can easily view the monitor.

3.4 Galaxy Setup Guidance

NOTE: Setup can be performed before or after login and procedure selection.

Begin Setup

1. Enter Setup by selecting **SKIP TO SETUP** on the login screen or by selecting a procedure after login.
2. The system provides two setup options: Guided Setup and Abbreviated Setup. Guided Setup provides step-by-step guidance. Abbreviated Setup includes instructions for the steps that require user action on the system only with a checklist at the end of setup to ensure all system components are connected properly.

Setting up Navigation Accessories

1. Mount the field generator.
   a. Observe the intended orientation of the field generator and ensure the field generator is placed properly with respect to the intended patient orientation. Proper placement is indicated on the field generator and TiLT^{+} board. The icon should be facing up with the head directed towards the head of the patient.

Figure 3.3 Field Generator & TiLT+ Board Orientation Icon

b. If using the expanding field generator mount:
    - Slide the field generator beneath the bed such that the mount hooks onto the bed. The mount can be expanded to fit the bed, if needed.
    - Ensure the field generator is placed directly below the intended location of patient's chest.
    - Lock mount using both locking knobs.

c. If using the Velcro field generator mount:
    - Attach velcro straps to the bed, leaving adequate space to insert the field generator between the bottom of the bed and the bottom straps.
    - Slide the field generator through the straps underneath the bed. The straps should be at the ends of the black tubes.
    - Tighten the Velcro straps to secure the Field Generator.

2. Plug the field generator into the Cart.
3. Place the spacer board under the mattress directly above the field generator, if necessary (if using Steris 36 in. Carbon Fiber Fluoroscopy Extension).
4. Place the TiLT+ board.
    a. Observe the intended orientation of the TiLT+ board, and ensure it is placed properly with respect to the intended patient orientation, with the labeled side facing upwards.
    b. Place the TiLT+ board under the mattress such that the purple marking lines up with that of the field generator on both sides.
    c. Carefully align the board to be parallel with the patient bed and field generator for best TiLT+ results.

NOTE: For greatest navigational accuracy, keep metallic and electronic equipment at least 1 meter from the field generator.

CAUTION: Improper positioning of the Galaxy Field Generator that does not adequately capture patient's chest during setup may result in the need for repositioning during the procedure.

CAUTION: Improper positioning of the Galaxy TiLT+ board during setup may result in the need for repositioning during the procedure.

Figure 3.4 TiLT+ Board and Field Generator with Expanding Mount

Figure 3.5 TiLT+ Board and Field Generator with Velcro Mount

Connect Controller

1. Connect the Controller to the Cart. The software will automatically start the initialization of the Controller in the background of the Setup workflow.

   Note: The Controller must be initialized to complete the Setup process.

2. Press the Enable/Disable button to activate it.

NOTE: Do not touch the joystick while the Controller is initializing.

Prepare Patient

1. Once patient enters the room, place patient close to the head of the table.

   a. Ensure patient's chest is directly above the TiLT^{+} board and field generator.

2. The anesthesiologist will sedate patient.

NOTE: The endotracheal tube should be placed no closer than 40mm from the main carina to facilitate navigation initialization.

NOTE: The endotracheal tube should not be cut.

CAUTION: Improper positioning of patient during setup may result in the need to reposition patient during the procedure.

NOTE: The procedure should be performed under General Anesthesia with Electrocardiography (ECG) monitoring and ventilator alarms.

3. The anesthesiologist or physician will intubate patient.

   - Use of this device is restricted to endotracheal tubes 7.5 mm and greater.
   - Patient should not be moved when the Bronchoscope or related equipment is inserted into patient airways.

Mounting Patient Side Accessories

1. Mount Patient Side Mount on bed near patient's head on the same side of the bed that the Cart is positioned, and either on left or right side of the bed if the Cart is positioned cranially.

   a. Turn the clamp knob to lock the clamp in place on the table.

Figure 3.5 Patient Side Mount

   b. The column height can be adjusted using the column handle. If the handle is obstructed, the handle position can be adjusted by pulling outwards and rotating.

2. Unpack the Bronchoscope Connector from the Accessory Kit and attach it to the endotracheal tube.
3. Adjust Patient Side Mount such that the knob is pointing downwards (as illustrated above).
4. Mount the Bronchoscope Connector to Patient Side Mount.
5. Angle the Bronchoscope Connector between 0-30 degrees relative to the ground.
6. Lock Patient Side Mount using the knob.

NOTE: Ensure that the positioning of Patient Side Mount enables alignment of the Scope Drive and sufficient clearance for 60^{o} rotation of the C-arm. Improper position may interfere with future steps in the setup workflow.

Align

1. Initiate hand-guide by pressing and holding the buttons on both sides of the Scope Drive.
2. Align the Scope Drive to Patient Side Mount.
    a. Ensure the alignment feature of the Scope Drive is fully seated in Patient Side Mount. The purple alignment feature on the Scope Drive is flush with the front of the Patient Side Mount when fully seated.

NOTE: If resistance is experienced when performing alignment, do not force the Scope Drive past the boundaries. Instead, adjust the Cart and/or Patient Side Mount such that alignment can be performed with the Scope Drive in the resistance-free zone.

CAUTION: Proper alignment between the Scope Drive and Patient Side Mount is important for smooth scope insertion and retraction as well as preventing air leakage during ventilation.

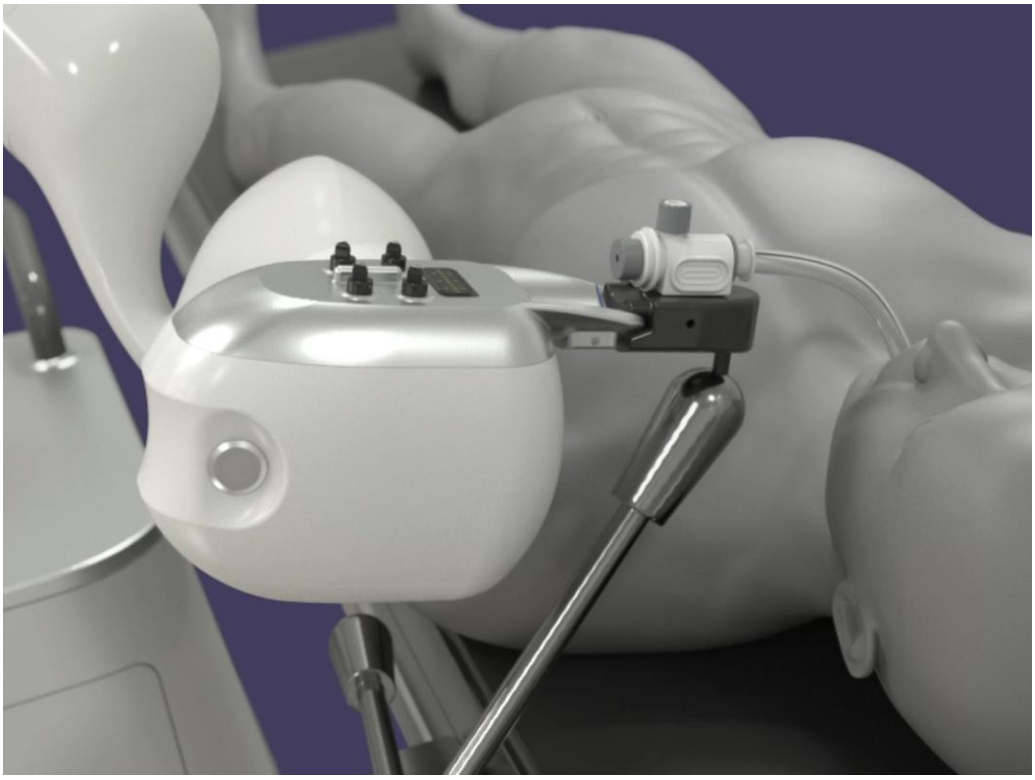

Figure 3.6 Alignment

Retract the Robotic Arm

1. Press and hold **RETRACT** to retract the robotic arm in preparation for scope loading.
    a. To stop robotic motion at any time, let go of the button. To resume, press and hold **RETRACT**.

Load the Bronchoscope

1. Unpack the Scope Guide and load onto the Scope Drive.
2. Open the Bronchoscope package and remove the Bronchoscope.

NOTE: If the Bronchoscope is dropped after being removed from its sterile pouch, it shall not be used as its sterility has been compromised. Replace with a new, sterile Bronchoscope.

3. Lubricate the Bronchoscope shaft.

NOTE: Placing lubricant on the camera may result in compromised image quality.

NOTE: Use only medical grade, silicone-based lubricants such as Silkospray™ Universal Silicone Spray and Olympus Silicone Oil Endoscope Lubricant.

4. Load the Bronchoscope onto the Scope Drive.
    a. Ensure the Scope Guide is in the collapsed position during Bronchoscope loading.
    b. Insert the Bronchoscope through the collapsed Scope Guide and Bronchoscope Connector.
    c. Mate the handle onto the Scope Drive until audible and tactile feedback is received indicating a proper engagement. The Graphical User Interface will indicate successful engagement.
5. Extend the Scope Guide over the scope shaft and connect it to the Bronchoscope Connector.

Fluidics Tubing Setup

1. Hang a saline bag on the saline bag hook.
2. Unpack the Fluidics Tubing from its sterile packaging.
3. Hang the tubing on the fluidics hook.
4. Setup the irrigation line (blue tubing).

a. Route the irrigation line through the pump by opening the pump cover, placing the black segment of the tubing into the pump, and then closing the cover. The pump cover can be opened and closed by lifting and pressing down on the black tab at the top of the pump. Note the direction of the arrow, which defines the pumping direction.

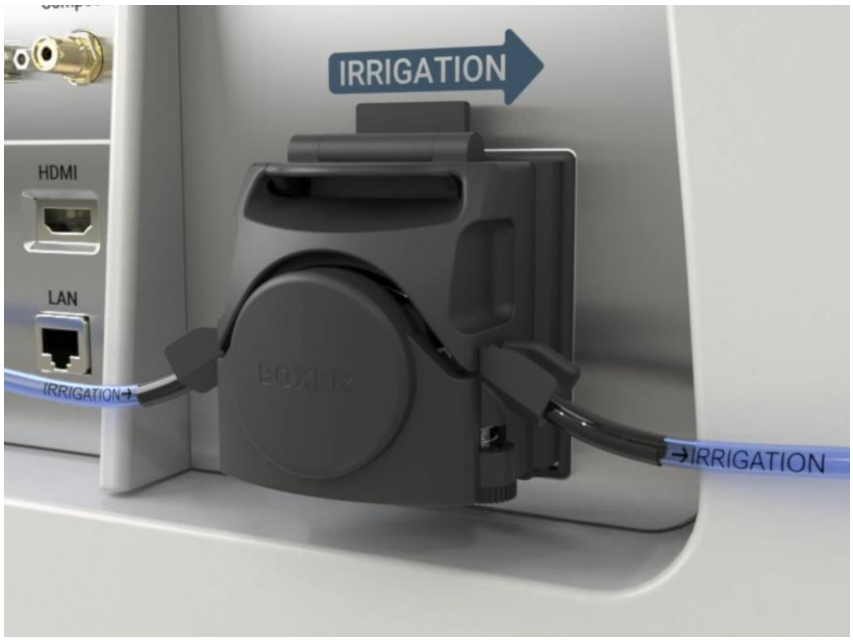

Figure 3.7 Irrigation Line Setup

b. Connect the irrigation line to the saline bag with the attached spike.

5. Setup the suction line (clear tubing).

a. Route the suction line through the pinch valve. To open the pinch valve, depress the black button.

Figure 3.8 Suction Line Setup

b. Attach the suction line to wall suction

6. Prime the tubing by pressing and holding the irrigation button on the Controller until saline reaches the end of the tubing.
7. Attach the fluidics connector to the Bronchoscope.

NOTE: Ensure there are no kinks in the Fluidics Tubing.

NOTE: Ensure suction is set at a low pressure. Increase as needed during the procedure.

4 Performing a Procedure

This chapter covers the following sections:

4.1 Overview

Each procedure consists of tasks and each task has one or more steps. In performing a procedure, you will typically perform the following steps:

1. Load a Procedure.
2. Register.
3. Navigate to the lesion.
4. Perform TiLT+.
5. Align the Galaxy Bronchoscope with lesion.
6. Insert the biopsy instrument.
7. Obtain biopsy.

4.2 Galaxy Controller

The Galaxy Controller is used to control the Galaxy Bronchoscope. The individual controls are described in the following table and figure:

Figure 4.1 Galaxy Controller

Table 4.1 Galaxy Controller Functions

No.	Item
1	**Directional-Pad (D-Pad) and Select Button** (inactive)
2	**Enable/Disable button**
3	**Snapshot Button**
4	**Menu Button**
5	**Brightness Adjustment Button**
6	**Relax Button**
7	**Insert/Retract Joystick**
8	**Articulation Joystick**

Figure 4.2 Galaxy Controller Fluidics Functions

Table 4.2 Galaxy Controller Fluidics Functions

No.	Item	Description
1	**Irrigation Button**	Press and hold to irrigate.
2	**Suction Button**	Press and hold to suction.

WARNING: Always secure the Controller. In the enabled state, dropping the Controller or any other unintended motion may lead to accidental commanded motion which may cause patient injury, such as pneumothorax, hemorrhage or endoluminal irritation. It is recommended to disable the Controller when it is not held.

WARNING: When driving the Bronchoscope, ensure the intended joystick is actuated. Failure to do so may result in accidental commanded motion which may cause patient injury.

4.3 Galaxy System™ User Interface

Procedure Selection Screen

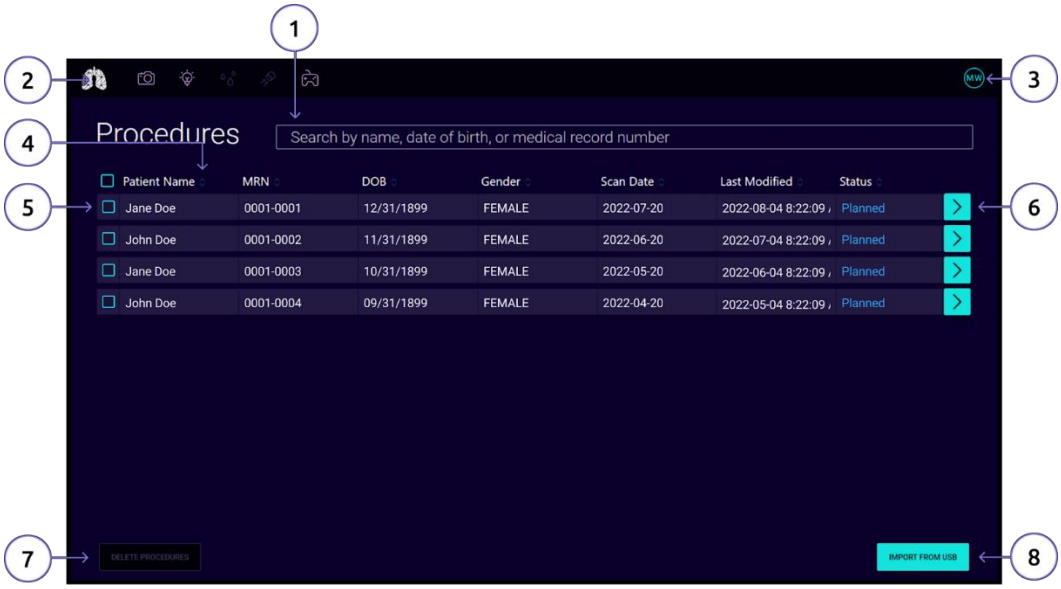

Figure 4.3 Procedure Selection Screen

Procedure Selection Screen Elements

Table 4.3 Procedure Selection Screen Functions

No.	Item	Description
1	**Search**	Search for a procedure.
2	**Header**	Displays header.
3	**User Menu**	Select to open the menu to log out or update user password.
4	**Sort**	Select to sort by selected column.
5	**Select Procedure**	Select to select procedure(s).
6	**Start Procedure**	Select to begin or view procedure information if already previously conducted.
7	**Delete Procedure**	Select to delete selected procedure(s).
8	**Import Procedure**	Select to import a new procedure from USB.

Procedure Information

The Procedure List displays the following general information.

Table 4.4 Procedure Information

Item	Description
Name	Patient's name.
MRN	Patient's MRN/ID.
Date of Birth	Patient's date of birth.
Gender	Patient's gender.
Scan Date	Date of CT scan.
Last Modified	Last modified time of the procedure.
Status	Procedure status, planned or completed.

Procedure Import Screen

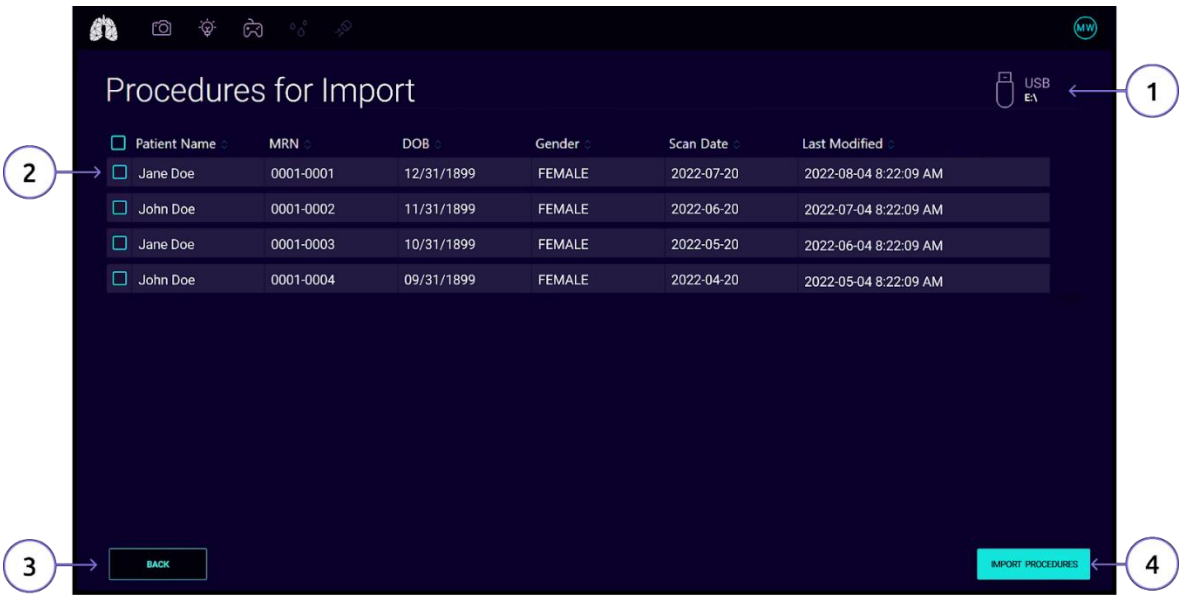

Figure 4.4 Procedures for Import Screen

Procedure Import Screen Elements

Table 4.5 Procedure Import Screen Elements

No.	Item	Description
1	**Source**	Displays source.
2	**Procedure Selection**	Select checkbox(es) to select procedure(s) for import.
3	**Back**	Select to return to previous screen.
4	**Import Procedure**	Select to import selected procedure(s).

Registration Screen

The registration screen provides the physician with the information and elements needed to perform registration.

Registration Screen Header Elements

Figure 4.5 Registration Screen Header Elements

Table 4.6 Registration Screen Functions

No.	Item	Description
1	**Camera Icon**	A red dot indicates continuous recording. A white icon appears when a screenshot is taken.
2	**Light Source Icon**	Displays live camera view brightness.
3	**Irrigation Icon**	Appears when irrigation is active.
4	**Suction icon**	Appears when suction is active.
5	**Controller Icon**	Displays Controller connection status.
6	**Wall power icon**	Displays wall power status.
7	**EM Signal Lost**	Appears orange when no EM signal is detected, appears purple when EM signal is intermittent.
8	**Patient Information**	Displays the patient's name, date of birth, and MRN.
9	**Hide/Show Patient Information**	Select to hide the patient information/ Select to show the patient information.
10	**Menu**	Select to open menu. Menu is also accessible through the Controller.

Registration Screen Elements

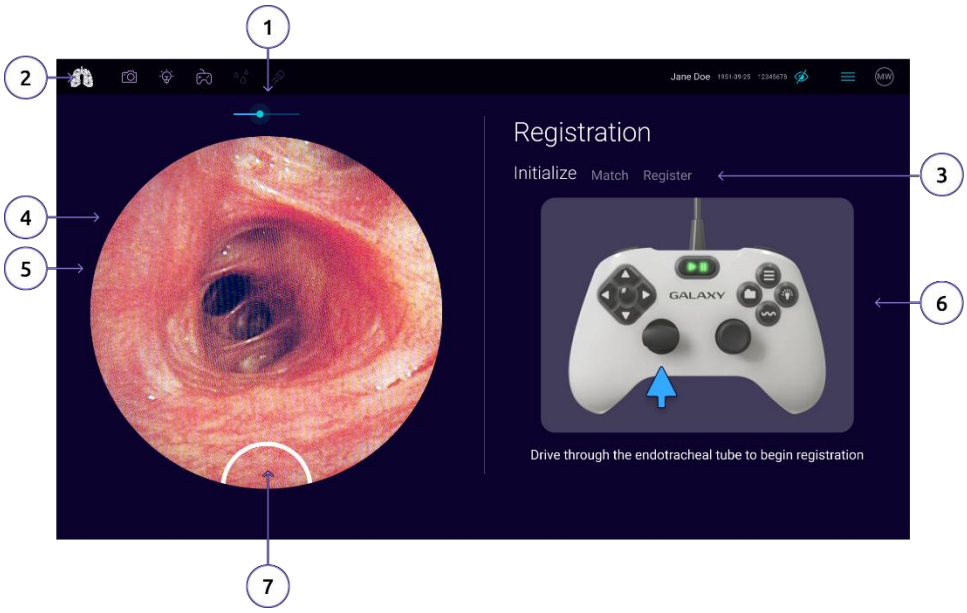

Figure 4.6 Registration Screen Elements

Table 4.7 Registration Screen Elements

No.	Item	Description
1	**Roll Adjustment Slider**	Slide to adjust the roll of the camera.
2	**Header**	Contains header elements.
3	**Registration Steps**	Displays all registration steps and highlights current step.
4	**Live Camera View**	Displays live camera image from scope tip.
5	**Initialization Status**	Displays status of scope initialization.
6	**Instructions**	Displays registration instructions.
7	**Working Channel Indicator**	Displays position of working channel

Registration Menu Elements

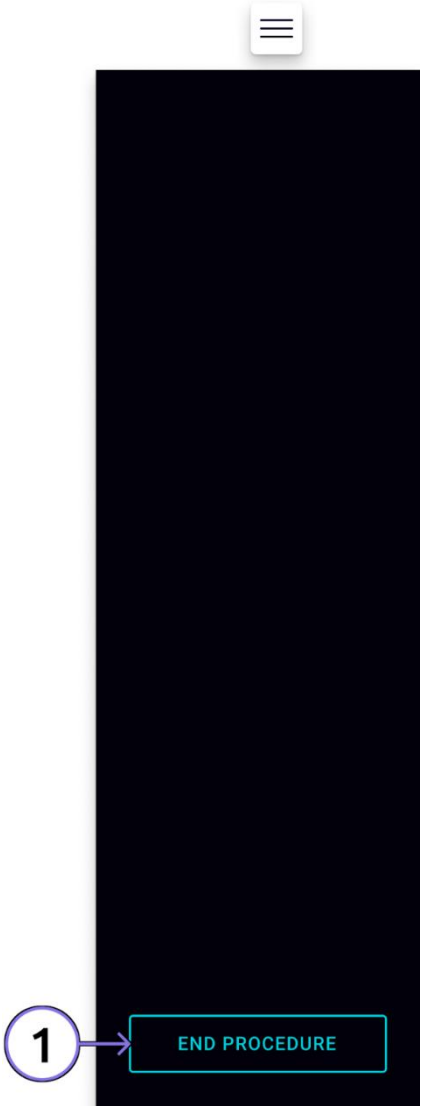

Figure 4.7 Registration Menu Elements

Table 4.8 Registration Menu Element Functions

No.	Item	Description
1	**End Procedure**	Select to end the procedure

Treatment Screen

The Treatment Screen provides the physician with the information and elements needed to perform a bronchoscopy procedure.

Treatment Screen Header Elements

Figure 4.7 Treatment Screen Header Elements

Table 4.8 Treatment Screen Header Element Functions

No.	Item	Description
1	**Camera Icon**	A red dot indicates continuous recording. A white icon appears when a screenshot is taken.
2	**Light Source Icon**	Displays the brightness for live camera view.
3	**Irrigation Icon**	Appears when irrigation is active.
4	**Suction Icon**	Appears when suction is active.
5	**Controller Icon**	Displays Controller connection status.
6	**Wall Power Icon**	Displays wall power status.
7	**EM Signal Lost**	Appears orange when no EM signal is detected, appears purple when EM signal is intermittent.
8	**Patient Information**	Displays the patient's name, date of birth, and MRN.
9	**Hide/Show Patient Information**	Select to hide the patient information/ Select to show the patient information.
10	**Menu**	Select to open menu. Menu is also accessible through the Controller via a button with a similar icon.

Treatment Screen Elements

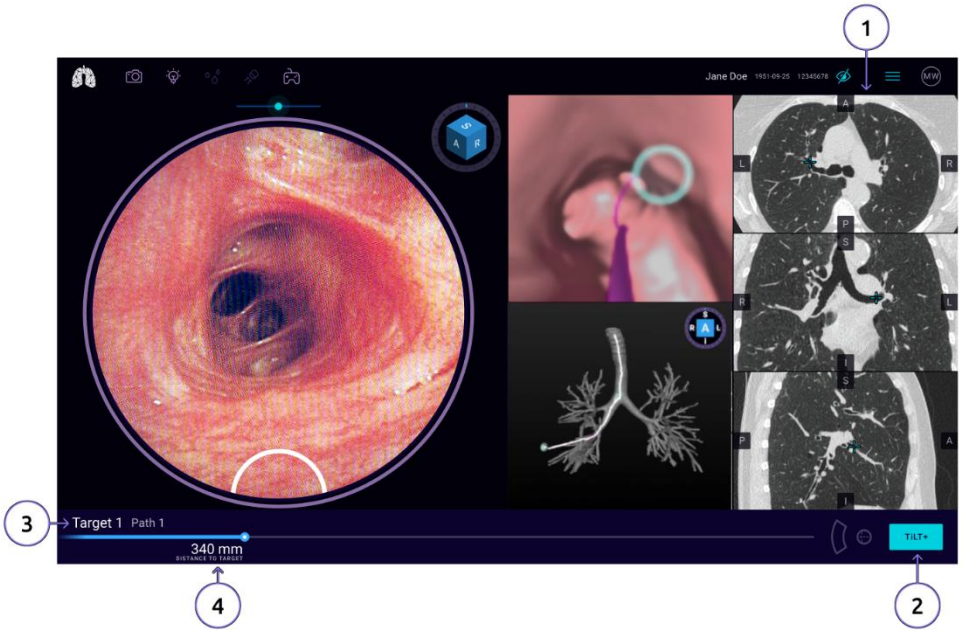

Figure 4.8 Treatment Screen Elements

Table 4.9 Treatment Screen Elements

No.	Item	Description
1	**Navigation Viewports**	Navigation and external imaging views will appear here. The layout of these views can be customized.
2	**TiLT⁺ Button**	Select to initiate TiLT⁺.
3	**Target and Path**	Displays the selected target and path name.
4	**Distance to Target**	Displays distance to the center of the selected target.

Treatment Menu Elements

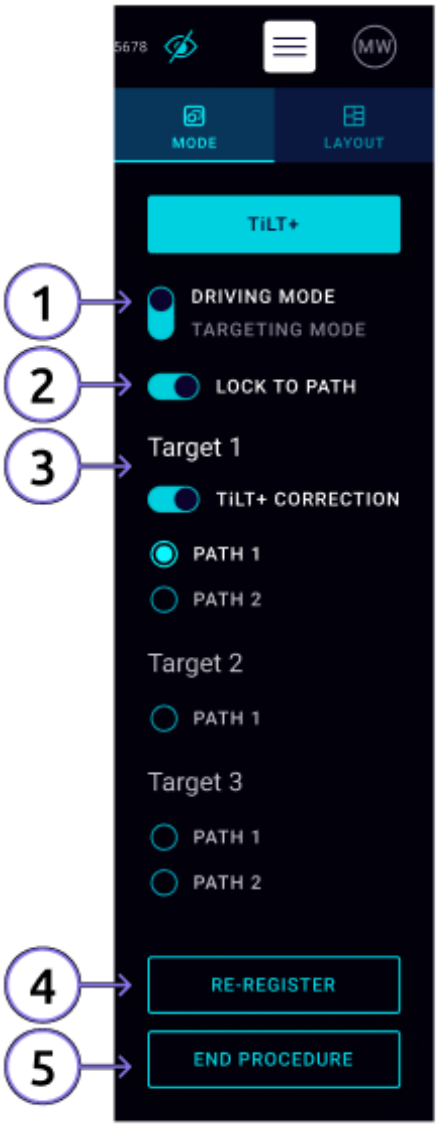

Figure 4.9 Treatment Menu

Table 4.10 Treatment Menu Elements

No.	Item	Description
1	**Mode**	Toggle between Driving Mode or Targeting Mode. **Driving Mode:** Intended to be used while navigating to the lesion. Virtual views are based on camera position. **Targeting Mode:** Intended to be used when making final adjustments for targeting. Virtual views are based on working channel position.
2	**Lock to Path**	Toggle to enable the Lock to Path feature. This locks your navigational position to the pre-planned path.
3	**Target/Path Selection**	Select desired target/path.
4	**Re-registration**	Select to re-register.
5	**End Procedure**	Select to end the procedure

Layout Tab

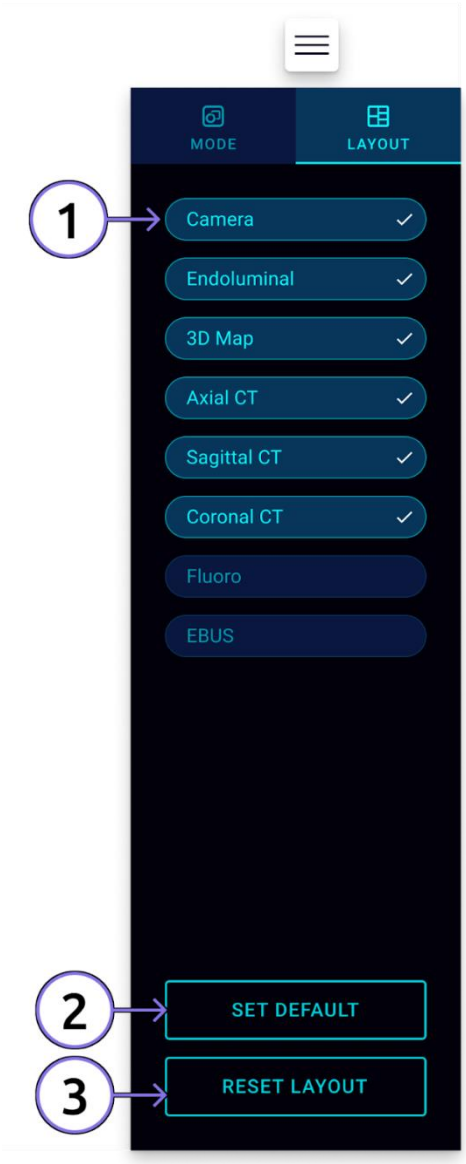

Figure 4.10 Layout Tab

Table 4.11 Layout Tab Functions

No.	Item	Description
1	**Select Views**	Adjust layout of navigation views. To move views or replace a view on the Treatment screen: 1. Select the tile on the Treatment Menu that corresponds to the view that is to be moved or swapped. 2. Select the desired viewport on the Treatment Screen to place the selected view. Note: The camera view cannot be moved off the screen and must always remain in the first two columns of viewports.
2	**Set As Default**	Select to set current view arrangement as default.
3	**Switch to Default**	Select to reset view arrangement to default.

Navigation Views

The Galaxy System™ provides access to several navigation views which include live-imaging views and virtual views of the airway segmentation. The layout of these views can be customized based on physician preference and rearranged during the procedure as needed.

A pre-procedure CT scan is integrated into the procedure interface displaying scope tip location relative to the pre-procedure scan anatomy. The navigational information displays the Galaxy Bronchoscope tip location relative to the CT scan. The application's interface includes a virtual representation of the lung airways with scope tip location and direction. The following views describe the way that the scope tip location appears on the CT scan images or virtual representations as well as live-imaging views (Live Camera, Fluoroscopy, rEBUS).

NOTE: If EM signal is lost, as indicated on the header, virtual navigation views may not accurately display scope position.

Live Camera

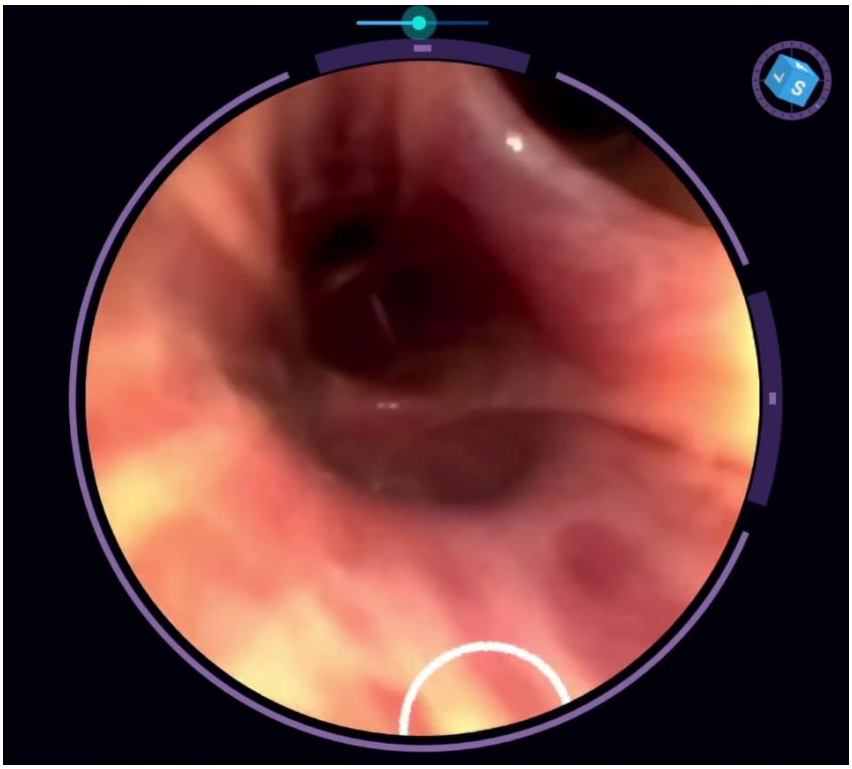

Figure 4.11 Live Camera

The Live Camera view provides continuous vision throughout the procedure. The location of the working channel is represented by a half circle at the edge of the camera image. The view orientation (anterior/posterior/inferior/superior/left/right directions) is indicated by the cube in the top right corner of the view which rotates in response to scope motion and manual camera rotation.

The circle around the camera view represents the status of the scope. After the scope is initialized, the purple circle around the camera will appear, and the scope can be articulated. As the scope is articulated, the arc(s) around the camera will begin to fill to indicate direction and magnitude of articulation.

Table 4.12 Scope Status

Scope Status	Description
Scope unattached	Scope camera view black with ‘Acquiring Video’ message
Scope uninitialized	Empty circle.
Scope initialized	Complete circle.

The camera view cannot be removed from the screen or moved into the rightmost viewport column of the Treatment Screen.

Endoluminal View

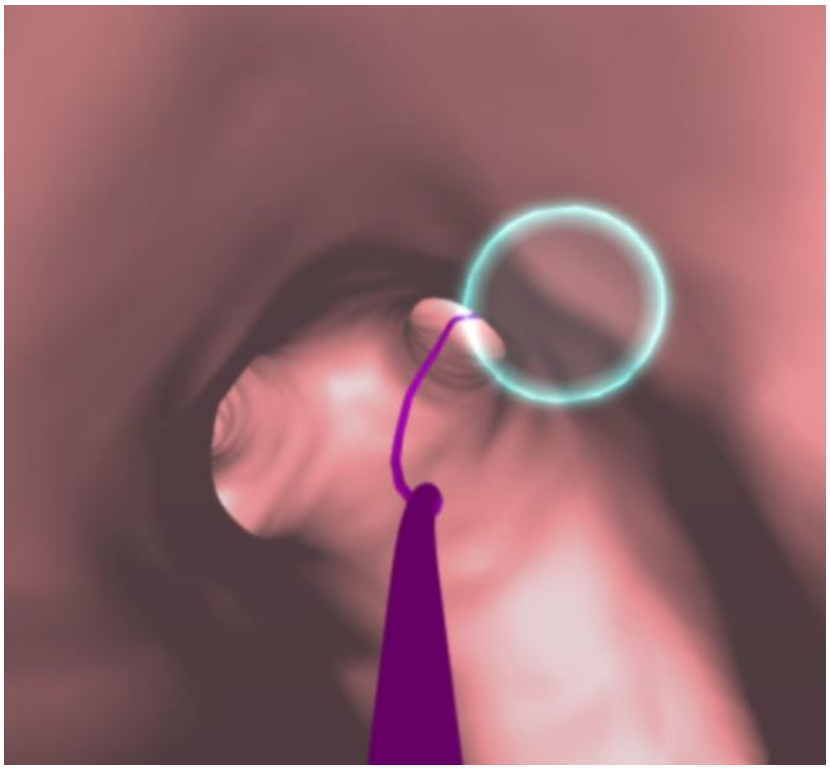

Figure 4.12 Endoluminal View

In Driving mode, the endoluminal view shows the scope position and orientation from inside the airways, generally mirroring the view of the live camera. The Endoluminal view is designed to provide turn-by-turn guidance to the target.

The Endoluminal view shows the pathway as a 3D line in the center of the Endoluminal view. When the scope deviates from the path, the path will disappear until the scope moves back toward the navigational path.

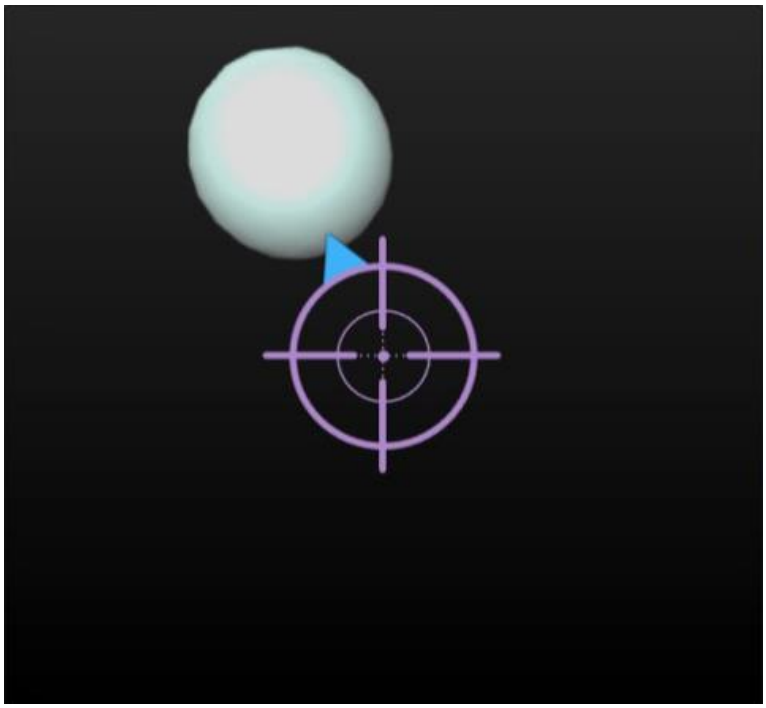

Figure 4.13 Targeting View

In Targeting mode, the Endoluminal view displays the biopsy position from the perspective at the scope tip to aid in the alignment of the working channel toward the selected target. The view consists of a crosshair, aligned with the working channel of the scope, and the target, represented by a blue ellipsoid.

When the target is not directly in the center of the Targeting mode, an arrow will appear on the rim of the crosshairs that will guide the user which direction to move the scope.

3D Map

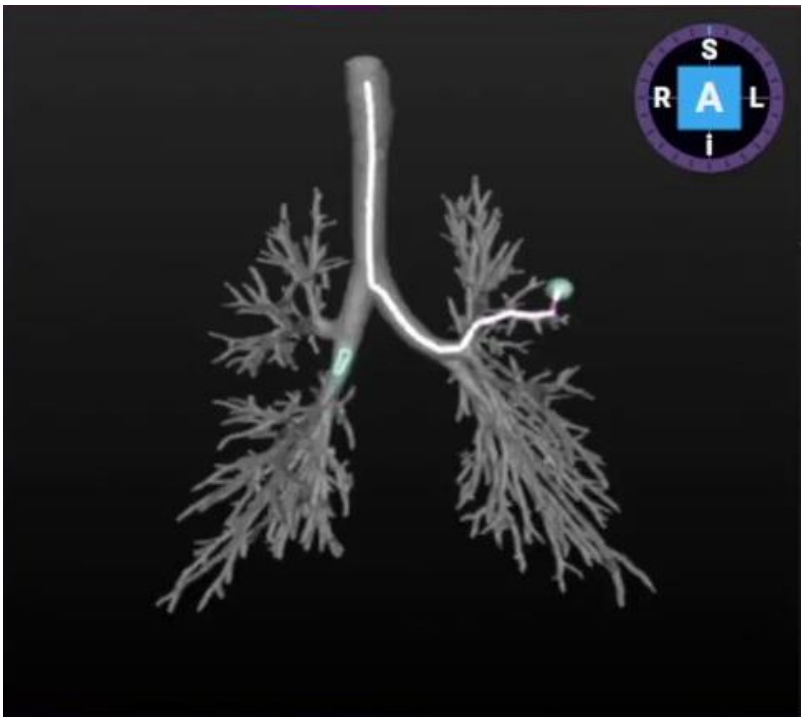

Figure 4.14 3D Map

3D Map is a virtual representation of the patient's airway tree with the location of the selected pathway and target superimposed. As the scope moves through the airways, its position and orientation are reflected on this map. The orientation of the airway tree is represented by a cube representing the direction of anterior/posterior/inferior/superior/left/right.

CT Views (Axial, Sagittal, and Coronal)

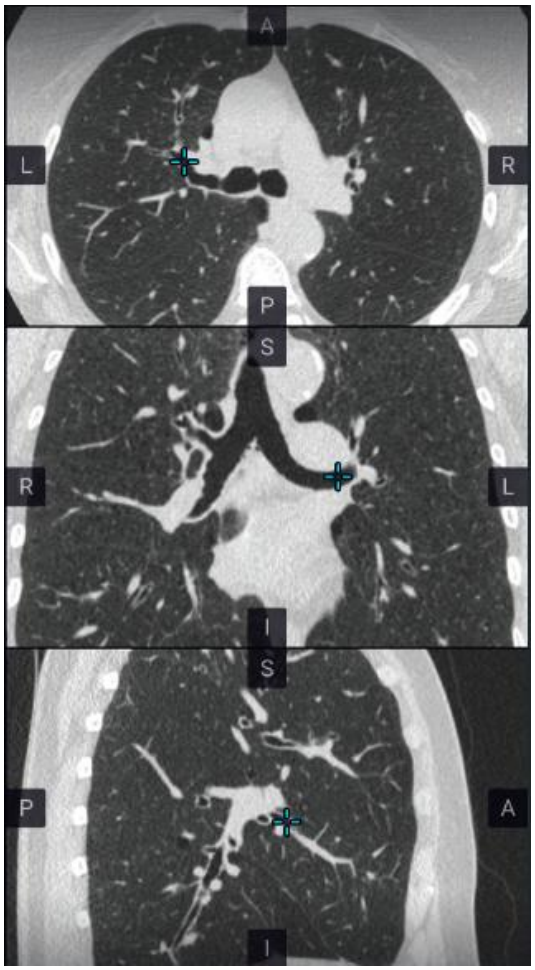

Figure 4.15 CT Views

The CT views include Axial, Sagittal, and Coronal planes which display the location of the scope tip and the selected target. The CT images automatically scroll, following the position of the scope tip within the patient's anatomy.

Fluoroscopy

The Galaxy System™ provides the option to integrate live fluoroscopy imaging into the Treatment screen. The fluoroscope system can be connected to the system through the Audio Visual (AV) Connections Panel.

After TiLT^{+} is performed, augmented fluoroscopic imaging can be enabled. Select or deselect the augmented fluoroscopy toggle at the bottom of the fluoroscopy viewport to turn on/off the augmented imaging on the fluoroscopy view. (See TiLT^{+} chapter for additional details).

rEBUS

The Galaxy System™ provides the option to integrate live rEBUS imaging into the Treatment screen. The rEBUS system can be connected to the system through the Audio Visual (AV) Connections Panel.

CAUTION: For an effective procedure, gain familiarity with the views, screens, and interactions in the Galaxy System™.

4.4 Procedural Steps or Actions

WARNING: Ensure there is enough clearance around the Cart prior to moving equipment during the procedure. Unintended contact of the Cart with external equipment may result in patient injury.

CAUTION: Use caution while managing cables and fluidic lines as they can pose tripping hazards. Be cautious when moving about the procedure room.

Load Procedure

1. Login using login credentials.
2. If procedure plan has not already been imported, import the procedure plan into the Cart.
    a. Connect the USB to the Galaxy Cart.
    b. Select **IMPORT NEW.**
    c. Identify the intended procedure(s) and check the corresponding checkbox(s).
    d. Select **IMPORT PROCEDURE.**
3. Select the procedure plan on the Touchscreen.
    a. Confirm patient details (name, date of birth, MRN, gender).
    b. Confirm procedure details (last modified date).
4. A popup will appear with options to either conduct setup, if not already completed, or start procedure. Select **START PROCEDURE** once setup is complete (See Setup chapter for details on system setup).

Initialize Scope

WARNING: Do not insert the Bronchoscope unless there is a clear endoscopic field of view. Failure to maintain visibility during insertion may result in patient injury such as tissue damage, pneumothorax, or other adverse events.

WARNING: Do not continue inserting the scope if scope buckling is detected. Continued insertion may result in patient injury.

WARNING: While the scope is mounted, the handguide function on the Scope Drive is disabled. Please utilize the Controller to command motion of the scope.

1. Activate the Controller by selecting the Enable/Disable button.
2. Using the Insertion joystick, insert the scope down the endotracheal tube until the scope begins initializing. The initialized state is indicated by a complete circle around the camera on the screen.
    - When the scope is initializing, insertion/retraction motion will be inhibited.

Register

Registration is the process used to match the scope position in the patient's anatomy with the Navigation views. Follow the steps on the screen to perform registration.

1. Match the main carina.
    a. Drive to the main carina and match the camera view to the virtual rendering depth while maintaining the scope in the center of the airway. If desired, the rotation can be adjusted using the roll slider above the camera view.
    b. Select **CONFIRM.**
2. Drive down either of the main bronchi. The lung diagram on the screen will begin to fill to indicate registration process until the progress indicator is complete.

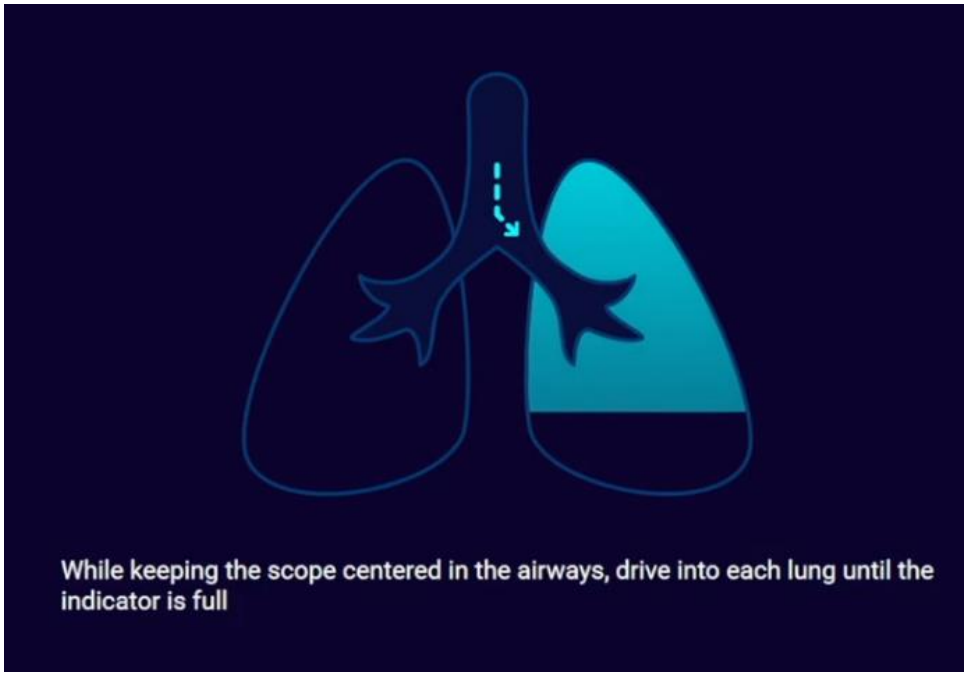

Figure 4.16 Registration Progress Indicator

3. Once the first lung indicator is complete, retract the scope back to the main carina, and drive down the other main bronchus until the progress indicator is complete and a check mark appears over the lungs.

Figure 4.17 Registration Complete Indicator

In the case that the patient's anatomy does not allow for registration to be completed, **CONTINUE EARLY** may be used to complete registration prematurely.

NOTE: Continuing early could affect the accuracy of the provided navigation.

If a mismatch is detected after registration, re-registration can be accessed through the Treatment menu in the Options tab by selecting **RE-REGISTRATION.**

NOTE: To maximize navigation accuracy, keep the scope centered within the airways during registration.

Navigate and Target

After registration is complete, the first planned target and path is automatically selected. The planned pathway to the target appears on the Endoluminal view and 3D Map view.

Driving of the Bronchoscope through the airways should be performed in a minimally traumatic manner by attempting to stay in the center of the airways at all times.

CAUTION: Virtual navigation views should be used as guidance only. Exercise clinical judgment during the procedure.

1. Use the Controller to drive the scope through the airways following the planned pathway to the target.
2. Once the scope is within 20 - 30 mm of the target, TiLT^{+} may be used to perform a local registration. This step is optional. (See Chapter 5)

If the scope needs to be removed during the procedure, retract the scope back to the main carina prior to removal.

Administering Saline or Another Agent Through the Working Channel

If you want to administer cold saline or any other agent through the working channel with a syringe, rotate the stopcock on the fluidics tubing, and the syringe can be connected to the manual irrigation port.

Biopsy

Needles, Forceps, and Brushes

Compatible working channel instruments may be used with the Galaxy System™.

1. Insert compatible third-party tools through the valve on the fluidics tubing at the backend of the Bronchoscope.
2. Deploy the tool to retrieve the sample of the target tissue.
3. Remove the tool and evaluate the airway.

WARNING: Confirm scope and/or biopsy tool location prior and during biopsy. Failure to do so may result in patient injury. Other imaging modalities such as radial ultrasound and fluoroscopy may be used with the Galaxy System™.

WARNING: Do not attempt to move the robotic arm during biopsy. Robotic arm motion may result in motion of the scope.

WARNING: Ensure the biopsy is completed by a trained physician and use correct tool insertion depth to reduce potential damage to patient airways during biopsy.

NOTE: Do not irrigate with working instruments in the working channel. This can cause pressure build up in the irrigation tubing.

NOTE: Metallic working channel instruments near the scope tip may temporarily compromise navigation accuracy.

NOTE: Do not apply excessive force when withdrawing biopsy instruments through the Galaxy Bronchoscope. If resistance is experienced, relax the bronchoscope, and if necessary, retract the scope and relax the scope until there is no longer excessive force when attempting to retract the biopsy instrument.

4.5 Post-Procedure

When the procedure is complete, use the following guidelines to properly retract the Galaxy Bronchoscope.

Retraction

When retracting the Galaxy Bronchoscope, fully relax the scope as you retract.

NOTE: If the Galaxy Bronchoscope is articulated during retraction, and there are no articulation commands during retraction, it will automatically relax after a retraction distance of 15 mm.

WARNING: Relax or de-articulate the scope during retraction. Failure to do so may result in patient injury.

WARNING: Remove the scope handle from the Scope Drive when removing the scope. Do not remove the scope shaft without removing the scope handle. Do not insert the scope shaft unless the handle was detached prior. Failure to do so may result in patient injury.

WARNING: Wait for the robot arm to retract prior to re-engaging a scope. Failure to do so may result in patient injury.

End Procedure

Select **END PROCEDURE** to conclude the procedure.

5 TiLT+ Technology™

This chapter provides information regarding the Galaxy System™ Tool in Lesion Tomography, or TiLT+ Technology™. TiLT+ enables the generation of a partial 3D reconstruction of the lung. Augmented Fluoroscopy is an optional feature that can be enabled after TiLT+ that gives the user the option to visualize the location of the target on a live fluoroscopy image with a graphic overlay for more accurate navigation of the Bronchoscope and the biopsy tool.

This chapter will cover the following sections:

CAUTION: This workflow involves the use of X-ray radiation. All individuals present in the room must adhere to radiation safety guidelines

5.1 TiLT+ Overview

The Galaxy System™ TiLT+ Technology™ provides the option to perform a local registration for each target using tomosynthesis. This registration is performed to provide an accurate estimate of the location of the target of interest. Set up and preparations for TiLT+ must be made during the pre-procedure setup.

Objective

TiLT+ utilizes a mobile C-arm that is already available and routinely used in lung biopsy procedures. Tomosynthesis is used to improve the visibility of the lesion and enable three-dimensional localization of the scope and lesion to confirm tool-in-lesion.

5.2 Setup

The following section describes the setup procedure for the implementation of TiLT+.

Initiation

When the scope tip is within 20mm -30mm of the target and TiLT+ is ready to be performed, select the TiLT+ button in the bottom right corner of the screen or at the top of the mode section of the menu.

Setup

Before beginning the procedure, ensure that the field generator is mounted below the patient bed and connected to the Cart. Additionally, ensure that the TiLT+ board and spacer board (if applicable) are placed under the mattress such that the purple markings align. See Section 3.4 Galaxy Setup for more details.

CAUTION: Ensure that the TiLT+ board is aligned with the field generator. Improper positioning of the TiLT+ board may negatively impact future steps during TiLT+.

The Setup screens provide instruction on how to set up and position the C-arm. Setup is as follows:

1. Position the C-arm such that it is directly perpendicular to the patient at a 90˚ angle.

NOTE: Improper positioning of the C-arm may interfere with future steps in the setup workflow.

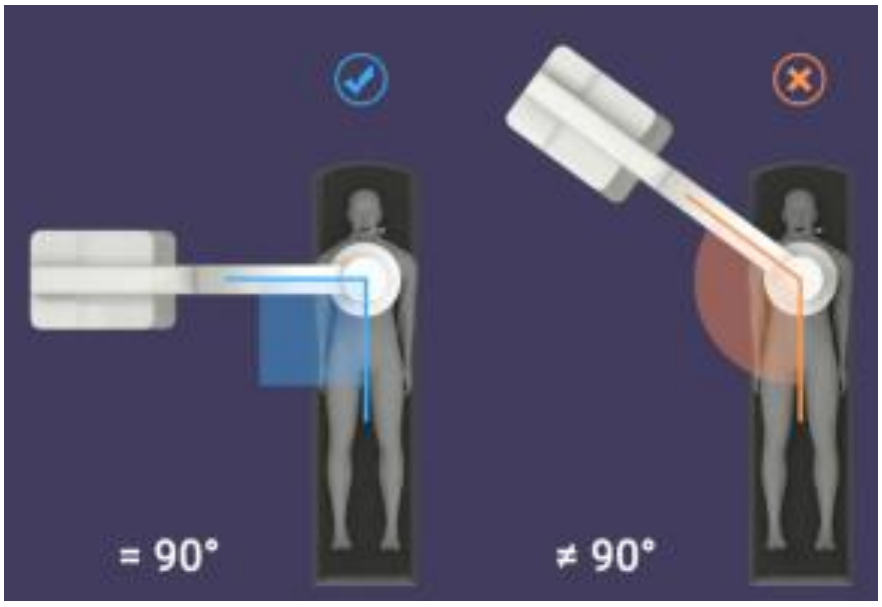

Figure 5.1 Positioning of C- Arm

2. Plug the C-arm into the appropriate Fluoro port on the Audio Visual (AV) Connection Panel using the appropriate video cable.

Figure 5.2 Audio Visual (AV) Connection Panel

Configure

1. Select the C-arm model and video port combination from the drop-down menu. Once a C-arm is selected, the settings and recommended parameters for the specific C-arm will be displayed. A C-arm must be selected to proceed to the next step.

2. Configure the C-arm settings such that they match the parameters displayed on the screen.

CAUTION: Using C-Arm parameters other than the ones described below or on the instruction screen may result in lower quality images and results which may interfere with future steps during TiLT^{+}.

Frame

Follow all instructions provided on the screen and as listed below:

1. Set the C-arm detector about 20 cm above the patient's chest and take an image.

2. Set the C-arm image orientation to match the labels on the sides of the image.

3. Adjust the C-arm such that the scope tip is within the blue circle and ensure six or more rows of beads are visible.

4. Capture an image at RAO 30° and LAO 30° to ensure the beaded board and scope tip are still visible, and no collisions occur.

5.3 Image Acquisition

Image acquisition is performed by rotating the C-Arm from 30° LAO to 30° RAO over 15-20 seconds while the patient is subjected to a breath hold.

Capture

Follow the steps below to initiate image acquisition:

1. Position the C-arm so that it is at 30° LAO or RAO.
2. Initiate a tidal volume breath hold.
3. Begin fluoroscopy using HLF. Hold the C-arm constant for two seconds to allow for the breath hold and automatic exposure control (AEC) to stabilize (if applicable).
4. Begin capture by selecting **START**. Ensure the sweep takes about 15-20 seconds.
    - The on-screen animation on the left of the screen indicates the time that has elapsed since the capture began and the approximate position that the C-arm should be in at that time.
    - The image presented on the right side of the screen is the live fluoroscopy view during the sweep.
5. Once the C-arm has reached 30° on the other side, end the capture by selecting **STOP**.
6. End patient breath hold.

CAUTION: Capture should always be performed while the patient is under breath hold. Failure to do so may result in lower quality images and results that negatively impact future steps during TiLT+ and navigational guidance.

CAUTION: Sweeps should always be targeted to take approximately 15 seconds. The allowable range is 5-30 seconds. Failure to complete the sweep and image capture within this range will result in needing to repeat the capture step.

CAUTION: Ensure that the start and end capture are performed as listed above. Failure to do so may result in lower quality images and results that negatively impact future steps during TiLT+ and navigational guidance.

NOTE: The sweep should be performed at a steady speed over approximately 15 seconds such that the resulting video does not contain motion blur. It is recommended that the C-arm is pulled (instead of pushed) during the sweep for a smoother rotation.

Review

Once the capture is complete, the video playback will appear, and the system will prompt a review of the playback. If there is significant motion blur in the video, recapture is recommended. This can be done by selecting **RECAPTURE**. If the video obtained is sufficient, select **NEXT** to proceed.

5.4 Scope and Lesion Selection

When image acquisition is complete, the next step is to mark the Bronchoscope tip on two images and the target of interest on the TiLT^{+} reconstruction. These positions are used to update the location of the lesion with respect to the position of the Bronchoscope in navigation. If necessary, this information can be used to adjust the position and alignment of the Bronchoscope to the lesion after TiLT^{+}.

Scope Selection

Two images will be displayed side by side corresponding to the first and last image of the sweep, respectively. Select the tip on each image.

The default slices used are the most optimal. If the tip is obstructed in either of these images, use the slider or arrows below the image to scroll to another.

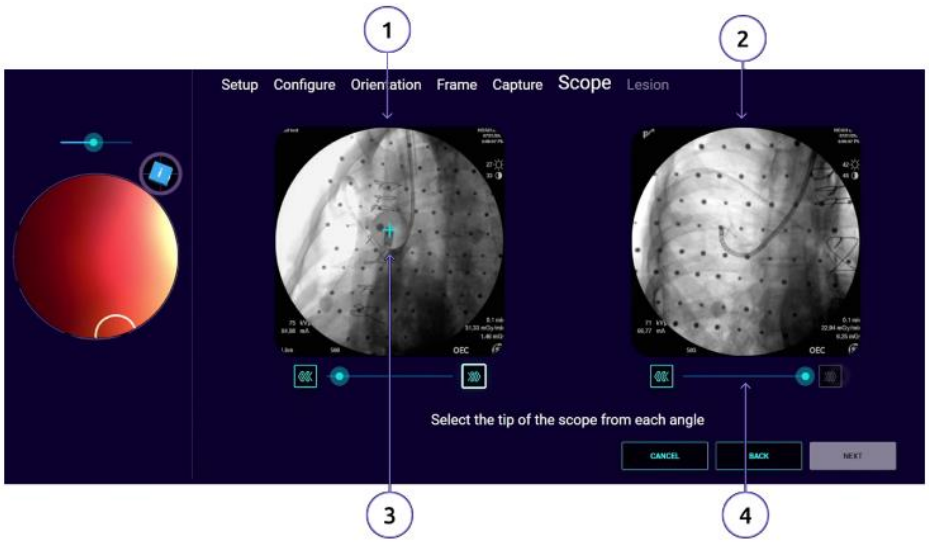

Figure 5.2 Scope Selection Screen Elements

Table 5.1 Scope Selection Screen Elements

No.	Item	Description
1	**First Image**	Displays image at the start of capture.
2	**Last Image**	Displays image at end of sweep.
3	**Selection crosshair**	Adjust to position crosshair at scope tip.
4	**Scroll bar**	Drag or click buttons to scroll through captured images.

Selecting anywhere on the image will pull up a zoomed view with crosshairs in the middle for a more precise selection. Press and drag anywhere on the image to reposition the crosshairs to the center of the distal surface of the Bronchoscope. Repeat this process on the other image.

Lesion Selection

Three pairs of images will appear. The image pair on the left, top right, and bottom right represent the Coronal, LAO 45º, and RAO 45º views, respectively. For each pair of images, the image on the left displays the TiLT+ reconstruction. The image on the right is the reference pre-procedural CT image.

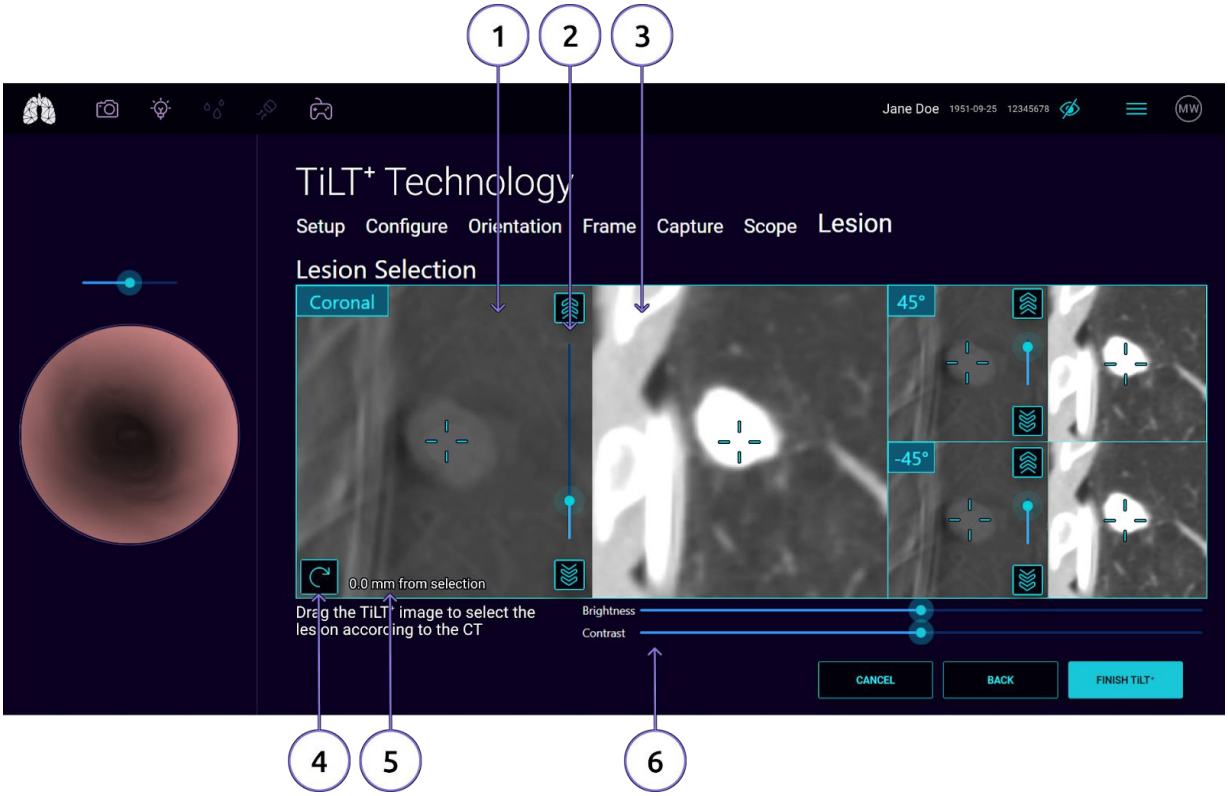

Figure 5.3 Lesion Selection Screen

Table 5.2 Lesion Selection Screen Elements

No.	Item	Description
1	**TiLT+ Reconstruction**	Displays TiLT+ reconstruction.
2	**Scroll bar**	Drag or click buttons to scroll through TiLT+ Reconstruction.
3	**CT Reference Image**	Displays CT with planned target.
4	**Reset**	Select to reset TiLT+ Reconstruction.
5	**Strikepoint**	Displays distance and direction between the current image and the selected lesion location.
6	**Brightness/Contrast**	Drag slider bars to adjust TiLT+ Reconstruction brightness/contrast.

NOTE: Anatomical landmarks, such as bones, on the reference CT image can be used by the user to help visually identify the target.

Follow the steps below to select the lesion from the reconstructed image:

1. Use the slider located on the right side of the images to find the image that has the lesion with the most prominent borders.
    a. Adjust image brightness and contrast for better visualization by using the sliders located under the images
2. Select the lesion on the reconstruction to initiate lesion selection. The image will zoom in and crosshairs will appear.
    a. Press and drag anywhere on the image to move the crosshairs to the center of the target.
    b. Confirm that the target is correct by comparing the selection with the CT image.
3. Select **FINISH TILT+** to complete the TiLT+ workflow.

CAUTION: Ensure that lesion is selected accurately. Failure to do so may negatively impact navigational guidance.

NOTE: If the lesion cannot be reliably identified, cancel TiLT+ and retry.

5.5 After Initial TiLT+

Once the TiLT+ workflow is complete, the system will return to the navigation screen. If the navigation was in Driving Mode prior to TiLT+, the system will automatically change to Targeting mode. An update to the location of the target will be made according to the most recent TiLT+ image acquisition.

TiLT+ Correction

The system will automatically update the location of the target according to the results of the TiLT+ workflow.

The original pre-procedural CT-based target can be viewed by toggling the TiLT+ Correction button below the TiLT+ button in the menu. This allows for comparison of the previously defined target from the original CT and the updated TiLT+ based target in the targeting and 3D map views. The distance to lesion will not change upon toggling and will always reflect the location of the updated TiLT+ based target. The TiLT+ Correction toggle button can be seen below:

Figure 5.4 TiLT+ Correction Toggle Button

1. Make any additional corrections to the Bronchoscope location using this updated information, if needed.
2. Insert the biopsy tool and proceed to biopsy or repeat the TiLT+ workflow for Tool-In-Lesion Confirmation.

NOTE: If the target is switched, TiLT+ will have to be performed again. Switching targets will erase the TiLT+ data for the target.

TiLT+ for Tool-in-Lesion Confirmation

TiLT+ may be repeated to confirm Tool-in-Lesion. There is no limit to the number of times this can be performed.

The reconstructed image consists of Strikepoint, a feature that represents the distance between the displayed image within the reconstruction and the selected lesion in the anterior-posterior direction. Strikepoint can be used to help inform whether the tool is in the lesion by selecting the lesion and navigating to the image where the needle image is the most well defined. The distance and direction displayed is the location of the tool with respect to the center of the lesion. For example, if the difference between the positions of the needle and lesion is 10 mm, and the lesion is 10 mm in diameter, there is a low likelihood of the tool being in the lesion. But if the difference is 1 mm, there is a high chance that the tool is within the lesion.

The position of the needle can be determined by identifying the image where the needle converges and is the brightest.

5.6 Augmented Fluoroscopy

Overview

Augmented Fluoroscopy is a feature that overlays graphics on a live fluoroscopy. Many smaller lesions within the lungs are not directly visible under 2D fluoroscopy, and the biopsy tool may not go straight due to airway or tool deflection. In this case, augmented fluoroscopy can provide live visual feedback of the biopsy tool in relation to the target by overlaying an outline of the target onto the live fluoroscopy image or video.

Enable Augmented Fluoroscopy

Augmented fluoroscopy is only available after TiLT+ has been completed. Once the TiLT+ workflow is completed, augmented fluoroscopy will automatically be enabled. A blue outline will appear on the fluoroscopy image indicating the position of the lesion. This outline will update for every subsequent fluoroscopy image that is taken until another target is selected.

CAUTION: Using magnification on the C-Arm may result in failure of the augmented fluoroscopy feature.

CAUTION: Moving the TiLT+ board may result in failure of the augmented fluoroscopy feature or inaccurate navigational information

CAUTION: Using the TILT + Correction toggle will show the pre-TiLT + target location, which may impact user biopsy location.

6 Cleaning, Maintenance, and Storage

Service and maintenance other than what are indicated in this chapter shall be performed by trained Noah Medical Service Personnel only. This chapter covers the following sections:

CAUTION: Clean and disinfect the Galaxy System™ by wiping components with a moist disinfecting cloth. The bedside components should be cleaned and disinfected before each case. All other components should be cleaned and disinfected at least monthly. The Galaxy System™ components are compatible with the following types of cleaning agents: distilled water, Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant – Hydrogen Peroxide 1.4%, Sani-Cloth Bleach Germicidal Wipe – Sodium Hypochlorite 0.63%, 70% Isopropyl Alcohol Wipes, 96% Ethanol Solution, and 0.425% Quaternary Ammonium Compound Wipes.

NOTE: Using cleaning agents on the Touchscreen during normal operation can result in unintentional button presses and/or short-term Touchscreen difficulty due to moisture.

WARNING: Do not shut down the system while the Galaxy Bronchoscope is still inserted in patient.

WARNING: Do not remove or disconnect system components (other than the Galaxy Bronchoscope) while the Galaxy Bronchoscope is in patient.

WARNING: Do not remove protective covers from any system component. No user serviceable parts are inside. Contact Noah Medical Customer Service for any service concerns or questions.

WARNING: Unpowered storage of the Galaxy System™ for extended periods (longer than three months), especially after running on the UPS, will result in degradation of the UPS batteries.

WARNING: When disposing of instruments, accessories, or any of their components, follow all applicable national and local laws and guidelines.

CAUTION: Do not mobilize the Cart while the field generator is connected and attached to the bed.

6.1 Media Export

Once the procedure is complete and **END PROCEDURE** is selected, there is an option to export any videos and screenshots taken during the procedure.

Insert a USB

Insert a USB drive into any USB port located on the Galaxy Cart. If a file that is larger than 4 GB is being exported, the USB drive should be formatted as NTFS (New Technology File System) or exFAT (Extensible File Allocation Table).

Select Media to Export

The Procedure Summary & Export screen provides the option to review the complete procedure video as well as select media to export. The following media can be exported:

- Complete Procedure Video
- Snapshots
- 40 second clips with each snapshot

Export

Once the media has been selected, select **EXPORT** in the bottom right corner.

6.2 Remove and Clean Equipment

Remove the Irrigation Aspiration Tubing

Disconnect and discard the Irrigation Aspiration Tubing.

Remove the Galaxy System™ Bronchoscope

Detach the Bronchoscope handle from the Scope Drive and discard the Bronchoscope.

Remove the Scope Guide

Detach the Scope Guide from the Bronchoscope Connector and Scope Drive and discard the Scope Guide.

Remove the Bronchoscope Connector

Disconnect and discard the Bronchoscope Connector.

Remove, Clean, and Store the Galaxy Field Generator

Remove, wipe down, and store the Galaxy Field Generator.

Remove, Clean, and Store the Galaxy TiLT+ Board and Spacer

Remove, wipe down, and store the Galaxy TiLT^{+} Board and Spacer Board.

Clean and Store the Wired Controller

1. Unplug and wipe down the Galaxy Controller.
2. Return Controller to the storage drawer in the Cart.

Disassemble and Clean Patient Side Mount

1. Remove Patient Side Mount from the bed and wipe down.
2. Return Patient Side Mount to the storage drawer in the Cart.

Clean and Store the Galaxy System™ Cart

1. Mobilize the Cart and move it away from the bed, taking care to avoid large obstacles.
2. Wipe down the robot arm, monitor, and Cart.

Clean and Store the Galaxy System™

The options to stow the arm and logout or go to the next procedure will be provided after ending the procedure.

1. Select **STOW & LOGOUT** to stow the robot arm and return to the login screen.
2. Select **SHUTDOWN** to turn off the Galaxy Cart. Shutdown can also be initiated by pressing the Power button on the Cart.
3. Unplug the Cart.
    - Ensure that the Power button LED indicator turns off before unplugging the Cart.
4. Wipe down the power cable and store using the cable hooks.
5. Move the Cart to the storage area.

NOTE: If the Power button is held for more than 10 seconds, the system automatically shuts down. This should be reserved only if the system cannot be shut down through the software interface.

CAUTION: Ensure the monitor is moved out of the way and maintain a clearance of one to two feet between the Galaxy Cart and patient, staff, and other equipment to stow the arm safely. Release the STOW button on the Touchscreen to pause robotic motion, if necessary.

6.3 Servicing

Preventative Maintenance

Routine preventive maintenance procedures will be performed every six months (or as needed) by an authorized Noah Medical representative. These procedures may include functional checks, inspections, replacements, and repairs on the Galaxy System™ Cart and Reusable Accessories.

Configuration

Video Display

The Galaxy System™ allows for the use of external monitors to duplicate the Galaxy System™ video on an external display. The external monitor may be connected to the Galaxy System™ using the HDMI port located on the Cart. Cables and/or converters required to connect the monitor are not supplied with the Galaxy System™. Contact Noah Medical Customer Service for additional information.

Maintenance

Backup Batteries

The Galaxy System™ contains lithium-ion batteries which are capable of holding a charge for up to three months. Unplugged storage of the Galaxy System™ for extended periods (longer than three months) will result in degradation of the uninterruptible power supply (UPS) batteries. The batteries are not user-serviceable and should only be replaced by authorized Noah Medical representatives.

Parts Replacement

The Galaxy System™ does not have any user-replaceable parts except for the following system accessories:

- Galaxy Controller
- Patient Side Mount
- Galaxy Field Generator
- Galaxy TiLT+ Board
- TiLT+ Spacer Board

All other replacement parts must be provided by Noah Medical Corp. Contact Noah Medical Customer Service for assistance. Use of third-party components or modifications of the Galaxy System™ may result in unexpected behavior, safety risks, and voids product warranties. Noah Medical Corp. is not responsible for any damages resulting from use of unauthorized parts or modifications.

Replacement of Galaxy Controller

1. Disconnect the Galaxy Controller connector from the system.
2. Connect the replacement Galaxy Controller to the system.
3. Press the Enable/Disable button on the Controller to ensure the Controller is active.

Replacement of Patient Side Mount

1. Ensure that the Galaxy System™ is not in a procedure.
2. Remove Patient Side Mount.
3. Follow the instructions in Chapter 3: System Setup to install the replacement Patient Side Mount.

Replacement of the Galaxy Field Generator

1. Ensure that the Galaxy System™ is not in a procedure.
2. Remove the Galaxy Field Generator
3. Follow the instructions in Chapter 3: System Setup to install the replacement Galaxy Field Generator.

Replacement of the Galaxy TiLT+ Board

1. Ensure that the Galaxy System™ is not in a procedure.
2. Remove the Galaxy TiLT+ Board
3. Follow the instructions in Chapter 3: System Setup to install the replacement Galaxy TiLT+ Board.

Replacement of the TiLT+ Spacer Board

1. Ensure that the Galaxy System™ is not in a procedure.
2. Remove the TiLT+ Spacer Board
3. Follow the instructions in Chapter 3: System Setup to install the replacement TiLT+ Spacer Board.

Recommended Spare Components

Noah Medical recommends that the following spare components and accessories are readily available as necessary:

- Controller
- Bronchoscope
- Single-use accessories

7 User and System Administration

The chapter covers the following sections:

7.1 User Administration

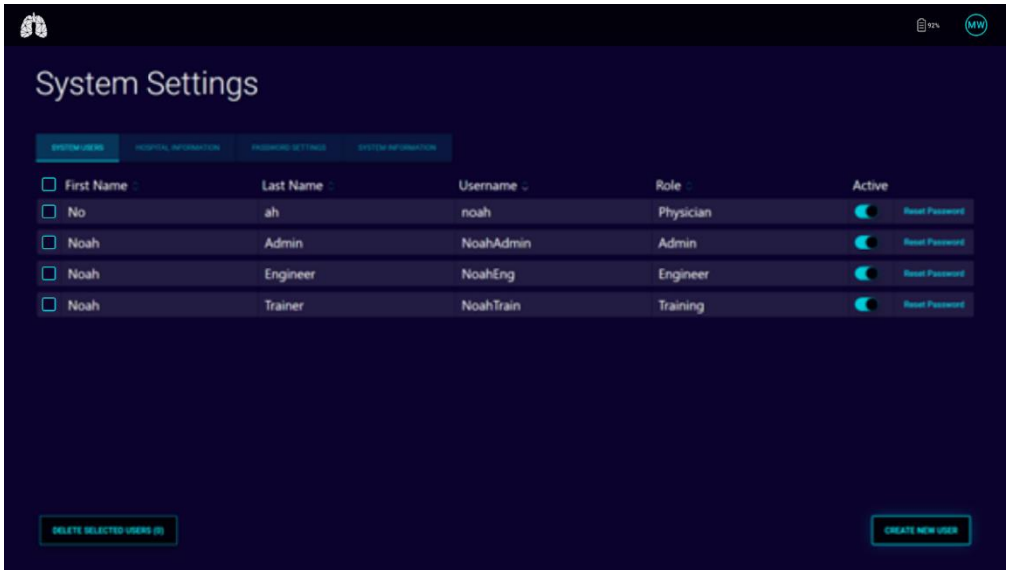

Figure 7.1 System Screen Setting

An Admin profile for the system will be created and provided to the site administrator during system installation. The site administrator can create and remove all user accounts and reset a user's password if lost or forgotten.

User Types

There are two user types: Administrator and Physician. The Administrator can only manage users. The Physician can create and perform procedures.

Specify a user's access to create and perform a procedure, as well as administration permission to manage other users.

Table 7.1 User Permission

Task	Admin	Physician
Create a procedure		X
Perform a procedure		X
Manage users	X	

Create New User

To create a new user:

1. Log on as admin.
2. Select **SYSTEM SETTINGS** to view the Settings screen
3. Select **CREATE NEW USER**. The following dialog box appears

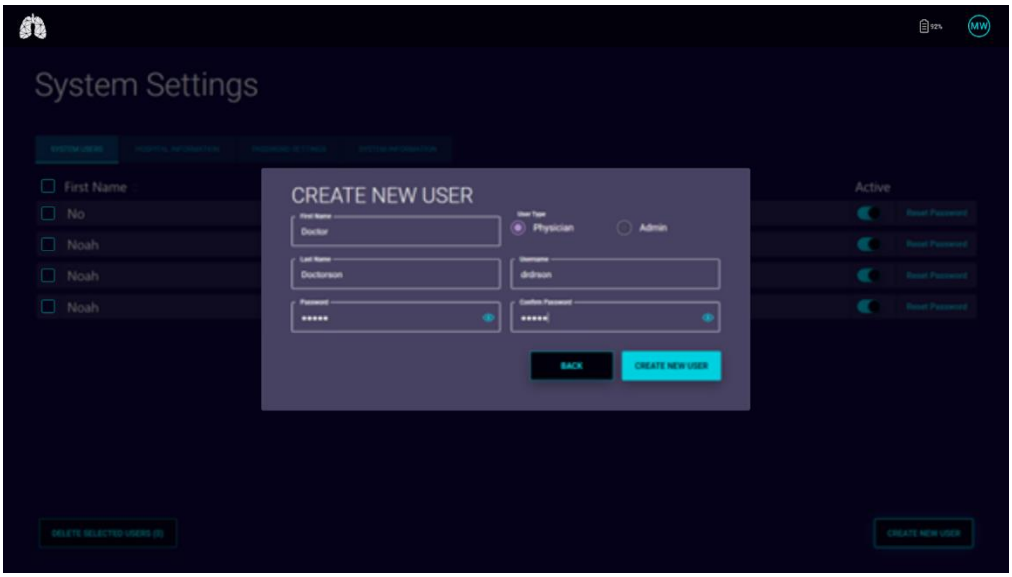

Figure 7.2 Create New User Popup

4. Enter the following information for the new user:
   a. Username
      - A username should be more than one character and be unique.
   b. Last Name and First Name.
   c. Password
      - A password should be set based on the password requirements defined by your hospital. The Galaxy

System™ supports many password requirements settings.

d. Confirm Password by retyping password.

5. Select **CREATE NEW USER** to save.

Change User Password

To change user password from an administrator account

1. Log on as admin.
2. Select **SYSTEM SETTINGS** to view the Settings screen. A user list will populate for current users.
3. Select **RESET PASSWORD** in the row of the user profile whose password needs to be changed.
4. Enter the following information:
   a. New Password
      - A password should be set based on the requirements defined by your hospital. The Galaxy System™ supports many password requirements settings.
   b. Confirm Password
      - Confirm by retyping the password.
5. To save your changes, select **OK**.

To change user password from a physician account

1. Log on with physician credentials.
2. Select **CHANGE PASSWORD** in the User Menu by retyping password.
3. Enter the following information:
   a. New Password: a password should be set according to the requirements defined by your hospital. The Galaxy System™ supports many password requirements settings.
   b. Confirm Password by retyping password.
4. To save your changes, select **OK**.

Disable Existing User

1. Log on as admin.
2. Select **SYSTEM SETTINGS** to view the Settings screen.
3. Find the user that you want to disable and toggle the **ACTIVE** setting to off.

Adding a Hospital Logo

1. Log on as admin.
2. Select **SYSTEM SETTINGS** to view the Settings screen.
3. Navigate to the **HOSPITAL INFORMATION** tab.
4. Insert a USB into the Cart and upload a hospital logo that meets the requirements shown on the screen.

7.2 System Security

Virus Protection

The Galaxy System™ is built with strict user permissions and antimalware mechanisms to prevent installation of unauthorized software. Only qualified Noah Medical Service Personnel have the required permissions to install software on the Galaxy System™.

NOTE: Do not attempt to install any software, including anti-virus, on any components of the Galaxy System™. Do not attempt to access or modify the internal components of the Galaxy Cart.

NOTE: USBs are transport vehicles for malicious software. Only use USBs that are strictly under the users' control and verified as being free from malware.

Patient Data Security

The Galaxy System™ fully encrypts all Patient Health Information (PHI) at rest using the Advanced Encryption Standard AES - 256. This applies to all internal hard drives as well as any plans that users create and transfer via USB drives.

PHI is also protected by role-based access controls. Users with the Administrator role are responsible for managing the lifecycle of user accounts, including disabling inactive accounts.

Additionally, it is strongly recommended to enable the following configuration in the System Settings to minimize the risk of unauthorized PHI disclosure:

- Enable strict password rules, including password expiration
- Enable the inactivity timeout

The Galaxy System™ is configured with strict password settings and the inactivity timeout enabled by default. These settings are configurable by the user.

Never leave the Galaxy System™ unattended when a user is logged in.

Appendix A Troubleshooting and Notifications

Troubleshooting

When any errors that require intervention are detected, the notification center will be displayed with instructions on how to recover on the right-hand side of the screen. Please follow the instructions shown to recover.

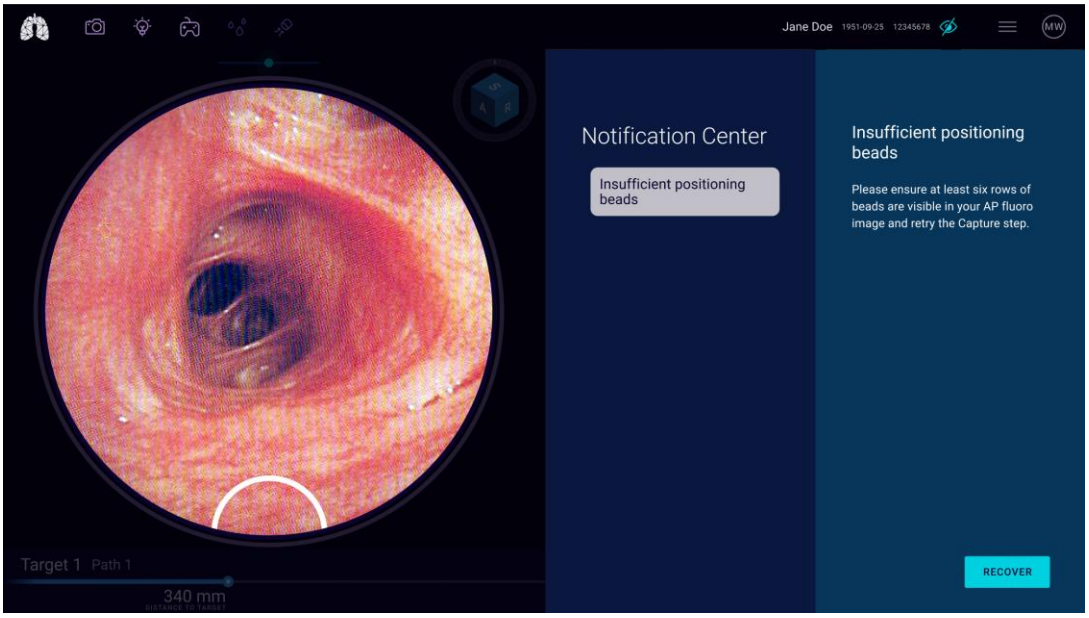

Figure A.1 Notification Center

General Troubleshooting Steps

Follow any instructions presented on the screen.

If an Emergency Stop (E-stop) has occurred:

1. Detach the Bronchoscope from the Scope Drive and select **RECOVER**. Notice that the Scope Drive will retract back to its initial position 3 seconds after **RECOVER** is pressed.
2. Re-mount the scope to continue the procedure after recovering from an E-stop.

NOTE: Wait until the arm is fully retracted before re-mounting the scope.

This same process can be implemented for any other type of alert that requires system recovery.

If the problem persists or recovery attempts fail, restart the system and contact Noah Medical Customer Service so the issue can be investigated.

CAUTION: Accidental actuation of the E-stop button may result in the need to repeat some portions of the procedure.

WARNING: Failure to activate the E-stop in an emergency scenario within an appropriate time period may result in negative patient outcomes.

Emergency Bronchoscope Removal

If the Bronchoscope must be quickly removed from patient, detach the Bronchoscope handle from the Scope Drive and manually remove it from patient.

WARNING: In the case of a patient cardiac event, ensure Patient Side Mount is not in contact with the patient during defibrillation. Failure to do so will reduce the effectiveness of the defibrillation.

Inaccurate Navigation

Lock-to-path locks the scope position in the navigation views to remain on the path to the target and can be enabled if the estimated scope position is not accurate. The navigation views continue to follow the insertion and retraction of the scope.

To enable Lock-to-Path

1. On the procedure screen, open the menu and toggle Lock-to-Path

All panels on the driving screen that are impacted by this change are wrapped in a dotted border. These panels include: Virtual Endoluminal, Virtual Lung, and CT.

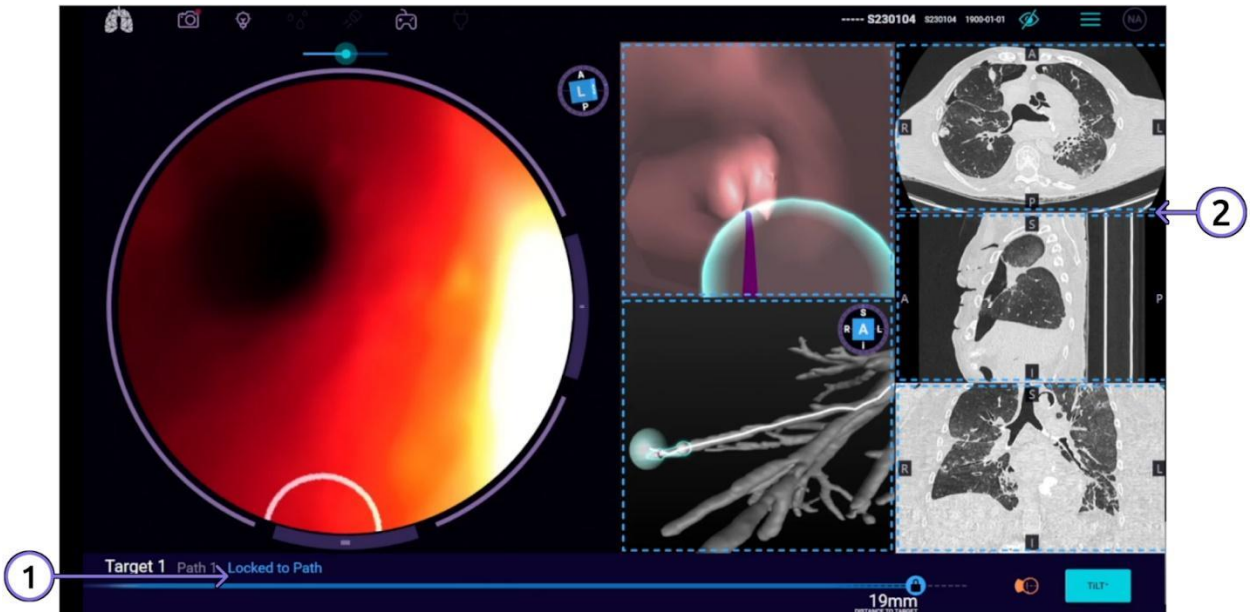

Figure A.2 Lock to Path Screen Elements

Table A.1 Lock to Path Element Functions

No.	Item	Description
1	**Locked to Path Indicator**	When Lock to Path is on, the text above the distance to target will state “Locked to Path” and the distance indicator will end in a dotted line.
2	**Dotted border on navigation views**	All EM based screens and information will be bordered with dotted lines when Lock to Path is on.

Joystick Articulations Not Matching Directionally

1. Detach and reattach the Bronchoscope from the Scope Drive.
   a. If the problem persists, replace the scope.
   b. If the problem persists, reboot the system.
   c. Contact Noah Medical Customer Service if the problem persists.

Failed Controller Initialization or Dropped Controller

In the event of a failed Controller Initialization or dropped Controller, a notification pop-up will appear. Perform the following:

1. Press **Recover** on the screen. The Controller Initialization process will begin.

NOTE: Do not touch the joystick while the Controller is initializing.

2. Upon completion, you may proceed with your procedure. Press the Enable/Disable button to activate the controller.

Controller Does Not Appear Functional

1. Check the Galaxy Controller Enable/Disable button status to ensure that it is enabled.
2. Check the Controller icon on the header of the Galaxy screen to ensure the connection is recognized by the system.
3. Check the Controller port on the Cart and make sure the Controller is plugged all the way in.
4. Unplug and re-plug the Controller.
5. Plug the Controller in a different port.
6. Contact Noah Medical Customer Service if the problem persists.

Field Generator or Patient Side Mount Clamps Do Not Tighten

1. Detach the mount from the table.
2. Inspect the clamp for fluid residue or debris blocking the clamp. Do not disassemble the clamp to inspect.
3. Exercise the clamp by loosening and tightening the knobs.
4. Contact Noah Medical Customer Service for a replacement mount if the knobs cannot be tightened.

Galaxy Cart Will Not Turn On

1. Confirm that the Galaxy Cart main power cables are connected to active, dedicated power outlets.
2. Confirm that the Galaxy Cart main power cables are connected to the Cart.
    a. Inspect the power cables to ensure there are no tears.

3. Confirm that the Power Control Switch is switched on.
4. Press the Power button on the Cart. The light ring around the Power button will illuminate when the system is turned on.
5. Contact Noah Medical Customer Service if the problem persists.

Cart Monitor Does Not Turn On

1. Confirm that the light ring on the Cart's Power button is illuminated.
2. If within a few minutes of turning on the system, the user interface does not appear on the monitor, reboot the system.
3. Contact Noah Medical Customer Service if the problem persists.

Loss of Video on Cart monitor (During Procedure)

1. Confirm that the light ring on the Cart's Power button is illuminated.
2. Remove instruments inserted in the working channel of the Bronchoscope System.
3. Use the Galaxy Controller to relax and then retract the Bronchoscope.
4. Detach the Bronchoscope from the Scope Drive.
5. Reboot the system.
6. Contact Noah Medical Customer Service for support if Cart video is not present after system reboot.

General Planning Laptop Troubleshooting Steps

1. If the laptop is not turning on, confirm laptop is connected to power.
2. If the planning software is unresponsive, reboot the laptop.
3. Contact Noah Medical Customer Service if the problem persists.

Cannot Export Procedure

1. Confirm that your plan has both a confirmed target and a confirmed path.
2. Confirm that the USB drive you wish to export to is the only USB plugged into the laptop.
3. Confirm that there is sufficient space in your USB.
4. Save the case plan and reboot the laptop. Retry procedure export.
5. Contact Noah Medical Customer Service if the problem persists.

Alerts

The Galaxy System™ software constantly monitors system status and reports any error conditions that may trigger a notification. The tables in this appendix include errors, messages, and recommended actions for the Galaxy System™. Only the alert titles and resolutions will be presented.

Definitions:

Notification: Provides information and does not require any immediate action. These are transient notifications that disappear after 6 seconds.

Minor Alert: Provides information and requires user acknowledgement. To acknowledge, read the message provided and select **ACKNOWLEDGE**.

Major Alert: Conditions that require user action. To recover, follow the instructions provided on the screen, and select **RECOVER**.

Severe Alert: Conditions that cause motion to stop. To recover, follow the instructions provided on the screen, and select **RECOVER.**

System Error: Conditions that require the system to be shutdown.

Alerts Table

Table A.2 Planning Alerts Table

Type	Title	Resolution
Notification	Training Account	This account cannot be used for exporting procedures.
Notification	Low Disk Space	Consider deleting some procedures before running out of space
Notification	Export Disabled	Training plans cannot be exported.
Minor Alert	User does not have privilege to change system time.	System failed to set system time zone due to the privilege level of the current user.
Minor Alert	User does not have privilege to change the time zone.	System failed to set system time zone due to the privilege level of the current user.

Minor Alert	Invalid Operation	You can only access Engineering screen when not in the Settings or Login screens
Minor Alert	Export Failed	Unable to export this procedure. Please contact customer support.
Minor Alert	Delete Failed	Failed to delete procedure. Please contact customer support.
Minor Alert	No Removable Drives Found	Please insert a removable drive and retry.
Minor Alert	Multiple Drives Found	Please only keep the drive of your choice plugged in.
Minor Alert	Error Detecting Drive	Unable to detect the inserted drive. Please contact customer support.
Minor Alert	Error Importing Scans	Unable to import scans from USB. Please contact customer support.
Minor Alert	Error Importing Scans	Unable to import scans from DVD. Please contact customer support.
Minor Alert	Multiple Drives Detected	Please insert only one drive
Minor Alert	No Drives Detected	Please insert a drive containing a scan
Minor Alert	Missing Removable Media	Missing Training Scans, Please contact customer service.
Minor Alert	Error While Loading Scan	Unable to load this scan. Please contact customer support.

Minor Alert	Not enough storage space to import	Please delete previous procedures and try again.
Minor Alert	Existing Patient Found	Found existing patient with MRN: {0} and name {1}. Please delete the existing patient before importing a new one.
Minor Alert	Incompatible Scan	The scan you are trying to import has a zero star rating. The following tags are violating our minimum requirements: {0}
Minor Alert	Error Importing Scans	Unable to load this scan. Please contact customer support.
Minor Alert	Patient Processing Error	Unable to process this patient. Please contact customer support.
Minor Alert	Error Importing Scan	Unable to import this scan. Please contact customer support.
Minor Alert	No CT Scans Available	No CT scans found on this media. Please insert media with a valid CT scan.
Minor Alert	Unable to Extend Airway	The maximum allowed airways have been reached.
Minor Alert	Save Failed	Failed to save procedure. Please contact customer support.
Minor Alert	Screenshot Failed	Unable to take a screenshot. Please contact customer support.
Minor Alert	Failed to save updated airways. The exported procedure will keep your paths	Failed to update extended airways

	but will not have updated airways.	
Minor Alert	Failed to load procedure.	Please contact customer support.
Minor Alert	Segmentation Failed	Unable to segment scan. Please contact customer support.
Minor Alert	Export Failed	Unplanned procedures cannot be exported. Please select only planned procedures.
Minor Alert	Invalid Patient Data	This patient cannot be loaded. Please delete this procedure and try importing again.
Minor Alert	Insufficient Disk Space	Please delete some procedures to continue creating new cases.
Minor Alert	Not enough storage space to import.	Please delete previous procedures and try again.

Table A.3 Procedure Alerts Table

Type	Title	Resolution
Notification	Camera Framerate Error	If the notification is persistent, please contact Noah Medical Customer Service so we can investigate
Notification	Controller Disconnected	Connect the Controller to proceed with the procedure.
Notification	Licensing Error	Please contact Noah Medical Customer Service so we can investigate.

Notification	User role invalid	Select a valid user role.
Notification	Low camera framerate	If the notification is persistent, please contact Noah Medical Customer Service to investigate.
Notification	Administrator access required	Login with an administrator account.
Notification	EM signal lost	If the alert is persistent and unexpected, please contact Noah Medical Customer Service so we can investigate.
Notification	Import complete	No action required.
Notification	Practice scope attached	No action required.
Notification	Scope buckling detected	Utilize fluoroscopy to visualize scope positioning. If the scope is buckling, retract the scope and reattempt navigating to the target.
Notification	Controller paused due to drop	Enable the Controller to proceed with the procedure.
Notification	Camera reconnecting	If the notification is persistent, please contact Noah Medical Customer Service so we can investigate.
Notification	Scope disconnected	Connect a scope to proceed with the procedure.
Notification	Not enough storage space	Clear space on the system by deleting procedures to proceed.
Minor Alert	Wall power lost	The Cart has lost wall power and is now using the backup battery. Please end any procedures

		immediately and attempt to regain wall power.
Minor Alert	Failed to delete procedure	Please contact Noah Medical Customer Support so we can investigate the issue.
Minor Alert	Failed to get camera visual	Please reattach the scope. If this problem persists, attach a new Galaxy scope and contact Noah Medical Customer Support so we can investigate the issue.
Minor Alert	Scope data error	Please attach a new Galaxy scope and contact Noah Medical Customer Service so we can investigate the issue.
Minor Alert	Database error	Please attempt to restart the system and contact us so we can investigate the issue.
Minor Alert	Database error	If a Severe Alert is present, tap it to see recovery instructions. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
Minor Alert	Blocker detected	All robot motion has been stopped. Please detach the scope and press Recover.
Minor Alert	Recovery failed	Please attempt to restart the system and contact Noah Medical Customer Service so we can investigate the issue.
Minor Alert	EM sensor error	Please replace the EM sensors and contact Noah Medical Customer Service so we can investigate the issue.
Minor Alert	Driving mechanism error	If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.

Minor Alert	Driving mechanism firmware error	If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
Minor Alert	High system temperature	Please ensure nothing is blocking airflow to the Cart or driving mechanism. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
Minor Alert	Low system temperature	If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
Minor Alert	Procedure plan corrupted	Please export the procedure from the Galaxy planning system again. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
Minor Alert	No storage devices found	Please ensure your storage device is fully plugged in.
Minor Alert	Procedure import failed	Please import the procedure again. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
Minor Alert	Procedure import blocked	A procedure with the same MRN already exists in the system. Please remove that procedure and try again.
Minor Alert	Insufficient storage	There is not enough storage available for this task. Please delete some procedures and try again.
Minor Alert	EM signal lost	Please ensure the field generator is fully plugged in and retry the Capture step. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.

Minor Alert	Incorrect field generator orientation	Please rotate the field generator such that the cable is routed from the inferior side of the patient.
Minor Alert	Low storage	Please consider deleting some procedures.
Minor Alert	No paths found	No planned paths were found for this procedure. Please export the procedure from the Galaxy planning system again. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
Minor Alert	Plan data lost	Please import the procedure again and contact Noah Medical Customer Service so we can investigate the issue.
Minor Alert	No targets found	No planned targets were found for this procedure. Please export the procedure from the Galaxy planning system again. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
Minor Alert	Patient not found	Please import the procedure again. If this problem persists, export a new copy of the procedure from Planning and contact Noah Medical Customer Service so we can investigate the issue.
Minor Alert	Procedure loading failed	Please load the procedure again. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
Minor Alert	Plan not found	Please import the procedure again. If this problem persists, export a new copy of the procedure from Planning and contact Noah Medical Customer Service so we can investigate the issue.

Minor Alert	Plan loading	Please wait for the plan to finish loading and restart registration.
Minor Alert	More trachea data needed	Please restart registration from the beginning of the trachea.
Minor Alert	Driving mechanism outside workspace limit	Please hand-guide the driving mechanism into a position with less resistance.
Minor Alert	Robot signal lost	All robot motion has been stopped. Please detach the scope and press Recover.
Minor Alert	High insertion force detected	Please retract and try again.
Minor Alert	Remove scope to recover	The system requires the scope to be removed before recovering. Please remove the scope and try again.
Minor Alert	Clinical scope attached	The attached scope is a single-use scope intended for clinical use. Please discard this scope and use a practice scope for practice cases.
Minor Alert	System error	If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
Minor Alert	Robot control signal intermittent	If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
Minor Alert	Scope buckling detected	Please retract until scope insertion is responsive to controls, then try again. If this problem persists, please take a fluoro image to check the shape of the scope.
Minor Alert	Tomo processing error	Please retry the Capture step. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.

Minor Alert	Tomo error	Please confirm that the C-arm orientation in the fluoro view is correct, and the TiLT board is positioned such that the purple orientation indicators on the left and right sides of the board are oriented with the arrow facing upwards. Retry the Capture step. If this problem persists, please contact us so we can investigate the issue.
Minor Alert	Tomo motion interference	Please ensure the patient is under breath hold and retry the Capture step. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
Minor Alert	Insufficient positioning beads	Please ensure at least six rows of beads are visible in your AP fluoro image and retry the Capture step.
Minor Alert	Unrecognized bead pattern	Please ensure the marker on the tomosynthesis board lines up with the marker on the field generator and retry the Capture step.
Minor Alert	Sweep error	Please retry the Capture step. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
Minor Alert	Data error	Please retry the Capture step. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
Minor Alert	Narrow sweep angle	Please retry the Capture step, sweeping from LAO 30° to RAO 30°.
Minor Alert	Incorrect field generator placement	Please slide the field generator toward the patient's head and try again.

Minor Alert	Incorrect field generator placement	Please slide the field generator toward the patient's feet and try again.
Minor Alert	Cart brakes disengaged	Cart brakes must be engaged before performing alignment.
Minor Alert	Unknown Controller connected	Please connect a Galaxy Controller.
Minor Alert	Invalid airway tree	Please export the procedure from the Galaxy planning system again. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
Minor Alert	Not enough storage space to import	Please delete previous procedures and try again.
Major Alert	Procedure plan corrupted	Please export the procedure from the Galaxy planning system again. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
Major Alert	Controller incompatible	Please disconnect the Controller and press Recover. Then connect a different Galaxy Controller and contact Noah Medical Customer Service so we can investigate the issue.
Major Alert	Controller initialization failed	Recovery guidance: 1. Set down the controller and ensure that the joysticks are not actuated. 2. Press Recover. If the problem persists, please contact Noah Medical at 888-325-6624 to replace your controller.
Major Alert	Controller dropped	Recovery guidance: 1. Verify that there are no signs of physical damage to the controller.

		2. Set down thecontroller and. Ensure that the joysticks are not actuated. 3. Press Recover. If. The problem persists, please contact Noah Medical at 888-325-6624 to replace your controller.
Severe Alert	High insertion force detected	All robot motion has been stopped. Please detach the scope and press Recover. Then, retract and try again.
Severe Alert	Joint adjustment failed	Please restart the system and try again. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
Severe Alert	Routine brake test required	All robot motion has been stopped. Please detach the scope, clear any obstructions surrounding the robot arm, and press Recover.
Severe Alert	Joint positioning test required	Please attempt to restart the system and contact Noah Medical Customer Service so we can investigate the issue.
Severe Alert	Cart Error	All robot motion has been stopped. Please detach the scope and press Recover.
Severe Alert	Backup battery critically low	Please detach the scope and remove it from the patient immediately. All robot motion has been stopped. Once your connection to wall power has been restored, press Recover.
Severe Alert	Cart brakes disengaged during procedure	All robot motion has been stopped. Please detach the scope, engage the brakes, and press Recover. Then exit the procedure and complete setup again.

Severe Alert	E-Stop Button Pressed	All robot motion has been stopped. Please detach the scope and press Recover.
Severe Alert	Driving Mechanism Firmware Error	All robot motion has been stopped. Please detach the scope and press Recover.
Severe Alert	E-Stop Signal Lost	All robot motion has been stopped. Please detach the scope and press Recover.
Severe Alert	Driving Mechanism Error	All robot motion has been stopped. Please detach the scope and press Recover.
Severe Alert	Driving Mechanism Overheating	All robot motion has been stopped. Please shut down the system and give it time to cool down.
Severe Alert	Unknown Field Generator Connected	All robot motion has been stopped. Please connect a Galaxy field generator, detach the scope and press Recover.
Severe Alert	Unknown scope attached	All robot motion has been stopped. Please detach the scope and press Recover, then attach a new Galaxy scope.
Severe Alert	Scope damage detected	All robot motion has been stopped. Please detach the scope and press Recover. If the problem persists, please attach a new Galaxy scope.
Severe Alert	Driving mechanism error	All robot motion has been stopped. Please restart the system. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
Severe Alert	Unknown scope attached	All robot motion has been stopped. Please detach the scope and press Recover, then attach a new Galaxy scope.
Severe Alert	Scope attached during e-stop	All robot motion has been stopped. Please detach the scope and press Recover.

Severe Alert	Scope already used	All robot motion has been stopped. Please detach the scope and press Recover, then attach a new Galaxy scope.
Severe Alert	Scope data error	All robot motion has been stopped. Please detach the scope and press Recover, then attach a new Galaxy scope. Please contact Noah Medical Customer Service so we can investigate the issue.
Severe Alert	Backup battery critically low	Please detach the scope and remove it from the patient immediately. All robot motion has been stopped. Once your connection to wall power has been restored, press Recover.
Severe Alert	Driving mechanism signal error	All robot motion has been stopped. Please detach the scope and press Recover.
Severe Alert	Positioning sensors connection lost	All robot motion has been stopped. Please detach the scope and press Recover.
Severe Alert	Control computer error	All robot motion has been stopped. Please detach the scope and press Recover.
Severe Alert	Robot power error	All robot motion has been stopped. Please detach the scope and press Recover. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
Severe Alert	Safety circuit error	All robot motion has been stopped. Please detach the scope and press Recover.
Severe Alert	Scope data error	All robot motion has been stopped. Please detach the scope and press Recover.
Severe Alert	Remove scope to recover	The system requires the scope to be removed before recovering. Please remove the scope and try again.

Severe Alert	Software error	All robot motion has been stopped. Please detach the scope and press Recover.
Severe Alert	Remove practice scope	This is a practice scope and cannot be used on patients. All robot motion has been stopped. Please detach the scope and press Recover, then attach a new Galaxy scope.
Severe Alert	System error	All robot motion has been stopped. Please detach the scope and press Recover.
Severe Alert	Driving mechanism error	All robot motion has been stopped. Please detach the scope and press Recover.
Severe Alert	Robot error	All robot motion has been stopped. Please detach the scope and press Recover.
Severe Alert	Robot collision detected	All robot motion has been stopped. Please detach the scope and press Recover.
Severe Alert	Robot internal error	All robot motion has been stopped. Please detach the scope and press Recover.
Severe Alert	Robot joint limit reached	All robot motion has been stopped. Please detach the scope and press Recover, then retract and try again.
Severe Alert	Robot arm was unable to move	All robot motion has been stopped. Please detach the scope and press Recover. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
Severe Alert	Scope attached during retraction	All robot motion has been stopped. Please remove the scope until retraction is complete.
Severe Alert	High robot arm velocity detected	Proceed with caution.

Severe Alert	Scope expired	All robot motion has been stopped. Please detach the scope and press Recover, then attach a new Galaxy scope.
System Error	Camera firmware error	Please shutdown the system and contact Noah Medical Customer Service so we can investigate the issue.
System Error	EBUS firmware error	Please shutdown the system and contact Noah Medical Customer Service so we can investigate the issue.
System Error	Fluoro firmware error	Please shutdown the system and contact Noah Medical Customer Service so we can investigate the issue.
System Error	Driving mechanism firmware error	Please shutdown the system and contact Noah Medical Customer Service so we can investigate the issue.
System Error	Robot firmware error	Please shutdown the system and contact Noah Medical Customer Service so we can investigate the issue.
System Error	Control firmware error	Please shutdown the system and contact Noah Medical Customer Service so we can investigate the issue.
System Error	System error	All robot motion has been stopped. Please restart the system and contact Noah Medical Customer Service so we can investigate the issue.
System Error	Robot error	Please shutdown the system and contact Noah Medical Customer Service so we can investigate the issue.
System Error	Safety circuit error	The system was unable to start. Please shutdown the system and try again. If this problem persists, please contact Noah Medical

		Customer Service so we can investigate the issue.
System Error	E-Stop button pressed	The system was unable to start. Please shutdown the system and try again. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
System Error	Cart error	The system was unable to start. Please shutdown the system and try again. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
System Error	Robot power error	The system was unable to start. Please shutdown the system and try again. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
System Error	Backup battery critically low	The system was unable to start. Please shutdown the system, plug into wall power, and try again. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
System Error	Software error	The system was unable to start. Please shutdown the system and try again. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
System Error	Control computer error	The system was unable to start. Please shutdown the system and try again. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
System Error	Driving mechanism signal error	The system was unable to start. Please shutdown the system and try again. If this problem persists, please contact Noah Medical

		Customer Service so we can investigate the issue.
System Error	Positioning sensors connection lost	The system was unable to start. Please shutdown the system and try again. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
System Error	E-Stop signal lost	The system was unable to start. Please shutdown the system and try again. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
System Error	Driving mechanism error	The system was unable to start. Please shutdown the system and try again. If this problem persists, please contact Noah Medical Customer Service so we can investigate the issue.
System Error	System configuration incomplete	The system is unable to start. Please contact Noah Medical Customer Service so we can finish configuring the system for your c-arm.

Appendix B Electromagnetic Compatibility (EMC) and Associated Risks

The Galaxy System™ complies with the requirements of IEC 60601-1-2:2014. The system was tested to the following standards. The system is designed for use in a hospital in a non-protected electromagnetic environment. It should not be located in parts of the hospital where there are high frequency surgical or magnetic resonance systems in use.

Table B.1 Electromagnetic Compatibility Standards

Emissions (Class A, Group 1)	CISPR 11:2019 (Radiated Emissions)
	CISPR 11:2019 (Conducted Emissions)
	IEC 61000-3-2:2018 – Harmonic Emissions
	IEC 61000-3-3:2013 – Flicker Emissions
The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals. If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.	
Immunity	IEC 61000-4-2:2008 – ESD
	IEC 61000-4-3:2006 – Radiated
	IEC 61000-4-4:2012 – EFT
	IEC 61000-4-5:2014 – Surge
	IEC 61000-4-6:2013 – Conducted
	IEC 61000-4-8:2009 – Magnetic
	IEC 61000-4-11:2020 – Voltage Dips and Interrupts
The normal test levels for Professional Healthcare equipment as specified in tables 4, 7 and 9 of IEC 60601-1-2 were applied for the immunity tests noted above.	

To comply with the regulations on electromagnetic interference for a Class A FCC Device, all interconnect cables to external devices (for example, monitors) must be shielded and properly grounded. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference in violation of the FCC regulations.

All types of electronic equipment may characteristically cause electromagnetic interference with other equipment, either transmitted through air or connecting cables.

The term EMC (Electromagnetic Compatibility) indicates the capability of equipment to curb electromagnetic influence from other equipment and at the same time does not affect other equipment with similar electromagnetic radiation from itself.

Proper installation is required to achieve the full EMC performance of the product. Operate the system with all covers closed. Operating the system with any cover open may affect EMC performance.

The Galaxy System™ is to be used per the specified guidance and only in the electromagnetic environment listed below. Failure to do so may result in degraded system performance.

During electromagnetic interference, the camera will continue to provide a live video feed. Momentary interruptions may occur and will be accompanied by a warning. Additionally, once set to an intended position, the robotic arm and Bronchoscope will not move unless commanded by the user. Should these functions fail to work as intended, discontinue use and contact Noah Medical Customer Service. To help ensure the system functions as intended as it pertains to electromagnetic interference, follow all instructions in this IFU and contact Noah Medical Customer Service for any repairs. Do not modify the system - contact Noah Medical Customer Service for any replacements.

If this equipment causes interference with other devices or if other equipment is causing interference with this equipment, which may be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the device receiving the interference.
- Increase the separation between the equipment (minimum 30cm is recommended)
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Replace unshielded cables with shielded ones.
- Consult the manufacturer or field service technician for help.

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

WARNING: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation

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

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