User Manual

Fuse™ 1C Colonoscope with FuseBox™ Processor

Part Number FSE-050-EN-6.0
Released March, 2014.

This manual includes all operating instructions for the Fuse™ 1C Colonoscope and FuseBox™ Processor. Please refer to the companion "Fuse™ Endoscope Reprocessing Manual" for complete reprocessing instructions.

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

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IMPORTANT: Read this User Manual in its entirety prior to using the Fuse™ 1C Colonoscope.

EndoChoice, Inc. reserves the right to alter the equipment specifications and descriptions in this publication without prior notice. No part of this publication shall be deemed to be part of any contract or warranty unless specifically incorporated by reference into such contract or warranty.

The information contained herein is merely descriptive in nature, and does not constitute a binding offer for the sale of the product described herein. Neither EndoChoice, Inc. nor its agent make any representations for fitness for any purpose, other than specifically mentioned in this manual.

DISCLAIMER

EndoChoice, Inc. shall not be obligated in any manner in respect to bodily injury and/or property damage arising from the use of the device if such use is not in strict compliance with instructions and safety precautions contained in the relevant operating manuals and in all supplements thereto, in all product labels, and according to all terms of warranty and sale of this device, or in any change not authorized by EndoChoice, Inc.

WARNING

- **User provided ancillary equipment and/or accessories are NOT validated or warranted by EndoChoice, Inc. The use of such user provided items is the sole responsibility of the party using such items.**

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Safety Information – Please Read Prior to Use

Using this manual

This manual provides information required to enable you to use the Fuse™ 1C Colonoscope with FuseBox™ Processor system. Read this manual thoroughly before using the device and ensure that you understand the proper use of and care for the device. If you have any questions or comments regarding the use of the device, please contact EndoChoice, Inc.

Note that the complete instruction manual set for this endoscope also includes the companion "**Fuse™ Endoscope Reprocessing Manual**".

The following conventions are used in this manual:

Symbol	Description
WARNING	A warning is a statement that alerts / indicates a potentially hazardous situation associated with the use or misuse of the device, which, if not avoided, could result in serious injury or death.
CAUTION:	A caution is a statement that alerts / indicates a potentially hazardous situation associated with its use or misuse which may, if not avoided, result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.
info	An informational note provides additional information of interest to the user.

Support

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Summary of instrument symbols

Symbol	Description
	Serial number
	Consult instructions for use
	Attention, see instructions
	Shock protection type (BF)
	Power button
	Equipotentiality
	Manufactured by
	Catalog number
	Must not be disposed of as unsorted municipal waste but should be collected separately.
	Number of units
	CE Mark (Class IIa)
	European Representative
	Federal US law restricts this device for sale by or on the order of a physician.
	Non-sterile
	Manufacturing date
	Manufactured according to Restriction of Hazardous Substances Directive

E364813

Medical Electrical Equipment
WITH RESPECT TO ELECTRICAL SHOCK
FIRE, AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL60601-1 /
CAN/USA C22.2 No. 601.1 / IEC60601-2-18

E363751

Medical Electrical Equipment
WITH RESPECT TO ELECTRICAL SHOCK
FIRE, AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH AAMI ES60601-1,
CAN/CSA C22.2 No. 60601-1-08 / IEC60601-2-18

Safety Guidelines – please read prior to use

- This product was designed and manufactured to meet all safety requirements applicable to electronic medical equipment. However, anyone operating the system must be fully aware of the potential safety hazards. It should be operated and maintained in strict compliance with the safety precautions and operating instructions contained herein.
- This product must be installed, maintained, and serviced by EndoChoice qualified service personnel. Operation and maintenance must be done in strict compliance with the operation instructions contained in the manual.
- The system is not to be modified in any way. Any attempt to disassemble, repair, or modify this device by anyone other than an EndoChoice authorized service technician presents risk to the patient or operator and may result in equipment damage. Equipment that has been disassembled, repaired, altered, changed, or modified by persons other than EndoChoice's own authorized service personnel is excluded from EndoChoice's warranty and is not warranted by EndoChoice in any way.
- Where applicable, follow the official standards on the applicability of colonoscopy and colonoscopic treatment that are defined by the hospital's administrators or other official institutions, such as academic societies on endoscopy. Before starting colonoscopy and colonoscopic treatment, thoroughly evaluate its properties, purposes, effects, and possible risks (their nature, extent and probability).
- Procedures and treatment should only be performed when the potential benefits outweigh the risks. Immediately stop the procedure if the patient risks exceed the potential benefits.
- Do not use the system if unsafe conditions exist. In the event of hardware failure that could potentially cause hazardous conditions (smoke, fire, etc.), turn the power off and unplug the power cord.
- In the event of product malfunction, discontinue operation and contact an authorized service person immediately.

User Qualification – please read prior to use

- The Fuse™ 1C Colonoscope should only be used by a physician who is well trained and capable of performing the planned colonoscopy and colonoscopic treatment. This manual does not explain or discuss endoscopic procedures.
- The manufacturer or vendor of the equipment makes no claim that the act of reading this manual renders the reader qualified to operate the system.
- It is important that this manual remain available, studied carefully, and reviewed periodically by the authorized operators.
- All external components connected to the Fuse™ system (such as monitors, printer, etc.) should be medical grade only.

Warnings and cautions

Follow the warnings and cautions given below when handling this endoscope. This information is to be supplemented by the warnings and cautions provided in each chapter.

WARNING

- Following endoscope use, clean, reprocess and store it according to the instructions found in the endoscope's companion **"Fuse™ Endoscope Reprocessing Manual"**. Using instruments that have either been improperly or incompletely reprocessed or stored may cause cross-contamination or infection.
- Before endoscopy, remove any metallic objects (watch, glasses, necklace, etc.) from the patient. Performing high-frequency cauterization treatment while the patient is wearing metallic objects may cause burns on the patient in areas around a metallic object.
- Do not strike, hit, or drop the endoscope's Distal End, Bending Section, Insertion Tube, Umbilical Tube, Control Handle, or endoscope Connector. Also, do not bend, pull, or twist the endoscope's Distal End, Insertion Tube, Bending Section, Control Handle, Umbilical Tube, or endoscope Connector with excessive force. The endoscope may be damaged and could cause patient injury, burns, bleeding, and/or perforations.
- Never perform angulation control forcibly or abruptly. Never forcefully pull, twist, or rotate the angulated Bending Section. Patient injury, bleeding, and/or perforation may result due to unintended retroflexion of the Bending Section. It may also become impossible to straighten the Bending Section during an examination.
- Never insert or withdraw the endoscope's insertion section while the Bending Section is locked in position. Patient injury, bleeding, and/or perforation may result.
- Never operate the Bending Section, feed air or perform suction, insert or withdraw the endoscope's insertion section, or use accessories without viewing the endoscopic image or while there is no image. Patient injury, bleeding, and/or perforation may result.
- Never insert or withdraw the insertion section abruptly or with excessive force. Patient injury, bleeding, and/or perforation may result.

- If it is difficult to insert the endoscope, do not forcibly insert the endoscope; stop the endoscopy. Forcible insertion can result in patient injury, bleeding, and/or perforation.
- The temperature of the endoscope's Distal Tip may exceed 41°C (106°F) due to endoscopic illumination. As surface temperatures over 41°C (106°F) may cause mucosal burns, always maintain a distance suitable for adequate viewing while using the minimum illumination level for the minimum length of time. Do not use stationary viewing in close proximity to the mucous membrane or leave the Distal Tip of the endoscope close to the mucous membrane for an extended length of time without necessity.

CAUTION:

- *Do not attempt to manually bend the endoscope's insertion section. Insertion section damage may result.*
- *Do not hit or impact the Distal End of the insertion section, especially the objective lens surface at the Distal End and sides. Damage may affect the image.*
- *Do not twist, squeeze or bend the Bending Section with your hands. Equipment damage may result.*
- *Electromagnetic interference may occur on this endoscope near portable and mobile RF (Radio Frequency) communications equipment, such as cellular phones. Check electromagnetic interference from other equipment prior to use. Shielding or relocation of the device may be necessary if interference occurs.*
- *If there is a change in lighting quality during the procedure, or if the image dims during the procedure, tissue or debris might have adhered to the Distal End. Slowly extract the endoscope to avoid an increase in temperature.*

Electrical safety

- The multiple portable socket outlet (power strip) used with the Fuse™ system shall only be used for powering equipment which forms a part of the Fuse™ system. Maximum load on the U.S. power strip (EDSB-486) is 12A–120V. Maximum load on the international power strip (FSA-2064) is 10A-250V.
- Do not connect any non-medical equipment supplied with the Fuse™ system (such as the printer) directly to the wall outlet when the system is supplied via a power strip with a separating transformer. Connect supplied non-medical Fuse™ system equipment to the isolation transformer only.
- A power cable is supplied with the system to provide the appropriate electrical grounding. To minimize the potential for electrical shock, the power cable must be plugged into an approved grounded electrical outlet. Do not use an adapter to plug the system into an ungrounded outlet.
- Do not operate the system if damaged wires or open leads are detected.
- Do not remove or open system covers. The operator should never open the panels of the system. Only qualified personnel are authorized to maintain and service the system.

- Be sure to install the Fuse™ system equipment in one of the recommended combinations for optimal use. If combinations other than those shown throughout this and other Fuse™ manuals are used, optimal operation cannot be assured.

WARNING

- **Do not place a power strip on the floor.**
- **Do not connect an additional power strip to the system.**
- **Do not connect items which are not specified as part of the Fuse™ system. Using incompatible equipment can result in patient or operator injury and/or equipment damage, and will increase the leakage current.**

CAUTION

- *The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include: 1.) use of the accessory in the PATIENT VICINITY, and 2.) evidence that the safety certification of the ACCESSORY has been performed in accordance to the appropriate IEC 60601-1 and/or IEC 60601-1-1 harmonized national standard. (Refer to the Appendix for a list of compatible accessories.)*

Electric interference safety

This equipment generates and can radiate radio frequency energy. The equipment may cause radio frequency interference to other medical and non-medical devices as well as to radio communications. To provide reasonable protection against such interference, the system complies with the IEC60601-1-2 standard*. If the device is suspected of interfering with other nearby electrical equipment, power down the device to see if the interference is eliminated. If the endoscope system is determined to be the source of interference, additional shielding or relocation of the device or neighboring equipment may be necessary.

Use of improperly shielded and grounded cables may result in the equipment causing radio frequency interference in violation of the local regulations. The manufacturer is not responsible for any interference caused by using cables other than those recommended or by unauthorized changes or modifications to this equipment.

Do not use devices that intentionally transmit RF signals (cellular phones, transceivers, or radio-controlled products) in the vicinity of this equipment as it may cause performance outside the published specifications. Keep the power of these types of devices turned off when located near this equipment. The medical staff in charge of this equipment is required to instruct technicians and other people who may be around this equipment to fully comply with the above requirement.

Fire and explosion safety

- Conductive fluids that drain into the active circuit components of the system may cause short circuits potentially resulting in electrical fire.
- Do not block the ventilation ports of the electronic equipment. Always maintain a minimum 6-inch (15 cm) clearance around the ventilation ports to prevent overheating and damage to the electronic hardware.
- To avoid electric shocks and burns potentially caused by application of the wrong type of fire extinguisher, ensure that the fire extinguisher at the site has been approved for use on electrically induced fires.
- Do not operate the equipment in the presence of flammable or explosive liquids, vapors or gases such as flammable anesthetic, oxygen or nitrous oxide. Do not plug in or turn on the system if hazardous substances are detected in the environment. If flammable substances are detected after the system has been turned on, do not attempt to turn off the system or unplug it. Evacuate and ventilate the area before turning the system off.
- Do not operate in the presence of explosive gas concentrations in the area of use of high frequency endoscopically-used accessories. See also, Section 6.1.2, “Using nonflammable gases”.

Operation environment

- Do not place any object on top of the FuseBox™ hardware. These objects may prevent proper cooling of the electronic equipment.
- The system should not be exposed to a wet or humid environment.
- When positioning the system, make sure that the main plug and socket are accessible.
- Avoid exposing the system to direct sunlight or other heat sources.

Reprocessing

- The Fuse™ 1C Colonoscope is a flexible semi-critical device that contacts intact mucus membranes or non-intact skin. Therefore, as with any other flexible endoscopes, it must be reprocessed to be free from all microorganisms before use. The FDA recommends reprocessing by thoroughly cleaning this device and then by performing appropriate disinfection. Validated procedures for reprocessing this device are provided in the “**Fuse™ Endoscope Reprocessing Manual**”.
- The Fuse™ 1C Colonoscope was not reprocessed before shipment. Before first time use, reprocess the device according to the instruction provided in the companion “**Fuse™ Endoscope Reprocessing Manual**”.
- After use, reprocess and store according to the “**Fuse™ Endoscope Reprocessing Manual**”. Improper and/or incomplete reprocessing or storage can create an infection control risk, cause equipment damage, or reduce performance.

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CHAPTER 1 Regulatory Information

1.1 Intended use

The Fuse™ system is intended for diagnostic visualization of the digestive tract. The system also provides access for therapeutic interventions using standard endoscopy tools. The Fuse™ system consists of EndoChoice camera heads, endoscopes, video system, light source and other ancillary equipment. The Fuse™ 1C Colonoscope in conjunction with the FuseBox™ processor is indicated for use within the lower digestive tract (including the anus, rectum, sigmoid colon, colon and ileocecal valve) for adult patients.

1.2 USA regulations

CAUTION:

- *Federal U.S. law restricts this device to sale by or on the order of a physician.*

1.3 CE conformity

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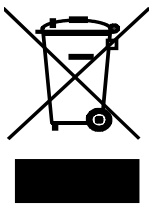
Email: info@medneteurope.com

This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class IIa.

In the European Union, the following symbol indicates that when the last user wishes to discard this product, it must be sent to appropriate facilities for recovery and recycling. Contact your local EndoChoice representative for additional information on the collection and recovery programs available for this product.



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CHAPTER 2 System Overview

The Fuse™ system is an endoscopic platform indicated to provide visualization and therapeutic access to the lower intestinal tract in the adult population. The Fuse™ system is a wide field of view endoscopic system.

The Fuse™ 1C Colonoscope must be used in conjunction with the FuseBox™. The following table provides catalog and model numbers for the Fuse™ 1C Colonoscope and FuseBox™.

Table 1. Fuse™ 1C Colonoscope System Catalog Numbers

Catalog Number	Description
FSC-3300-ST	Fuse™ 1C Colonoscope
FSP-100	FuseBox™ Processor
FSR-2004	White Balance Cap
FSA-2015	FusePanel™ Image Management System: • FusePanel™ • Keyboard • Video Capture Device • Remote Control Cable • USB Extension Cord
SFU-458	Air/Water Reusable Scope Valve
SFU-463	Suction Reusable Scope Valve
FSR-3300-KT	Endoscope Reprocessing Adaptor Kit*: • Air/Water Suction Cleaning Adapter • Working Channel Cleaning Adaptor • Soaking Cap (also available separately, see below) • Water Jet Connector Tube Assembly • Cleaning Plugs
HPP-2313-10	Valve O-Rings
FSA-4240	Auxiliary Water Port Cap
SIT-470-100	Water Jet Connector, Disposable
SBC-460-10	Seal Biopsy Valve, Reusable
SBC-365-100	Seal Biopsy Valve, Disposable
SCT-468	Water Bottle, Cap, and Tubing Set, Reusable
SCT-469	Water Bottle, Cap, and Tubing Set with CO_2, Reusable

Catalog Number	Description
SCT-466	Water Bottle Cap, and Tubing Set, Disposable
SCT-467	Water Bottle Cap, and Tubing Set with CO_2, Disposable
FSR-2000	Endoscope Leak Tester*
FSR-2001	Soaking Cap*

* See the "**Fuse™ Endoscope Reprocessing Manual**" for reprocessing steps for these products.

In this document, the Fuse™ 1C Colonoscope may be referred to as the colonoscope, and the camera head may be referred to as the Distal Tip or Distal End.

The FuseBox™ serves as a control platform for the Fuse™ 1C Colonoscope. The FuseBox™ is responsible for image processing, transferring video signals from the colonoscope, pneumatic control, and control of various external accessories that interface with the system.

The Fuse™ 1C Colonoscope is an adult-sized wide field of view video colonoscope. It has a 12.8mm Insertion Tube, a large 3.8mm channel; it also incorporates a dedicated forward water jet feature.

The Fuse™ System features multiple viewing options: 160° (standard) and 330° (wide). The wide (330°) mode includes the 160° standard front field of view. The operator can change the viewing mode from 160° to 330° or 330° to 160° by selecting the appropriate monitors using the FuseBox™ interface.

CHAPTER 3 System Components

3.1 Fuse™ 1C Colonoscope

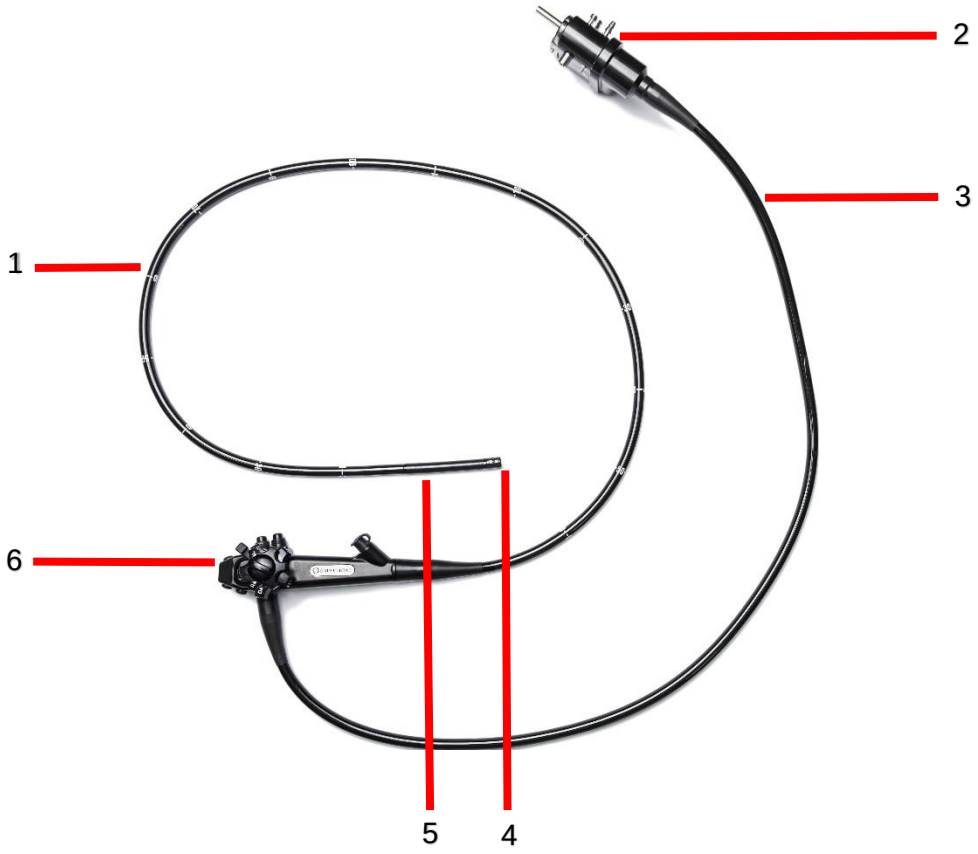
3.1.1 Packaged components

The Fuse™ 1C Colonoscope and the colonoscope's accessories come packaged in a portable case and an accessories box. Open the packaging and carefully remove the colonoscope and the colonoscope accessories. Verify that all of the following items are included in the packaging:

Item #	Name of Item	Function
1	Fuse™ 1C Colonoscope	Colonoscope
2	Working Channel Cleaning Adapter	Enables cleaning the working channel; adaptor and accompanying silicone tube are attached to the Biopsy Port.
3	Endoscope Case	Case that houses the colonoscope upon delivery.
4	Soaking Cap	Used during the leak test and cleaning process.
5	Air/Water Channel Cleaning Adaptor	Enables cleaning of the Air/Water and working channels and is attached to the Air/Water and Suction Ports.
6	Leak Tester	Used to test for leaks in the colonoscope and is attached to the Leak Tester Port on the Main Connector.

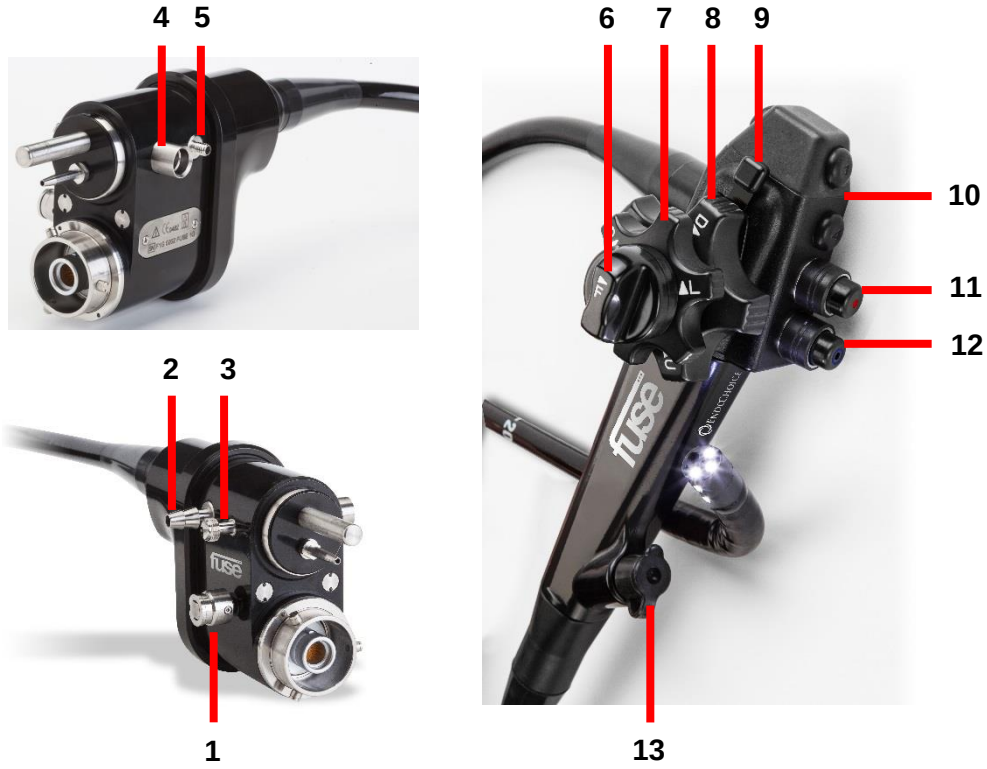
7	Spare O-Ring Set	Used for O-Ring replacement in the valves.
8	Biopsy Valve	The cap is attached to the Biopsy Port. Instruments are inserted through the Biopsy Valve into the work channel.
9	Air/Water Reusable Scope Valve	Covering the hole on top of the valve enables insufflation (pressurized air delivered to the Distal Tip).  Depressing the valve enables water to pass to the Distal Tip for lens washing. 
10	Suction Reusable Scope Valve	Depressing the valve creates negative pressure in the work channel; activates suction to remove fluids, debris, flatus, or air from the patient.
11	Water Jet Cleaning Adaptor	Connects the cleaning apparatus to the water jet port.
np	Water Jet Cap	Used to close the Water Jet Port when it is not in use. (Not pictured)
12	Fuse™ 1C Colonoscope with FuseBox™ Processor User Manual and Reprocessing Manual	Provides information and instructions for using and maintaining the Fuse™ 1C Colonoscope with FuseBox™ Processor.

3.1.2 Colonoscope – general view



Item #	Name of Item	Function
1	Insertion Tube	The Insertion Tube is the main shaft of the colonoscope and contains the working channel, air/water channel, and video cable. The Insertion Tube has markings to indicate the colonoscope's location within the colon.
2	Main Connector	The Main Connector connects the colonoscope to the FuseBox™. The Main Connector contains the Video Socket, S-Cord Connector, auxiliary water port, Air/Water Bottle Port, and Leak Tester Connector.
3	Umbilical Tube	The Umbilical Tube is a hollow tube that connects the colonoscope's FuseBox™ connector to the Control Handle and contains the suction and air/water channels, and the video cable.
4	Distal Tip	The Distal Tip contains the video assembly, light sources, work channel outlet, and air/water outlets.
5	Bending Section	The Bending Section enables angulation of the tip of the colonoscope. The Bending Section's movement is controlled by the angulation knobs.
6	Control Handle	The Control Handle contains the angulation knobs, angulation brakes, Suction Opening, air/water opening, and Biopsy Port.

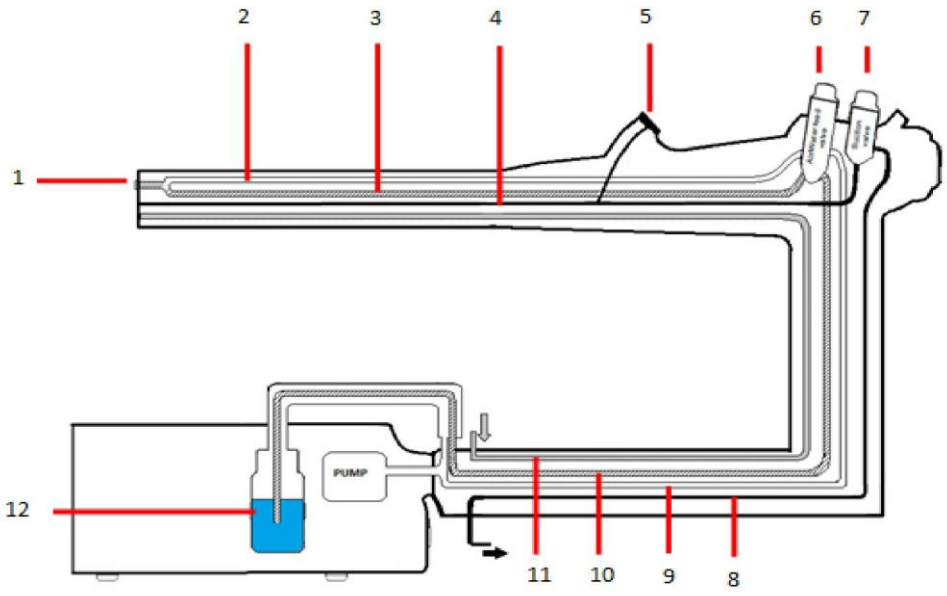
3.1.3 Colonoscope interface



Item #	Name of Item	Function
1	Leak Tester Port	Connects the Leak Tester to the colonoscope.
2	Suction Port	Connects the suction source to the colonoscope.
3	Grounding / S-cord port	Connect the colonoscope with the electrosurgical unit via the S-cord. The S-cord conducts leak current from the colonoscope to the electrosurgical unit. *To connect the S-cord, refer to the instruction manual for the electrosurgical unit.*
4	Air/Water Bottle Port	Connects the Air/Water bottle to the colonoscope.
5	Auxiliary Water Supply Port	Connects the auxiliary water supply tube to the colonoscope. This threaded port is also referred to as the Water Jet Connector. *When an auxiliary water supply is not connected, make sure the cap is on.*
6	Left/Right Angulation Knob Brake	When this knob is turned so that the F>RL is near the ^L mark, the Distal Tip is unlocked. When this knob is turned so that the F>RL is near the ^R mark, the Distal Tip is locked (will hold in the set position).

Item #	Name of Item	Function
7	Left/Right Angulation Control Knob	When this knob is turned in the “R” direction, the Bending Section moves RIGHT; When this knob is turned in the “L” direction, the Bending Section moves LEFT.
8	Up/Down Angulation Control Knob	When this knob is turned in the “U” direction, the Bending Section moves UP; When this knob is turned in the “D” direction, the Bending Section moves DOWN.
9	Up/Down Angulation Knob Brake	Moving this lock counter clockwise locks the Up/Down angulation. Moving the lock in the opposite direction disengages the Up/Down angulation brake.
10	Auxiliary Button Housing	Contains five (5) auxiliary buttons with textural numerals: 1 = Capture/Print image 2 = Record/Stop recording image 3 = Timer 4 = Zoom (toggles through 6 zoom levels) 5 = Freeze/Release (unfreeze) image
11	Suction Opening	Attach the Suction Reusable Scope Valve to this opening.
12	Air/Water Opening	Attach the Air/Water Reusable Scope Valve to this opening.
13	Biopsy Port	Attach the Biopsy Valve to this opening.

3.1.4 Colonoscope internal channels



Item #	Name of Item
1	Air/Water Nozzles
2	Air Channel
3	Water Channel
4	Suction/Working Channel
5	Biopsy Port
6	Air/Water Reusable Scope Valve
7	Suction Reusable Scope Valve
8	Suction Channel
9	Air Channel
10	Water Channel
11	Auxiliary Water Channel
12	Water Bottle

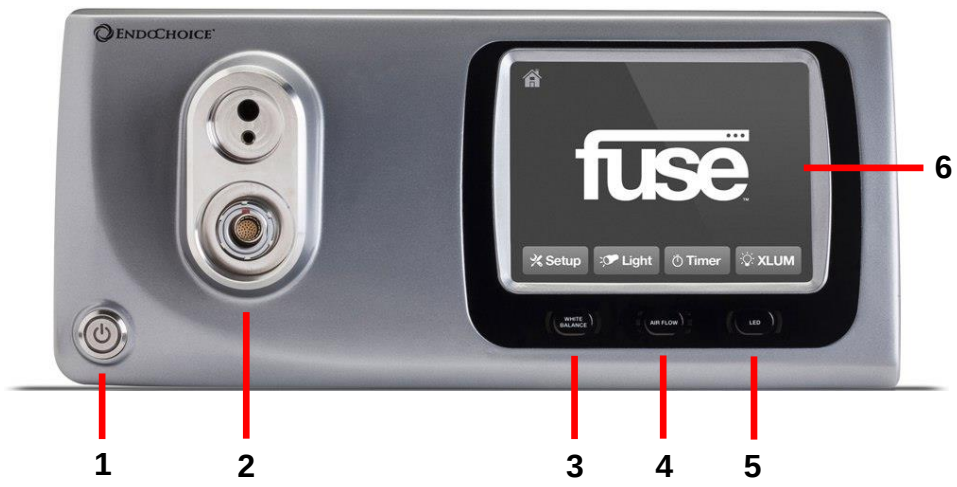
3.2 FuseBox™

3.2.1 Packaged components

Carefully remove the FuseBox™ from its packaging. Verify that the following items are available:

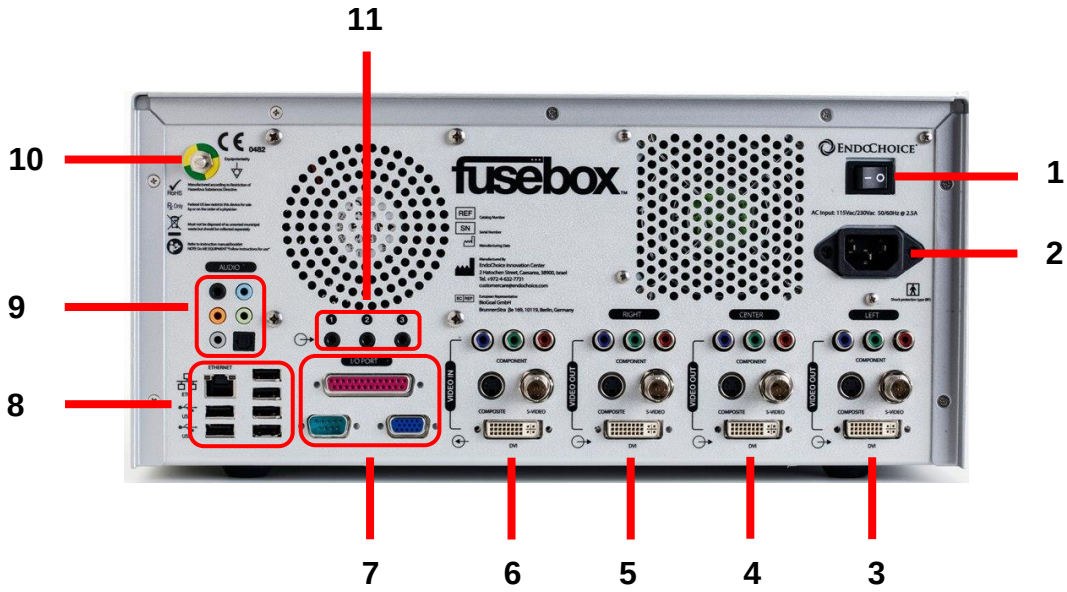
Item #	Name of Item	Function
1	FuseBox™	The control platform for the Fuse™ 1C Colonoscope
2	AC Cable (power cable)	Provides power to the FuseBox™
3	White Balance Cap	Proprietary white balance tool
4	User Manual (Flash drive)	Provides information and instructions for using the FuseBox™

3.2.2 FuseBox™ front panel interface



Item #	Name of Item	Function
1	ON/OFF Button	Turns the system ON/OFF
2	Main Connecter Socket	Connect the colonoscope to this opening.
3	White Balance Button	Perform white balance by pressing and holding for longer than 2 seconds.
4	Air Flow Button	Controls the operation of the pump. Pressing the pump level button toggles the pump operation level. There are three LEDs on each side of the button. The LEDs indicate the following: • No LEDs lit = Pump is OFF • Bottom LEDs lit = Pump is operating at a low level • Middle and bottom LEDs lit = Pump is operating at a medium level • All LEDs lit = Pump is operating at a high level
5	LED Button	Illuminates the Distal Tip LEDs. Toggles between ON/OFF.
6	System Main Screen	User interface touch screen
np	Water Bottle Holder	Mounts on side of FuseBox™ or on the side of the FuseCart™, using hardware provided. (Not pictured)
np	Reusable Water Bottle	Mounts on Water Bottle holder, applied to side of FuseBox™ or on the side of the FuseCart™, using the hardware provided. (Not pictured)
np	White Balance Cap	Used to conduct the white balance test. Magnetically mounts to the side of the FuseBox™. (Not pictured)

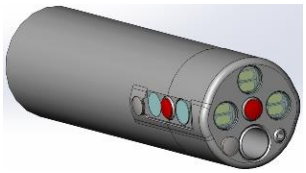
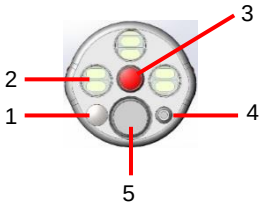
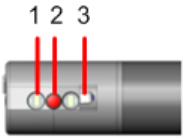
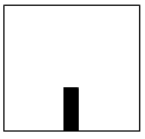
3.2.3 FuseBox™ back panel interface



Item #	Name of Item	Function
1	ON/OFF Main Power Button	Switch ON/OFF the power supply to the FuseBox™
2	Power Socket	Connects the power cord to supply the AC power
3	Left Video Connection (Y/C, Composite, DVI, YPbPr)	Connects video signal to a monitor
4	Center Video Connection (Y/C, Composite, DVI, YPbPr)	Connects video signal to a monitor
5	Right Video Connection (Y/C, Composite, DVI, YPbPr)	Connects video signal to a monitor
6	Video In (Y/C, Composite, DVI, YPbPr)	Allows AUX video input. Reserved for future versions.
7	I/O Port, RS232 Ports	Reserved for future versions
8	USB and Ethernet Ports	• USB: Keyboard, mouse and external drive connection • Ethernet: Reserved for future versions
9	Audio Ports	Reserved for future versions
10	Equipotential Pin	When connected to a potential equalization terminal of another device, the electrical potentials of the devices are equalized.
11	Remote Control Ports	Allows remote device connection (FusePanel™)

3.3 Specifications

3.3.1 Fuse™ 1C Colonoscope

Function/Feature	Description	Details
Optical System	Field of view	Standard view 160˚ Wide view 330˚
	Direction of view	Front and side views
	Depth of field	3.0-100 mm
Insertion Tube	Distal End outer diameter	13.9 mm
	Distal End  (Right side view shown.)	FRONT VIEW  1. Air/Water front nozzle 2. LED cover 3. Front lens 4. Auxiliary Water (jet) channel opening 5. Working Channel opening SIDE VIEW  (Left side view shown.) 1. LED cover 2. Side lens 3. Air/Water side nozzle
	Insertion Tube outer diameter	12.8 mm
Working Channel	Working Channel inner diameter	3.8 mm
	Direction from which endoscope accessories enter the endoscopic image	

Function/Feature	Description	Details
Bending Section	Angulation range	Up/Down 180˚ Left/Right 160˚
Working length		168 cm
Degree of protection against electric shock	Type BF applied part	

3.3.2 FuseBox™

Function	Feature	Value
Power	Voltage	115 V - 230 V
	Frequency	50 Hz / 60 Hz
	Voltage Fluctuation	+/- 10%
	Max Power	300 W
Scope Compatibility		Fuse™ 1C Colonoscope, Fuse™ 1G Gastroscope
Video Signals	Analog Video Output	3 x Y/C
		3 x Composite (NTSC)
	Digital Video Output	3 x DVI
Control Signals	White Balance	Activation via Front Panel
	Pump Control	Off, Low, Medium, High
	Light Control	Light ON/OFF
Weight		14.5 kg
Dimensions		350 mm x 170 mm x 450 mm
Electrical class & Electrical type		Class I , Type BF
Air Pump Type	Diaphragm Pump	
Max Pressure		45 kPa
Irrigation flow Rate (when connected to Fuse™ 1C Colonoscope)		1.3 cm^3/s

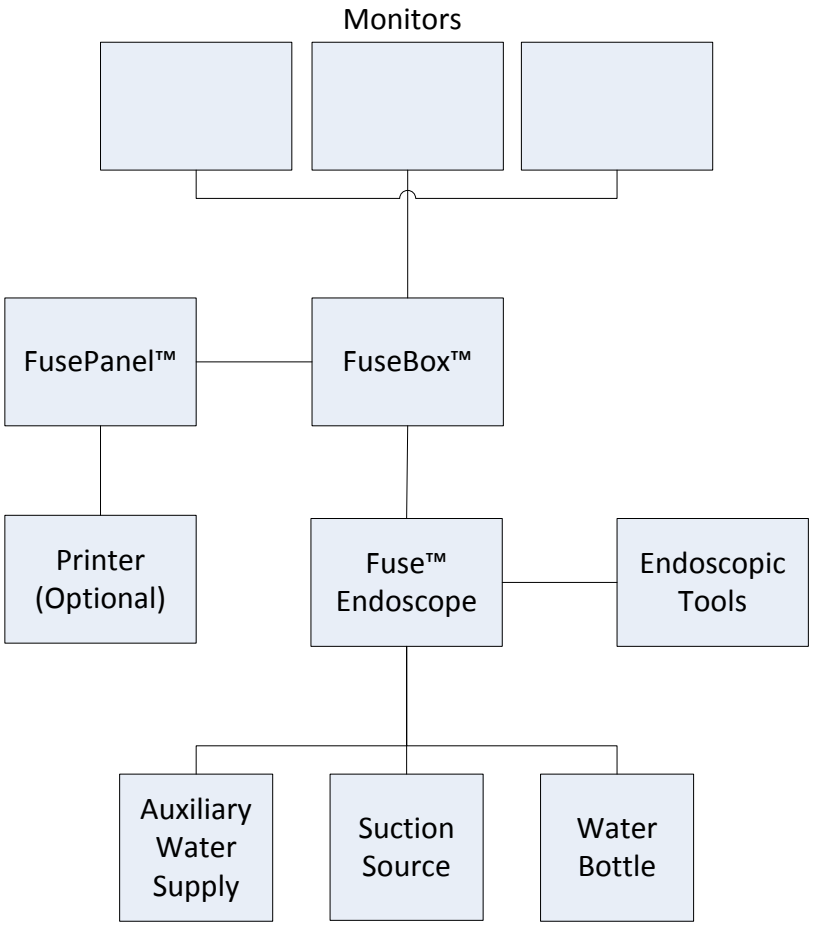
3.3.3 Environment

Environment	Value
Operating Conditions	
Temperature	+ 5C (41F) +40C (104F)
Relative Humidity	Uncontrolled 85% RH
Transportation and Storage Conditions	
Temperature	- 29C (-20F) +38C (100F)
Relative Humidity	Uncontrolled – 85% RH

CHAPTER 4 Preparing and Inspecting the System

This chapter provides an overview of the system's setup, and instructions for system preparation and inspection.

4.1 Overview - system connection chart



4.2 Preparation and inspection workflow

WARNING

- **The Fuse™ 1C Colonoscope must be inspected for device integrity before use. Do not use the Fuse™ 1C Colonoscope if it appears damaged or has missing parts. Using an instrument that is damaged or incomplete may compromise the patient or operator's safety and may result in equipment damage or personal injury. If the Fuse™ 1C Colonoscope appears damaged or has missing parts, contact your EndoChoice representative before using the device.**
- **The colonoscope was not cleaned and high-level disinfected before shipping, therefore, it MUST be cleaned and high-level disinfected prior to its first use. Refer to the "Fuse™ Endoscope Reprocessing Manual" for the validated cleaning and high-level disinfection procedures for this device. Failure to clean and high-level disinfect the device will increase the risk of patient infection.**
- **Wear personal protective equipment such as protective gloves, eyewear, and facemask to ensure user safety. Failure to do so could lead to infection control risk.**

The following table illustrates the preparation and inspection process for the Fuse™ 1C Colonoscope. Before each use, it is the operator's responsibility to prepare and inspect all equipment/accessories to be used in conjunction with the Fuse™ 1C Colonoscope as per their respective instructions for use. Should any irregularities occur, refer to Chapter 8 Troubleshooting.

Table 2. FUSE™ System Preparation and Inspection Process

Step #	Section	Description
1	4.3.1	Reprocess the endoscope system before use.
2	4.3.2	Inspect the endoscope.
3	4.3.3	Inspect the accessories and connect to the endoscope.
4	4.3.4	Set up the FuseBox™ system.
5	4.5	Connect the endoscope and accessories to the FuseBox™.
6	4.6	Inspect system functionality.

Spare/Backup Equipment: *Preparation of another colonoscope, related accessories, and backup generator is recommended to avoid unexpected procedure termination / interruption due to equipment failure or malfunction.*

4.3 Prepare the Fuse™ 1C Colonoscope

4.3.1 Reprocess the Fuse™ 1C Colonoscope prior to use

- Refer to the "**Fuse™ Endoscope Reprocessing Manual**" for detailed instructions.

4.3.2 Inspect the Fuse™ 1C Colonoscope prior to use

- Visually inspect the Control Handle for excessive scratching, deformation, loose parts, missing parts, or other irregularities.
- Visually inspect the Insertion Tube section specifically the section interfacing with the Control Handle for bends, twists, or other irregularities.
- Visually inspect the external surface of the entire insertion section including the Bending Section and the Distal End for dents, swelling, scratches, holes, bends, adhesion of foreign bodies, missing parts, protruding objects, or other irregularities.
- Holding the control section with one hand, carefully run your other hand back and forth over the entire length of the insertion section. Confirm that no rough surfaces, sharp edges, objects or metallic wire protrude from the outer surface of the insertion section, nor from any endoscopically-used accessories. Also, confirm that the Insertion Tube is not abnormally rigid.
- Visually confirm that all the markings on the Insertion Tube are clearly visible.
- Visually inspect the three objective lenses (located at the front and on both sides of the Distal Tip) for scratches, cracks, stains, openings around the lens, or other irregularities.
- Visually inspect the three air/water nozzles (located at the front and on both sides of the Distal Tip) for abnormal swelling, dents, blocks, scratches, stains, missing parts, or other irregularities.
- Using both hands, gently bend the Insertion Tube (not the Bending Section near the Distal Tip) of the endoscope into a semicircle. Then, moving your hands confirm that the entire Insertion Tube can be smoothly bent to form a semicircle and that the Insertion Tube is flexible. Gently hold your finger in the middle of the Bending Section. Gently push and pull with your other hand the Insertion Tube to ensure that the joint between the Bending Section and the Insertion Tube is not loose.
- Wipe dry the endoscope connector, including the electrical contacts, using sterile, clean, lint-free cloths. Also confirm that the electrical contacts are completely dry and clean.

4.3.3 Connect the suction, air/water and biopsy valves

1. Push the Suction Reusable Scope Valve into the Suction Opening of the colonoscope and turn until you feel it drop into position. Visually confirm the valve is seated properly.

2. Push the Air/Water Reusable Scope Valve into the air/water opening until it is securely in place. Visually confirm the valve is seated properly.

3. Attach the flat end of a Biopsy Valve onto the Biopsy Port, and twist the cap clockwise to ensure that it is on tightly. Verify that the Biopsy Valve is closed.

WARNING

- **Improper handling of the Biopsy Valve may pose an infection control risk or degrade or prevent correct device function. Observe the following warnings when using the Biopsy Valve:**

- **Refer to the manufacturer instructions for use for the Biopsy Valve. Failure to follow instructions for use can result in patient infection, device contamination, degraded performance, or loss of functionality.**
- **Prior to use, inspect the Biopsy Valve package and the product, itself, for signs of damage or tampering. If tampering or damage exists to the cap or its package, do not use.**
- **If the Biopsy Valve is not properly connected to the Biopsy Port, it can cause patient debris to leak or spray and can reduce the efficacy of the colonoscope suction system. To avoid any leaks, verify that the Biopsy Valve is properly closed.**
- **After use, discard Biopsy Valves according to the manufacturer instructions following all applicable national and local laws and guidelines.**

4.3.4 Connecting the reusable suction and air/water scope valves

To connect the Suction Reusable Scope Valve, perform the following steps:

1. Grasp the Suction Reusable Scope Valve at its widest point.
2. To remove the valve, pull gently upward while twisting. The valve will slip out when the channel aligns with its slot in the Suction Port.
3. Replace the valve by pushing gently into the section port and twisting. When the channels align, the valve will slip into place.
4. Test to make sure the valve is securely seated.

To connect the Air/Water Reusable Scope Valve, perform the following steps:

1. Grasp the Air/Water Reusable Scope Valve at its widest point.
2. Pull gently to remove the valve.
3. Replace the valve by re-inserting the valve into the air/water port.
4. Test to make sure the valve is securely seated.

4.4 Set up the FuseBox™ system

Use the following steps to set up the FuseBox™.

4.4.1 Connect the FuseBox™ to a power supply

1. Connect the power cable to the FuseBox™ back panel.
2. Plug the FuseBox™ power cable into the power supply.
3. On the back panel of the FuseBox™, switch the power button ON.
4. On the front panel of the FuseBox™, in the lower left-hand corner, press the ON/OFF button.
   The ON/OFF button illuminates green when the system is ON.

CAUTION

- *If the FuseBox™ is already connected to the endoscope, avoid looking directly at the Distal Tip when the device is ON as this could cause temporary blindness due to the illumination.*

4.4.2 Connect the FuseView™ monitors

1. Set up the 3 FuseView monitors on the monitor stand or properly-secured bracket system. For monitor operation, refer to the monitor instructions for use.
2. Locate the monitor cable bundle.
3. Connect the FuseBox™ to the monitors using the cables.
4. Select the appropriate video input on the monitor; refer to the monitor instructions for use.

By default, upon startup, the letters for the Left (L), Center (C), and Right (R) views are displayed on the corresponding monitors.

4.4.3 Select monitor display mode

Depending on the operator's needs, the Right or Left monitors may be turned ON and OFF; the Center monitor always remains ON. Use the FuseBox™ to configure the monitors following these steps:

1. From the FuseBox™ Main screen, press the [SETUP] icon four times.
   This will take you to the "Monitor Selection" screen.

Left and Right monitors can be selected or deselected individually. By default, all monitors are ON.

2. Press the [ON/OFF] icon corresponding to the Left or Right monitor to toggle that monitor ON/OFF.

If the FuseBox™ is connected to the monitors, each monitor will go blank as it is turned OFF.

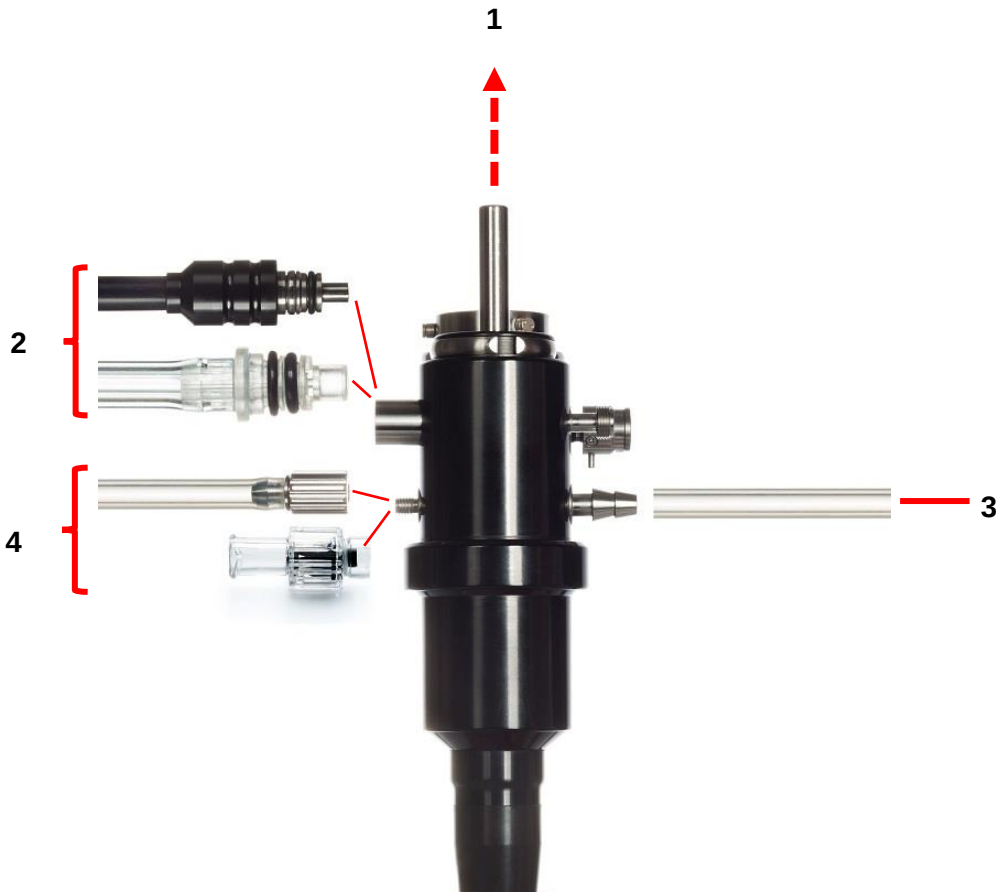
4.4.4 Connect FusePanel™

There are two paths that connect the FusePanel™ to the FuseBox™:

- Video cable path (x3)
- Remote trigger path (x3)

*Consult the "Connecting Cables" section of the "**FusePanel™ User Guide**" to learn how to connect these paths.*

4.5 Connect Fuse™ 1C Colonoscope and ancillary equipment to the FuseBox™



Item #	Description
1	Fuse™ 1C Colonoscope to FuseBox™
2	Fuse™ 1C Colonoscope to Air/Water Supply Port Cap
3	Fuse™ 1C Colonoscope to Suction source
4	Fuse™ 1C Colonoscope to Auxiliary water supply

WARNING

- Prior to connecting the colonoscope connector to the FuseBox™, confirm that the colonoscope electric connector, and the electrical contacts are completely dry and clean. If the colonoscope is used with the electrical contacts wet and/or dirty, the colonoscope and the FuseBox™ may malfunction. Failure to follow the instruction listed below can result in unexpected image loss which may pose patient injury.

CAUTION

- *Do not bend, hit, pull, or twist the insertion section, Bending Section, umbilical, and colonoscope Main Connector.*
- *Do not pull the video cable or any connections during an examination.*

4.5.1 Connect the Fuse™ 1C Colonoscope

The following video connection procedure order is highly recommended to ensure device function.

Ensure the FuseBox™ is in a stable and secure location; hold it steady while connecting the endoscope and cables.

- Plug the endoscope Main Connector into the FuseBox™. Audibly confirm that it clicks into place.

4.5.2 Connect the water bottle

Follow the instructions for one of the following: Reusable Water Bottle or Disposable Water Bottle Cap.

Reusable Water Bottle

1. Prepare for use per manufacturer instruction for use.
2. Fill the water bottle with sterile water or the prescribed solution.
3. Fasten the cap with tube assembly onto the bottle by screwing it until tight. Do not over tighten.
4. Connect the tube to the Air/Water Bottle Port on the Fuse™ endoscope.

WARNING

- Improper handling of the Reusable Water Bottle may pose an infection control risk or degrade or prevent correct device function. Observe the following warnings when using the water bottle:
  - Refer to the instructions for use. Failure to follow instructions for use may result in contamination, degraded performance, or loss of functionality.
  - Prior to use, inspect the water bottle package and the product, itself, for signs of damage or tampering. If tampering or damage exists, do not use. Do not use if the sterile package is not sealed and/or the date has expired.
  - Do not store the water bottle outside of its package; remove the packing immediately before use.

- Do not use the water bottle for a longer period of time than recommended by the manufacturer.
- Use only sterile water or the prescribed solution to avoid bio contamination.

Disposable Water Bottle Cap

1. Attach the disposable water bottle holder to the FuseCart™, using the hardware provided.
2. Remove the cap from the bottle of sterile water (provided by solutions manufacturer).
3. Remove the Disposable Water Bottle Cap from its packaging.
4. Insert the narrow tube of the water bottle cap assembly into the bottle of water.
5. Screw the water bottle cap into place.
6. Place the water bottle, assembled, into the disposable water bottle holder.
7. Connect the tube to the Air/Water Bottle Port on the Fuse™ endoscope.

If using CO_2, remember to connect directly to the CO2 supply.

If using CO_2, turn the system pump OFF.

WARNING

- Improper handling of the disposable water bottle cap may pose an infection control risk or degrade or prevent correct device function. Observe the following warnings when using the disposable water bottle cap:
  - Refer to the instructions for use. Failure to follow instructions for use may result in contamination, degraded performance, or loss of functionality.
  - Prior to use, inspect the water bottle cap package and the product, itself, for signs of damage or tampering. If tampering or damage exists, do not use. Do not use if the sterile package is not sealed and/or the date has expired.
  - Do not store the water bottle cap outside of its package; remove the packing immediately before use.
  - Do not use the water bottle cap for a longer period of time than recommended by the manufacturer.
  - Use only sterile water or the prescribed solution to avoid bio contamination.

4.5.3 Connect the Water Jet Connector to the Auxiliary Water Port

- Open the sterile pouch and attach the disposable Water Jet Connector to the Auxiliary Water Port on the endoscope.

4.5.4 Connect the irrigation tubing to the Water Jet Connector

1. Prepare for use per manufacturer instruction for use.

4.5.5 Connect the suction source

- Connect the suction source to the Suction Port on the Main Connector.

WARNING

- Applying suction with the Distal End with higher suction pressure than required may cause bleeding and/or lesions.

4.5.6 Connect the auxiliary water supply (jet)

1. Prepare the auxiliary water supply system per manufacturer's instructions for use.
2. Unscrew the Auxiliary Water Supply Port Cap on the Fuse™ 1C Colonoscope.

3. Connect the Water Jet Connector to the Auxiliary Water Supply Port.
4. Connect the Auxiliary Water Supply Tube to the Water Jet Connector.

5. Replace the Auxiliary Water Supply Port Cap on the Fuse™ 1C Colonoscope after use.

WARNING

- If an auxiliary water source is not used, ensure that the Auxiliary Water Supply Port is closed. Failure to do so could result in infection control risk, such as retrograde flow of patient material to the Auxiliary Water Supply Port.

4.6 Inspect the Fuse™ 1C Colonoscope functions

4.6.1 Test the angulation mechanism

1. Hold the colonoscope with the controls resting in the palm of your hand so that the angulation control knobs are facing you.

2. Confirm that the brakes are not locked.

When the Up/Down brake handle points upward, the brake is locked. When the brake handle points 45° to the right the brake is not locked. When the Left/Right brake (labeled F>RL) is near the ^R mark, the Distal Tip is locked (will hold in the set position). Before moving on to the next step, be sure the brakes are unlocked.

Unlocked position (45° angle)

3. Rotate the Up/Down angulation knob and verify that the bending area moves smoothly and through the full range of up/down movement.
4. Rotate the Left/Right angulation knob and verify that the bending area moves smoothly and through the full range of left/right movement.

4.6.2 Turn the FuseBox™ system on

If the FuseBox™ system has not yet been turned on, follow these steps:

1. Press the ON/OFF button on the back of the FuseBox™.
2. Press the round ON/OFF button on the lower left-hand side of the FuseBox™ front panel.
   The ON/OFF button illuminates **green** when the system is ON.
3. Turn the Distal Tip light ON by pressing the LED button in the front panel.

CAUTION

- *Avoid looking directly at the Distal Tip when the light is ON as this could cause temporary blindness due to the illumination.*

4.6.3 Test the video signal and white balance

1. Place the **Distal Tip** inside the **White Balance Cup**. Note that the LEDs are currently white.
2. Perform white balance test by pressing the **WHITE BALANCE** button on the FuseBox™. Continue pressing the WHITE BALANCE button until the white light blinks.
   The white balance button will indicate white balance operation by blinking. The white balance LED will turn from white to **blue**.
3. Verify that each video screen displays a clear image.

WARNING

Ensure the endoscope is clean before white balancing. Cross-contamination can be caused if the white balance cap is soiled inside.

Note:

Ensure to adjust the white balance every time an endoscope is used to achieve accurate color.
• While adjusting white balance, avoid exposing the distal tip to external light, as this may compromise white balance adjustment.
• If the cap is visibly dirty, proper white balance adjustment cannot be performed.

White balance Cap handling

If the white balance cap becomes soiled, perform the following cleaning procedure immediately after use:

• Use a soft, clean lint-free cloth to wipe the inside of the cap, to avoid damaging its surface.

• If the white balance cap cannot be cleaned, or the color of the inside of the white balance cap is no longer white, replace the white balance cap.

• To remove dust, dirt, and other non-patient debris, wipe using a soft, lint-free cloth moistened with 70% ethyl or isopropyl alcohol.

• If the equipment becomes soiled with blood or other potentially infectious materials, first wipe off all gross debris using detergent. Then decontaminate the equipment using a surface disinfectant.

- Ensure that the equipment is completely dry before use.

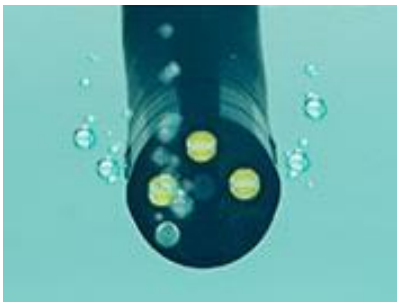
White balance Cap Storage

Store the White Balance Cap at room temperature in a clean, dry, well-ventilated environment.

4.6.4 Test the insufflation mechanism

1. Fill a cup to a minimum of 75% total volume with sterile water.
2. Immerse the Distal Tip of the colonoscope to a depth of 10-15 cm in the sterile water.
3. Cover the hole of the **Air/Water Reusable Scope Valve** with your finger.

4. Confirm that air bubbles are continuously emitted from all three air/water nozzles.



5. Uncover the hole in the Air/Water Reusable Scope Valve and verify that no air bubbles are being emitted from the nozzles.

WARNING

- Failure to check correct insufflation function can result in patient injury. If a stream of air bubbles is emitted from any of the three air/water nozzles while the Distal Tip is submerged in 10-15 cm or more, even though the Air/Water Reusable Scope Valve is not being operated, an irregularity in the air feeding function potentially exists. Refer to Chapter 8 Troubleshooting. Over insufflation can cause patient pain, injury, bleeding, and/or perforation.

*When the Distal Tip is immersed **less than 10 cm** below the surface of the sterile water, a small amount of air bubbles may be emitted from the air/water nozzles even when the Air/Water Reusable Scope Valve is not being operated. This does not indicate a malfunction.*

4.6.5 Test the irrigation mechanism

1. Remove the Distal Tip from the cup and press the **Air/Water Reusable Scope Valve**.
2. Confirm that water exits from all three nozzles in the Distal Tip.

It may take a few seconds for the water to reach the Distal Tip.

4.6.6 Test the suction mechanism

1. Fill a cup with sterile water.
2. Immerse the Distal Tip in the cup of sterile water.
3. Press on the **Suction Reusable Scope Valve**.

4. Confirm that the water level in the cup recedes.

WARNING

- Insufficient suction may cause loss of clear endoscopic image during the procedure. Use of the device without clear image quality can result in patient injury.

4.6.7 Test the auxiliary water mechanism

If you are using an auxiliary water mechanism, perform the following test. Otherwise, verify that the auxiliary water cap is tightly closed.

1. Confirm that the auxiliary water pump is connected.
2. Operate the auxiliary water pump.
3. Confirm that water is forced out of the auxiliary water opening in the Distal Tip.

4.6.8 Test the XLUM (blinking) mode

1. Confirm that the system is turned ON and that the system light is ON.
2. From the FuseBox™ Main screen, press on the **XLUM** icon.
3. Confirm that light on the Distal Tip blinks for seven (7) seconds

CAUTION

- *Avoid looking directly at the Distal Tip when the light is ON as this could cause temporary blindness due to the illumination.*

The following five tests apply to all active monitor screens.

4.6.9 Test the Capture function

The following functionality is used with the FusePanel™. Make sure the FusePanel™ is connected to the FuseBox™ for this test.

1. Confirm that the FusePanel™ is properly connected and turned ON.
2. Press the Capture (#1) button on the endoscope.
3. An image capture thumbnail will appear at the bottom of the FusePanel™ screen.

4.6.10 Test the Record function

The following video recording functionality is used with the FusePanel™ only. Make sure the FusePanel™ is connected to the FuseBox™ for this test.

1. Confirm that FusePanel™ is properly connected and turned on.
2. To start the video recording, press on the **Record** (**#2**) button on the endoscope.
3. A red “REC” icon will flash in the upper right corner of the FusePanel™ screen.
4. To stop the video recording, press on the **Record** (**#2**) button on the endoscope.
5. A thumbnail of the video recording will appear at the bottom of the FusePanel™ screen.

4.6.11 Test the Timer function

1. Press the **Timer** (**#3**) button on the endoscope.
2. Confirm that the digital time appears on the Left monitor display.
3. Press the **Timer** (**#3**) button three more times, in sequence, to test display of Insertion Time, Withdrawal Time, and Total time.
4. Press the **Timer** (**#3**) button one final time to reset.

4.6.12 Test the Zoom function

1. Press on the Zoom (#4) button on the endoscope.
2. Confirm that the endoscopic image zooms in by verifying that the zoom magnification (OFF, X 1.2, X 1.4, X 1.6, X 1.8, X 2,0) appears in the center monitor display.
3. Press on the Zoom (#4) button five (5) more times to cycle through all zoom levels.
4. Confirm that the endoscopic image returns to normal view.

4.6.13 Test the Freeze/Release function

The following functionality is used with the FusePanel™. Make sure the FusePanel™ is connected to the FuseBox™ for this test.

1. Press the **Freeze** (**#5**) button on the endoscope.
2. Confirm that the endoscopic images freeze.

   During Freeze, the live endoscopic image appears in a small Picture-in-Picture.

3. Press on the **Freeze** (**#5**) button again.
4. Confirm that the endoscopic images return (Picture-in-Picture disappears).

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CHAPTER 5 Understanding the FuseBox™ System Screens and Functions

This chapter provides descriptions and functionality of the FuseBox™ system touch screen user interface.

5.1 User screens

5.1.1 Navigating the GUI

Icon	Icon name	Function
	Back icon	Use this icon to move backward one screen.
	Main screen icon	Use this icon to go directly to the system's main screen.
	Setup Screen Navigation icons	Touch these numerals to move to the desired Setup screen. Alternative to pressing the Setup icon to reach the Setup screens. 1 = Image Settings 2 = LED Intensity 3 = System Information 4 = Monitor Selection

5.1.2 FuseBox™ main screen

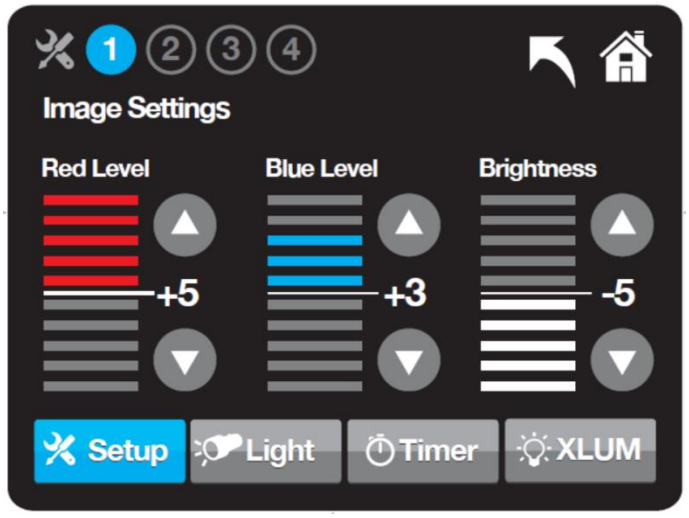
The FuseBox™ system uses a touch screen user interface.

Label/Icon name	Function
Type	Displays the type of endoscope attached to the FuseBox™.
Scope S/N	Displays the serial number of the endoscope attached to the FuseBox™.
Setup	Pressing this icon multiple times cycles through to the various setup screens in the following order: • Image Settings • LED Intensity • System Information/Scope Information • Monitor Selection
Light	Turns the FuseBox™ touch screen light ON/OFF. When on, the entire screen acts as a local illumination source, useful in a low light environment.
Timer	Displays the Timer screen which can be used like a stopwatch to mark the duration of a procedure.
XLUM	Operates the XLUM mode trans illumination function (Distal Tip blinking). Enables the operator to determine the position of the scope from outside the body.

5.1.3 Setup screen 1 – image settings

Press the **Setup** icon one time to access this screen. The Image Settings screen appears as below, and contains settings for red and blue colors, and for brightness.

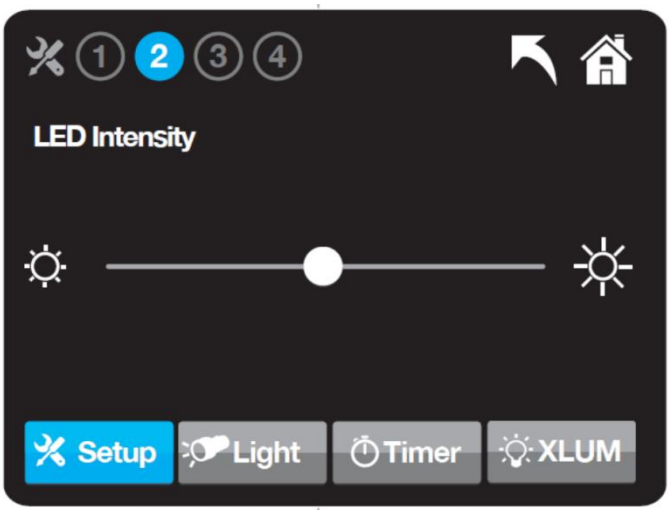
The settings modified via this screen affect all active views (1-2-3).



Label name	Function
Red level	Use the UP/DOWN arrows to increase or decrease the red color level of all active monitors. • The image shown above indicates a level of +5. • The range available is -5 to +5.
Blue level	Use the UP/DOWN arrows to increase or decrease the blue color level of all active monitors. • The image shown above indicates a level of +3. • The range available is -5 to +5.
Brightness	Use the UP/DOWN arrows to increase or decrease the brightness level of all active monitors. • The image shown above indicates a level of -5. • The range available is -5 to +5.

5.1.4 Setup screen 2 – LED intensity

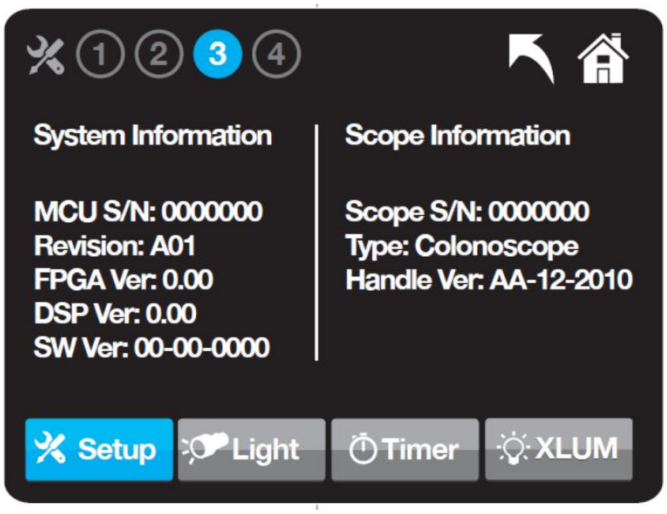
The LED Intensity screen allows adjustment of the LED.



Label name	Function
LED Intensity slider	Use the slider to increase or decrease the light intensity level of the Distal Tip.

5.1.5 Setup screen 3 – system / scope information

The System Information/Scope Information screen displays the current system configuration. Press the **Setup** icon three times to access this screen.

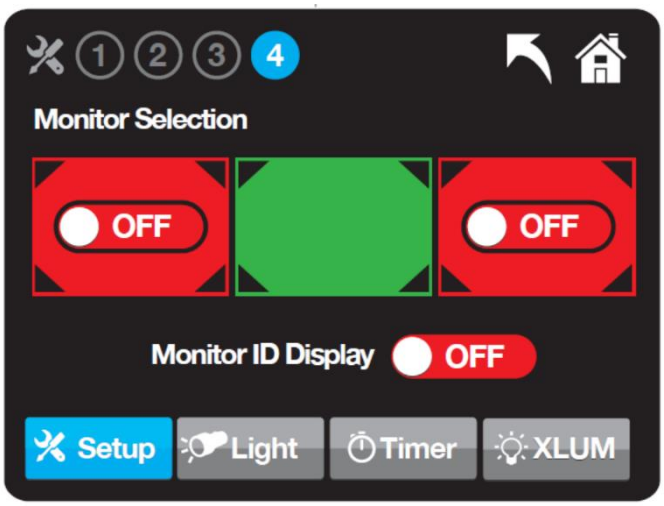


No modifications can be made through this screen.

Label name	Function
FuseBox™ System Information	Displays the FuseBox™ configuration: • Serial number • Software version
Scope Information	Displays the endoscope's information (when connected): • Endoscope type • Endoscope serial number • Endoscope version

5.1.6 Setup screen 4 – monitor selection (1-2-3 monitors)

The Monitor Selection screen allows the user to turn ON/OFF the Left and Right monitors in order to switch between the standard and wide views.



Label name	Function
ON/OFF	Allows combinations of the desired monitors. Press the **ON/OFF** icon to toggle between ON/OFF views for Left and Right monitors. The Center monitor is always ON.
Monitor ID Display	Used to display the letters L, C and R on the Left, Center and Right monitors if desired.

NOTE – the center screen cannot be turned OFF.

5.1.7 Light mode

Use the Light mode when additional light is required in a low light environment.

Light mode can be activated by pressing the **Light** icon located on the Main screen. During Light mode, the screen on the FuseBox™ illuminates to maximum intensity, allowing the user to use the FuseBox™ as a local illumination source. This may be useful when observing the content of an attached polyp trap in a low light environment.

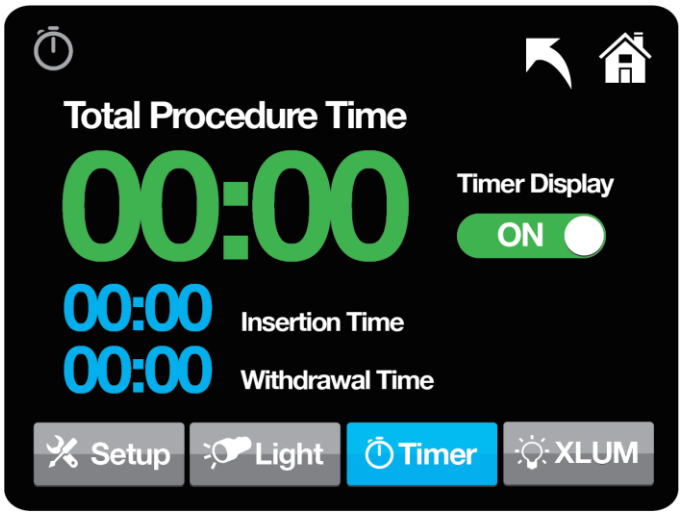
Icon name	Function
Light activation	Use this icon to activate the Light.

5.1.8 Timer

The Timer allows the user to record elapsed time between events during the procedure.

Each press of the scope button affects the timer as follows:

- Click 1: Starts Total Procedure Time (green) timer
- Click 2: Freezes/marks the moment of total insertion time, and begins timer for withdrawal (starting at 00:00)
- Click 3: Stops all timers
- Click 4: Resets all timers



Icon name	Function
Timer	Use this icon to record procedure time.

5.1.9 XLUM (Distal Tip LED blinking) mode

The position of the Distal Tip may be determined from outside the patient's body by using the XLUM (Trans illumination) mode.

XLUM mode can be activated by pressing the **XLUM** icon located on the far right of the Main screen. When in XLUM mode, the Distal Tip light is set to cycle between maximum and minimum light intensity ('blinking').

Pressing the XLUM icon activates only the Distal Tip light. No additional screen will appear on the FuseBox™ when using this mode.

Icon name	Function
XLUM mode activation	Use this icon to activate the XLUM mode. *XLUM mode automatically deactivates after seven (7) seconds.*

5.2 System functions

The following system functions performed using the numbered buttons located on the endoscope Control Handle apply to all active monitor screens.

5.2.1 Capture image

The capture image function stores a still image to an external drive.

- To use the capture function, press the **Capture** button on the endoscope Control Handle (marked as button #1).

5.2.2 Video recording

The endoscopic video can be recorded in real time.

Recording using the endoscope Control Handle:

1. Prior to procedure verify that the FusePanel™ is connected to the system via the appropriate ports on the FuseBox™ back panel.
2. To begin recording, press the **Record** button (marked as button #**2**) on the endoscope Control Handle.
3. To stop recording, press the **Record** button (#**2**) again.

5.2.3 Timer

The Timer function allows procedure time to be displayed on-screen from the Control Handle.

Timer captures and displays three increments of time: Insertion Time, Withdrawal Time, and Total Time.

To use Timer:

1. Press the Timer button (marked as button #3) once to start the clock.
2. Press the Timer button again to set your first “Mark”, such as Insertion Time.
3. Press the Timer button a third time to set your second “Mark”, such as Withdrawal Time.
4. Pressing the Timer button a fourth time stops the Timer, freezing all three values (total time, Mark 1 and Mark 2) on the screen.
5. Pressing the Timer button a fifth time clears times from the screen.
   Start = starts the timer
   Mark = marks the first and second durations
   Stop = stops the timer
   Reset = resets the timer back to 00:00:00
   Display ON = displays the timer information on the LEFT monitor

5.2.4 Zoom

The Zoom function allows magnification of the endoscopic image during procedure.

Per the operator preference, Zoom can be applied on the endoscopic image or on a frozen image.

The zoom function magnifies all three image views.

To operate the Zoom function:

- Press the **Zoom** button (marked as button #4) on the endoscope Control Handle. Each press of the zoom button toggles through one of the 6 Zoom levels: OFF, X 1.2, X 1.4, X 1.6, X 1.8, X 2.0.

5.2.5 Freeze/Release image

The freeze function creates a still image that is displayed on the screen but not recorded.

The freeze function freezes all three image views.

Freeze the image using the endoscope Control Handle:

1. Press the **Freeze/Release** button (marked as button #**5**).
2. To release the image, press button #**5** again.

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CHAPTER 6 Performing the Procedure

6.1 Important safety information

WARNING

- The Fuse™ 1C Colonoscope should only be used by a physician. It is the responsibility of the personnel using this equipment to be well trained in the use of clinical endoscopy techniques. This manual only provides basic instructions and precautions related to the operation of this equipment.
- The colonoscope and its reusable accessories MUST be reprocessed prior to use. Refer to the "**Fuse™ Endoscope Reprocessing Manual**" for complete reprocessing instructions. Failure to do so may pose an infection control risk.
- In case of instrument failure/malfunction during a procedure, it is recommended to always keep a spare colonoscope system in the room ready for use.
- Perform all device inspections described in these instructions prior to use. Do not use the Fuse™ 1C Colonoscope if it is not functioning correctly. Using an impaired or damaged device may result in patient injury.
- Wear personal protective equipment to guard against dangerous chemicals and potentially infectious materials during use of the device.
- Do not use the colonoscope if the markings are not clearly visible. Insertion and manipulation of the endoscope without visibility of the markings may cause patient pain, injury, bleeding, and/or perforation.

6.1.1 Examples of improper handling

Patient safety in colonoscopic examinations and colonoscopic treatment can be obtained through appropriate handling by the physician and the medical facility. Examples of improper handling are listed below.

WARNING

- Over-insufflating the lumen may cause patient pain, injury, bleeding, and/or perforation.
- Do not excessively inflate air or a nonflammable gas into the patient. This could cause gas embolism.
- Applying suction with the Distal End in prolonged contact with the mucosal surface, with higher suction pressure than required, or with a prolonged suction time may cause bleeding and/or lesions.
- Inserting or withdrawing the endoscope, feeding air, applying suction, or operating the Bending Section without a clear image may cause patient injury, bleeding, and/or perforation.

- Using the endoscope with no image: If the endoscope image disappears unexpectedly during an examination, immediately stop using the endoscope and withdraw it. Inserting or withdrawing the endoscope, using endoscopic tools, performing suction, feeding air, or performing angulation control under these conditions could result in patient injury, bleeding, and/or perforation.

6.1.2 Using nonflammable gases

If the intestines contain a flammable gas, replace with air or a nonflammable gas such as CO_2 before performing high-frequency treatment.

WARNING

- **Performing treatment while the intestines are filled with a flammable gas could result in an explosion, fire, and/or serious injury.**

NOTE

Using CO2 during endoscopic examinations may reduce post-examination pain.

6.2 Inserting the colonoscope

1. Confirm that the angulation brakes are not in the locked position.
2. Slowly and gently insert the colonoscope Insertion Tube while viewing the colonoscopic image.
3. Operate the angulation controls to guide the Distal Tip for insertion and examination.

WARNING

- Do not force the endoscope Insertion Tube! Serious injury may result from use of excessive force.

CAUTION

- *Do not apply petroleum-based materials/lubricants on the Distal Tip, as they may accelerate the degradation of the Bending Section.*
- *If the image dims during the procedure, tissue or debris might have adhered to the Distal End which may cause the temperature to rise. Slowly extract the colonoscope to avoid patient and/or operator burn injury.*

6.3 Using endoscopic devices and accessories

CAUTION

- ***Failure to observe the following cautions may cause device damage or patient injury.***
- *Make sure the endoscopic devices/accessories diameter is suitable for the work channel.*
- *Do not open or attempt to articulate endoscopic devices/accessories inside the work channel. Open tools can cause damage to the channel.*

- *Do not use endoscopic devices/accessories if the field of vision is not clear.*
- *Take care not to tear the Biopsy Valve when inserting or extracting the endoscopic devices/accessories.*
- *Make sure that there is enough distance between the endoscopic devices/accessories and the Distal Tip.*
- *Always use the instrument according to the manufacturer's instructions for use.*
- *Never operate an electrosurgical tool while the working element is in the work channel.*
- *Never use an electrosurgical tool if the field of vision is not clear.*
- *Make sure that there is enough distance between the electrosurgical tool and the Distal Tip and that it is correctly positioned for the procedure before activating the power.*
- *When performing electrosurgical procedures, do not use any accessories or tools that are not specifically designed for electrosurgical procedures during endoscopy.*
- *When using high frequency surgical equipment, do not exceed the following ratings:*

Accessory Intended Use Mode	Maximum rated recurring peak voltage
Spray Coag	VPK 3800V
Cut	VPK 840V
Soft Coag	VPK 200V

WARNING

- **Patient leakage currents may be additive when endoscopes are used with energized endoscopically-used accessories**.

6.3.1 Using endoscopic accessories

1. Open the biopsy valve.
2. Verify the mechanical integrity of the biopsy valve.
3. Gently push the endoscopic devices/accessories through the Biopsy Port, into the work channel, and out through the Distal Tip.
4. Operate the endoscopic devices/accessories according to the manufacturer's instructions.
5. Gently pull the endoscopic devices/accessories out of the work channel.
6. When the endoscopic devices/accessories is removed, close the biopsy valve.

6.3.2 Using electrosurgical accessories

1. Open the biopsy valve.
2. Gently push the electrosurgical tool through the Biopsy Port, into the work channel, and out through the Distal Tip.
3. After performing the procedure, gently pull the electrosurgical tool out of the work channel.

4. When the electrosurgical tool is removed, close the Biopsy Valve.

6.4 Withdrawing the colonoscope

Slowly and gently withdraw the colonoscope Insertion Tube while viewing the colonoscopic image.

CAUTION

- *Make sure that the angulation brakes are not in the locked position.*
- *Reprocess the colonoscope after the procedure as described in the companion "**Fuse™ Endoscope Reprocessing Manual**" with the colonoscope model listed on the cover.*

CHAPTER 7 Storage and Handling

WARNING

- **The endoscope and its parts must be reprocessed prior to use. Refer to the "Fuse™ Endoscope Reprocessing Manual" for complete reprocessing instructions. Failure to properly reprocess the device may pose an infection risk.**

7.1 Servicing

This product must be installed, maintained and serviced by EndoChoice personnel.

The probability of failure of the endoscope and ancillary equipment increases as the number of procedures performed and/or the total operating hours increase. The product and ancillary equipment must be inspected before each use. In addition to the inspection before each procedure, it is highly recommended that the person in charge of medical equipment maintenance inspect the items periodically.

Do not use the endoscope or ancillary equipment if any irregularity is suspected. Follow the procedures in Chapter 8 Troubleshooting, to resolve the issue. If you are unable to resolve the issue, contact EndoChoice.

The system does not contain any user-serviceable parts. Do not modify or attempt to repair it; patient or operator injury and/or equipment damage may result.

7.2 Disassembly

Disassembly of the Fuse™ 1C Colonoscope with FuseBox™ Processor is performed in the opposite order of the assembly. Refer to Chapters 3 and 4.

CAUTION

- *Be careful not to flip the water bottle while the system is connected to avoid equipment damage.*
- *Handle the system with care when disconnecting the colonoscope from the FuseBox™ to ensure the connectors and cables are not damaged, or that the FuseBox™ is not displaced.*
- *Dispose of the single use items according to the manufacturer instructions for use.*

7.3 Transportation

If the system is located on a mobile workstation, carefully move the system to its storage location.

The Distal Tip of the endoscope contains highly vulnerable optical end electrical components. Avoid any mechanical damage to the tip during transport.

CAUTION

- *Do not store the endoscope in its transport case. Routine storage in a non-ventilated, humid environment may result in contamination and/or damage the device.*

7.4 Storage

Refer to the "**Fuse™ Endoscope Reprocessing Manual**" for storage between usage instructions.

CHAPTER 8 Troubleshooting

8.1 Troubleshooting the Fuse™ 1C Colonoscope

This table provides a list of common potential problems you may experience, and possible solutions to these problems. If the problem persists, do not use the endoscope and contact your EndoChoice representative.

Problem with…	Possible Solutions
Air/Water functionality	• Remove and inspect the Air/Water Reusable Scope Valves. Verify that there are no blockages in the button. • Verify that the air/water tube is connected correctly. • Verify that the system is turned on. • Verify that the pump is turned on. • Verify that the water bottle is tightly closed. • If the above options do not resolve the problem, try using a new Air/Water Reusable Scope Valve.
Suction functionality	• Remove and inspect the Suction Reusable Scope Valve. Verify that there are no blockages in the valve. • Verify that the suction tube is connected correctly. • Verify that the suction pump is turned on. • Verify that the Biopsy Valve is closed and attached correctly. • If the above options do not resolve the problem, irrigate the channel with sterile water. If irrigating does not resolve the problem, push a biopsy forceps through the channel to clean the channel.
Auxiliary water functionality	• Verify that the pump is turned on. • Verify that the auxiliary water supply is tightly connected.
Angulation functionality: Unexpected resistance when turning angulation knobs	• Verify that the brakes are not locked. • If the brakes are not locked and you still experience resistance, do not use the endoscope. Contact an EndoChoice representative for further instructions.

Problem with…	Possible Solutions
WARNING • **If there is unexpected resistance when turning the angulation knobs during a procedure, immediately stop the procedure and remove the colonoscope by unlocking the brakes, straightening out the colonoscope, and carefully removing the colonoscope. Continued use of the device may cause patient injury or damage the device.**	
Does not reach full range of motion	• Do not use the endoscope. Contact your EndoChoice representative for further instructions.
No video signal	• Verify that the system is turned on. • Verify that the video cables from the FuseBox™ to the monitors are securely connected. • Verify clean electrical contacts. • Verify that the monitors are turned on. • Verify the video selection on the monitor. • If the issue is still not resolved, do not use the endoscope. Contact your EndoChoice representative for further instructions. • If the video signal is lost during a procedure and cannot be restored, refer to section 8.2 Withdrawal of the colonoscope with no image.
System does not turn on	• Verify that the power (back power button) is on. • Verify that the system is connected to a source of electricity. • Press the ON/OFF button until you hear a click.
Pump button does not react	• Verify that the system is turned on.
Image not clear	• Feed water to remove mucus, debris from lens at the Distal Tip.

8.2 Withdrawal of the colonoscope with no image

When the image disappears and cannot be restored, use the following steps:

1. Turn OFF the FuseBox™ and then restart the system. If the image is not restored, use the following steps:
2. Turn the FuseBox™ and suction source OFF.
3. Slowly remove the endoscopic accessory (if applicable).
4. Release the angulation knob break.
5. Turn the Up/Down and Right/Left angulation knobs to their natural position.
6. Release the knobs and slowly withdraw the endoscope; do not apply any excessive force.

Appendix

Compatible accessories

The following table outlines compatible accessories to be used with the Fuse™ 1C.

Table 3. Fuse™ 1C Accessories Compatibility*

Fuse™ System component name	Recommended compatible accessory to be used	Recommended accessory	Type
Fuse™ 1C	Auxiliary water pump	Any product compatible with the Fuse™ system	Reusable
Fuse™ 1C	Auxiliary water pump tube set	SIT-355-10 Hydra™ Disposable Irrigation Tubing System by EndoChoice®	Disposable (Sterile)
Fuse™ 1C	Suction pump	Use a suction pump with a tube set that suctions at rates up to 30L/min	Reusable
Fuse™ 1C + FuseBox™	Water bottle cap	SCT-466 Hydra™ Water Bottle Cap and Tubing Set by EndoChoice® SCT-467 Hydra™ Water Bottle Cap and Tubing Set with CO2 by EndoChoice®	Disposable
Fuse™ 1C	Biopsy cap	SBC-460-10 Seal™ Reusable Biopsy Valve by EndoChoice®	Reusable
Fuse™ 1C	Valve cleaning brush	SBB-119-50 HedgeHog® Valve Brush by EndoChoice®	Disposable (Sterile)
Fuse™ 1C	Cleaning brush suited for 2.8 mm channels*	SBS-227-50 HedgeHog® Single-End Channel Brush by EndoChoice® SBD-228-50 HedgeHog® Double-End Channel Brush by EndoChoice® SBD-289-50 HedgeHog® Dual-End Channel/Valve Brush by EndoChoice® SBD-291-50 HedgeHog® Sweeper by EndoChoice® SBD-371-50 HedgeHog® Sweeper Bundle by EndoChoice® SBD-382-50 HedgeHog® Double Bundle by EndoChoice®	Disposable (Sterile)

* All of the HedgeHog® brush products listed above are used in channels 2 mm and larger.

EMC Information

Compliance information and recommended electromagnetic emission

Guidance and Manufacturer's Declaration – Electromagnetic Emission		
The Fuse™ 1C Colonoscope System is intended to be used in the electromagnetic environment specified below. The user and the medical staff should ensure that it is used only in these environments. EMC applied standard: IEC 60601-1-2: 2007 3rd edition		
Emission Standard	**Compliance**	**Electromagnetic Environment**
Radiated Emission CISPR 11: 2009 AM. A1: 2010 Frequency range 30 MHz to 1000 MHz	Class A limit	The Fuse™ 1C Colonoscope System uses RF (Radio Frequency) energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
Conducted emission CISPR 11: 2009 AM. A1: 2010 Frequency range 150 KHz to 30 MHz	Class A limit	The Fuse™ 1C Colonoscope System RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic Emissions IEC 61000-3-2: 2005	Class A	The Fuse™ 1C Colonoscope System harmonic emissions are low and are not likely to cause any problem in the typical commercial power supply connected to this instrument.
Voltage fluctuations\flicker emissions IEC 61000-3-3: 2008	Complies	The Fuse™ 1C Colonoscope System stabilizes its own radio variability and has no effect, such as flickering of a lighting apparatus.

Compliance information and recommended electromagnetic immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Fuse™ 1C Colonoscope is intended to be used in the electromagnetic environment specified below. The user and the medical staff should ensure that it is used only in these environments.			
Immunity Test	**IEC 60601-1-2 test level**	**Compliance Level**	**Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2:2008	Contact Discharge: ±6 kV Air Discharge: ±8 kV	Same as left	Floors should by be made of wood, concrete, or ceramic tile that produces limited static. If the floors are covered with synthetic material that tends to produce static, the relative humidity should be at minimum 30%.
Electrical fast transient/burst IEC 61000-4-4:2004	±2 kV Power supply lines ±1 kV Input/output lines	Same as left	Mains power quality should be that of a typical commercial (original condition feeding the facilities) or hospital environment.
Surge IEC 61000-4-5:2005	Differential mode: ±1 kV Common Mode: ±2 kV	Same as left	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11: 2004	<5% U_T (>95% dip in U_T) For 0.5 cycle	Same as left	Mains power quality should be that of a typical commercial or hospital environment. If the user of this instrument requires continued operation during power mains interruptions, it is recommended that this instrument be powered from an uninterruptible power supply or battery.
	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 seconds		

Immunity Test	IEC 60601-1-2 test level	Compliance Level	Guidance
Power Frequency (50/60Hz) Magnetic field IEC 61000-4-8:2009	3V/m	Same as left	It is recommended to use this instrument while maintaining enough distance from any equipment that operates with high current.

Cautions and recommended electromagnetic environment

This section provides cautions and recommendations for electromagnetic environments in regards to portable and mobile RF communications equipment such as cellular phones.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Fuse™ 1C Colonoscope is intended to be used in the electromagnetic environment specified below. The user and the medical staff should ensure that it is used only in these environments.

Immunity Test	IEC 60601-1-2 test level	Compliance Level	Guidance
Radiated RF IEC 61000-4-3:2006 Amendment A1:2007 Amendment A2:2010	3V/m 80-2500MHz	3V/m (E_1)	Conditions not written in report recommend: $d = 1.2\sqrt{P}$ 80MHz – 800 MHz $d = 2.3\sqrt{P}$ 800MHz – 2500 MHz
Conducted RF IEC 61000-4-6:2003 Amendment A1:2004 Amendment A2:2006	$3V_{RMS}$ 0.15-80MHz 80% A.M by 1Khz	3V (V_1)	Conditions not written in report recommend: $d = 1.2\sqrt{P}$

- This instrument complies with the IEC 60601-1-2:2001. However, under electromagnetic environment that exceeds its noise level, electromagnetic interference may occur on this instrument.
- Electromagnetic interference may occur on this instrument near a high-frequency electrosurgical equipment and/or other equipment marked with the following symbol:

Recommended separation distance

This section provides recommended separation distances between portable and mobile RF communications equipment and the Fuse™ 1C Colonoscope.

Separation Distance according to Frequency of Transmitter (m)			
The Fuse™ 1C Colonoscope is intended for use in the electromagnetic environment specified below. The user and the medical staff should ensure that it is used only in these environments.			
Rated maximum output power of transmitter P(W)	**0.15– 80 MHz d = 1.2√P**	**80– 800 MHz d = 1.2√P**	**800– 2500 MHz d = 2.3√P**
0.001	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
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 of and reflection of structures, objects, and people.			

Warranty

Limited Warranty.

(a) EndoChoice warrants that the Fuse™ endoscope(s), FuseBox™ and FuseCart™ products shall be free from defects in material and workmanship for a period of two years from the date of shipment, all other EndoChoice products shall be free from defects in material and workmanship for a period of one year from the date of shipment (as applicable, the "Warranty Remedy Period").

(b) If a nonconformity is discovered in a product during the Warranty Remedy Period under normal and proper use, then EndoChoice shall, at its option, either repair or replace any allegedly defective part or parts at its expense. It is a condition precedent to EndoChoice's undertakings that written notice of such nonconformity is provided to EndoChoice promptly after such discovery, but in no event later than ten (10) business days thereafter, and within the applicable Warranty Remedy Period. Such notice shall describe the full extent and nature of the problem.

(c) EndoChoice shall have no obligation hereunder with respect to any product that (i) has been improperly stored, installed, operated or maintained or has otherwise been used in a manner contrary to the instructions for use; (ii) has been repaired or altered not in accordance with the instructions for use; (iii) has been subject to misuse, unauthorized use, negligence, accident (including fire, water, explosion, smoke, vandalism, etc.), moisture intrusion during cleaning, or any other cause beyond EndoChoice's control; or (iv) has failed as a result of ordinary wear and tear. Without derogating from the above, the warranty for the products is void if at any time anyone other than EndoChoice's authorized personnel removes a product casing and/or attempts to make or makes any internal changes, removals, attachments or additions to the product or components thereof.

(d) Defective parts replaced by EndoChoice shall be returned to the designated EndoChoice facility at EndoChoice's expense. Title and risk of loss with respect to such parts shall pass to EndoChoice upon delivery to EndoChoice's facility. Products or parts thereof may be returned for repair, replacement or adjustment only with EndoChoice's prior written consent, or in accordance with the FuseCare™ Global Service Program terms. No credit allowances will be given or replacements shipped unless defects are verified by EndoChoice or EndoChoice's authorized personnel.

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