

MONARCH™ PLATFORM

User Manual



Monarch™ Platform User Manual

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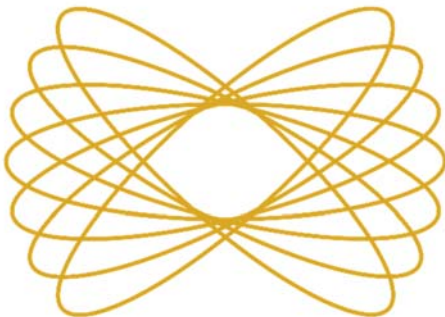
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MONARCH™



MONARCH™

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This manual applies to the Monarch™ Platform, Monarch™ Pre-Op Planning Application 2.1.1, and Monarch™ Navigation Application 2.1.1.

Expected Life Statement

With proper care and maintenance, the expected service life of the system is 7 years.

Introduction

This manual provides information specific to the Monarch™ Platform, also known as the Monarch™ Platform. The operating instructions and feature descriptions herein are specific to the software versions listed on page iii.



NOTE: Anyone who operates, services, maintains, or is otherwise associated with the Monarch Platform must read, understand, and be thoroughly familiar with the information in this manual, 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.

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Intended Use/Indications for Use

The Monarch™ Endoscopy Platform (Monarch Platform) 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:

- Patient 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 breathing difficulty, vocal cord spasm, hoarseness, slight fever, vomiting, dizziness, bronchial spasm, infection, low blood oxygen, bleeding from biopsied site, or an allergic reaction to medications. Only rarely do patients experience other more

serious complications (for example, collapsed lung, respiratory failure, heart attack and/or cardiac arrhythmia).

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 Monarch Platform 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 Monarch Platform can damage the system, its components or other property; cause poor performance; or lead to serious bodily injury and possibly death.

Auris Health, Inc. strongly recommends that personnel be trained by Auris on the Monarch Platform 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 declaration of immunity section, the system may fault in an immobilized state. Follow the directions indicated to return to normal operation.

System Error Messages

Under the error conditions described in Appendix B, all robotic functions are disabled. Follow the directions indicated to return to normal operation.

Notations

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



WARNING: Describes actions or conditions that could result in 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.

Disposal

When an Auris product reaches the end of its useful life and your facility desires to remove the device, contact Auris Customer Care at +1.800.434.0032 (toll-free within the United States) or +1.650.264.6000 (Worldwide) 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 Monarch Platform complies with the regulatory requirements of Directive 2017/745, the Medical Device Directive of the European Economic Community (EEC).

The Monarch Platform and accessories have been tested for compliance to the following standards:

Standard Number	Standard Title
AAMI/ANSI ES60601-1:2005 (Third Edition)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2007 (Third Edition)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-6:2010 (Third Edition)	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-2-18:2009 (Third Edition)	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
IEC 62366:2007	Medical devices -- Application of usability engineering to medical devices
IEC 62366-1:2015	Medical devices -- Part 1: Application of usability engineering to medical devices
ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
ISO 14971:2007	Medical devices -- Application of risk management to medical devices
ISO 11135:2014	Sterilization of health-care products – Ethylene Oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices
ISO 11607-1:2006	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems

Standard Number	Standard Title
ISO 11607-2:2006	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity (Biocompatibility)
ISO 10993-10:2010	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization (Biocompatibility)
ISO 10993-11:2006	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity (Biocompatibility)
ISO 8600-1:2015	Endoscopes -- Medical endoscopes and endotherapy devices -- Part 1: General requirements
ISO 8600-3:1997	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 8600-4:2014	Endoscopes -- Medical endoscopes and endotherapy devices -- Part 4: Determination of maximum width of insertion portion
BS EN 1041:2008	Information supplied by a manufacturer of medical devices
BS EN 556-1:2001	Sterilization of medical devices - Requirements for medical devices to be designated ""STERILE"" – Part 1: Requirements for terminally sterilized medical devices"
ANSI/AAMI/ISO 14937:2009	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

FCC ID: 2AOXMMonarch



NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

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Chapter 1

Safety Information and Technical Description

This chapter provides information that is essential for the safe operation, transport, and storage of the Monarch Platform.

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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 Auris representative. There are no user serviceable components. Contact Auris Customer Care at +1.800.434.0032 (toll-free within the United States) or +1.650.264.6000 (Worldwide) to schedule installation or service.

Monarch Platform Device Overview

This user manual refers to the Monarch Platform and the associated components used with it. Refer to the following table for a list of products.

Official Product Name	Shortened Name
Monarch™ Platform	
Monarch™ Pre-Op Planning Application	Planning Application
Monarch™ Pre-Op Planning System	Planning System
Monarch™ Tower	Tower
Monarch™ Cart	Cart
Monarch™ Controller	Controller
Monarch™ Touchscreen	Touchscreen
Monarch™ Navigation Application	Navigation App
Monarch™ Bronchoscope System	Bronchoscope System (consists of both the Bronchoscope and Sheath)
Monarch™ Bronchoscope	Bronchoscope
Monarch™ Bronchoscope Sheath	Sheath
Aspirating Biopsy Needle	Needle
Bronchoscope Patient Introducer Mount	Patient Introducer Mount
Bronchoscope Patient Introducer	Patient Introducer
Monarch™ Navigation Field Generator	Field Generator
Monarch™ Navigation Field Generator Mount	Field Generator Mount
Monarch™ Navigation Patient Sensors	Patient Sensors
Navigation Patient Patches	Patient Patches
Bronchoscope Swivel Adapter	Swivel Adapter
Bronchoscope Fluidics Tubing	Fluidics Tubing
Bronchoscope Sheath Valve	Sheath Valve
Instrument Device Manipulators	IDM

System Overview

The Monarch Platform enables electro-mechanical articulation and precise control of a flexible endoscope (bronchoscope) under continuous and direct control by a physician operator. The Monarch Platform includes fused navigation that integrates a pre-operative computed tomography scan into an intra-operative interface displaying endoscope tip location relative to the pre-operative scan anatomy.

Pre-Procedural Planning

Prior to the procedure, the Monarch Pre-Op Planning Application running on the Monarch Pre-Op Planning System or Monarch Tower Touchscreen 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 integrates a pre-procedural CT scan into a user interface.

The Monarch Pre-Op Planning Application provides the following features:

- CT viewing capabilities similar to standard CT DICOM viewer software.
- Airway segmentation: segmentation of the trachea and main airways to aid visualization of the airways and path planning.
- Target identification: ability to select one or more targets of interest.
- Path planning: computer generated path to the target based on segmented airways.
- Manual path planning: ability for user to identify airways and modify the path on the CT scan to finalize a pathway to the target as necessary.

Monarch Pre-Op Planning Application is accessible from both the Monarch Tower Touchscreen and the Monarch Pre-Op Planning System.

Monarch Cart

The Monarch Cart is a maneuverable piece of capital 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 Monarch Bronchoscope System (insertion, retraction, and articulation). It contains a Touchscreen monitor, two robotic arms, and mating robotic Instrument Device Manipulators (IDM) which are mountable, robotic interfaces for the bronchoscope.

The following image shows the Monarch Cart with the robotic arms in the stow position (left) and load Bronchoscope System position (right):



The Monarch Cart is a carrier for the robot arms. It includes two robotic arms which contain rotary pulleys to actuate the drive cables in the Monarch Bronchoscope System. The cart houses the electronic systems required to power and operate the robot arms.

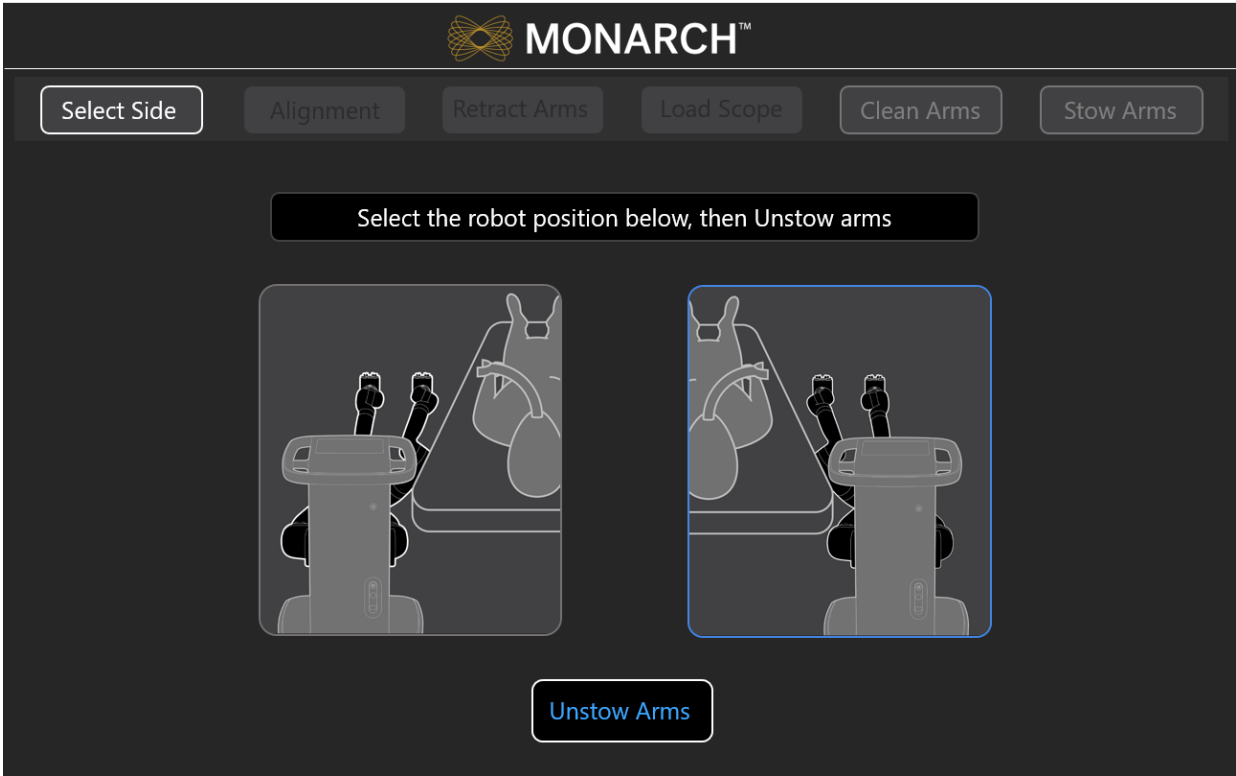


Item	Description
①	Foot pedal
②	Power cable
③	Umbilical port
④	Power button
⑤	Emergency stop button (E-stop)
⑥	Cart directional lock switch
⑦	Cart handle
⑧	Cart Touchscreen
⑨	Instrument Device Manipulator (IDM)
⑩	Robotic arm
⑪	Vertical lift
⑫	Immobilization feet (not shown)



Item	Description
①	Power button
②	Umbilical port to the Monarch Tower
③	Power cord plug

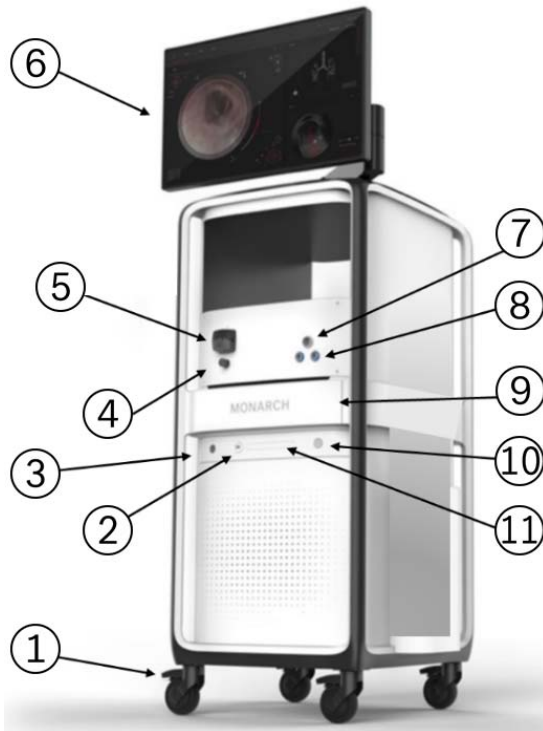
Automated lift controls will raise and lower the height of the robotic arms based on your control. The cart handle allows the cart to be directionally locked for ease of maneuverability. An embedded Touchscreen on the cart handle provides system setup instructions and allows user input, as shown in the following image.



Monarch Tower

The Monarch Tower is a maneuverable piece of capital equipment that can be transported in and out of the bronchoscopy suite and stowed away when not in use. It is the primary physician procedural display interface. It contains a monitor for physician viewing and computers running the Monarch Bronchoscopy Tower Software, the Monarch Navigation Application, which displays real time video captured from the Monarch Bronchoscope camera overlaid with information on the status of the Monarch Platform and the Monarch Pre-Op Planning Application. The tower also provides connectivity for the Monarch Bronchoscope camera and lighting, as well as the fluidics system. The fluidics system has an integrated pump and pinch valve to control irrigation and aspiration respectively. The monitor is Touchscreen for physician input during setup, planning, and procedure.

The following images shows the tower:



Item	Description
①	Caster lock
②	USB port
③	Monarch Navigation Field Generator port
④	Pinch valve
⑤	Peristaltic pump
⑥	Monarch Touchscreen
⑦	Bronchoscope umbilical port
⑧	Monarch Navigation Patient Sensors port
⑨	Drawer
⑩	Power button
⑪	Optical disc drive (DVD)



Item	Description
①	Power cable
②	Video ports
③	Service door lock
④	Hook
⑤	Side storage door
⑥	Umbilical cable

The following components are included in the Monarch Tower: non-real-time computer, real-time computer, endoscopic controller, camera, Monarch Navigation Field Generator and power distribution unit (PDU) box. The PDU contains the power supply to the tower only, as well as the batteries and UPS which provide auxiliary power in the event of system fault.

i **NOTE:** The Monarch Platform incorporates an uninterruptible power supply 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 Monarch Bronchoscope System and shut down the Monarch Platform.

The tower includes the Monarch Controller that allows the clinician to control the system during a procedure. Two joysticks are used to drive and articulate the Monarch Bronchoscope while various buttons are used to control irrigation, aspiration, Tower user interface, light, bronchoscope/sheath selection, and image capture.

The following image shows the Monarch Controller:



Monarch Bronchoscope System

The Monarch Bronchoscope System is comprised of two collinear and concentric devices, the inner Monarch Bronchoscope and the outer Monarch Bronchoscope Sheath, both of which possess 4-way steering control. This configuration enables the capability of telescoping, which enhances the Monarch Bronchoscope System stability and access capability.

The following figure images show the Monarch Bronchoscope System and the handles:



Item	Equipment
①	Monarch Bronchoscope Sheath
②	Monarch Bronchoscope

The Monarch Bronchoscope includes a camera that provides the operative perspective, an integrated light source in the handle, and a 2.1mm inner diameter working channel for the passing of manually controlled tools.

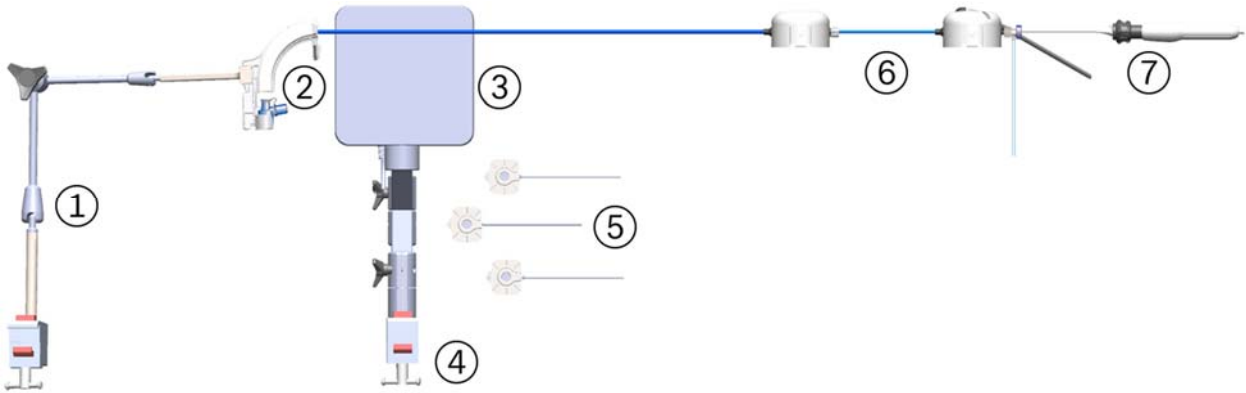
The Monarch Bronchoscope System has a distal section capable of achieving articulation in any direction and any combination of the two to enable precise control while driving the Monarch Bronchoscope. The Fluidics Tubing is equipped

with a valve at the end to facilitate the insertion and sealing of various ancillary devices, such as the Aspirating Biopsy Needle. Additionally, the proximal section routes irrigation and aspiration to the shared working channel.

Working Channel Instruments

The following single-use manually controlled Auris instruments compatible with the Monarch Platform are provided sterilized: Aspirating Biopsy Needle, Biopsy Forceps, and Cytology Brush. Refer to individual Instructions for Use included with each working channel instrument for additional information.

Accessories



Item	Equipment
①	Bronchoscope Patient Introducer Mount
②	Bronchoscope Patient Introducer with Bronchoscope Swivel Adapter
③	Monarch Navigation Field Generator
④	Monarch Navigation Field Generator Mount
⑤	Monarch Navigation Patient Sensors and single-use Navigation Patient Patches
⑥	Monarch Bronchoscope System and Sheath Valve
⑦	Working channel instrument (needle shown) inserted through Fluidics Tubing valve

Disposable Accessories

The system features sterilized single-use accessories necessary to perform bronchoscopic procedures. These accessories are:

- **Bronchoscope Patient Introducer:** A tube that guides the Bronchoscope System through the Bronchoscope Swivel Adapter and into the endotracheal tube.
- **Bronchoscope Swivel Adapter:** Standard bronchoscope accessory that attaches to the endotracheal tube to allow passage of a bronchoscope while maintaining ventilation pressure. It is packaged with the Bronchoscope Patient Introducer.
- **Bronchoscope Fluidics Tubing:** Separate tubing lines for saline irrigation and vacuum aspiration which converge at a valve that attaches to the bronchoscope working channel. Saline irrigation and aspiration lines connect to the tower. A valve is connected to the end of the Bronchoscope Fluidics Tubing and provides a means of introducing working channel instruments, irrigation, and aspiration into the working channel.
- **Bronchoscope Sheath Valve:** Attaches to the proximal hub of the sheath and provides a seal around the bronchoscope to reduce ventilation leakage.
- **Navigation Patient Patches:** Single-use disposable adhesive patches that are used to attach the Monarch Navigation Patient Sensors to the patient's chest. The patches are not provided sterile.

Non-Disposable Accessories

The following non-disposable accessories are included and stored with the tower.

- **Bronchoscope Patient Introducer Mount:** Adjustable mount that attaches to a bed rail and holds the Bronchoscope Patient Introducer.
- **Monarch Navigation Patient Sensors:** Attaches to the patient to provide an estimate of patient positioning for alignment of the Monarch Navigation Field Generator.
- **Monarch Navigation Field Generator:** Provides an electromagnetic field to be sensed by scope and patient sensors to provide locational information. The Monarch Navigation Field Generator plugs into the Monarch Tower.
- **Monarch Navigation Field Generator Mount:** Adjustable mounts that attaches to a bed rail and holds the Monarch Navigation Field Generator.

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 Group 1, Class A ISM Equipment.








The Monarch Platform is classified by the following:

- Protection against electric shock: Class 1 (grounded equipment).
- Applied part(s): All Applied Parts of the Monarch System are Type BF Applied Parts.
- Protection against harmful ingress of water: Rated IPX0 (ordinary equipment, not specially protected).
- Methods of sterilization or disinfection: Ethylene oxide processing.
- Mode of operation: The Monarch System is considered Continuous equipment as defined by IEC 60601-1.

Monarch Platform Labels

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.
	Equipment Manufacturer and date of Manufacture	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.

Symbol	Name	Meaning
	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 user manual 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.
	Temperature limit 10°C to 25°C	This symbol indicates the operating temperature limits of the device.
	Temperature limit -25°C to 70°C	This symbol indicates the non-operating temperature limits of the device.
	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.

Symbol	Name	Meaning
	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.
	Sterilized using ethylene oxide	This symbol indicates that the device is provided sterile and has been sterilized using ethylene oxide.
	Rx only	Federal (USA) law restricts this device to sale by or on the order of a physician.
	Do not re-sterilize	This symbol indicates that the device should not be re-sterilized after it once has been sterilized.
	Caution	This symbol indicates that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	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.

Label Locations

The following figures show the system labels and their locations. The Monarch System UDI is located on the tower.

Cart



Tower



Technical Specifications

Physical Dimensions, Weight, and Power Requirements



NOTE: AC power cord is mains disconnect device.

Subsystem	Monarch Tower	Monarch Cart
Height	66.4"/168.7 cm	39.8"/101.1 cm
Width	24.7"/62.8 cm	23.9"/60.7 cm
Depth	29"/73.6 cm	34"/86.4 cm
Weight (maximum)	892 lb/405 kg	785 lb/356.4 kg

Subsystem	Monarch Tower	Monarch Cart
Max weight on shelf	25 kg	
Power Requirement	100-240V~ 50/60Hz 1440W*	100-240V~ 50/60Hz 1000W*

*Requires separate dedicated branch circuits.

The Monarch Platform should be transported, stored, and used in the following environmental conditions:

Monarch Platform	Operating	Non-Operating (Storage or Shipment)
Temperature	10° C to 25° C	-25° C to 70° C
Humidity	30% to 60% Non-condensing	10% to 85% Non-condensing
Noise Generated	63 dB @ 1 meter & 20° C	NA
Altitude	Up to 3000 meters	N/A

Declaration of Emissions

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 not affect other equipment with similar electromagnetic radiation from itself.

Proper installation is required in order 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 Monarch Platform may be used safely while connected to other devices if the devices and their specifications, installation, and interconnection with the system conform to the requirements of IEC 60601-1 (3rd Edition) or IEC 60601-1-1(2nd Edition). This system is suitable for use in the following environment. The user must assure that it is used only in the electromagnetic environment as specified.

Table 1. Guidance and Manufacturer’s Declaration – Electromagnetic Emissions – For All ME Equipment and ME Systems

Guidance and Manufacturer’s Declaration – Electromagnetic Emissions		
The ME System is intended for use in the electromagnetic environment specified below. The customer or the user of the ME System should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The ME System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The ME System is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the ME System or shielding the location.

Declaration of Immunity

The Monarch Platform is to be used per the specified guidance and only in the electromagnetic environment listed below.


Table 2. Guidance and Manufacturer's Declaration – Electromagnetic Immunity – For All ME EQUIPMENT and ME SYSTEMS

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The ME System is intended for use in the electromagnetic environment specified below. The customer or the user of the ME System should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment. During an electrical fast transient event, the system may fault in the "Image Frozen" or "Robot Controller Error" states as described in Appendix B.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment. During a surge event, the system may fault in the "Image Frozen" or "Robot Controller Error" states as described in Appendix B.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ME System requires continued operation during power mains interruptions, it is recommended that the ME System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 3. Guidance and Manufacturer’s Declaration – Electromagnetic Immunity – For ME Equipment and ME Systems That Are Not Life-supporting

Guidance and Manufacturer’s Declaration – Electromagnetic Immunity			
The ME System is intended for use in the electromagnetic environment specified below. The customer or the user of the ME System should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	$[V_i]$ V	Portable and mobile RF communications equipment should be used no closer to any part of the ME System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m	$[E_i]$ V/m	

	80 MHz to 2,5 GHz		<p>Recommended separation distance</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.

Table 4. Recommended separation distances between portable and mobile RF communications equipment and the ME Equipment or ME System – for ME Equipment and ME Systems that are not Life-supporting

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the ME System			
The ME System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ME System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ME System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Original Documentation

This manual is originally written in English.

Chapter 2

Planning a Procedure

Prior to starting the procedure, the Monarch Pre-Op Planning Application is available on both the Monarch Pre-Op Planning System and Monarch Tower to create a patient case that contains DICOM and planning data. You can export files to be transferred between the tower and laptop. Files must be approved before you can export.

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Recommended CT Scan and Reconstruction Parameters

In order to produce CT images suitable for use with the Monarch Pre-Op Planning Application and the Monarch Navigation Application, the following conditions should be met while scanning the 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 breath-hold duration of patient.
- **Image noise:** Minimize noise standard deviation.

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.
- **Overlap:** 20% – 50%.
- **Field of view:** Minimal field required to cover at least 1cm of trachea and entire lung volume.
- **Maximum images:** 690.

The following table lists the slice thickness, slice interval, kernel, and filter to use for each scanner manufacturer:

Scanner Manufacturer	Slice Thickness (mm)	Slice Interval (mm)	Kernel and Filter	
GE™	1.25	1.0	Kernel Filter	Standard Body
Philips™	1.0	0.8	Kernel Enhancement	C 0
Siemens™	1.0	0.8	Kernel	B31f
Toshiba™	1.0	0.8	Kernel	FC05

The following table lists the slice thickness and slice interval for a 50% and 20% overlap:

Slice Thickness (mm)	Minimum Slice Interval (mm) (at 50% Overlap)	Maximum Slice Interval (mm) (at 20% Overlap)
1.0	0.5	0.8
1.25	0.625	1.0
1.5	0.75	1.2
2.0	1.00	1.6
2.5	1.25	2.0
3.0	1.50	2.4
4.0	2.00	3.2
5.0	2.50	4.0



NOTE: $\text{Overlap \%} = 100 \times (\text{thickness} - \text{interval}) / \text{thickness}$.



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



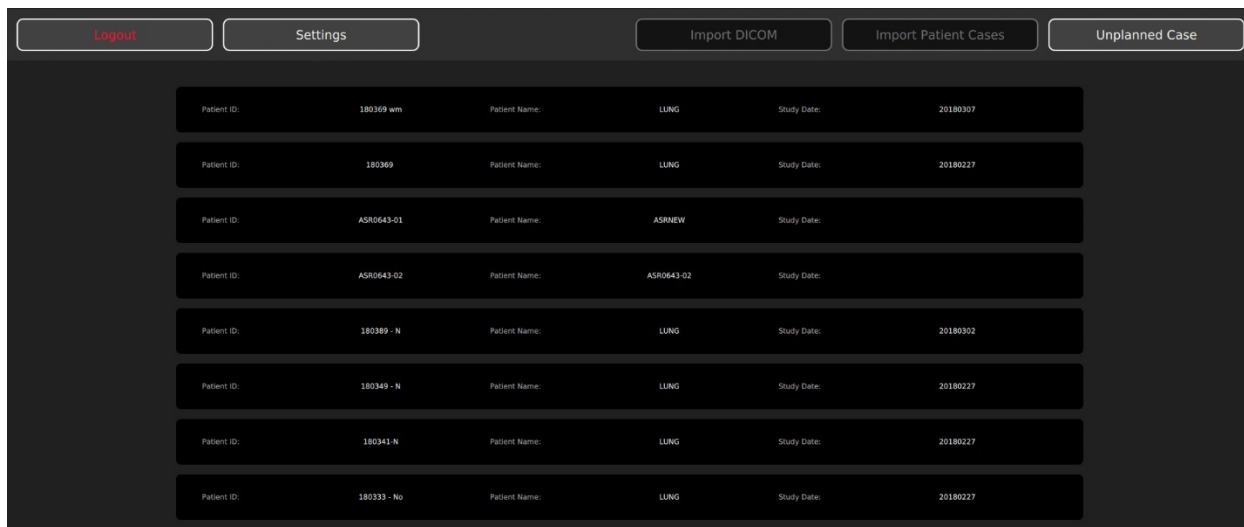
NOTE: CT scans must be in DICOM format. The DVD format must be UDF version 1.02 to 2.60. Verify the disk content when the DVD is created to ensure the disk is valid before attempting to use the disk with the Monarch Pre-Op Planning Application.

The Monarch Pre-Op Planning Application will not load the PET portion of a PET/CT scan.

Monarch Pre-Op Planning Application User Interface

When you log on to the Monarch Pre-Op Planning Application, the Patient List appears.

Patient List



Patient List Menu

Item	Description
Logout	Click or tap to log off from the Monarch Pre-Op Planning Application.
Settings	Click or tap to update password, add users, and administrative settings. For more information, see User Administration (page 92).
Import DICOM	Click or tap to import the patient's CT images.
Import Patient Cases	Click or tap to import patient cases.
Unplanned Case	Click or tap to create an unplanned case and use the Monarch Bronchoscope System as bronchoscope without the use of navigation.

General Patient Information

The Patient List displays the following general patient information.


Item	Description
Patient ID	Displays the patient's ID.
Patient Name	Displays the patient's name.
Study Date	Displays the date of the study.

Selected Patient Information



WARNING: Entering data in the wrong patient case can result in planning errors, which may lead to serious injury. To prevent these planning errors:

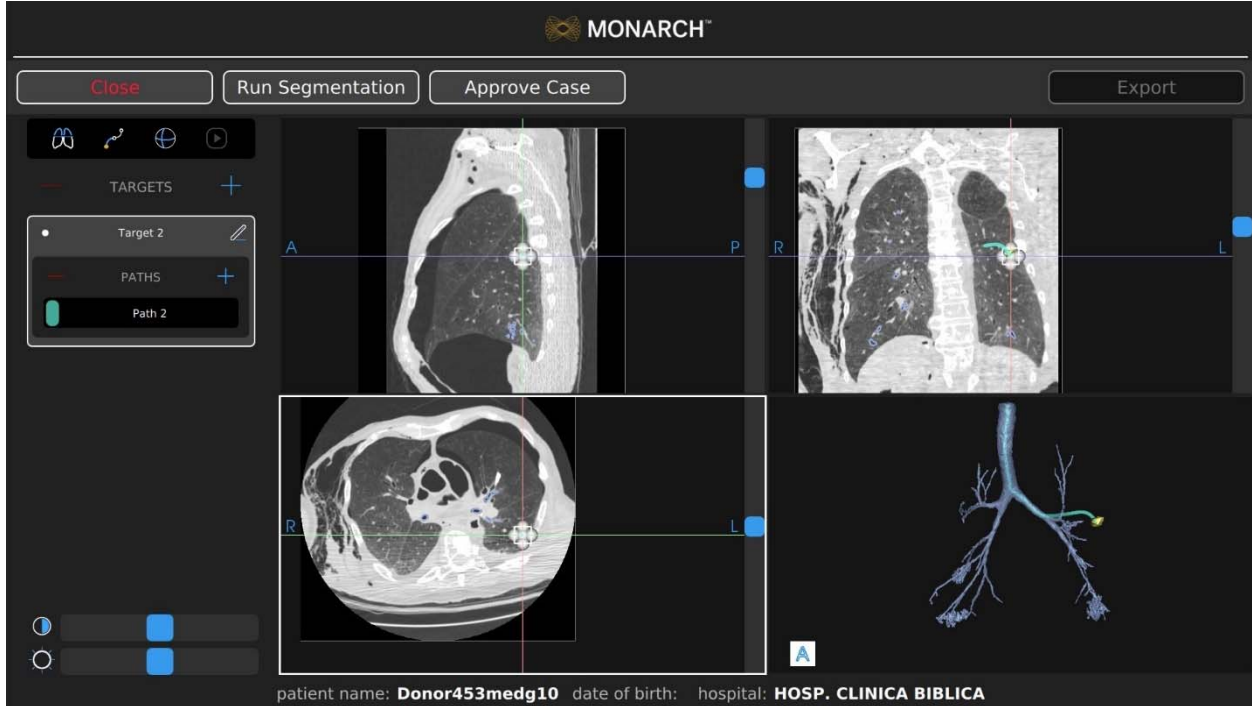
- Make sure you select the correct patient case for the patient.
- Verify that the patient information associated with the selected case identifies the patient you are planning to treat.
- Verify that you have selected the correct patient case by reviewing additional patient information, such as sex and date of birth.

When you select a patient from the list, additional information associated with the patient appears. To edit any patient information, click or tap  if available.

The screenshot shows a patient list interface. At the top, there are two buttons: "Settings" and "Import DICOM". Below this is a list of patient entries. Each entry shows "Patient ID:", "Patient Name:", and "Study Date:". The selected entry is expanded to show additional information: "Patient ID: APPROVED-05", "Patient Name: APPROVED-05", "Study Date: 20170806", "Sex: APPROVED", "Case ID: APPROVED", "Date of Birth: (with edit icon)", "State: APPROVED", "Hospital: (with edit icon)", "Acquisition Date: (with edit icon)", "Physician: (with edit icon)", and "Last Modified: 2018-03-12 11:15". There are "Delete" and "Open" buttons at the bottom of the expanded entry.

Item	Description
Patient ID	Displays the patient's ID.
Patient Name	Displays the patient's name.
Study Date	Displays the date of the study.
Sex	Displays the patient's sex.
Case ID	Displays the case ID associated with the selected patient.
Date of Birth	Displays the patient's date of birth.
State	<p>Displays the current planning status of the patient case.</p> <ul style="list-style-type: none"> • NO_SEG: Segmentation has not yet been performed. • SEG_DONE: Status after initial completion of segmentation. • SEG_ACCEPTED: Patient case has been segmented and planning has started, but case is not approved. • APPROVED: Patient case has been approved
Hospital	Displays the hospital where the procedure is being performed.
Acquisition Date	Displays the acquisition date of the patient's CTs.
State Change Date	Displays the last change date to the patient case's state.
Physician	Displays the name of the physician who planned the patient case.
Delete	Click or tap to delete the selected patient case.
Open	Click or tap to open the selected patient case to view.



Planning



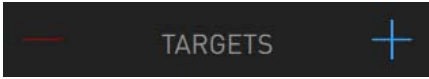
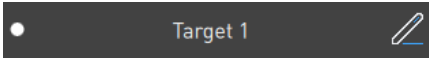









Patient Information

Item	Description
Patient ID	Displays the patient's ID.
Patient Name	Displays the patient's name.
Date of Birth	Displays the patient's date of birth.
Hospital	Displays the hospital where the procedure is being performed.

Tools

Item	Description
	Click or tap to add an overlay of an axial CT image on the airway tree in Segmentation view.
	Click or tap the Manual Path icon to create a manual path from target to segmented airways.

Item	Description
	<p>Click or tap to change the boundary box and highlighted target anatomy to a sphere.</p>
	<p>Click or tap to create a virtual “fly-through” video from the trachea to the target along the path. While the video plays, the play icon changes to a stop icon.</p> <p>Click or tap the icon to stop the video.</p>
	<p>Click or tap + to create a new target.</p> <p>Click or tap – to delete a target.</p>
	<p>To change the name of the new target, click or tap  and enter a new target name.</p> <p>The white dot indicates that the target is the primary target and is selected by default when starting a case.</p> <p>The blue-ringed black dot  indicates that the target is non-primary.</p>
	<p>Click or tap + to create a new path.</p> <p>Click or tap - to delete a path.</p>
	<p>To change the name of the new path, click or tap  and enter a new path name.</p> <p>The number in the upper-left corner of the new path segmentation represents the order of the path in relation to the procedure.</p>
	<p>Use the Contrast slider to adjust the image contrast.</p>
	<p>Use the Brightness slider to adjust the image brightness.</p>


Item	Description
	<p>A boundary box can be resized in any of the three 3 CT images. To adjust the outer boundaries of the target, drag a sizing handle away from or toward the center until the desired size is reached. The image is adjusted in all three CT images when updates are made in one image.</p> <p>The boundary box can be moved without changing the size by selecting the red ball in the center of the box (not shown).</p>

Image Viewers

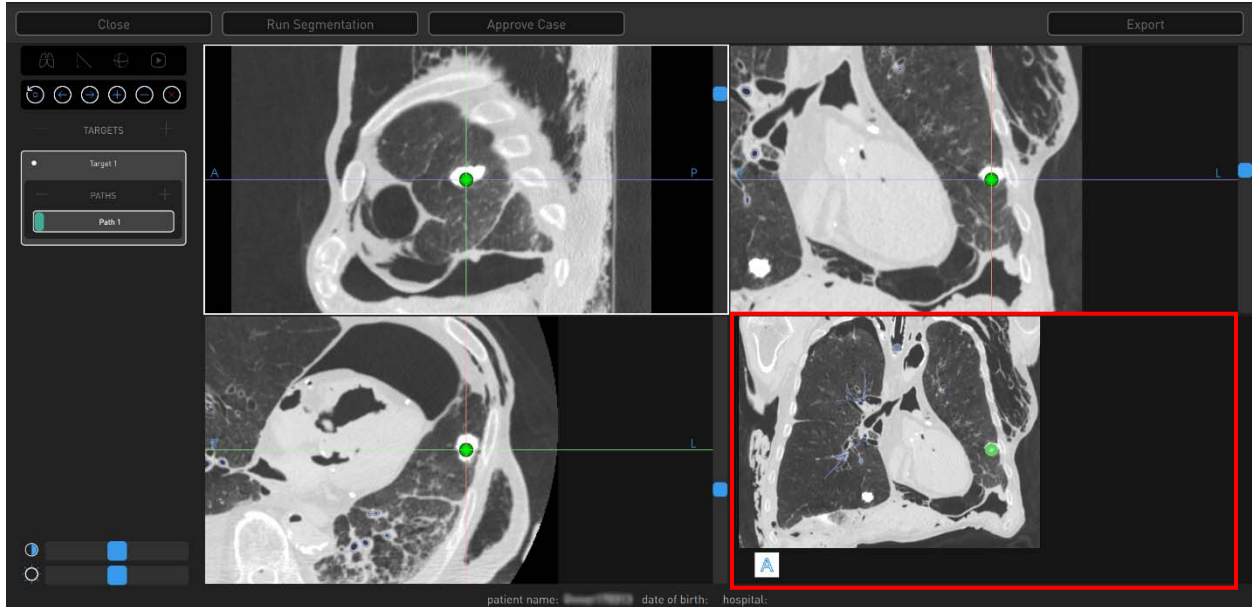
The image viewers display the CT images and the 3D model from the patient case.

Planning Menu

Item	Description
Close	Click or tap to close the current plan.
Run Segmentation	Click or tap to run or re-run a segmentation.
Approve Case	Click or tap to approve the current plan.
Export	Click or tap to export to plan to a Monarch USB drive.

Manual Path

Manual plans begin at the weighted center of the target and work towards the main airways. The green ball represents the weighted center of the target.






The lower-right image viewer is the Segmentation view.




Manual Path Menu



NOTE: All points are deleted if the manual path does not reach the segmented area.

Use the scroll wheel to zoom and press the scroll wheel button to pan.

Touchscreen Item	Mouse Action	Description
Reset		N/A Resets to the original segmentation path information.
Previous		Scroll up in any of the CT image viewers. Using either Previous or Next allows you to re-center the manual path view to the previous or next point that you have set.
Next		Scroll down in any of the CT image viewers. Using either Previous or Next allows you to re-center the manual path view to the previous or next point that you have set.

Touchscreen Item	Mouse Action	Description
Add 	Click a point in the segmentation screen.	Add multiple points to create a manual path.
Delete 	N/A	Deletes a point that you inserted.
Close 	Click Close .	Exits the Manual Path screen.

Segmentation Review



WARNING: Ensure that the segmentation generated from the CT scan accurately identifies the airways. Poor segmentation representation may result in incorrect navigational guidance. Failure to exercise clinical judgment and endoscopic view to determine appropriate navigation and biopsy plan may result in biopsy of unintended location.

Automatic Path Adjustments

Any auto generated path can be manually adjusted or manipulated by selecting and dragging the automatic path to the new location where segmentation exists. This can be performed in the Segmentation Review screen only.

Before You Can Plan

1. Prior to planning, the patient you are working with is required to be CT scanned. Refer to the Recommended CT Scan and Reconstruction Parameters (page 24) for optimal results.
2. Save CT scan to disk.

Create a Plan



NOTE: Multiple CT scans will result in multiple patient cases for the same patient.


1. Log on to the Monarch Pre-Op Planning Application.
2. Click or tap **Import DICOM**. The DICOM loads from the disk and creates a new Patient Case from this.
3. Click or tap the patient case to expand the menu and show additional patient and CT Data information. CT Data includes spacing between slices, slice thickness, and number of slices for the patient case.

4. Click or tap the patient DICOM and the select **Import**.
The new case automatically loads, and the Planning screen appears.
5. Click or tap a patient from the list and select **Open**. The Planning screen appears.
6. Double-click or double-tap for a full screen view of any of the image view windows. Segmentation automatically begins.



7. Click or tap **Cancel Segmentation** to stop.

The progress bar inside **Cancel Segmentation** indicates that "Segmentation" is proceeding. When segmentation is complete, the status bar updates and the segmented airway tree appears in the lower-right image viewer (Segmentation view).

8. Review the segmentation results.
 - a. If you do not like the segmentation results, click or tap **Run Segmentation**.
9. An overlay of an axial CT slice can be added to the segmented airway tree in Segmentation view by clicking or tapping the  icon. The axial slice overlay correlates to the section of the segmented airway selected.
 - a. Click or tap another section of the segmented airway tree to move the overlaid CT slice.



Identify a Target

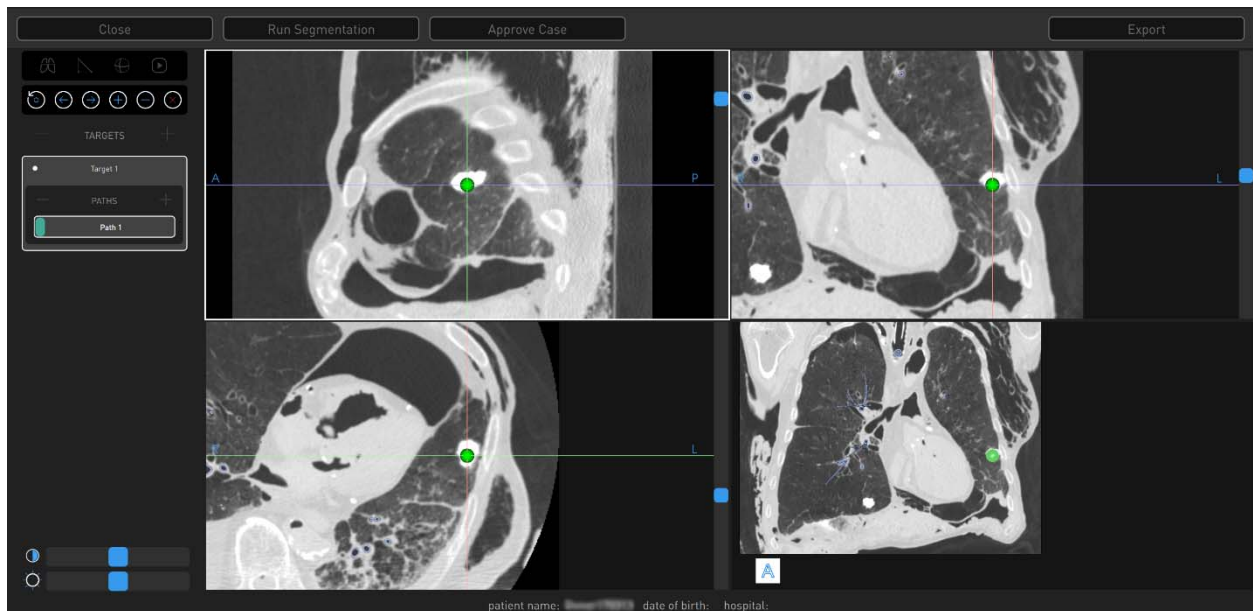


WARNING: Increased size of nodule selection may lead to path creation to critical anatomy. Confirm that the selected nodule is the intended target.



WARNING: Path creation provides supplemental information to navigate to nodule. Failure to exercise clinical judgment to determine appropriate navigation and biopsy plan may result in biopsy of unintended location.

1. Place crosshairs over a region of interest in any of the CT views and click or tap + next to Targets to create a new target. A new target and new path appear automatically.
 - a. The target shape is based on the anatomy of region selected. Click or tap the Sphere icon  to change the target shape to a sphere. Right-click and drag to adjust the sphere target size. Click or tap the Sphere icon again to return to original target shape.
2. Click or tap the Manual Path icon  if the target is beyond the default path created during segmentation view or to create a manual path.




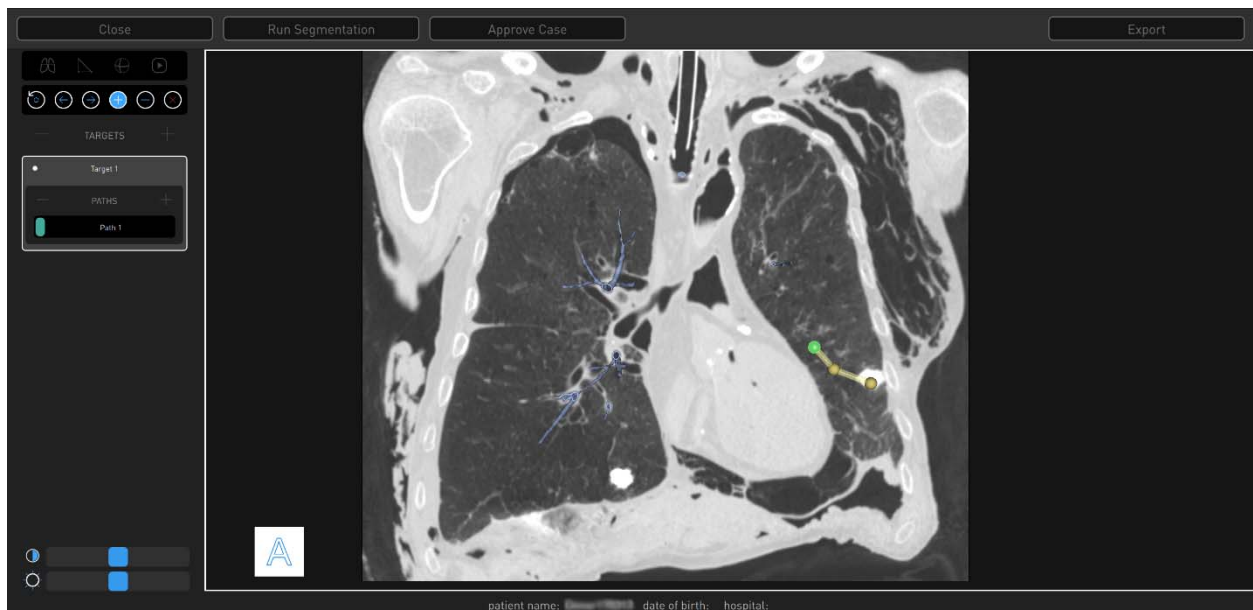
3. Insert drop points to create a manual path in the Segmentation view (lower-right image viewer). Paths start at the nodule by default and work back towards the main airway.





NOTE: Points can only be placed in the Segmentation view (lower-right image viewer). This can be done in the small image viewer (as shown in the previous image) or in full-screen mode. Full-screen mode is accessed by double-clicking

in the Segmentation view. To return to the small image viewer, double-click while in full-screen mode.

- To change the view angle, click (or tap and hold on the Touchscreen) and move the cursor around on the screen.
- Use the Add icon  and click to add points (or right-click with the mouse). Click or tap the Add icon to switch on the ability to add points. Click or tap the Add icon again to switch it off.
- To zoom in and out, scroll or tap, followed by tap and hold on the Touchscreen.
- Double-click or double-tap on the Touchscreen for a full screen view of the manual path image viewer.



4. When the manual path is close enough to connect to the default segmented airway tree, the manual path snaps to connect to the automatic path and the Manual Path screen automatically closes.
5. To name a target:
 - a. Select the target name and click or tap the Edit icon .
 - b. Delete the active name using the backspace on the keypad and type in a new name to identify the target.
 - c. Click or tap the Check icon to save the new name.
6. To name a path:
 - a. Select the path name and click or tap the Edit icon .
 - b. Delete the active name using the backspace on the keypad and type in a new name to identify the path.
 - c. Click or tap the Check icon to save the new name.

7. To delete a target:
 - a. Select the target to be deleted.
 - b. Click or tap – next to Targets to delete the target.
8. To delete a path:
 - a. Select the path to be deleted.
 - b. Click or tap – next to Paths to delete the path.
9. If you are satisfied with the plan, click or tap **Approve Case**. A confirmation message appears, which requires you to accept clinical responsibility for the created plans.
 - Selecting approve will make the Add, Delete, and Manual Path icons unavailable.
 - If you need to make modifications to a plan, you can click or tap **Unapprove** a plan to make changes.

Export a Patient Case

1. Visually review the plan and ensure all targets are planned accurately.
2. Select **Approve Case**.



NOTE: Only approve a case when all targets and target paths have been planned.

3. A prompt appears to confirm that you acknowledge the clinical risks of moving forward with the plan.
4. Do one of the following:
 - Select **Yes** to confirm. The target and path icons disappear from the menu.
 - Select **No** if you do not agree with the plan.
5. Select **Unapprove Case** to continue to edit the plan.
 - If **Unapprove Case** is selected, you are prompted to acknowledge clinical risks each time the case is approved.
6. Click **Export** to save to a Monarch USB drive.
 - Note that **Export** is unavailable unless a Monarch USB drive is inserted into the laptop. Once a Monarch USB drive is inserted, **Export** is available. A progress wheel appears once you select **Export**.

Import a Patient Case

Once a patient case is saved to a Monarch USB drive, the case can be imported to another Monarch laptop or Tower.

1. To import, insert the Monarch USB drive into a Monarch laptop or Tower.
2. Click or tap **Import Patient Case**, and select the patient case from the list.
3. Click or tap **Import**, and the patient case appears in the Patient List.
4. Click or tap the patient from the list, and select **Open**. The Planning screen appears.
 - If you need to make modifications to a plan, you can click or tap **Unapprove** a plan to make changes.

Perform an Unplanned Case

If you want to use the Monarch Platform using only the live camera without navigational assistance, you can perform an Unplanned Case. When you perform an unplanned case, you will only see the Live Bronchoscope view.

1. Log on to the Monarch Tower with your user name and password.
2. Select **Unplanned Case**. The Unplanned Case screen appears.
3. Enter the following information as necessary:
 - NAME.
 - DATE OF BIRTH.
 - HOSPITAL.
 - PHYSICIAN.
 - SEX.
 - PATIENT ID.
4. Select **Start Setup**.

Chapter 3

System Setup

The Monarch Tower and Cart provide step-by-step guidance to ensure that the Monarch Bronchoscope System and related components are ready for use. The software prevents you from advancing to the next screen if you have not successfully completed the task.

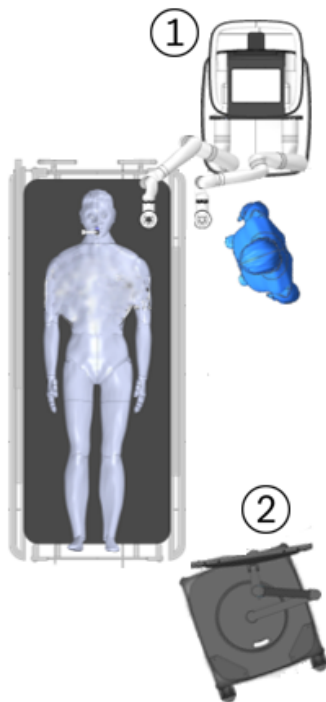
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- Prepare the Patient 41
- Prepare the Monarch Bronchoscope System..... 43
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- Monarch Cart System Setup Guidance..... 48

Software Information

Select the About icon on the Tower Touchscreen, Cart Touchscreen, or laptop logon menu to view information about the Monarch Software, including the UDI and copyright.

Suggested Bronchoscopy Suite Configuration


The following is a suggested configuration of where to place the Cart and Tower in respect to the patient's left side in the bronchoscopy suite. You can also mirror the same configuration for the patient's right side if it would be more appropriate. The length of the Monarch Bronchoscope cable that attaches to the Tower is 9ft. The length of the Tower umbilical cable that attaches to the Cart is 20ft. These cable lengths determine the maximum distance that the tower and cart can be separated during any time that the system is powered on.



Item	Description
①	Cart with robot arms facing the Tower.
②	Tower

Prepare the Bronchoscopy Suite

1. Bring the following Monarch single-use items into the procedure room.
 - a. Bronchoscope Fluidics Tubing.
 - b. Working channel instruments (Aspirating Biopsy Needle, etc.).
 - c. Bronchoscope Patient Introducer Kit (includes Bronchoscope Patient Introducer and Bronchoscope Swivel Adapter).
 - d. Monarch Bronchoscope System (includes Monarch Bronchoscope and Monarch Bronchoscope Sheath).
 - e. Monarch Bronchoscope Sheath Valve.
 - f. Navigation Patient Patches.
2. Bring Tower into room and place in the desired location in the procedure room.
3. Bring Cart into room and position it where it does not hinder normal room setup.
4. Plug in the umbilical cable from the Tower to the Cart.
5. Plug in the Tower to a dedicated electrical power outlet.
6. Plug in the Cart to a separate, dedicated electrical power outlet.

Ensure access to the Tower and Cart a.c. mains inlet cables is unimpaired as these are the mains disconnect devices.
7. Power the system on by pushing the power button on either the tower or the cart.
8. Select the Lung icon  on the Tower Touchscreen.
9. Log on to the Tower with your user name and password.
10. Load the desired patient case using the CD of the patient's CT in order to plan paths, or the Monarch USB drive with planned paths completed.


Prepare the Patient


1. Once the patient enters the room, place the patient close enough to the head of the table, with the patient head no more than 230mm away from the top edge of the table. It is recommended to use a headrest.
2. The anesthesiologist sedates the patient for intubation.



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

3. Anesthesiologist or physician will intubate the patient. Once the endotracheal tube is placed, the tube can be cut if desired.
 - Use of this device is restricted to endotracheal tubes 7.5mm and greater.
 - The patient should not be moved when the Monarch Bronchoscope System or related equipment is inserted into patient airways.
4. Place the Bronchoscope Patient Introducer Mount on the bed rail near the patient's head on the side of the bed opposite that which the cart will be positioned.
5. Open the Bronchoscope Patient Introducer Kit package.
6. Attach the Swivel Adapter to the endotracheal tube.
7. Place Bronchoscope Patient Introducer into the mount.
8. Connect the Patient Introducer to the Swivel Adapter and align the patient introducer perpendicular to patient, parallel to the top of the bed with the opening facing the side of the bed where the Cart is placed.

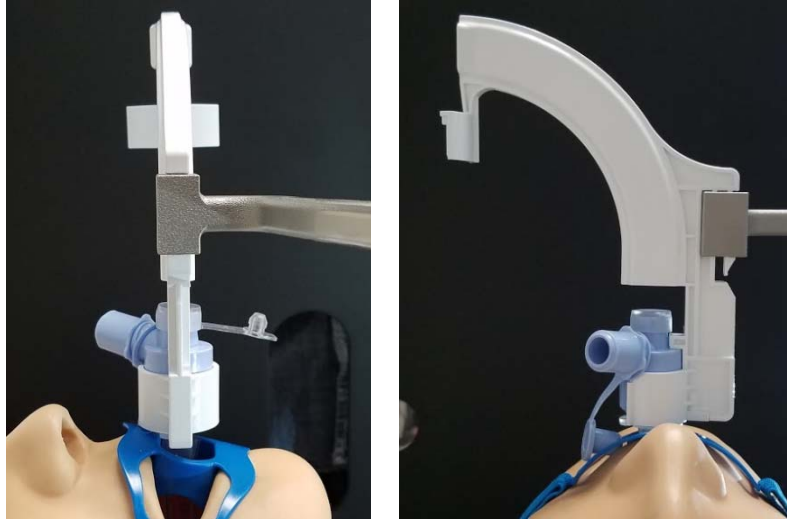
 **NOTE:** Proper alignment and attachment of the Bronchoscope Patient Introducer is important for smooth scope insertion and minimizing air leakage during ventilation.

 **NOTE:** Improper alignment may also cause navigation accuracy to be impaired.

- a. Make sure the Swivel Adapter is fully seated, as shown in the following image (right).



- b. Make sure the Bronchoscope Patient Introducer is vertical, snapped in, and the arm knob on the Bronchoscope Patient Introducer mount is completely tightened.



Prepare the Monarch Bronchoscope System



WARNING: The bronchoscope and sheath must be lubricated prior to insertion. Failure to lubricate the bronchoscope and sheath may cause buckling and poor scope driving responsiveness.

1. Open the Monarch Bronchoscope System package and remove the pouched tray.
 - Keep the package and all its components for repackaging, in case the Bronchoscope System needs to be returned at the end of the procedure.



NOTE: If the bronchoscope and/or sheath is dropped after being removed from its packaging, replace the bronchoscope and sheath to ensure that its cleanliness has not been compromised.

2. Open the pouch on the device handle side and pull out the tray, ensuring that the device handles do not fall out of their wells.
3. Hang the tray on a hook on the side of the Tower.
4. Remove the Monarch Bronchoscope from its packaging tube and lubricate the shaft. Not lubricating may cause navigation accuracy to be impaired.



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



NOTE: Use only silicone-based lubricants such as Silkospray Universal Silicone Spray. Do not use water-based lubricants. Use of such lubricants will increase friction between the bronchoscope and sheath while driving.

5. Insert the Monarch Bronchoscope back into the packaging tube and tray until the procedure begins.

6. Remove the Monarch Bronchoscope Sheath from its packaging tube and lubricate the shaft.



NOTE: Use only silicone-based lubricants such as Silkospray Universal Silicone Spray.

7. Open the Bronchoscope Sheath Valve package.
8. Place the Bronchoscope Sheath Valve over the Luer fitting on the back of the Monarch Bronchoscope Sheath.
9. Insert the Monarch Bronchoscope Sheath back into the packaging tube and tray until the Cart is set up and the procedure begins.

During start up, if the system is not yet initialized, a pop-up notification appears to inform you to wait.

Monarch Tower System Setup Guidance

Use the Monarch Tower Software guidance prompts to confirm steps that you have completed.

Monarch Controller

1. Plug in the Monarch Controller to the tower.
2. When **Controller** button turns green, press **Fluidics** to continue.

As each segment of the setup is complete, the corresponding button turns green.



Fluidics System

1. Unpack the Bronchoscope Fluidics Tubing from its sterile packaging. Connect the end of the tubing with a Luer fitting valve to the Monarch Bronchoscope System handle Luer fitting.
2. Attach the tubing (blue stripe) to the irrigation pump. Note the direction of the arrow, which defines pumping direction.



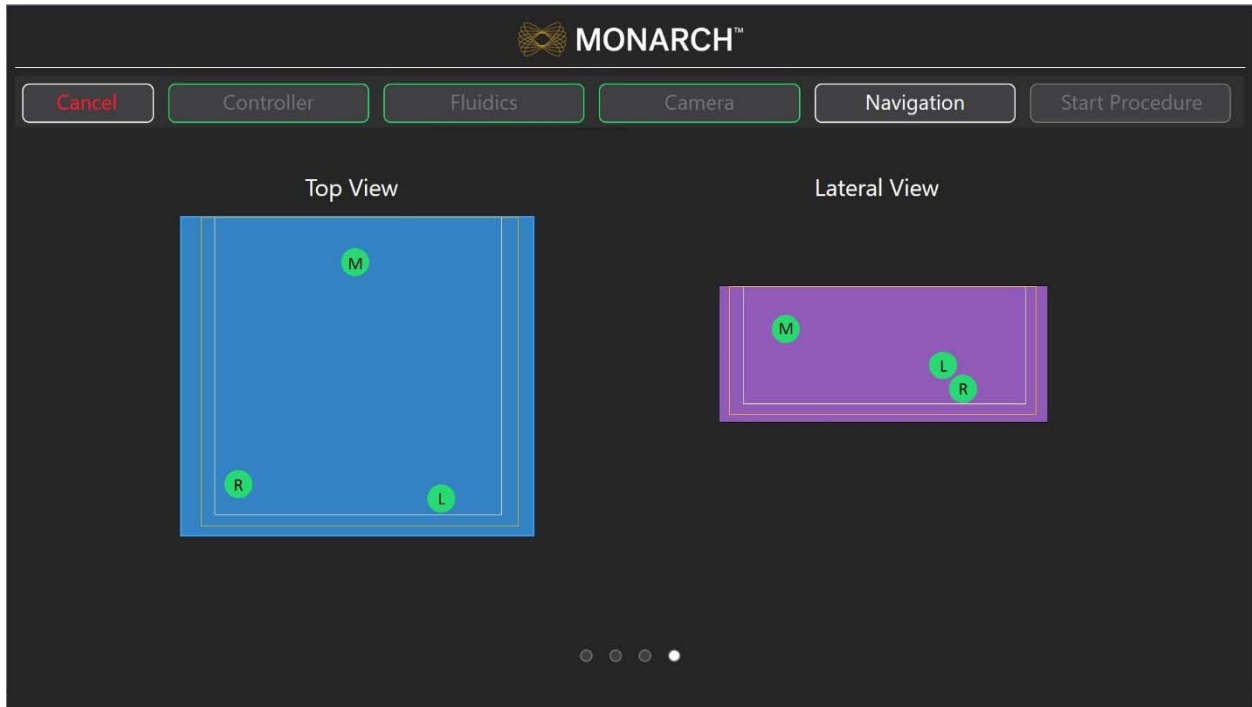
3. Close the pump cover, and connect the tube to the saline bag with the attached spike.
4. Open the clamp on the saline line. Hang saline bag on Tower hook.
5. Attach the other (clear) tubing to the aspiration pinch valve by sliding it in. To slide the aspiration tubing into the aspiration pinch valve, you can open the pinch valve by pushing in the front black surface of the aspiration pinch valve or by engaging the vacuum button on the Controller.
6. Attach the connector to the operating room suction or vacuum (canister).
7. Use the Controller's upper-left buttons to prime the irrigation line with fluid and to close the pinch valve for the aspiration line.
8. Press **Camera** to continue.

Camera

1. Plug in the Bronchoscope camera cable to the tower.
2. Verify that the camera is live.
3. Press **Navigation** to continue.

Navigation

1. Plug in Monarch Navigation Field Generator to the tower while leaving it in tower cabinet.
2. When the button turns blue, press DONE.
3. Remove Monarch Navigation Patient Sensors from the storage pouch in the door on the side of the tower.
4. Plug in Navigation Patient Sensors to the tower.
5. Attach Navigation Patient Sensors to the patient using the disposable adhesive Navigation Patient Patches. Patches are designed for a single adherence. Attach the labeled sensors as follows:
 - a. L patient left 8th rib mid axillary line.
 - b. R patient right 8th rib mid axillary line.
 - c. M patient sternal notch.
6. Remove the Monarch Navigation Field Generator Mount from storage compartment on the side of the tower.
7. Attach the Field Generator Mount to the bed rail on the side of the patient that the target nodule will be.
8. Remove the Navigation Field Generator from tower drawer.
9. Place the Field Generator into the mount by sliding into the top of it. Make sure that the notch of the Field Generator slides into one of the holes in the mount.
10. Position the Field Generator such that it is at the mid-chest wall approximately 5 cm from the patient's chest.
11. Swipe left on the Tower screen to move past the navigation setup instructions.
12. Adjust the Field Generator to ensure that the Patient Navigation Sensors are within the field of lung volume. On the tower screen, all three sensors will turn green if the Field Generator is in the optimal position.



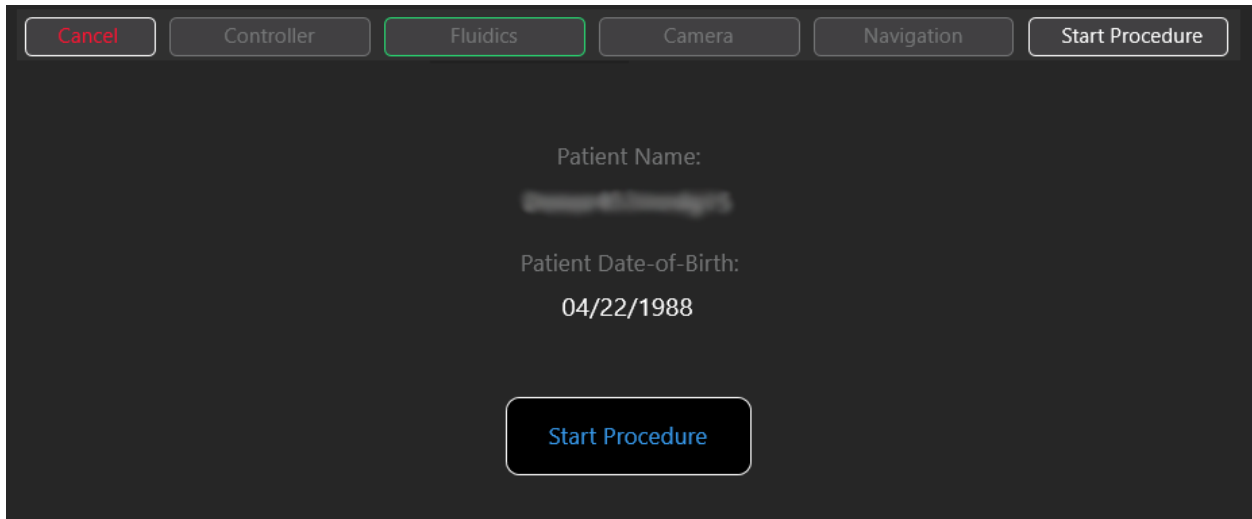
13. Press **Start Procedure** to continue.



NOTE: Ensure fluoroscopy system has a minimum clearance distance of 70 cm vertically and laterally from the Field Generator. To do so may affect the measurement volume, contributing to inaccurate transformations.



NOTE: In larger patients, it may be difficult for all three sensors to turn green. In this case, the sensor furthest away from the Field Generator should be the one designated as yellow or orange. Yellow, orange, and red indicate that portions of the lung may have sequentially less accurate navigational targeting.



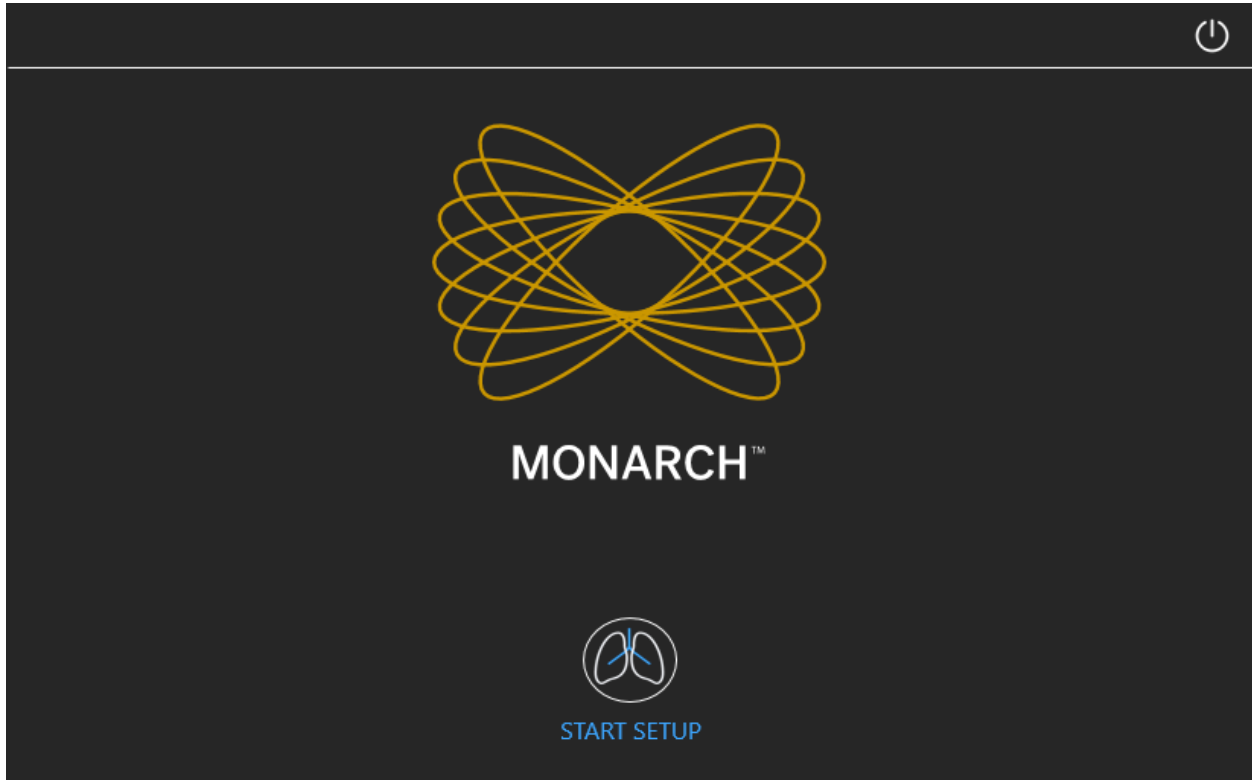
Monarch Cart System Setup Guidance



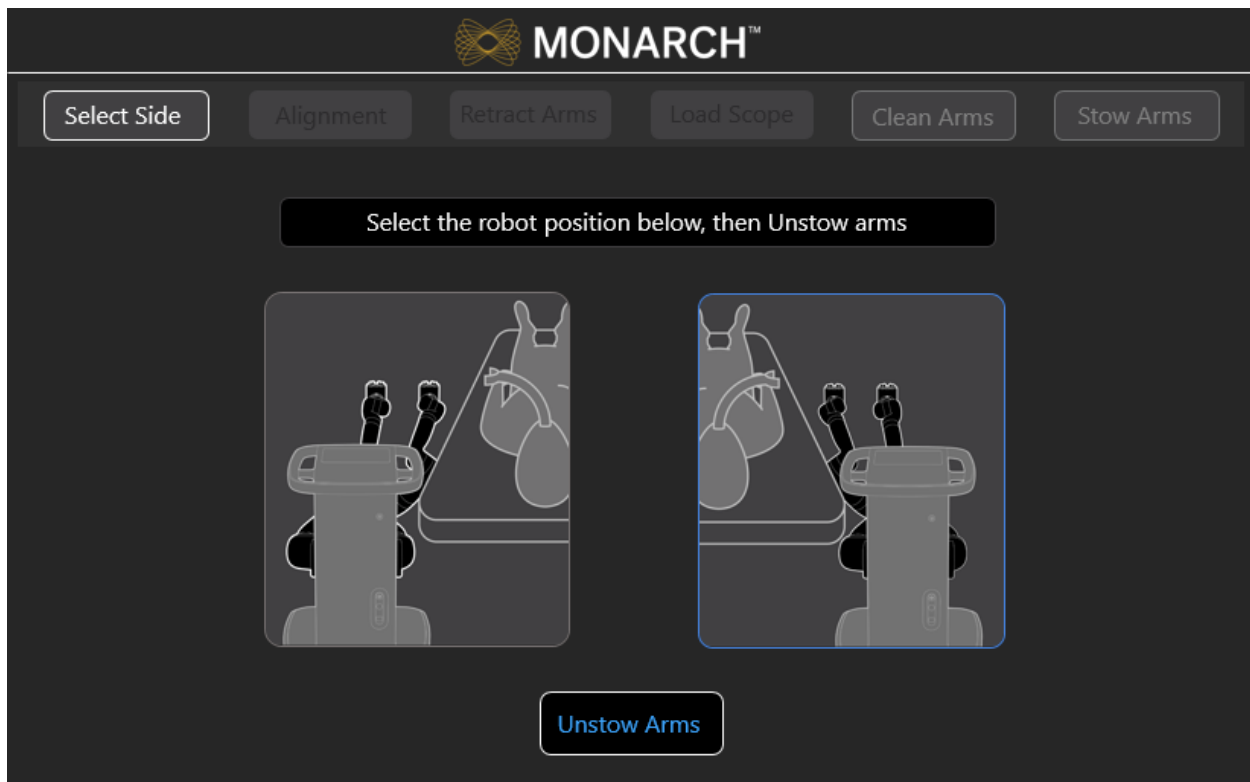
NOTE: Ensure there is appropriate clearance between the Monarch Cart and the patient and staff.

Unstow Cart

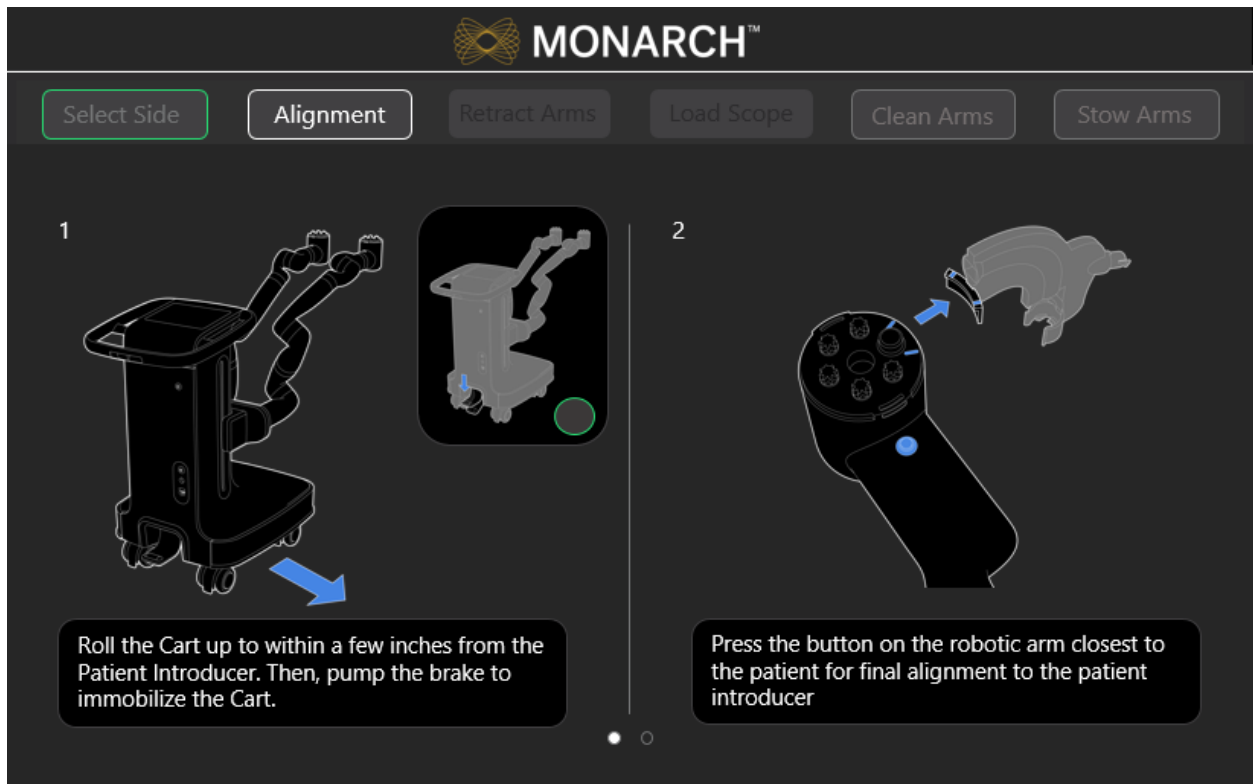
1. Press **Start** to confirm that the Monarch Cart is ready to set up to the patient.



2. Roll the Cart to the correct side of the patient with approximately 36" between the cart and the bed.
3. A blue box will highlight the direction that the arms will setup. Select which side you want the robot arms to move to and press **Unstow Arms** to move the robot arms in that direction.



4. Move the Cart to align the robot arms within approximately 2 inches of the Patient Introducer.
5. Immobilize the Cart by pumping the foot pedal until the cart is lifted and the green indicator light appears on the screen. You are unable to use the software until the cart is immobilized.
Wait 5 seconds to ensure that the green indicator light appears before continuing to the next step.
6. Press the button on the robot arm closest to the patient to adjust for fine positioning of the robot arms to the Bronchoscope Patient Introducer.



7. Make sure the IDM touches the alignment feature (as shown in the following image).



8. Press **Set**.

Load the Monarch Bronchoscope System



WARNING: Do not reuse the Monarch Bronchoscope System, Bronchoscope Fluidics Tubing, Bronchoscope Patient Introducer, or working channel instruments. These devices are single-use only.



WARNING: Do not use the Monarch Bronchoscope System, Bronchoscope Fluidics Tubing, Bronchoscope Patient Introducer, and working channel instruments if sterile barrier has been damaged. Do not use if packaging is opened or damaged.

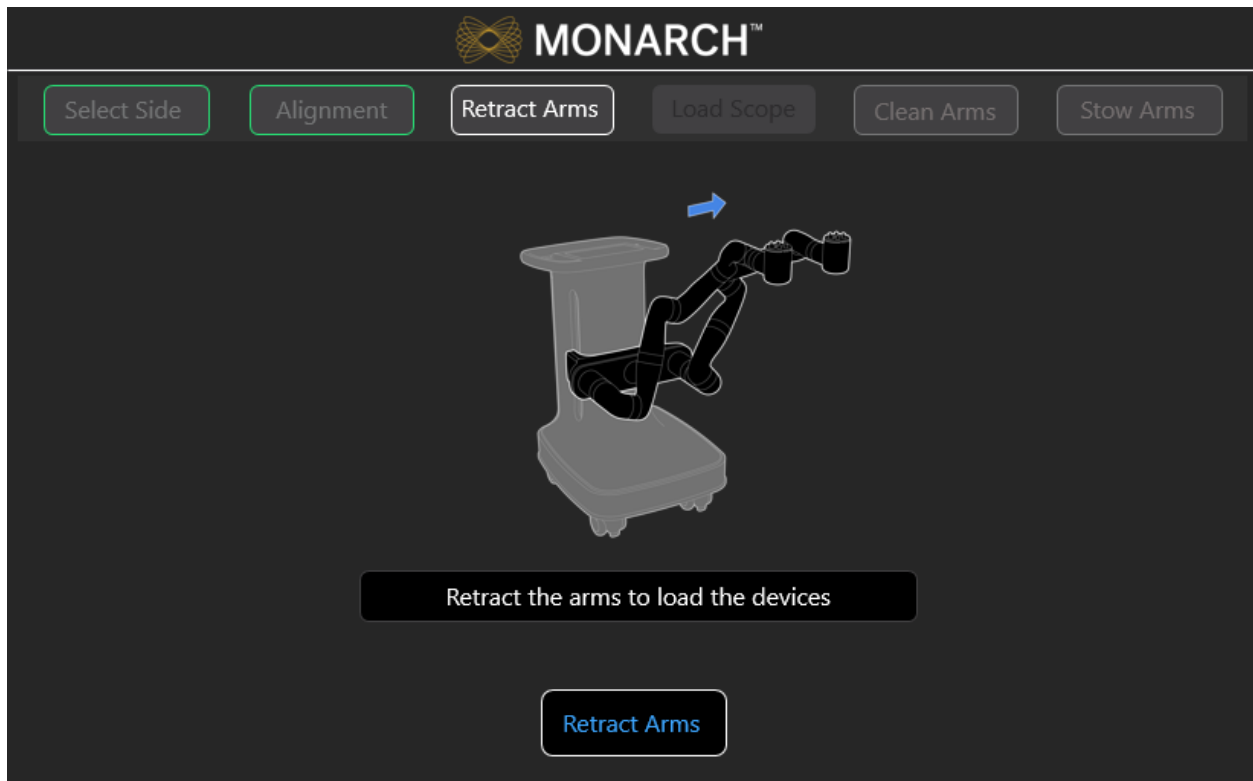


WARNING: The bronchoscope and sheath must be lubricated prior to insertion. Failure to lubricate the bronchoscope and sheath may cause poor scope motion.



WARNING: Take care to manage cables and fluidics tubing. Both may present a tripping hazard which can lead to user or patient injury or harm.

1. Press **Retract Arms**. Robot arms move to a loading position.



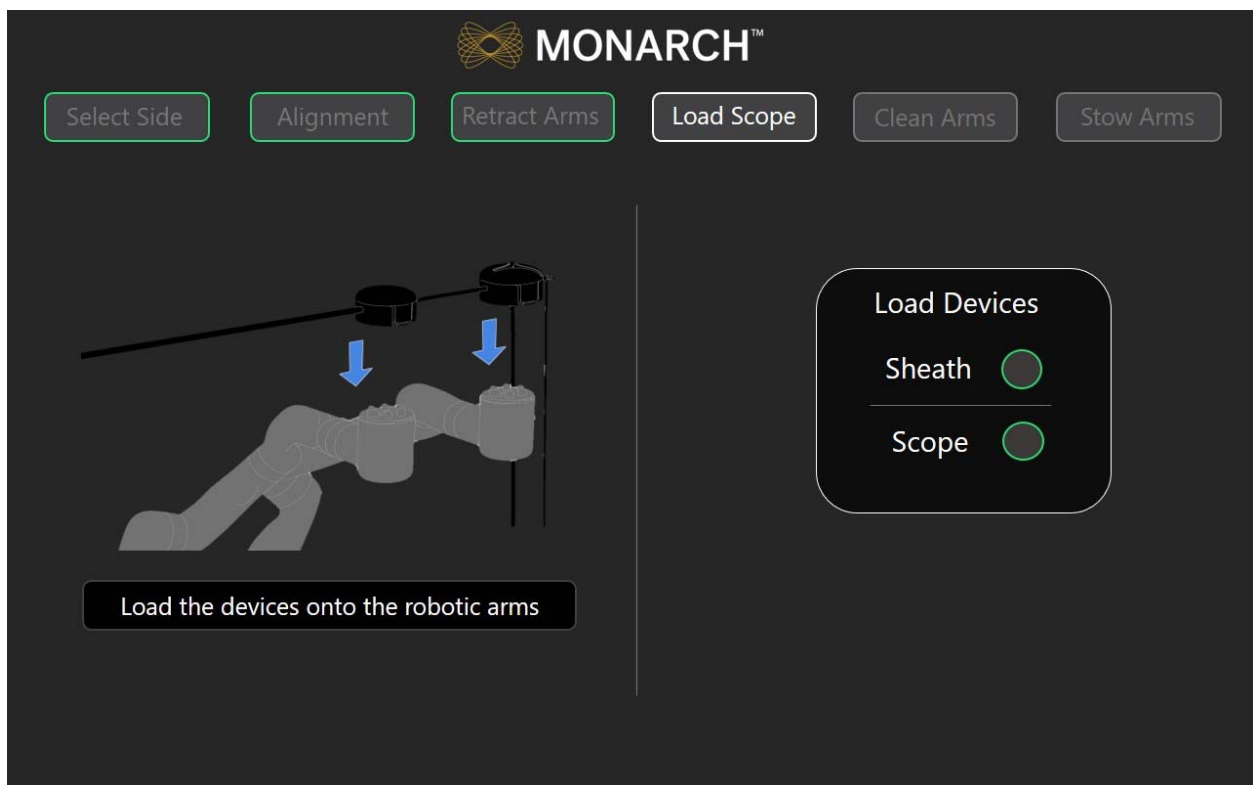
2. Remove the Monarch Bronchoscope System from the packaging tray.

3. Assemble the Monarch Bronchoscope and Monarch Bronchoscope Sheath by inserting the bronchoscope through the Bronchoscope Sheath valve and through the sheath.
4. Insert the tip of the Monarch Bronchoscope System into the Patient Introducer up to the end of the bronchoscope swivel adapter.
5. Load the Monarch Bronchoscope System handles onto the robot arms. The Monarch Bronchoscope Sheath should be loaded onto the robot arm closest to the patient.



WARNING: Excessive load on the robotic arms may cause rotation, arm slippage, or arm damage which may result in unintended motion and could result in patient injury.

6. Ensure that the handles fully latch onto the robot arms by slightly pulling up on the handles. Green indicator lights appear next to the Scope and Sheath on the **Load Scope** screen when the Monarch Bronchoscope System is detected by the system and is ready for use.



Chapter 4

Performing a Procedure

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Functional Descriptions of Monarch Components.....	54
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Monarch Navigation Application User Interface	58
Procedural Steps or Actions.....	78
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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. Drive the Monarch Bronchoscope System forward to the main carina.
2. Initialize navigation.
3. Drive the Monarch Bronchoscope System to nodule.
4. Confirm nodule location.
5. Align the Monarch Bronchoscope System with nodule.
6. Insert the biopsy instrument.
7. Target and actuate the biopsy instrument.

Functional Descriptions of Monarch Components

Monarch Bronchoscope and Monarch Bronchoscope Sheath

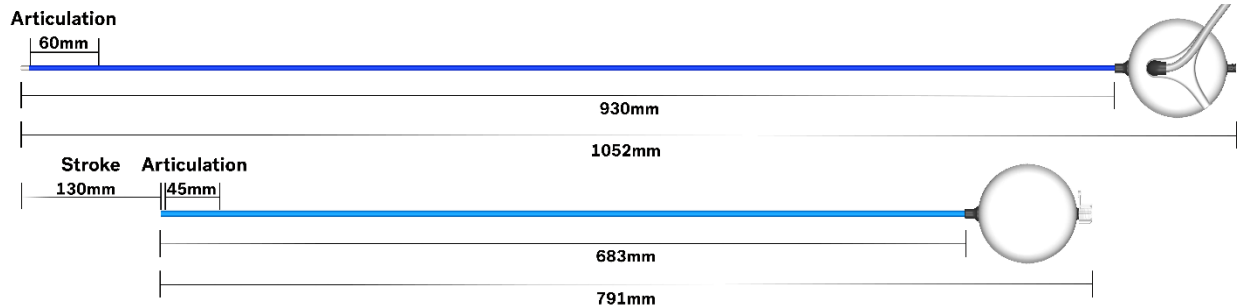
The Monarch Bronchoscope System works with two independently controlled telescoping, articulating devices. The dimensions of each are as follows:

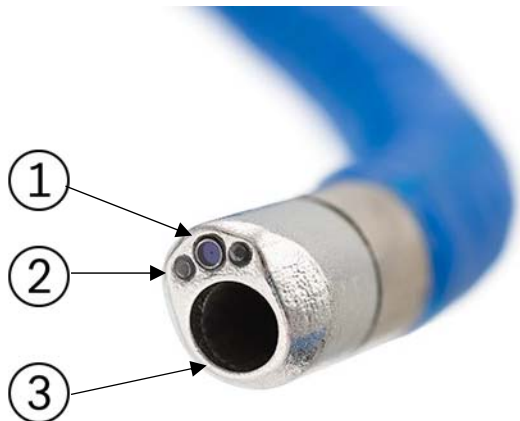
	Monarch Bronchoscope Sheath	Monarch Bronchoscope
Outer Diameter	6.0mm	4.4mm ¹
Lumen Diameter	4.7mm	2.1mm
Working Channel Length	791mm ²	1052mm ³
Articulation Section Length	45mm	60mm

¹ Diameter measured at the Bronchoscope tip.

² Takes into account use of the sheath valve.

³ Takes into account the bronchoscope valve.





Item	Description
①	Camera
②	Lights (x2)
③	Working channel (2.1mm)

Monarch Platform Device Compatibility

Working channel instruments are restricted to those that are compatible with a working channel diameter of 2.1mm.

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 sterile barrier has been damaged. For single-use only. Do not reuse, reprocess, or resterilize single-use products. Reuse, reprocessing, or resterilization 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 resterilization 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.

Monarch Controller

The Monarch Controller is used to control the Monarch Bronchoscope System. The individual controls are described in the following table.



Item	Description
①	Insert/Retract joystick
②	Menu button
③	Quick Action button
④	Pause/Start button
⑤	Articulate (outer) and Relax (inner) joystick
⑥	Light, Program, and Snapshot buttons
⑦	Directional pad



Item	Description
①	Toggle between Monarch Bronchoscope and Monarch Bronchoscope Sheath.
②	Irrigation button
③	Aspiration button



WARNING: Always secure the endoscopic controller. When in the enabled state, dropping or other unintended joystick motion may lead to accidental commanded motion which may cause patient injury, such as pneumothorax, hemorrhage or endoluminal irritation.

Working Channel Instruments



WARNING: Working channel instruments are intended for manual operation once the bronchoscope has reached the target location. Refer to individual Instructions for Use included with each working channel instrument for additional information.



NOTE: Presence of a fluoroscopy system near the Monarch Navigation Field Generator may compromise navigation accuracy. When using the fluoroscopy system, you should only refer to the live endoscopic views during manual biopsy.



NOTE: Metallic working channel instruments near the scope tip may temporarily compromise navigation accuracy. Examples include: instruments 20mm proximal to the tip or activation of a radial ultrasound probe within the scope.

Monarch Navigation Application User Interface

The Monarch Platform provides access to several custom views that combine the live Monarch Bronchoscope, CT data, and virtual reconstructions of the airway segmentation. These views can be mixed and matched based on physician preference and rearranged during the procedure as needed.

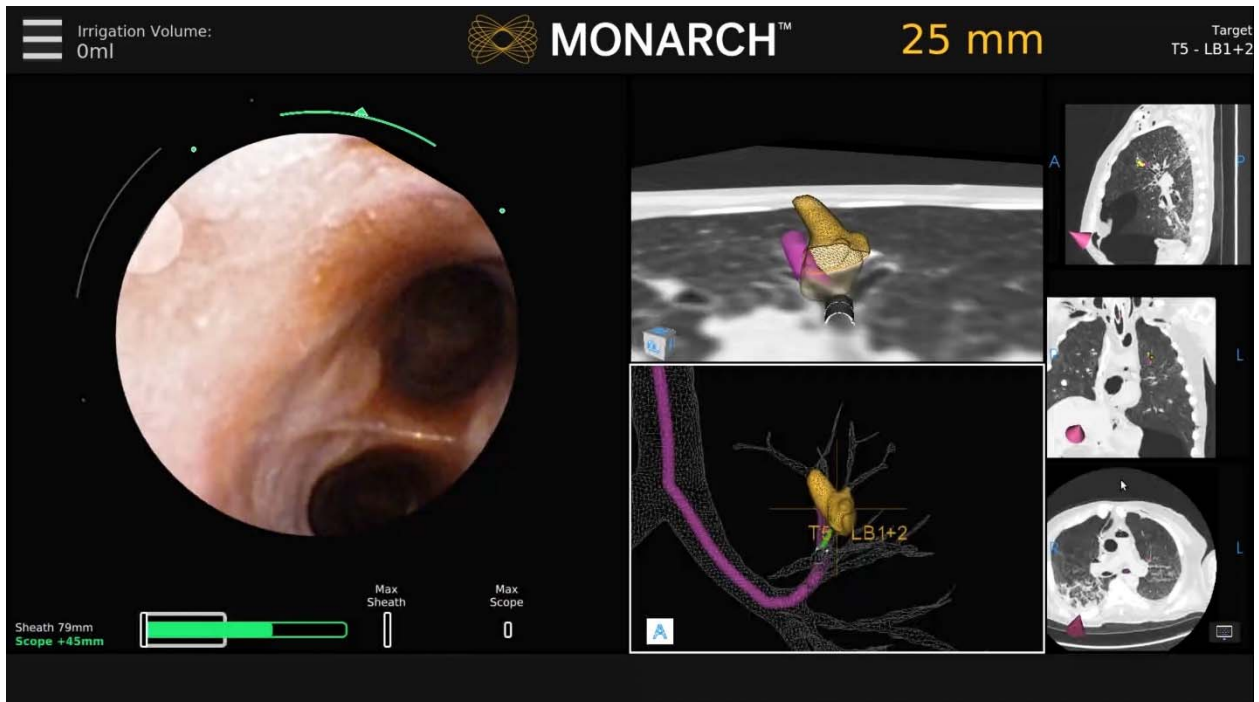
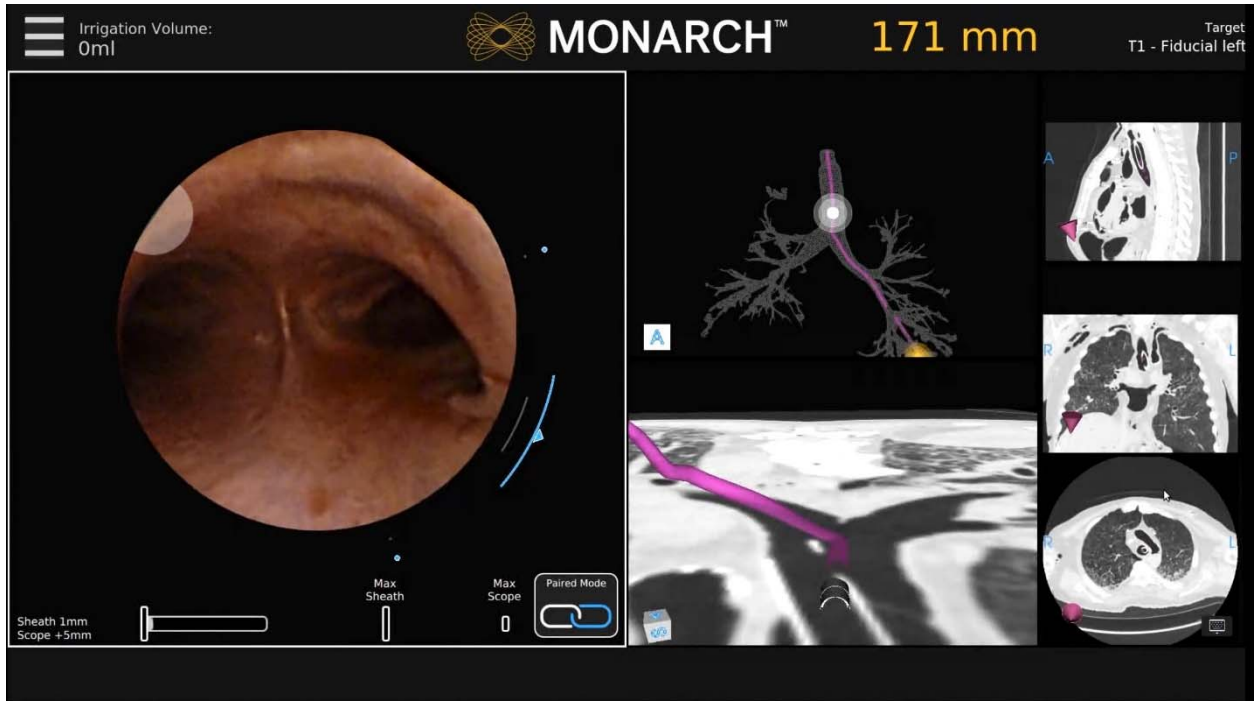
- Primary Area (page 60)
- Scrolling Area (page 61)
- CT Area (page 62)
- Full Screen Mode (page 63)
- Live Bronchoscope (page 66)
- Virtual Bronchoscope (page 69)
- 3D Map View (page 70)
- Local View (page 71)
- Targeting Views (page 72)
- Axial, Sagittal, and Coronal CTs (page 74)

At the core of the Monarch Navigation Application is the Live Bronchoscope view which provides vision in both the central airways and periphery. This camera view is available from any part of the user interface.



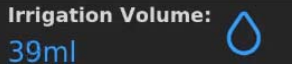


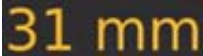
The CT views include Axial, Sagittal and Coronal planes which reflect the scope's current position within the airway tree while also showing the location of the target nodule. In addition to the traditional planar views, the user interface includes several views with oblique slices based on the orientation of the scope. These views include Local View.

Finally, the Monarch Navigation Application includes virtual views which are computer-based reconstructions of the CT data. These views show the airways and scope position from unique perspectives. The virtual views include Virtual Bronchoscope, 3D Map, Local View, and Targeting Views.

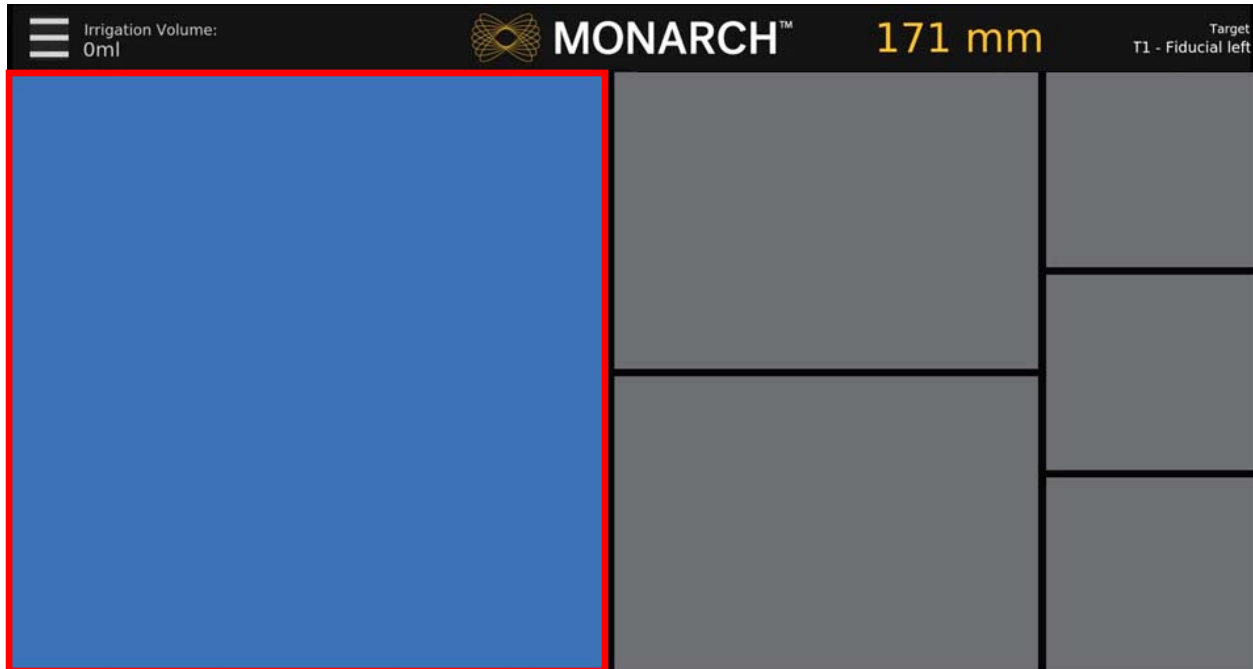
The following images show a representation of the overall screen.



Top Navigation Bar

Item	Description
	Menu icon
	High Beam icon appears when the Light button is pressed. The feature increases light emission from the tip.
	Irrigation indicator: Estimated total volume delivered from the pump is displayed. Text turns blue when irrigation is active.
	Aspiration icon: Appears when aspiration is active.
	Irrigation icon: Appears when irrigation is active.
	This text reflects the distance to from the tip to the nodule.

Primary Area

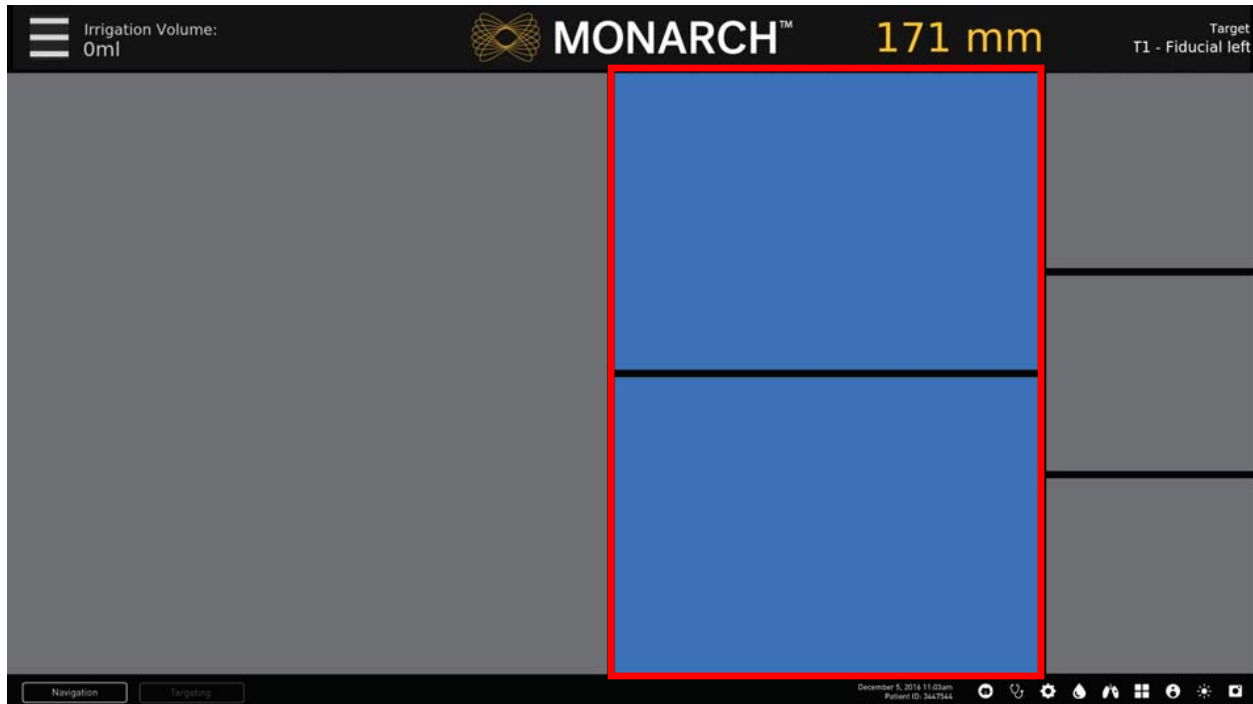


Any of the views from the center column can be selected using either the Touchscreen or the select button on the Monarch Controller to “promote” the view to the larger window.

This larger window is called the Primary Area. The increased size allows more information to be shown, in the form of more detailed graphics. When the Live Bronchoscope view is promoted to the Primary Area, additional data not available in the smaller viewing window appears.

See Live Bronchoscope (page 66) for examples of how the Primary Area can show additional information.

Scrolling Area

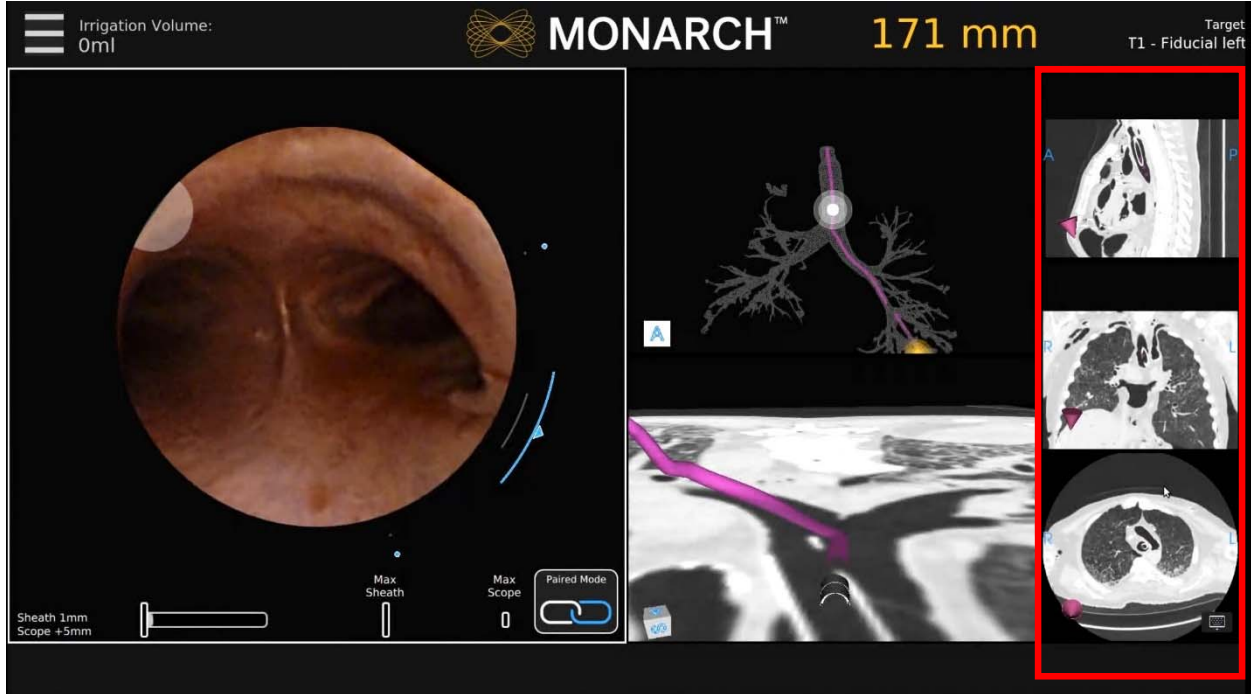


The center column of the Monarch Navigation Application can be scrolled to present any two relevant views. This column can be scrolled, using the up, down, and select navigation buttons on the Monarch Controller.

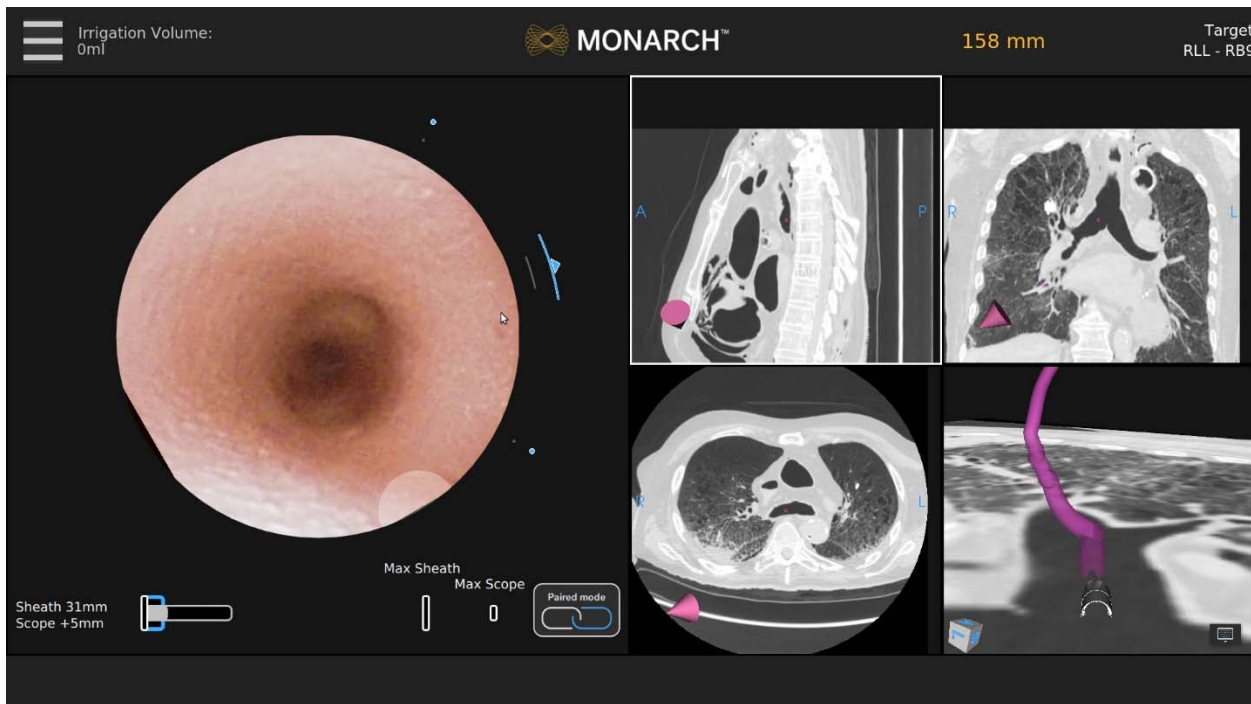
The Scrolling Area contains four views discussed in the following:

- CT Area (page 62).
- Full Screen Mode (page 63).
- Menu System (page 63).
- Navigation Views (page 65).

CT Area

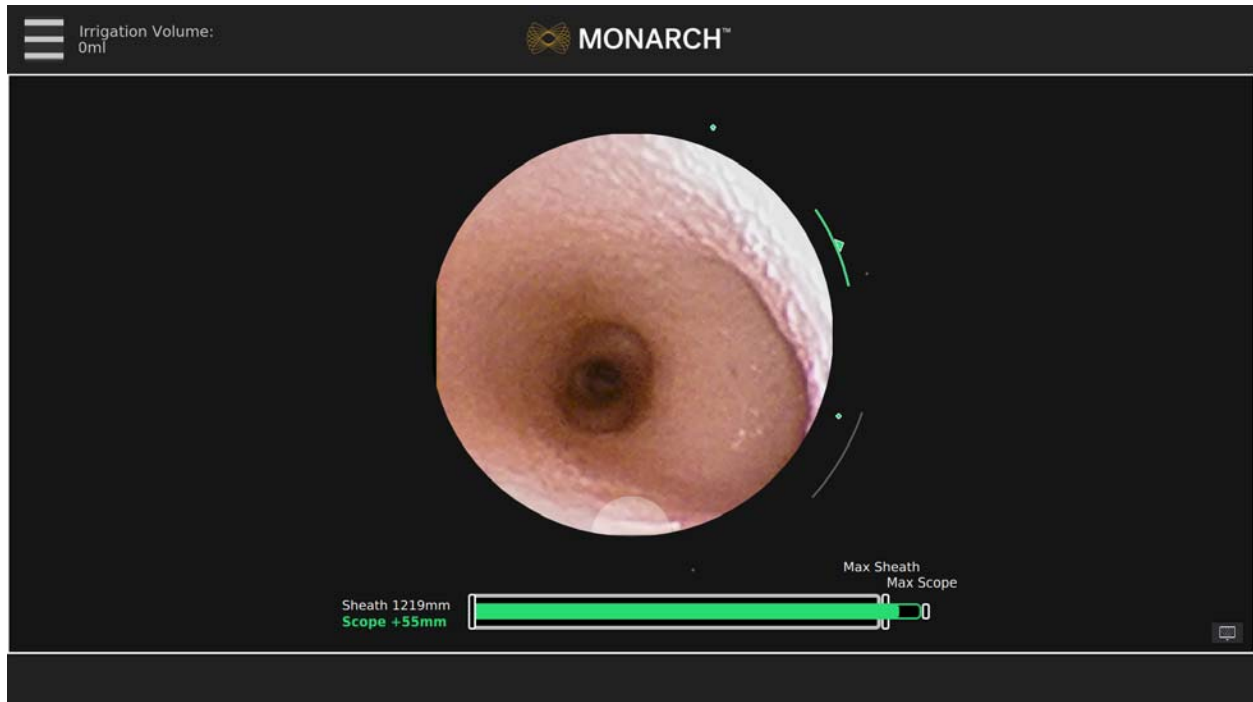


The right column offers a collection of supplementary CT views. The CT Area does not scroll and views cannot be promoted from the CT Area to Primary Area. Instead, the views can be selected for zoom to show more detail. When selected, an alternative view window configuration appears with enlarged CT slices as shown below.



This view was designed to support physicians who use the Axial, Sagittal, and Coronal CT views during the procedure. Selecting a CT window automatically dismisses the view.

Full Screen Mode



Live Bronchoscope – Full Screen Mode

When the Live Bronchoscope view is the Primary Area, selecting the Primary Area enlarges it to a Full Screen Mode. This removes the Monarch Navigation Application and displays only the Live Bronchoscope image. This is also the view that appears if you perform a case without a navigation plan.

Selecting the Full Screen Mode image automatically returns it to Primary Area.

Menu System

The menu system is available from the menu button on the Monarch Controller as well as the upper-left of the user interface and includes functions that you can access during the procedure such as selecting a new target or loading a new plan. The menu system is also used to control robot settings or exit the system.

Patient name and medical record number can be displayed on the main menu for quick reference. Hiding it within the menu makes it easily accessible but does not expose the information for screenshots and video.



Select the menu item using the Monarch Controller or press the corresponding item on the screen.

Back to Navigation

Press **Back to Navigation** to return to the Navigation tab.

Select Target

Press **Select Target** to select a target to navigate to.

Camera Parameters

Press **Camera Parameters** to adjust the camera roll.

Reinitialize Navigation

Press **Reinitialize Navigation** to reset the navigation procedure from the main carina.

Stop Procedure

Press **Stop Procedure** and choose one of the following:

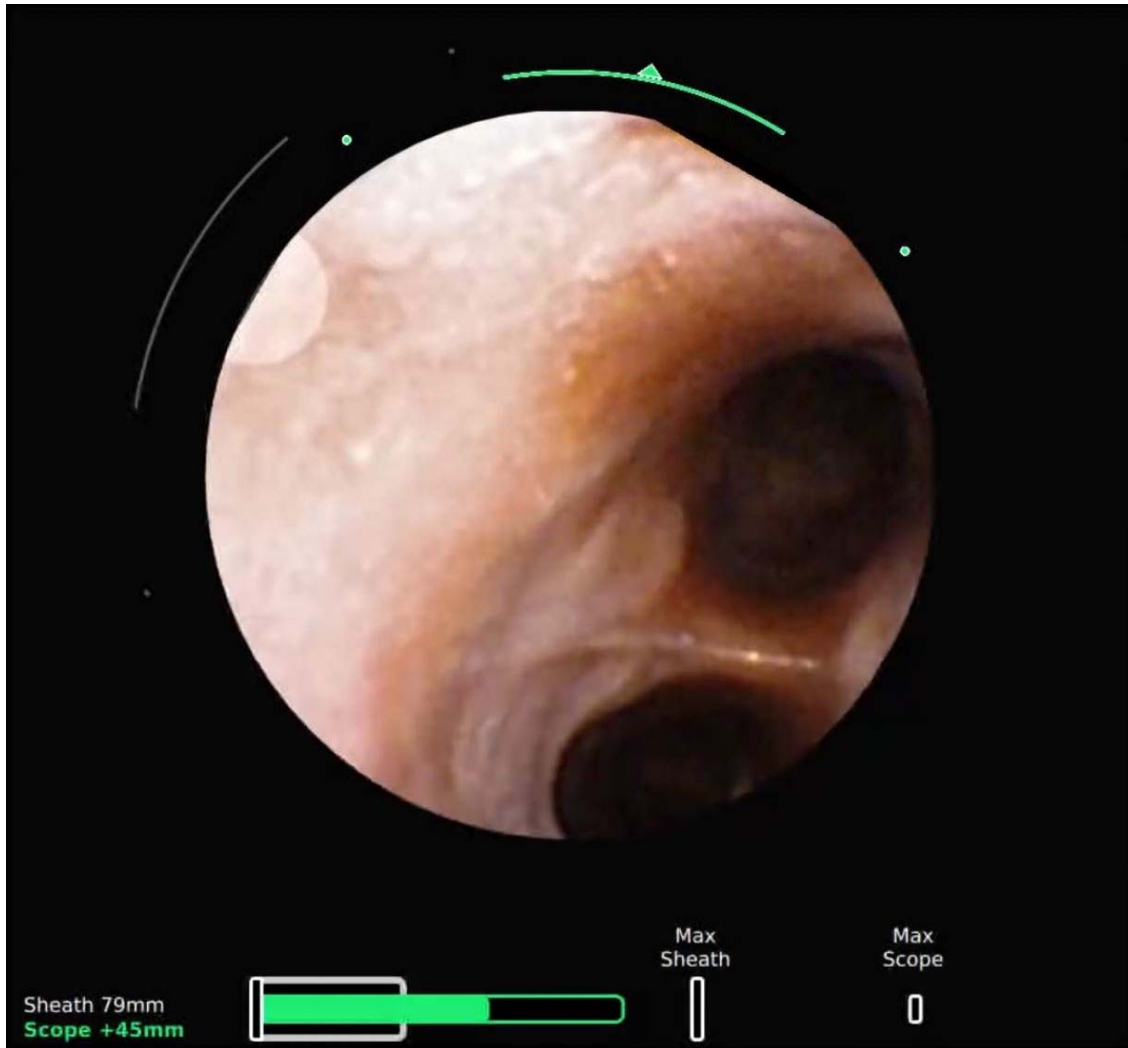
- **Export Media to USB.**
The Monarch USB drive must be inserted for this feature to be available.
- **Return to System Set-up.**
- **Load New Patient Case.**
- **Logout.**
- **Shutdown.**

Navigation Views

The Monarch Navigation Application integrates a pre-procedure-computed tomography scan into a peri-procedure interface displaying endoscope tip location relative to the pre-procedure scan anatomy. The navigational information displays the Monarch Bronchoscope tip location relative to the CT scan. The application's interface includes a virtual representation of the lung with scope tip location. The following views describe the way that the scope tip location appears on the CT scan images or virtual representations.

- Live Bronchoscope (page 66).
- Virtual Bronchoscope (page 69).
- 3D Map View (page 70).
- Local View (page 71).
- Targeting Views (page 72).
- Axial, Sagittal, and Coronal CTs (page 74).

Live Bronchoscope



The Primary Area of the Live Bronchoscope shows more detailed information than when located in the Scrolling Area.

The core of the Monarch Navigation Application is the Live Bronchoscope view which provides vision in both the central airways and the periphery. This camera view is always displayed in either Full Screen Mode, Primary Area, or Scrolling Area positions.

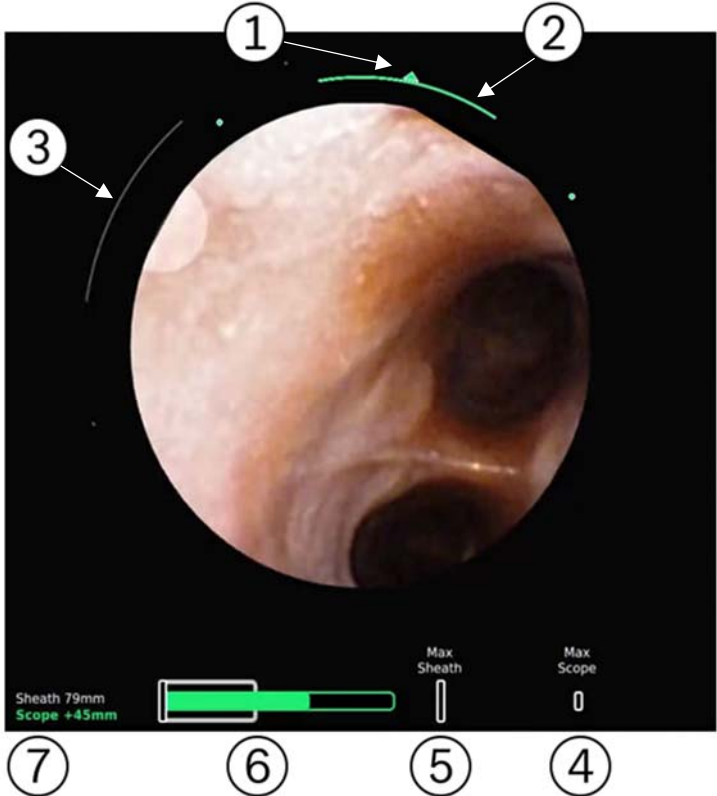
The Primary Area of Live Bronchoscope presents the camera image cropped to a 660px circle. Two concentric arcs represent the articulation of the scope (inner) and sheath (outer). As articulation increases, the arcs increase in length. The dots indicate the max articulation of the sheath/scope. The dots turn to hash marks when max articulation is reached. The device that is actively being articulated will be colored (blue: sheath; green: scope).

The location of the working channel is represented by a half circle at the edge of the camera image.

Insertion depth is at the bottom of the screen. The gray bar (which turns blue when the Sheath is selected) indicates the sheath insertion. The green bar indicates the insertion of the scope relative to the sheath. The green outline indicates the remaining stroke length of the scope. The hash marks indicate max insertion of the sheath and scope respectively. The numeric measurements are the relative insertion of the sheath (from the point of navigation initialization) or the scope (relative insertion from sheath). The selected device (scope or sheath) is in bold and is colored. When both the scope and sheath are active together, the “Paired” icon appears, indicating that the device tips are flush and insertion/articulation will insert/articulate both scope and sheath together.

The design of the Live Bronchoscope view changes when positioned in the Scrolling Area compared to the Primary Area. Scope and sheath insertions are reduced to numbers in this view in order to reduce visual clutter.

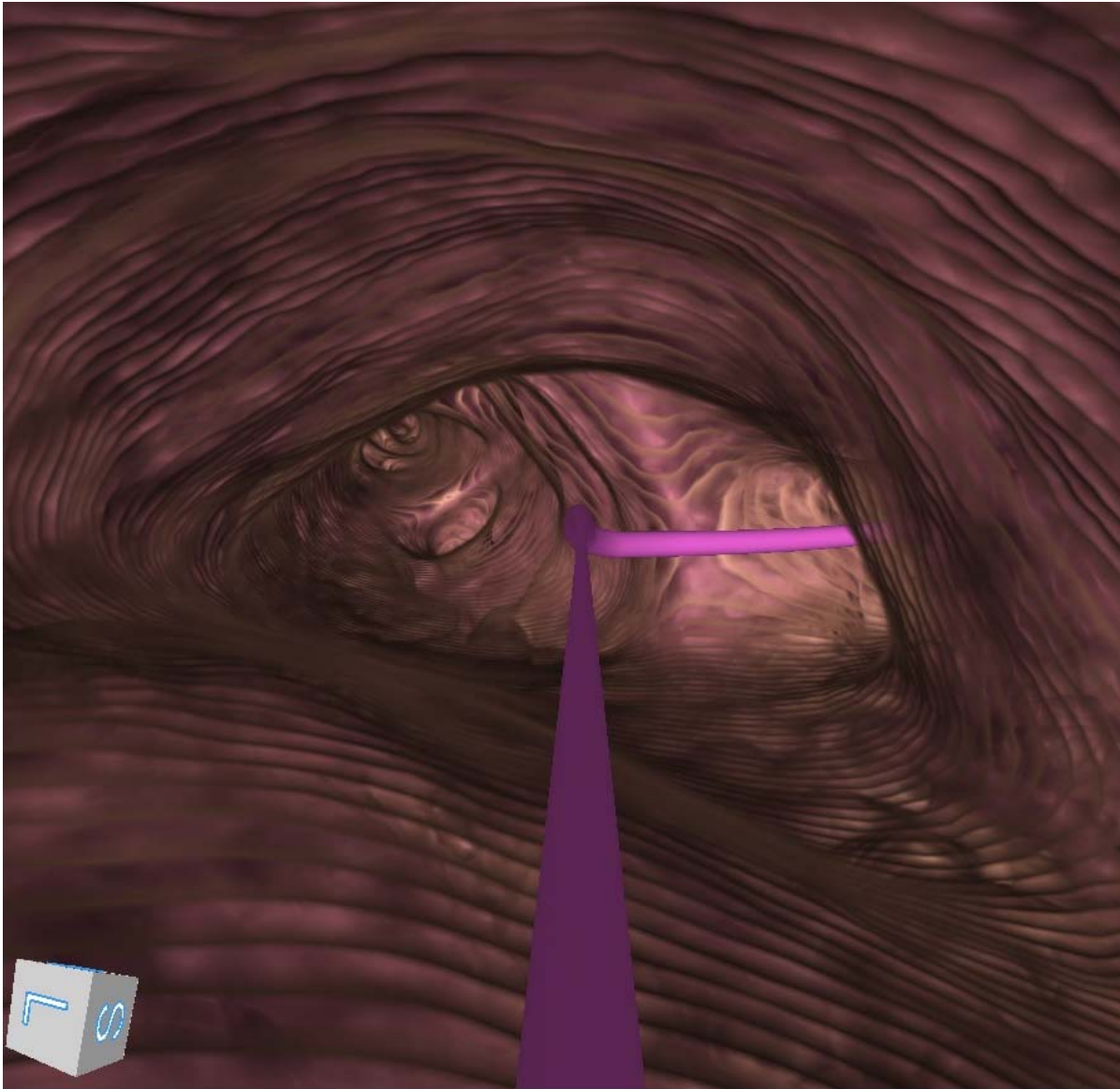
The Full Screen Mode adopts the Primary Area design.



Item	Description
①	Direction of articulation
②	Magnitude of Bronchoscope articulation

Item	Description
③	Magnitude of Sheath articulation
④	Maximum insertion that the Bronchoscope can reach
⑤	Maximum insertion that the Sheath can reach
⑥	Represents the relative insertion of the Bronchoscope (green) into the Sheath (white)
⑦	Relative insertion values for the Bronchoscope and Sheath

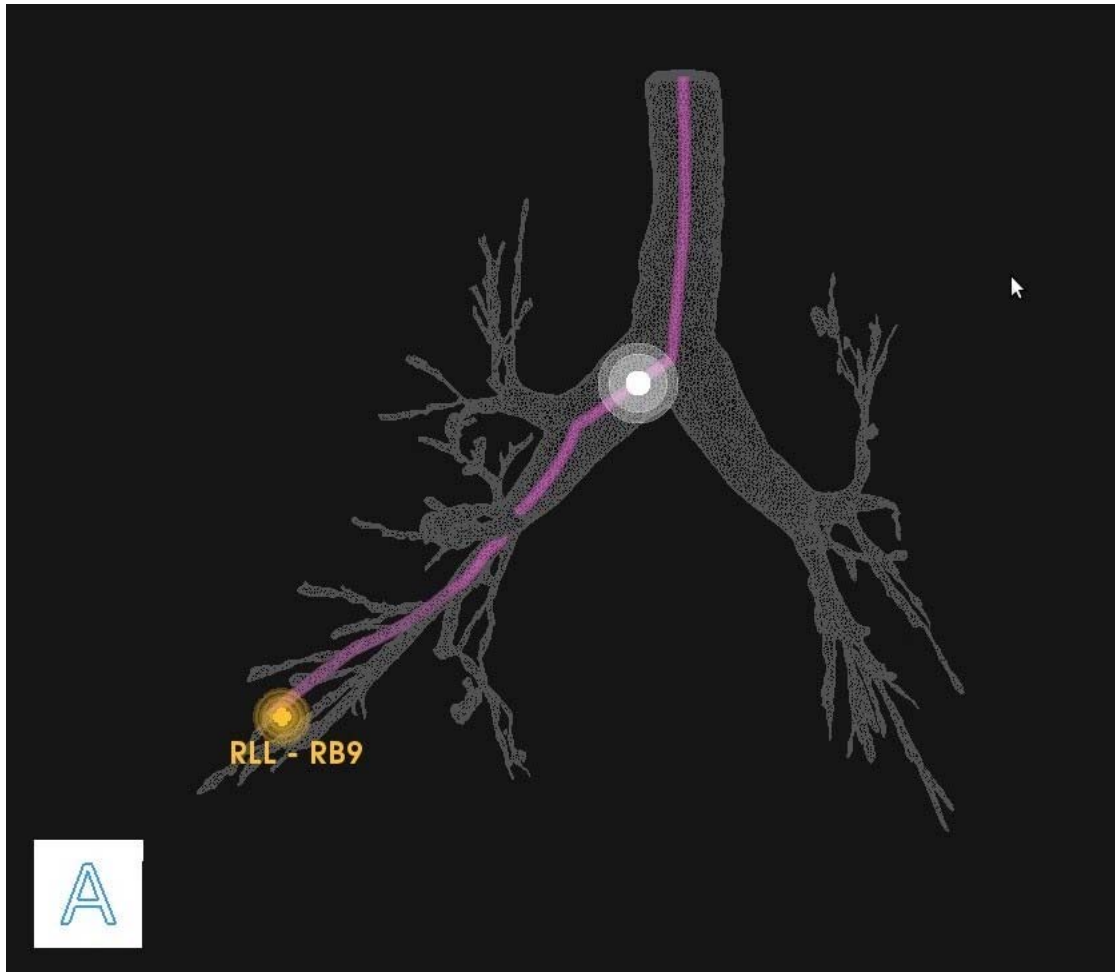
Virtual Bronchoscope



The Virtual Bronchoscope view shows the scope position and orientation from inside the airways, generally mirroring the view of the live camera. The Virtual Bronchoscope view is designed to help visualize the next turn. It is a real-time virtual representation of the pathway that updates relatively with camera pitch, yaw, roll, and position along the planned path.

The Virtual Bronchoscope shows the pathway as a 3D line in the center of the path that reflects the color of the available paths. Whenever the scope is traveling on two or more paths, the two paths appear overlaid.

3D Map View

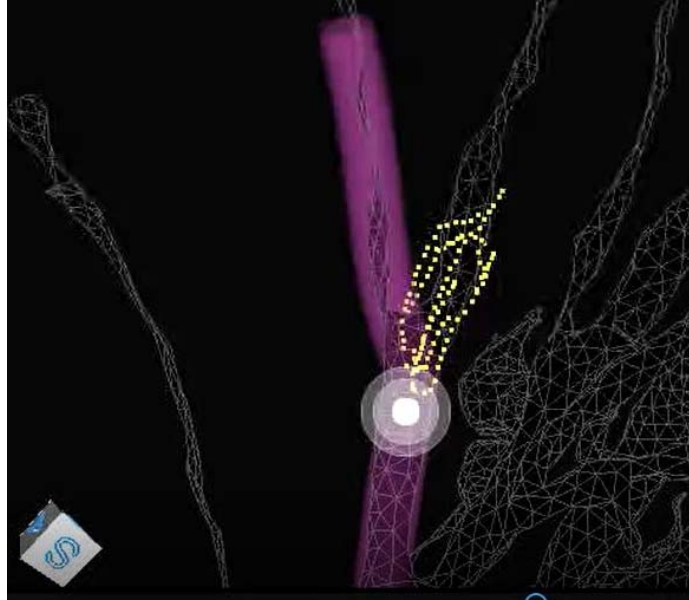


Example of a planned pathway relative to the airway tree: The white ball represents the scope position and the yellow ball represents the target.

3D Map view is a virtual representation of the patient's airway tree with the location of the planned pathways and targets superimposed. As the scope moves through the airways, its position is reflected on this map. Orientation is represented by a cube representing the direction of anterior/posterior/inferior/superior/left/right which rotates in three dimensions in response to scope movement.

By default, this view is displayed in the scrolling column upon starting navigation. The zoom and rotation of the airway tree can be performed on the Touchscreen on the tower as well as on the Monarch Controller.

When you leave the segmented path of the airways, the Monarch Navigation Application continues to trace the path that you have taken in the 3D Map. The scope trail is represented in yellow as the following image shows.

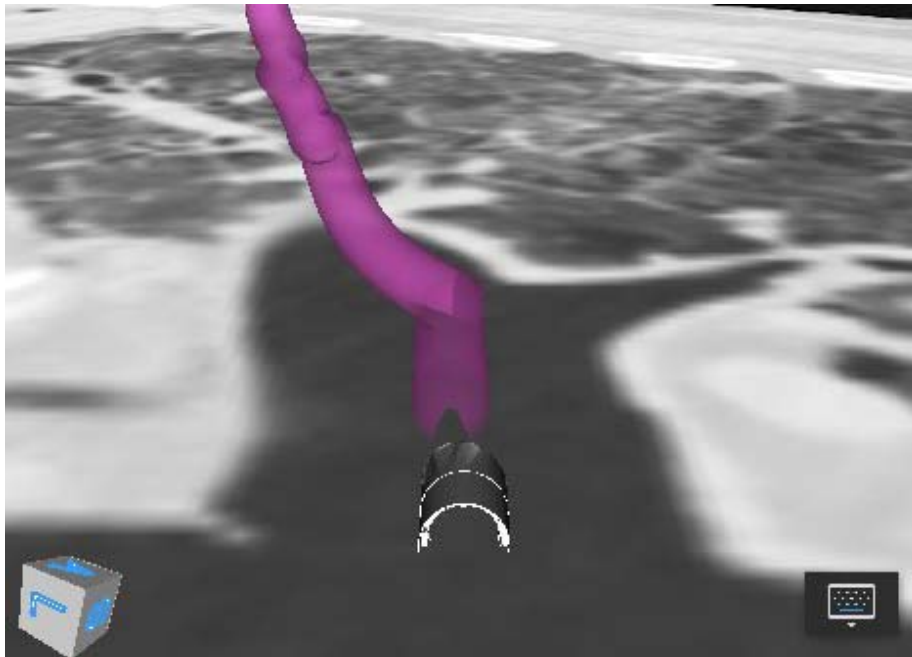


Local View

This CT-based view combines a virtual representation of the nodule with an oblique slice of the CT volume based on the scope orientation.

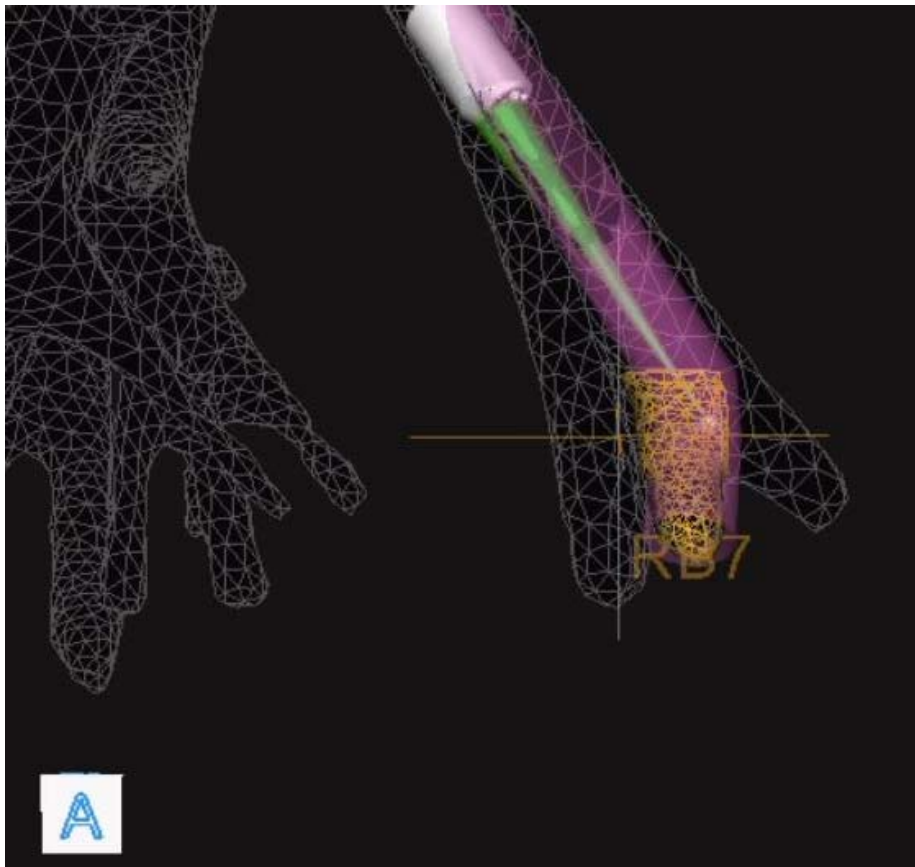
For targeting, the CT plane intersects the virtual nodule, allowing you to determine when the target is in plane. The CT forms a virtual “water line,” showing the point of intersection. The nodule should still be slightly visible when underneath the plane of the CT. The pathway is represented in this view as a 3D line that travels in and out of the CT plane-based path and airway direction.

A 3D representation of the scope tip appears in plane at the start of the pathway.



Targeting Views

Orbit View



The Orbit view for targeting shows the biopsy position from the nodule's perspective. The view "orbits" around the target allowing you to view the alignment from different angles.

This view always focuses on the nodule and attempts to adaptively keep the scope tip in frame during the approach by revolving around the nodule to keep both it and the scope in view.

You can control the orbit by holding the quick action button or by the Monarch Tower Touchscreen. Releasing the button maintains the new position.

The indicator at the tip of the scope turns green when it intersects with the nodule to confirm alignment.

Tip View



The Tip view is a targeting view that displays the biopsy position from the tip of the scope's perspective to aid in working channel alignment. The view is comprised of a crosshair, which is aligned with the scope's working channel, and the nodule, which consists of a yellow grid. All other segmentation information is removed.

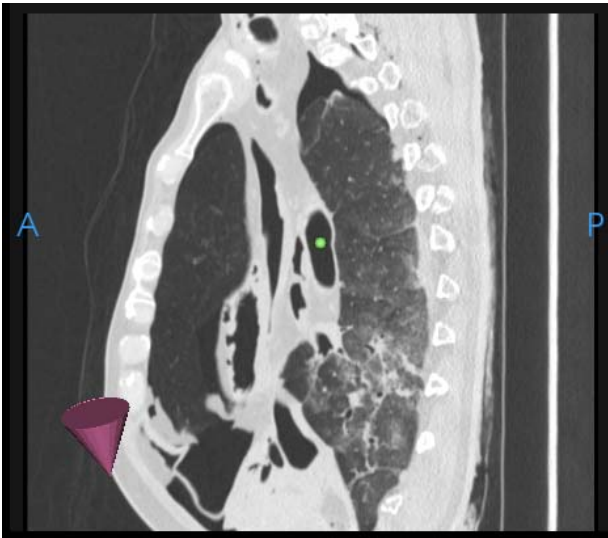
To access the Tip view, select the Orbit view and tap the quick action button. See Quick Action Button on page 77 for more information.

Axial, Sagittal, and Coronal CTs

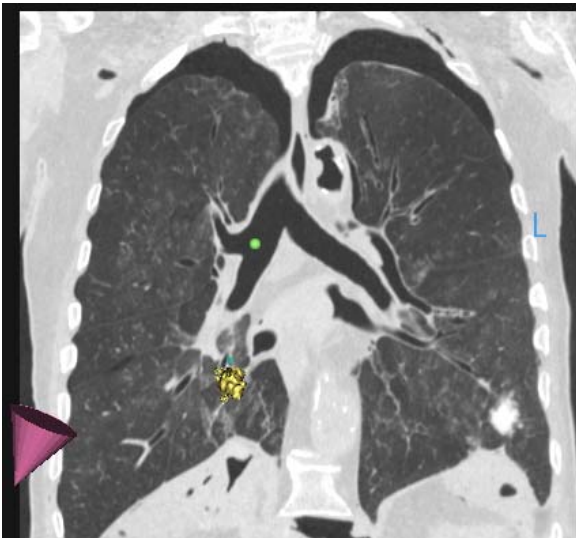
The planar CT views are sized to fit the sidebar windows and zoom window. The Monarch Navigation Application adaptively scrolls and pans the CT based on scope location, keeping the scope always in frame.

The CT images are sized to fit the width of the window, scrolling only vertically. When zoomed using the quick action button, the CT images scroll horizontally.

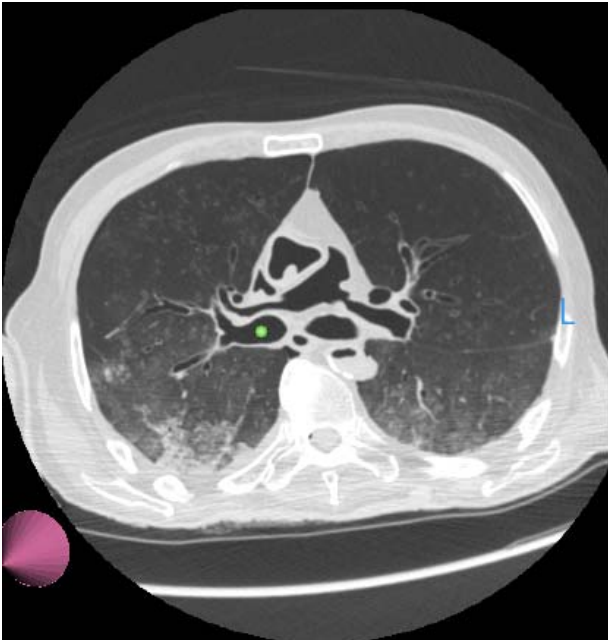
In the following images, the axial, sagittal, and coronal slices of the CT scan at the location of the scope tip appear. In these images, the scope tip is represented by a green ball and the direction of the tip is represented by a purple cone.



Sagittal



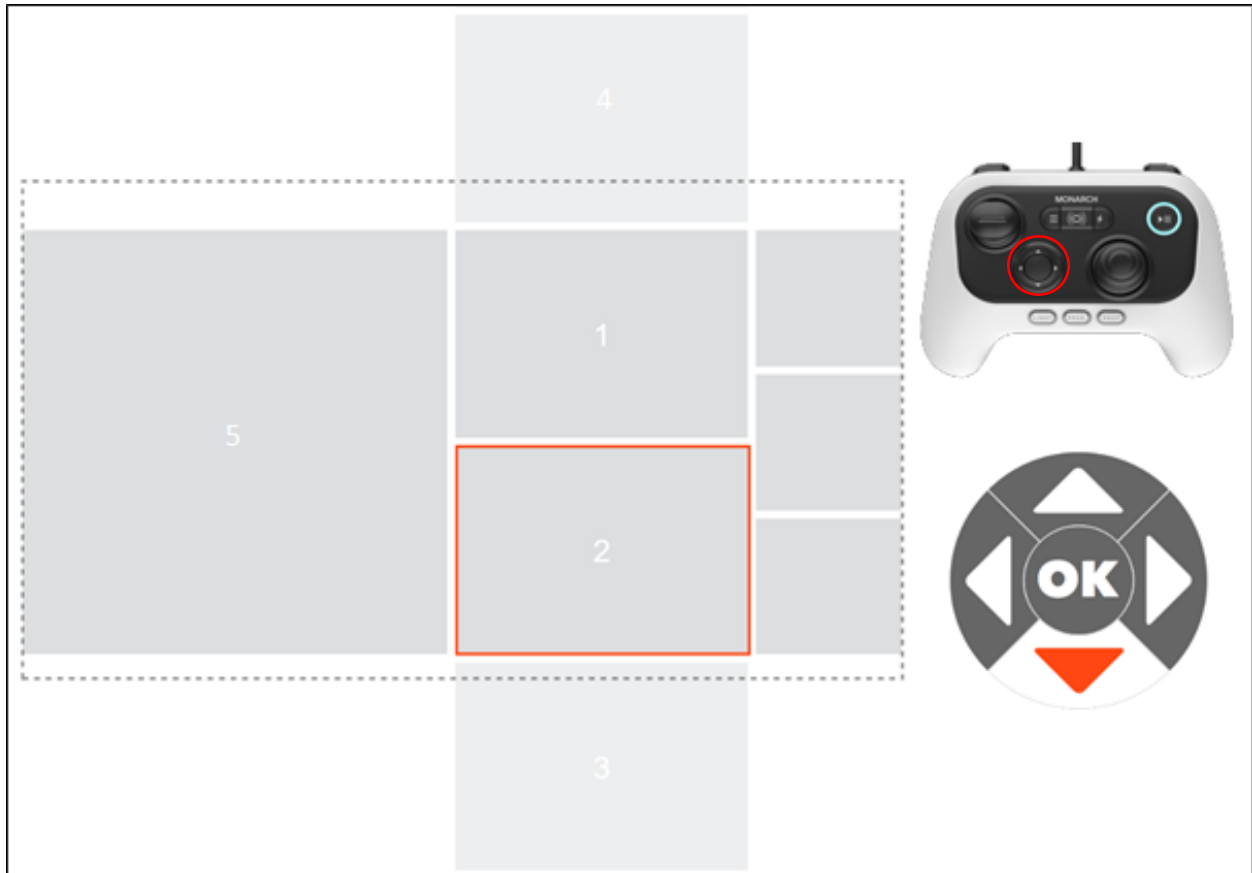
Coronal



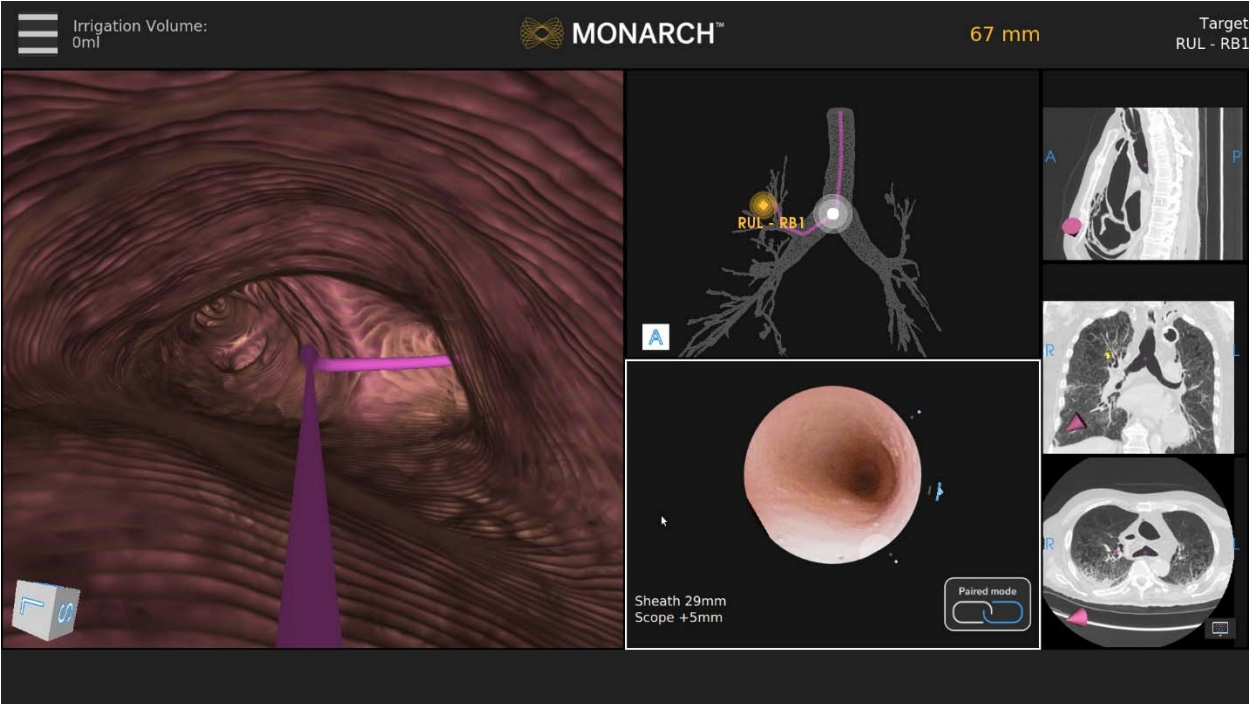
Axial

Configuring View Screens

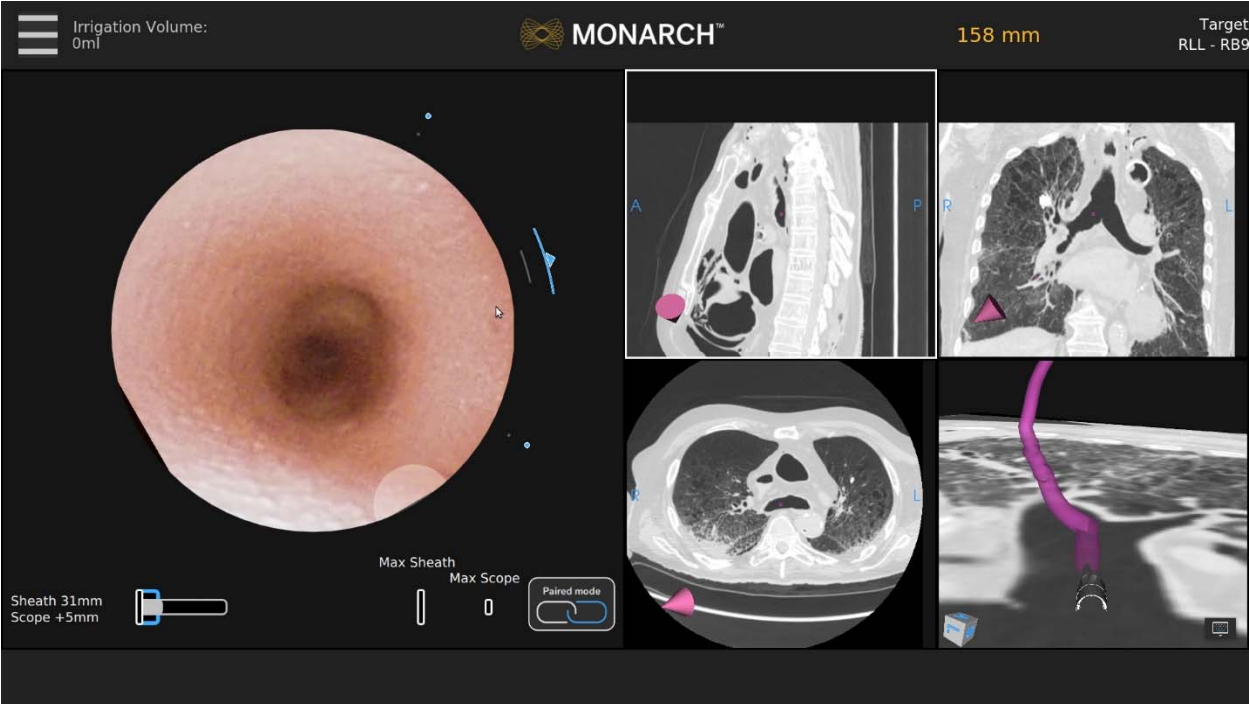
The Navigation views can be re-arranged during the procedure as needed. Using the directional pad on the Monarch Controller, scroll through the Scrolling Area to select your views. The following image is an overview of the view arrangement structure.



Use the Scrolling Area to select among different views. Once you select a view, it's promoted to Primary Area.



If you select one of the CT views, the screen transitions to a CT-centric view as described above.


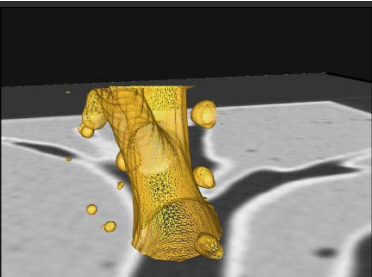


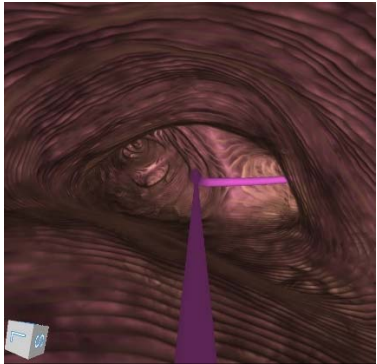
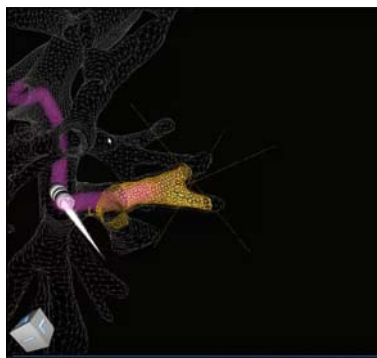
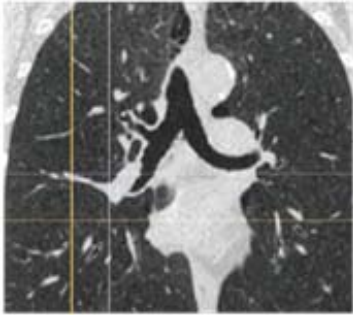
Quick Action Button

If you have the Monarch Controller highlighting any of these screens, the quick action button will give you the functions as illustrated below.



The Quick Action button activates on demand features that are unique for each view.

Item	Description
	<p>3D Map View</p> <ul style="list-style-type: none">• Press: Zooms.• Hold: Rotates the image.
	<p>Local View</p> <ul style="list-style-type: none">• Press: Zooms. Decreases camera-to-target distance.• Hold: Orients virtual camera towards target.

Item	Description
	<p>Virtual Bronchoscope View</p> <ul style="list-style-type: none"> • Press: Elevates virtual camera. • Hold: Moves the camera along the paths in the order of rank.
	<p>Orbit View</p> <ul style="list-style-type: none"> • Press: Transitions from Orbit View to Tip View. • Hold: Rotates the view around the nodule.
	<p>CT Views</p> <ul style="list-style-type: none"> • Press: Zooms. • Hold: Scrolls the slices from scope tip to target.

Procedural Steps or Actions

Scope Insertion



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.

1. On the Monarch Tower, press **Start Procedure**. The Monarch logo appears.
2. To activate the Monarch Bronchoscope System, take the Monarch Controller and press the **Pause/Start** button on the controller.

3. Press the Insert/Retract joystick to activate control of the Monarch Bronchoscope System.
4. Insert the Monarch Bronchoscope System through the bronchial adapter and endotracheal tube until you can visualize the main carina. You may need to articulate the scope with the controller to avoid impact with the endotracheal tube upon insertion.

Navigation Initialization

The Monarch Navigation Application continuously registers the scope tip location to the pre-procedural CT scan. However, the Monarch Navigation Application does require a little bit of information to initialize its starting location. The steps are as follows:

1. Access the **Adjust Camera Settings** from the menu to rotate the camera until the left and right airways are horizontal and press the Program button on the Monarch Controller.

If the camera orientation is not adjusted so that the anterior direction correlates to the top of the camera view, the camera orientation may not match the Virtual Bronchoscope view during navigation.

2. Touch the main carina and press the Program button on the Monarch Controller.
3. Retract the scope back some distance greater than or equal to 40mm and press the Program button on the Monarch Controller.



NOTE: If you pull the scope too far out of the trachea and into the endotracheal tube, an error message may appear and navigation initialization will need to be repeated.

4. Perform contra-lateral registration by inserting the Bronchoscope System into the opposite airway of the selected target until instructed by the interface to retract a defined distance.

Make sure to keep the scope center-luminal as much as possible.

5. Retract until the navigation screens become visible. The system is ready to begin the procedure.

Monarch Bronchoscope Advancement

Your right trigger finger is going to switch from the Monarch Bronchoscope Sheath to the Monarch Bronchoscope. As you insert the Monarch Bronchoscope, steer it in the direction that you want to go. The visual indicators update from the Monarch Bronchoscope Sheath to the Monarch Bronchoscope, but you still can see the articulation left on the Monarch Bronchoscope Sheath. The relative

insertion bar here indicates how much you have advanced beyond the Monarch Bronchoscope Sheath.

Drive Modes

Drive Mode	Description
Paired	When the scope/sheath tips are flush and the Paired icon appears, both devices will insert and retract together. Articulation will command the sheath articulation. Scope articulation will follow the sheath. In paired position, the scope is extended 5mm out of the sheath.
Autorelax	If the scope or sheath is retracted for >25mm without any additional articulation commanded, the device will automatically relax.
Autopair	If the sheath is advanced up to the scope, it will automatically pair with the scope. If the scope is retracted into the sheath, the scope will automatically pair with the sheath. Pairing has a momentary delay (1.5 seconds) to prevent inadvertent pairing.

Perform Biopsy



WARNING: Ensure fluoroscopy system is operating properly and does not interfere with the Monarch Platform before patient use.



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

Monarch Controller

You do not have to hold the Monarch Controller while taking biopsies. If you decide to place the Monarch Controller down, press the pause button. This will prevent any accidental manipulation. The Monarch Controller is also equipped with an accelerometer if it is accidentally dropped or knocked off the table. This automatically disables it. Pause the Monarch Controller and place it aside before continuing with the biopsy.

Lavage

If you want to perform a lavage, you must disconnect the valve on the backend of the Monarch Bronchoscope and access the working channel with a syringe.

Administer 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, you must disconnect the valve on the backend of the Monarch Bronchoscope and access the working channel with a syringe.

Post-procedure

When the procedure is complete, use the following guidelines when you retract the Monarch Bronchoscope System.

Retraction



CAUTION: Failure to relax the bronchoscope and sheath prior to retraction may cause increased stress on the scope.

When retracting the Monarch Bronchoscope, fully relax the scope as you retract. The Monarch Bronchoscope System will automatically relax the scope if you hold the Retract joystick down for >25mm or if the Monarch Bronchoscope retracts into the Monarch Bronchoscope Sheath.

As you retract the Monarch Bronchoscope into the Monarch Bronchoscope Sheath, the Monarch Bronchoscope will automatically pair with the Monarch Bronchoscope Sheath and Monarch Bronchoscope System retracts.

Chapter 5

Cleaning, Maintenance, and Storage

Service and maintenance other than what is indicated in this chapter shall be performed by trained Auris Service Personnel only.

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CAUTION: Clean and disinfect the Monarch Platform 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 Monarch Platform components are compatible with the following cleaning agents: distilled water, 70% isopropyl alcohol solution, 96% ethanol, Super Sani-Cloth Germicidal Wipes - Isopropyl Alcohol 55%, Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant - Hydrogen Peroxide 1.4%, and Sani-Cloth Bleach Germicidal Wipe - Sodium Hypochlorite 0.63%.

- Do not shut down the system while the Monarch Bronchoscope System is still inserted in the patient.
- Do not remove or disconnect system components (other than the Monarch Bronchoscope System) while the Monarch Bronchoscope System is in the patient.
- Do not remove protective covers from any system component. No user serviceable parts are inside. Contact Auris Customer Care for any service concerns or questions.
- Unpowered storage of the Monarch Platform for extended periods (longer than three months) will result in degradation of the UPS batteries.
- When disposing of instruments, accessories, or any of their components, follow all applicable national and local laws and guidelines.

Prepare the Patient for Discharge

Remove the Monarch Bronchoscope System

1. Detach the Bronchoscope System handles from the robot arms and remove the Monarch Bronchoscope System from the patient.
2. Place it aside or immediately pre-clean and place back in the packaging.

Remove Monarch Navigation Patient Sensors

1. Detach Monarch Navigation Patient Sensors from the patient.
2. Place the Monarch Navigation Patient Sensors on the tower.

Remove the Bronchoscope Patient Introducer

1. Disconnect and discard the Bronchoscope Patient Introducer from the Bronchoscope Swivel Adapter.
2. Remove the Bronchoscope Swivel Adapter and endotracheal tube from the patient.

Remove and Clean Equipment

Disassemble and Clean the Monarch Bronchoscope System

If necessary (e.g. product complaint investigation), the Monarch Bronchoscope System may be returned to Auris per the following instructions. Otherwise, all single-use devices, including the Bronchoscope and Bronchoscopic Sheath, should be disposed of according to applicable national and local laws and guidelines.



NOTE: Follow hospital, local, and state policies and guidelines for handling used medical devices.

Pre-cleaning the Monarch Bronchoscope System

1. Wipe down external shafts of the Monarch Bronchoscope and Monarch Bronchoscope Sheath with pre-cleaning solution.



NOTE: Recommended pre-cleaning solution is First Step by Cygnus (500 mL). Follow the manufacturer's instructions for specific pre-cleaning solution usage.

2. Immerse distal tip of the Monarch Bronchoscope into the pre-cleaning solution and aspirate enough pre-cleaning solution to remove gross contaminants, as you would for standard endoscopes.
3. Aspirate Monarch Bronchoscope in air until dry.
4. Remove the Monarch Bronchoscope Sheath Valve and attach the vacuum source tubing to the back of the Monarch Bronchoscope Sheath.
5. Repeat steps 2-3 for the Monarch Bronchoscope Sheath.
6. Use gauze to dry the external shafts of the Monarch Bronchoscope and Monarch Bronchoscope Sheath.
7. Disconnect the Bronchoscope Fluidics Tubing from the Monarch Bronchoscope and tower and discard the tubing.
8. Unplug and wipe the Monarch Controller before storing it in the tower.

Re-packaging the Monarch Bronchoscope System

1. Unplug the Bronchoscope camera cable from the tower.
2. Insert the device shafts into their respective tubes in the plastic tray and seat handles into tray wells.
3. Wrap and insert camera cable in the clam shell of the tray.
4. Insert the tray into the red biohazard bag, which is provided on the inner lid of the shelf box.
5. Fold the end of the biohazard bag 3-4 times and secure fold with the large labels provided on inner lid of the shelf box.
6. Place the bag snugly in the corrugated nest inside the shelf box.
7. Seal the box on multiple sides with the adhesive strips provided on the inner lid of the shelf box. Reinforce with packaging tape if necessary.
8. Ship the box via FedEx within 48 hours of procedure. A prepaid return label has already been placed on the box.

Clean Monarch Navigation Patient Sensors

1. Discard the patient patches used with the Monarch Navigation Patient Sensors.
2. Unplug the Monarch Navigation Patient Sensors from the tower.
3. Wipe down and stow Monarch Navigation Patient Sensors.

Disassemble and Clean the Monarch Navigation Field Generator

1. Remove and wipe down the Monarch Navigation Field Generator from the Monarch Navigation Field Generator Mount and store in the tower.
2. Remove and wipe down the Monarch Navigation Field Generator Mount from the bed.
3. Return the Monarch Navigation Field Generator Mount to its storage case.

Disassemble and Clean Bronchoscope Patient Introducer Mount

1. Remove and wipe down the Bronchoscope Patient Introducer Mount from the bed.
2. Return the Bronchoscope Patient Introducer Mount to its storage case.

Clean and Store the Monarch Cart

1. Mobilize the cart and move it away from the bed, taking care to avoid large obstacles.
2. Press **Clean** on the bottom navigation bar. Command cleaning configuration of robot arms.
3. Wipe down the robot arms and cart.
4. Press STOW on the bottom navigation bar to return the robot arms in the stow position.

Clean the Monarch Tower and Store the Monarch Platform

1. Click **Stop Procedure**.
2. Click **Shutdown** to turn off the Tower and Cart.
 - To manually initiate Shutdown, press and hold the power button on the Cart or Tower for 0.5 seconds. A message appears to prompt you to tap **Shutdown** to turn off the system.
 - If the power button is held for more than 4 seconds, the system automatically shuts down.
 - Manual shutdown should be reserved only if the system cannot be shut down through the software interface.
3. Unplug the Tower and Cart.
4. Disconnect the umbilical from the tower.

5. Wipe down the tower.
6. Move Tower and Cart to their storage area.

Servicing

Preventative Maintenance

Routine preventive maintenance inspections will be performed annually by an authorized Auris Health representative. The preventive maintenance inspection includes the following system inspections:

- Review of system logs and faults.
- System configuration inspection.
- Visual and functional test of the robot arms and instrument device manipulators.
- Robot arm alignment inspection.
- Power distribution test.
- Visual and functional test of Monarch Platform.

Configuration

Video Display

The Monarch Platform allows for the use of an external monitor to duplicate the Monarch Platform Tower video on an external display. The external monitor may be connected to the Monarch Platform using an SDI or DVI cable connected at the rear panel of the Tower. Cables and/or converters required to connect the monitor are not supplied with the Monarch Platform. Contact Auris Customer Care for additional information.

Maintenance

Backup Batteries

The Monarch Platform contains lithium Ion batteries which are capable of holding a charge for up to three months. Unpowered storage of the Monarch Platform for extended periods (longer than three months) will result in degradation of the UPS batteries. The batteries are not user-serviceable and should only be replaced by authorized Auris Health representatives.

Parts Replacement

The Monarch Platform does not have any user-serviceable parts with the exception of the following system accessories:

- Monarch Controller.
- Navigation Patient Sensors.
- Bronchoscope Patient Introducer Mount.
- Field Generator Mount.

All replacement parts must be provided by Auris Health, Inc. Contact Auris Customer Care for assistance. Use of third-party components or modifications of the Monarch Platform may result in unexpected behavior, creates safety risks, and voids product warranties. Auris Health, Inc. is not responsible for any damages resulting from use of unauthorized parts or modifications.

Replacement of Monarch Controller

1. Open the Monarch Tower drawer.
2. Disconnect the Monarch Controller connector from the drawer connector.
3. Connect replacement Monarch Controller to the drawer connector.
4. Press the pause/play button on the Controller to ensure the controller is active.

Replacement of the Navigation Patient Sensor Cable

1. Ensure that the Navigation Patient Sensor is detached from the patient and the Monarch Platform is not in a procedure.
2. Disconnect the Navigation Patient Sensor cable from the Tower connector.
3. Plug in the replacement Navigation Patient Sensors to the Tower.
4. Follow the instructions in System Setup (chapter 3) to attach the Navigation Patient Sensors to the patient and confirm that the sensors are detected in the Navigation setup menu.

Replacement of the Bronchoscope Patient Introducer Mount

1. Ensure that the Monarch Platform is not in a procedure.
2. Remove the Bronchoscope Patient Introducer from the Patient Introducer Mount, if needed.
3. Attach Bronchoscope Patient Introducer Mount to the bed rail.
4. Remove the Bronchoscope Patient Introducer Mount from the bed rail.
5. Follow the instructions in Chapter 3: System Setup to install the replacement Bronchoscope Patient Introducer Mount on the bed rail.

Replacement of the Field Generator Mount

1. Ensure that the Monarch Platform is not in a procedure.
2. Remove the Monarch Navigation Field Generator from the Monarch Navigation Field Generator Mount, if installed on the bed rail.
3. Loosen the clamp securing the Monarch Navigation Field Generator Mount to the bed rail.
4. Remove the Monarch Navigation Field Generator Mount from the bed rail.
5. Follow the instructions in Chapter 3: System Setup to install the replacement Monarch Navigation Field Generator Mount to the bed rail.

Recommended Spare Components

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

- Controller.
- Patient Sensors.
- Disposable accessories.

Chapter 6

User and System Administration

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User Administration

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. If a site administrator loses the Admin password, contact Auris Customer Care for password reset or recovery.

User Types

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

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

Add New User

1. Log on as admin.
2. Select SETTINGS to view the Settings screen.

USERNAME	NAME	USER ID	ADMIN	PHYSICIAN	ENABLE	ADD USER	CLOSE
NewUser	New User	nuser	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	PASSWORD	DELETE
physician	Test Physician User		<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	PASSWORD	DELETE
admin	Unit Test Admin		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	PASSWORD	DELETE

3. Select ADD USER. The following dialog box appears.

USERNAME

REAL NAME

AURIS USER ID

PASSWORD

CONFIRM PASSWORD

ADMIN

PHYSICIAN

OK CANCEL

4. Enter the following information for the new user:
 - USERNAME: a user name should be more than one character and be unique.
 - REAL NAME
 - AURIS USER ID: the user ID provided by Auris Health, Inc.
 - PASSWORD: a password should have at least 12 characters and contain at least one uppercase letter, one lowercase letter, one number, and one special character/symbol.
 - CONFIRM PASSWORD
5. Select whether the user rights include **ADMIN** or **PHYSICIAN** or both.
6. Select **OK** to save.
7. Click **CLOSE** to exit the Settings screen.

Change User Password

If You Have Security Access to Other User Accounts

1. Log on as admin.
2. Select **SETTINGS** to view the Settings screen. A user list will populate for current users.
3. Select **PASSWORD** in the row of the user profile whose password needs to be changed. The following dialog box appears.

ADMIN PASSWORD

NEW PASSWORD

CONFIRM PASSWORD

OK CANCEL

4. Enter the following information:
 - **ADMIN PASSWORD.**
 - **NEW PASSWORD:** a password should have at least 12 characters and contain at least one uppercase letter, one lowercase letter, one number, and one special character/symbol.
 - **CONFIRM PASSWORD.**
5. To save your changes, select **OK**.

If You Have Security Access to Your Account Only

1. Log on.
2. Select **SETTINGS** to view the Settings screen.
3. Enter the following information:
 - **NEW PASSWORD:** a password should have at least 12 characters and contain at least one uppercase letter, one lowercase letter, one number, and one symbol.
 - **CONFIRM PASSWORD.**
4. To save your changes, select **OK**.

Disable Existing User

1. Log on as admin.
2. Select **SETTINGS** to view the Settings screen.
3. Find the user that you want to disable and clear the **ENABLE** box.
4. Select **OK** to confirm that you want to disable the user.

System Security

Virus Protection

The Monarch Platform is built on a hardened Ubuntu Linux kernel, with strict user permissions set up. Only qualified Auris field service technicians have the required permissions to install software on the Monarch Platform.

Patient Data Security

The Monarch Platform fully encrypts all Patient Health Information (PHI) at rest utilizing the Botan library, using the Advance Encryption Standard AES - 256. This applies to all internal hard drives as well as any plans that users create and transfer via Monarch USB drives.

Networking

Firewall

The Monarch Platform utilizes the Ubuntu firewall, blocking all inbound connections, outbound connections, https, and DNS. One port is open to allow outbound data extraction.

Internet Connectivity

The Monarch Platform has the ability to send case information to the Auris data lake. The Auris system de-identifies all PHI from the case data before it is sent to the Auris data lake. Additionally, the connection that is utilized to send the information to the Auris data lake follows a well-architected framework and is communicated via 256-bit encrypted SSL.

Appendix A

Troubleshooting

Fault Messages and Troubleshooting98

Fault Messages and Troubleshooting

If any fault messages are unable to be cleared, remove the Bronchoscope System and reboot the system. When rebooting the system, the user must realign the cart to the patient introducer via the setup steps described previously.

If the user removes the bronchoscope while the robot arms are positioned for scope insertion, the robot cart will need to be moved so that the scopes can be attached to the robot arms outside of the patient. Once seated, reposition the robot arms for scope insertion and continue procedure.

Emergency Removal

- If for any reason you need to remove the Monarch Bronchoscope System quickly from the patient, remove the handles from the IDMs to relax the Bronchoscope System and immediately remove the bronchoscope and sheath.
- If you need to quickly access the endotracheal tube remove the Bronchoscope Swivel Adapter from the Bronchoscope Patient Introducer to facilitate direct access.
- If the Monarch Cart impedes access to the patient, mobilize the cart by lifting the foot pedal and wheel it away from the patient.

E-Stop Recovery

1. Unload the Monarch Bronchoscope System.
2. Disengage the emergency stop button.
3. Click OK on the tower or cart user interface.
4. Reload the scope and re-initialize navigation, following the instructions on the tower user interface.

Joystick Articulations Not Matching Directionally

1. Unload and load the scopes.
2. If the problem persists, replace the Monarch Bronchoscope System and/or reboot the system.

Controller Does Not Appear Functional

1. Check the Monarch Controller pause/play button to ensure that it is available.
2. Check the Tower user interface to ensure that the screen shows the Controller is active.

3. Load and unload the handles from the robotic arms.
4. Reboot the system.
5. If the problem persists, contact Auris Customer Care for support.

Field Generator or Patient Introducer 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. If the knobs cannot be tightened, contact Auris Customer Care for a replacement mount.

Monarch Platform Will Not Turn On

1. Confirm that the Monarch Tower and Cart main power cables are connected to dedicated power outlets.
2. Confirm that the dedicated power outlets are active.
3. Confirm that the umbilical cable is connected to the Cart.
4. Press the power button on either the Tower or Cart. The light ring around the power buttons will illuminate when the system is turned on.
5. If the Tower and Cart are connected to active power outlets, the umbilical cable is connected to the Cart, and the system cannot be powered on using either the Tower or Cart power buttons, contact Auris Customer Care for support.

Tower and Cart Do Not Turn On Simultaneously

1. Confirm that the Monarch Tower and Cart main power cables are connected to dedicated power outlets.
2. Confirm that the dedicated power outlets are active.
3. Confirm that the umbilical cable is connected to the Cart.
If the umbilical cable is not connected to the Cart:
 - a. Turn off the system.
 - b. Connect the umbilical cable.
 - c. Turn on the system.

4. Confirm that the light rings around the Tower and Cart power buttons are illuminated. If only one power button is illuminated, disconnect the umbilical cable and press and hold the power button on the Tower/Cart to turn off.
5. Once the Tower and Cart are both turned off (power button light rings are not illuminated), reconnect the umbilical cable to the Cart.
6. Turn on the system.
7. If problem persists, contact Auris Customer Care for support.

Video (Start Screen) Does Not Appear on Tower and Cart Monitor After System Turns On

1. Confirm that light rings on Tower and Cart power buttons are illuminated.
2. If within a few minutes of turning on the system, the Start screen does not appear on the Tower and Cart monitors, reboot the system.
3. If problem persists, contact Auris Customer Care for support.

Loss of Video on Tower or Cart Touchscreen (During Procedure)

1. Confirm that light rings on tower and cart power buttons are illuminated.
2. Remove instruments inserted in the working channel of the Bronchoscope System.
3. Use the Monarch Controller to relax and then retract the Bronchoscope System.
4. Disconnect the Bronchoscope System from the robotic arms.
5. Reboot the system.
6. If tower and cart video are not present after system reboot, contact Auris Customer Care for support.

Navigation Patient Sensors Not Detected During Setup

1. Confirm that sensors are placed on the patient within the Field Generator's field of view.
2. Slightly shift the location of the Field Generator to see if the sensor positions change on the setup screen. If the position of the sensors appears to move on the setup screen, the patient sensor and field generator positions may need to be adjusted to bring all sensors into view.
3. Detach and reconnect the Navigation Patient Sensor cable on the Tower connector.

4. Move the cable to the opposite connector on the Tower.
5. If problem persists, contact Auris Customer Care for support.

CT Scan or Pre-Planned Case Cannot be Uploaded to Tower

1. Reseat disc in DVD player or Monarch USB drive.
2. Confirm if the export button becomes available on the Patient List screen.
3. If problem persists, contact Auris Customer Care for support.

Keyboard on Planning Laptop Is Unresponsive

1. Reboot laptop.
2. If problem persists, contact Auris Customer Care for support.

Planning Laptop Will Not Turn On

1. Confirm laptop is connected to power.
2. If problem persists, contact Auris Customer Care for support.

Unable to Log on to Physician User Account on Tower or Planning Laptop

1. Reboot system and log on.
2. If problem persists, contact hospital admin user for password reset.

Unable to Log on to Admin User Account on Tower or Planning Laptop

1. Reboot system and log on.
2. If problem persists, contact Auris Customer Care for support.

Appendix B

Errors and Messages

System Messages 104

System Messages

The Monarch Platform 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 Monarch Platform.

Table 1

ID	Description	Message
0	Config server error	A system error has occurred and all robotic functions have been disabled. Press OK to continue. If problem persists, contact Auris support.
1	Lost SlaveApp Heartbeat	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
2	Master heartbeat timeout.	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
2	Instrument Manager Timed Out	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
3	System Error	A system error has occurred and all robotic functions have been disabled. Press OK to continue. If problem persists, contact Auris support.
4	System Error	A system error has occurred and all robotic functions have been disabled. Press OK to continue. If problem persists, contact Auris support.

ID	Description	Message
5	Nav Error	A system error has occurred and all robotic functions have been disabled. Press OK to continue. If problem persists, contact Auris support.
6	Nav Error	A system error has occurred and all robotic functions have been disabled. Press OK to continue. If problem persists, contact Auris support.
7	Nav Error	A system error has occurred and all robotic functions have been disabled. Press OK to continue. If problem persists, contact Auris support.
8	System Error	A system error has occurred and all robotic functions have been disabled. Press OK to continue. If problem persists, contact Auris support.
9	System Error	A system error has occurred and all robotic functions have been disabled. Press OK to continue. If problem persists, contact Auris support.
100	System Error	A system error has occurred and all robotic functions have been disabled. Press OK to continue. If problem persists, contact Auris support.
101	Auto Bring-up failure	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
103	Configuration Server Failure	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris Technical support.

ID	Description	Message
104	System Error	A system error has occurred and all robotic functions have been disabled. Press OK to continue. If problem persists, contact Auris support.
105	The Cart is disconnected from the Tower. Please make sure the Cart is connected to the Tower.	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
107	SlaveApp Restart detected	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
108	EndoConsole restart detected	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
200	Sheath insertion force limit	Sheath insertion force limit has been reached. Check the sheath and arm alignment to the patient introducer, check the device lubrication, and clear the insertion pathway. Press OK to continue.
201	Scope insertion force limit	Bronchoscope insertion force limit has been reached. Retract and visually inspect the device for damage and kinks. Lubricate as necessary prior to reinsertion. Press OK and initialize navigation at the main carina.
202		High sheath insertion force has been detected.
203		High bronchoscope insertion force has been detected.
204		Bronchoscope insertion limit has been reached.

ID	Description	Message
205		Bronchoscope retraction limit has been reached.
206		Sheath insertion limit has been reached its limit.
207		Sheath retraction limit has been reached.
208		Sheath insertion limit has been reached.
209	Bronchoscope System loading error	The Bronchoscope System failed to load properly. Unload and reload the device.
210	Tensioning error	The Bronchoscope System failed to load properly. Unload and reload the device.
212		Bronchoscope articulation limit has been reached.
213	Robot collision	An arm collision has been detected, remove obstructions to proceed. Press OK to continue.
214	Potential Collision Detection	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
215	Wire break detection	Bronchoscope System wire breakage has been detected. Unload and replace the device.
217	Instrument Still Loaded	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.

ID	Description	Message
221	Invalid command	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
300	Robot joint limit desired	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
301	Robot joint limit actual	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
302	<ul style="list-style-type: none"> • Actual Velocity Threshold • Robot joint actual velocity limit 	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
303	Robot joint actual acceleration limit	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
304	<ul style="list-style-type: none"> • Desired Velocity Threshold • Robot joint desired velocity limit 	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
305	Robot joint desired acceleration limit	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.

ID	Description	Message
306	Robot joint actual torque limit	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
307	<ul style="list-style-type: none"> • Elmo Axis Following Error • Tracking error 	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
308	Axis Power Error	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
309	Axis Error	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
310	Actual Current	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
311	Encoder mismatch	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
400	IDM Fault	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.

ID	Description	Message
402	Robot IDM power up	A system error has occurred and all robotic functions have been disabled. Press OK to continue. If problem persists, contact Auris support.
403	IDM Velocity	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
406		System temperature has exceeded its limit.
407	IDM Max Temperature Exceeded	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
408	Kinova FW Mismatch	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
409	Tension Threshold Exceeded	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
500	Robot controller error	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.

ID	Description	Message
501	Robot controller comm timeout	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
504	Robot Controller Status Frozen	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
505	Robot control loop disabled	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
506	Robot controller ESTOP	The E-stop has been activated. All robotic functions have been disabled. To resolve, release the E-stop button, then unload and reload the Bronchoscope System. Lastly, re-initialize navigation at the main carina.
600	Staging Error	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
601	Staging Velocity	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
602	Staging Initialization	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.

ID	Description	Message
603	Staging Power up	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
604	Staging Axis FW Mismatch	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
605	Cart not properly immobilized	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
700	Camera thread has failed to be setup.	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
701		A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
702		A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
703		A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
705	Could not preform file operation	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.

ID	Description	Message
706		A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
707		Camera frame rate issue detected. Check camera visibility.
708		Camera frame rate issue detected. Check camera visibility.
709	Failed to initialize camera.	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
710	Failed to read image.	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
711	Scope disconnected	Warning: The bronchoscope cable has been disconnected. Live Bronchoscope view is unavailable and may lead to patient injury. Reconnect the cable and press OK to continue.
712	Image frozen	Warning: The bronchoscope image is frozen and the system has been halted to prevent patient injury. Press OK to continue and if problem persists, replace the bronchoscope system or contact Auris support.
713	Camera FPGA FW or HW Version Mismatch	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.

ID	Description	Message
800	PDU EtherCAT Communication Problem	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
801	PDU Version Mismatch	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
802	PDU Initialization Error	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
803	PDU Power Critical Error	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
804	PDU EStop Error	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
805		System has switched to battery power. 5 minutes remaining!
806	Battery	System battery is running low! Connect to power as soon as possible.
807	PDU Battery Critically Depleted	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.

ID	Description	Message
900	Fluidics error	A system error has occurred and all robotic functions have been disabled. Press OK to continue. If problem persists, contact Auris support.
901	Fluidics Initialization Error	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
902	Fluidics pump error	An irrigation pump error has been detected. Press OK to continue.
903	Fluidics valve error	An aspiration pinch valve error has been detected. Press OK to continue
904	Fluidics max volume	Saline delivery threshold has been reached. Press OK to continue.
1000	Pendant non-recoverable hardware fault	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
1001	Controller HW error	The endoscopic controller has detected a drop or upside-down placement and all robotic functions have been paused. Press the play button on the controller to make functionality available again. Press OK to continue.
1002	<ul style="list-style-type: none"> • Pendant Revision Fault • Pendant Revision does not match 	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.

ID	Description	Message
1003	<ul style="list-style-type: none"> • Pendant Software Fault • Pendant control software fault 	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
1004	<ul style="list-style-type: none"> • Pendant Communication • Pendant communication fault 	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
1100	EM device fault	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
1101	EM device communication fault	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
1102	EM device revision match not found	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
1103	Scope configuration data invalid	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
1105	EM software fault	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.

ID	Description	Message
1200	Nav scope EM quality	Poor quality navigation field generator data detected. Navigation accuracy may be compromised. Press OK to continue.
1201		Poor quality image detected. Navigation may be compromised.
1202		Poor quality EM data detected. Navigation may be compromised.
1203	Nav error	A navigation error has been detected. Navigation accuracy may be compromised. Press OK to continue.
1204		Navigation error detected. Navigation may be compromised.
1205	Nav initialization error	A navigation initialization error has occurred. Repeat initialization.
1206	Nav initialization error	Insufficient EM data for navigation initialization. Repeat initialization.
1208		EM distortion has been detected. Navigation may be compromised.
1209		Field generator or patient sensor motion has been detected.
1210	Patient or FG motion	Navigation field generator and/or patient movement has been detected. Navigation accuracy may be compromised. Visually inspect the navigation field generator and/or patient sensor positioning and initialize navigation at the main carina.
1211	Nav retraction outside trachea	The bronchoscope tip location is outside of the segmented trachea. Move the bronchoscope tip closer to the main carina and initialize navigation.
1212		Bronchoscope buckling has been detected. Check bronchoscope.

ID	Description	Message
1213	Scope buckling	Bronchoscope buckling has been detected. Retract and visually inspect the Bronchoscope System for damage or kinks. Lubricate as necessary prior to reinsertion. Press OK and initialize navigation at the main carina.
1214	Nav EM registration error	An EM error has been detected. Repeat navigation initialization. If problem persists, contact Auris support.
1215	Nav contralateral registration	Contralateral registration failed. Repeat navigation initialization.
1216		Navigation latency detected. Navigation may be compromised.
1217		Navigation error detected. Navigation may be compromised.
1300	Bronchoscope System loading error	The Bronchoscope System failed to load properly. Unload and reload the device.
1301	Instrument Manager FW Mismatch	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
1401	EtherCAT Missing Frame(s) Over Max Limit	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
1402	EtherCAT Jitter Over Max Limit	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.

ID	Description	Message
1403	<ul style="list-style-type: none"> • Critical EtherCAT fault • EtherCAT Initialization Failure 	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
1500	Inverse Kinematics Failed	A system error has occurred. All robotic functions have been disabled. To resolve, unload then reload the Bronchoscope System and click OK to acknowledge the fault. Then, re-initialize navigation at the main carina.
2000	DAQ communication fault	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
2001	DAQ communication fault	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
2002	DAQ communication fault	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
2004	Linear slide comm error	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
2005	System Error	A system error has occurred and all robotic functions have been disabled. Press OK to continue. If problem persists, contact Auris support.
2007	Invalid SW Revision	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.

ID	Description	Message
2009	PDU not running	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
2010		A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
2011	DAQ Comm Fault	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
2012	Flush Aspiration Valves Error	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
2013	Syringe Pump Error	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
2014	Peristaltic Pump Error	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
2015	Linear slide not working right.	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
2016	Force sensor comm error	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.

ID	Description	Message
2019	DofLimit	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.
2020	IterationLimit	A system error has occurred. All robotic functions have been disabled. Unload the Bronchoscope System and reboot the system. If problem persists, contact Auris support.

Table 2

The following indicates a variable in the message, such as a number (case ID) or text (file name): "%1".

Category	Description
System message	Robot Initializing...
	By pressing Approve, you are acknowledging review and approval of this plan for use.
	Do you also want to export the video?
	Do you want to shut down the system?
	The CT data is more than 30 days old. Ensure the CT data reflects the current patient anatomy accurately.
	%1 already exists on the system. Would you like to overwrite it?
	Import %1?
	Permanently delete %1?
	This patient case was previously imported and cannot be imported again
Approximately %1 space is available. To save new cases, delete cases that are no longer needed.	

Category	Description
System message	Successfully exported \"%1\"
	Failed to export \"%1\"
	There is not enough space available on the USB to export the case.
	Couldn't find \"%1\"
	Directory \"%1\" does not exist.
	Failed to import CT dataset. Re-insert the disk and try again. If problem persists, contact Auris support.
	Failed to segment CT data. Retry segmentation. If problem persists, contact Auris support.
System Error	\"%1\" cannot be accessed, contact Auris support.