MP1212, MP1213

Fluorescence Endoscope

User Manual

www.edgemedicalrobotics.com

Document Version V04 Jan. 06, 2025

Important Regulatory Information

Contact Information

For Customer Service and Reporting of Complaints or Adverse Events

During the use of fluorescence endoscopes, if a serious incident has occurred, it shall be reported to the manufacturer and/or its authorized representative and to competent authority.

Use the following information for customer service, including ordering, reporting complaints or adverse events, general information regarding Edge Medical or our products and services, if the endoscope requires maintenance or service. Preventive maintenance is required and must be performed by authorized Medical Edge personnel.

In China

Manufacturer: Shenzhen Edge Medical Co., Ltd.

Manufacturer Address: 2B 1901, Phase II, Smart Home, No.76, Baohe Avenue, Baolong Community, Baolong Street, Longgang District, 518116, Shenzhen, P.R.China

Manufacturer Site Address: 2B 0401, 1901, 2001, 2101, Phase II, Smart Home, No.76, Baohe Avenue, Baolong Community, Baolong Street, Longgang District, 518116, Shenzhen, P.R.China

E-Mail: contact@edgemed.cn

Web: www.edgemedicalrobotics.com

In Europe

Authorized Representative in the European Community: Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg, Germany

E-Mail: shholding@hotmail.com

Prescription Information

Rx Only

In the USA, federal law restricts this device to sale or use by or on the order of a physician.

Copyrights

Disclaimers

The company reserves the right of final interpretation of this document.

All figures provided in this document are for reference only, and the settings or parameters in the figures may not be exactly the same as the products.

The company shall be responsible for the safety, reliability and performance of the products only if all of the following requirements are met:

- Assembly operation, extensions readjustment, improvement and maintenance are carried out by professionals approved by the company.
- All replaceable parts, accessories and consumables involved in maintenance are original or approved by the company.
- The electrical equipment complies with local standards and the requirements of this document.
- Carry out product operations according to this document.

About This Manual

Thank you for choosing fluorescence endoscopes. The manual provides feature descriptions and operating instructions of the endoscopes. Please read the manual carefully before using, and keep the manual properly after reading.

Documentation Conventions

Symbol	Description
	**Note:** Indicates important information.
	**Caution:** Indicates situations that could cause equipment damage.
	**Warning:** Indicates situations that could cause personal injury or even death.

Table of Contents

1. Introduction

This manual provides instructions for fluorescence endoscopes used with the Endoscopic Instrument Control System.

Note: Do follow all instructions provided with the applicable user manuals for the Endoscopic Instrument Control System not included in this manual.

Note: Reusable endoscopes are shipped non-sterile and should be cleaned and sterilized thoroughly before first use and after every use. Refer to the Fluorescence Endoscopes Reprocessing Instructions Manual for detailed instructions.

1.1 Product Components

The product consists of fluorescence endoscope and endoscope cable. The fluorescence endoscope consists of tip, shaft, base, housing, cable, connector, and connector cover.

1.2 Intended Purpose/Indication for Use

The fluorescence endoscope is intended to provide real-time, 3D, high-definition endoscopic imaging of the surgical field in minimally invasive surgery used in conjunction with the Endoscopic Instrument Control System during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, and thoracoscopic surgical procedures.

1.3 Clinical Benefits

The clinical performance of the fluorescence endoscope can be defined as the effectiveness and reliability of fluorescence endoscope and intended purpose as claimed by Edge Medical. Thus, the key clinical benefits for patients, including precise surgical positioning and surgical operations during surgical procedures, thereby supporting surgeons in clinical decision making and monitoring treatment progress to finally ensure the successful completion of the surgery.

1.4 Intended Users

The device is intended for use by trained physicians in an operating room environment in accordance with the representative specific procedures set forth in the professional instruction for use.

1.5 Intended Patient Population

The fluorescence endoscope is intended for adult patients suitable for urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, and thoracoscopic surgical procedures. Patient general health and medical history must be adequately assessed along with potential benefits and risks prior to performing procedures with the fluorescence endoscope.

1.6 Training

Warning: Only trained users and those who have developed adequate skills should use the endoscopes. Training provided by the company is limited to the use of the endoscopes and does not replace the necessary medical training and experience required to perform surgery.

1.7 Safety Information

Fluorescence endoscopes are intended to be used by trained physicians in an operating room environment according to the specific instructions in this manual. Please read all instructions of safety information carefully. Failure to properly follow the instructions, cautions and warnings related to the endoscopes may result in serious injury or surgical complications to the patient. While these instructions appear throughout the manual, this chapter provides some general precautions.

1.7.1 Contraindications

Any and all relative and absolute contraindications to endoscopic, thoracoscopic and laparoscopic surgical techniques applicable to the use of conventional endoscopic surgical instruments apply to the use of the fluorescence endoscope. The device is not intended for use when endoscopic techniques are contraindicated.

1.7.2 General Precautions

Warning: The endoscope shall not be used for any purpose other than the intended purpose.

Warning: High-energy light radiated by the endoscope connected with Endoscope Illuminator may cause eye hazards. Only personnel with adequate technical training and rich experience can operate the equipment.

Warning: Use of third-party components in conjunction with the system presents risk of exposure to laser energy that could result in injury to operator or patient, and could cause improper functioning of the system.

Warning: Each time before use, inspect the endoscope for any abnormalities or damage. Otherwise, it may cause injury to the patient.

Warning: Each time before use, inspect the endoscope for rough surfaces, sharp edges or protrusions. Do not leave any defected or damaged parts in the patient.

Warning: The highly concentrated light energy can cause the distal end, the light port, adjacent components and tissue in front of the light emission window to heat up (may exceed 41℃). This may cause tissue burns. The following safety guidelines should be observed to reduce the risk of injury:

- Avoid direct tissue contact with the endoscope distal end, as well as with the light port of the endoscope and the light guide bundles.
- Avoid excessively long continuous direct tissue contact with the shaft.
- Always select the lowest possible light output, which still allows optimal illumination of the operating field.
- Avoid resting the endoscope or the light guide bundles on the patient or in direct contact with surgical instruments or accessories.
- Avoid direct contact with high-temperature parts of the endoscope during intraoperative removal or replacement of the endoscope, which may cause burns to the operator or patient.

After using the endoscope, ensure all parts cool down before reprocessing. Improper operation may cause burns.

Warning: High-energy light radiated by the endoscope may cause eye hazards. Never look at light emitted directly from the endoscope or the light guide bundles, which could cause eye injury.

Warning: To minimize exposure to laser energy that could result in injury to operator or patient, deactivate fluorescence imaging when removing the endoscope from the patient.

Warning: To avoid burns or flammation, always turn off the Endoscope Illuminator when removing the light guide bundles, replacing or stop using the endoscope. Do not contact high-temperature parts of the endoscope with the operator, patient, drapes or flammable materials.

Warning: Do not clean the endoscope when inserted to the patient's tissue.

Warning: When using the endoscope with insufflation, only CO_2 should be used as the insufflating gas. Insufflation should be performed by personnel with adequate technical training and rich experience, otherwise hazards may exist with over-insufflation, such as gas embolism.

Warning: The insertion portion of endoscope is the type BF applied part. Do not apply it to cardiac surgical procedures. Otherwise, it may cause irreversible injury to the patient.

Warning: Interference produced by the operation of the endoscope may adversely influence the operation of other electronic equipment. For patients with cardiac pacemakers or other active implants, a possible hazard exists because interference with the action of the active implant may occur, or the active implant may be damaged. In case of doubt, please consult the manufacturer of qualified device.

Warning: Leakage current to the patient may increase when the endoscope is interconnected to or used with other ME EQUIPMENT. To ensure safety, only the equipment that meets the requirements of the ME EQUIPMENT standards IEC 60601-1 can be interconnected with the endoscope.

Warning: When high frequency surgical equipment and the system are used simultaneously, observe the following:

- After disinfection, check and clean the residual liquid before high frequency surgery.
- During cleaning or disinfection, disconnect the power supply of high frequency surgical equipment.
- To avoid electric shock or interference, keep the cables of high frequency surgical equipment as far away as possible.

- After starting high frequency surgical equipment, do not contact it with the metal parts of the endoscope or Camera Control Unit.
- Using high frequency surgical equipment may increase leakage current to the patient.
- The system should not be used adjacent to or stacked with high frequency surgical equipment, or it may cause interference.

Warning: To avoid electric shock, do not attempt to open or remove the endoscope housing.

Warning: A thorough understanding of the principles and techniques involved in laser is essential to avoid burn hazards to the operator and patient, damage to equipment and other instruments. Never immerse an instrument in a liquid unless it is designed and labeled for the function.

Warning: The Endoscope Illuminator in combination use with the fluorescence endoscope is a class 3R laser product which may emit invisible laser radiation. Failure to follow the instructions, cautions and warnings related to the product may result in hazardous laser radiation exposure that can cause severe eye injury to the operator or the patient.

Caution: Failure to adhere to approved operating practices may damage the endoscope. Improper practices include dropping, collisions, and improper cleaning and sterilization techniques.

Caution: Only a surgeon having adequate technical training and rich experience can use the endoscope for endoscopic procedures.

Caution: If a feature failure occurs (such as illumination or image failure) during operating the endoscope, immediately remove the endoscope from the patient and never try to repair it before removal.

Caution: The endoscope is not suitable for use in environments with flammable anesthetic mixture of air, oxygen and/or nitrous oxide.

Caution: Do not place endoscope cables or accessory cables over the arms of the Patient Cart. The cables may limit the range of motion of the arms, or become pinched or damaged.

Caution: Be careful with the light guide bundles. Serious bends or kinks can damage the optical materials inside the cable and increase fiber loss.

Caution: When connecting the light guide bundles to the endoscope, tighten the knurled screw of the cable connector to prevent it from coming off.

Caution: The personnel operating or repairing the product, looking or observing it for a long time should wear laser protective spectacles to protect their eyes. Recommend to choose protective spectacles which are reflective, at protective laser wavelength of 808nm, at protective laser power of 2.4W and at the optical density no less than 4.

Caution: Always have backup endoscope available to complete the surgical procedure in case of endoscope failure.

Caution: Handle the endoscope with care. Avoid mechanical shock or stress that can cause damage to the endoscope.

Caution: Do not modify the endoscope without authorization. Modifications can result in electrical hazards or performance degradation.

Caution: Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facilities. Contact your local government for information regarding the collection systems available. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and get into the food chain, damaging your health and well-being.

Caution: The operator shall not touch SIP/SOP connector and the patient simultaneously.

Caution: Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 62368-1 for data processing equipment). Furthermore, all configurations shall comply with the requirements for medical electrical systems (See IEC 60601-1 or clause 16 of the 3.2Ed. of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local

laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.

Caution: If a high-frequency generator is required, the generator that meets the IEC 60601-2-2 requirements must be used.

Note: The endoscope is the type BF applied part. To ensure safety, only Type BF or CF medical electrical equipment can be used with the endoscope.

Note: Although the endoscope complies with the requirements of IEC 60601-2-18, it may cause electromagnetic interference to other equipment. Ensure that other equipment in the operating room also meets the requirements of IEC 60601-2-18.

Note: Due to Electromagnetic Interference (EMI) hazards in the presence of MRI, CT, diathermy, or Electromagnetic Security Systems, the endoscope should not be used in the vicinity of these devices.

Note: Portable and mobile communications equipment may produce EMI, which may affect the function of the endoscope. Use the equipment with EMI characteristics proven below recognized limits.

Note: To check the electromagnetic interference from other equipment, the endoscope should be observed to verify its normal operation in the configuration in which it will be used.

1.8 Symbol Reference Table

Symbol	Meaning	Symbol	Meaning
	View direction: 0 degree		View direction: 30 degree
	30° up arrow		30° down arrow
	Hash mark		Take photo
	Illumination		Left-Right eye swap

Symbol	Meaning	Symbol	Meaning
	Caution		Type BF applied part
	Consult instructions for use		Serial number
	CE mark		Medical device
	Manufacturer		Date of manufacture
	Authorized representative in the European Community	Rx only	Federal (USA) law restricts this device to sale by or on the order of a physician
	Dispose of in accordance with local regulations—particularly applies to electronic components		Temperature limit
	Humidity limitation		Atmospheric pressure limitation
	This way up		Fragile, handle with care
	Keep dry		Keep away from sunlight
	Stacking limit by number	IPX7	Protection against the effects of temporary submersion in water
	Refer to instruction manual		MR Unsafe

Laser Aperture Label

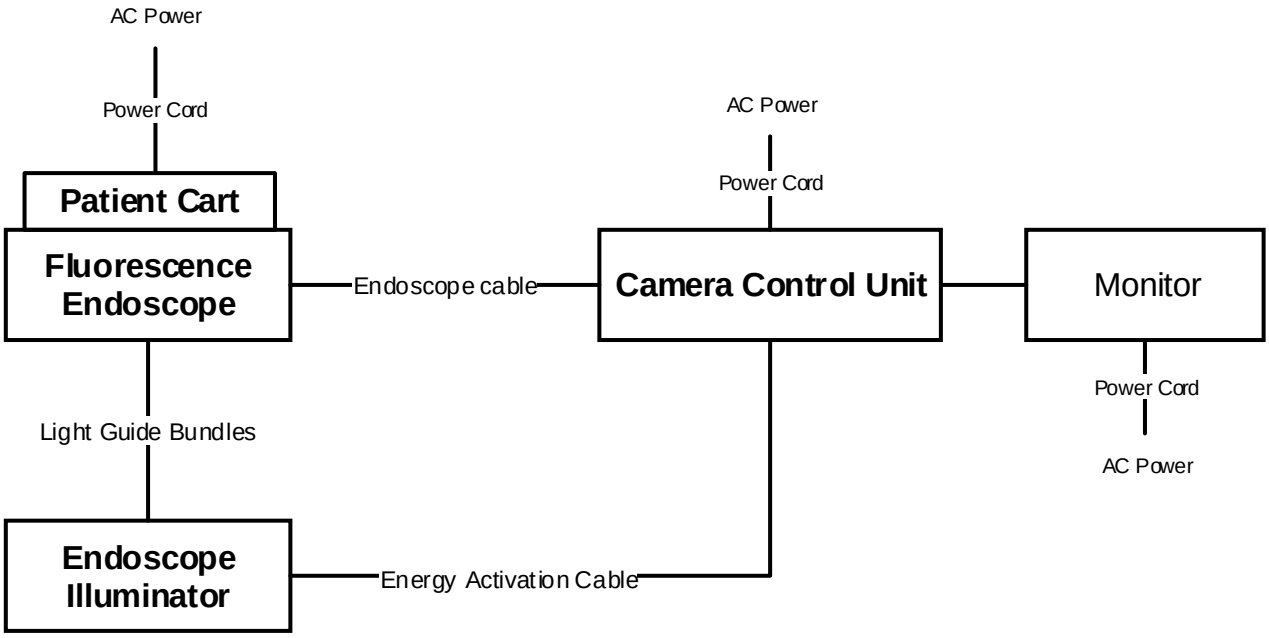
When the endoscope is connected to the Endoscope Illuminator, the light is transmitted to the endoscope through the light guide bundles. The laser aperture label labeled on the housing of the fluorescence endoscope points in the direction that the laser light is emitted when using with the Endoscope Illuminator.

Figure 1.1 Laser Aperture Label

1.9 Combination Use

Caution: Only connect equipment and accessories to the fluorescence endoscope that have been specified for use with the vision system. Connecting incompatible equipment and accessories may cause unexpected results.

Fluorescence endoscopes are designed for use mainly in conjunction with the Endoscope Illuminator (Model HE1003) and the Endoscopic Instrument Control System (Model MP1000, including the Camera Control Unit, the Patient Cart, the Surgeon Console and the Signal Distributor). The connection diagrams of the fluorescence endoscope, the Endoscope Illuminator and the Endoscopic Instrument Control System are shown below.



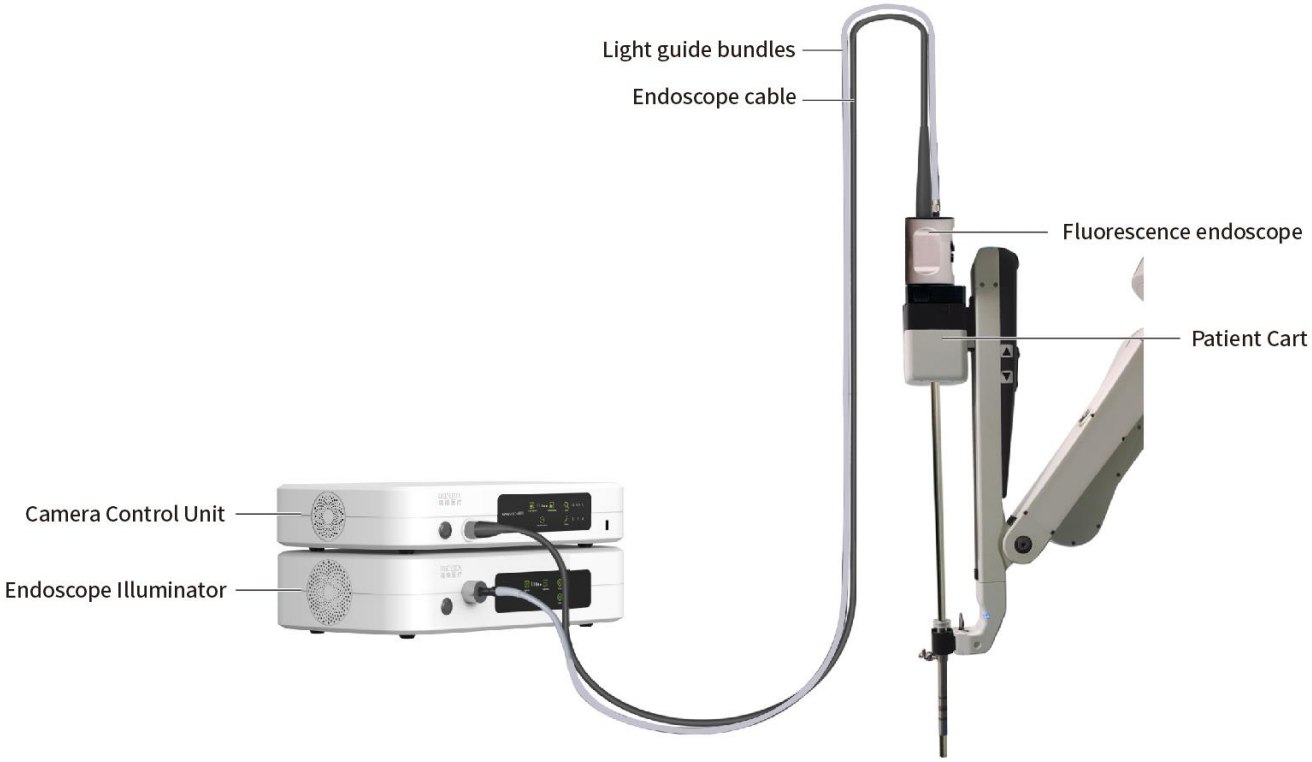


Figure 1.2 Connection Diagrams

1.9.1 Connection with Camera Control Unit

Camera Control Unit (Model MP1202) is included in Endoscopic Instrument Control System MP1000. The endoscope is connected to the Camera Control Unit through the endoscope cable, which processes and transmits images captured by the endoscopes.

For details of the connection, please see 3.2 Connecting to the Camera Control Unit.

1.9.2 Connection with Patient Cart

Patient Cart (Model MP1102) is included in Endoscopic Instrument Control System MP1000. In conjunction with cannula adaptation, endoscopes can be mounted on both the No. 2 and No. 3 instrument arms of the Patient Cart, and then the image, display and fluorescence parameters can be set via the touchscreen of the Surgeon Console. The system automatically recognizes the arm to which the endoscope is mounted, and auxiliary UI messages shown on the viewer and monitor can indicate the associated endoscope information including installed arm number, endoscope name, rotation angle, telestration eye, view direction and digital zoom. In addition, such connection ensures that the driving force on the instrument arm from the Surgeon Console is effectively transmitted to the endoscopes to perform the corresponding motions, for example moving in or out, moving from side to side, or rotating.

For details of the connection, please see 3.5 Endoscope Installation and 3.6 Endoscope

Removal and Replacement.

1.9.3 Connection with Endoscope Illuminator

The endoscope is connected to the Endoscope Illuminator (Model HE1003) through the light guide bundles, which provides illumination for endoscopy and endoscopic surgery.

For details of the connection, please see 3.3 Connecting the Light Guide Bundles.

1.10 Lifetime

Fluorescence endoscopes are reusable medical devices and designed for a predetermined number of uses, which also means number of reprocessing cycles. The fluorescence endoscope has an expected lifetime of 100 times under normal use and maintenance conditions.

Note: Any repair, refurbishment, reconditioning, or servicing of endoscopes is strictly prohibited. Otherwise, it will result in expiration of the lifetime.

1.11 Date of Manufacture

See product label for date of manufacture.

2. Product Overview

2.1 Overview

The endoscope provides high resolution 3D HD (high definition) lens, which can magnify the surgical field and display 3D stereo HD images inside the patient's body.

The following endoscopes are available for the system:

Product	Model Number	View Direction (Tolerance ±3°)	Visualization Mode
Fluorescence Endoscope	MP1212	0°	Visible light imaging and near-infrared imaging
Fluorescence Endoscope	MP1213	30°	Visible light imaging and near-infrared imaging

The fluorescence endoscope uses near-infrared light in conjunction with the imaging agent Indocyanine Green (ICG).

Note: For specific information of ICG, refer to the manufacturer's instructions.

Note: The imaging agent Indocyanine Green (ICG) is used for near-infrared imaging, in which the excited wavelength is 808nm±10nm, the emitted wavelength is 850nm±30nm and there is enough quantum yield to be detected by the fluorescence endoscope.

Note: Spilled blood or other body fluids containing ICG in the surgical field can maintain their fluorescence for the duration of the procedure.

Caution: The factors such as dosing of the imaging agent, timing of imaging agent administration, working distance, near-infrared imaging mode, etc. are variables that affect image quality. Adjusting these factors can improve image quality. When planning or providing alternative or additional interventions, it is necessary to combine with clinically relevant information.

2.2 Components

The endoscope consists of tip, shaft, base, housing, cable, connector, and connector cover. It is available with 0° (straight) or 30° (angled) tip, which is marked on the housing. With 30°

endoscopes, the surgeon can switch between upward or downward angular orientation by the Surgeon Console without removing the endoscope from the patient.

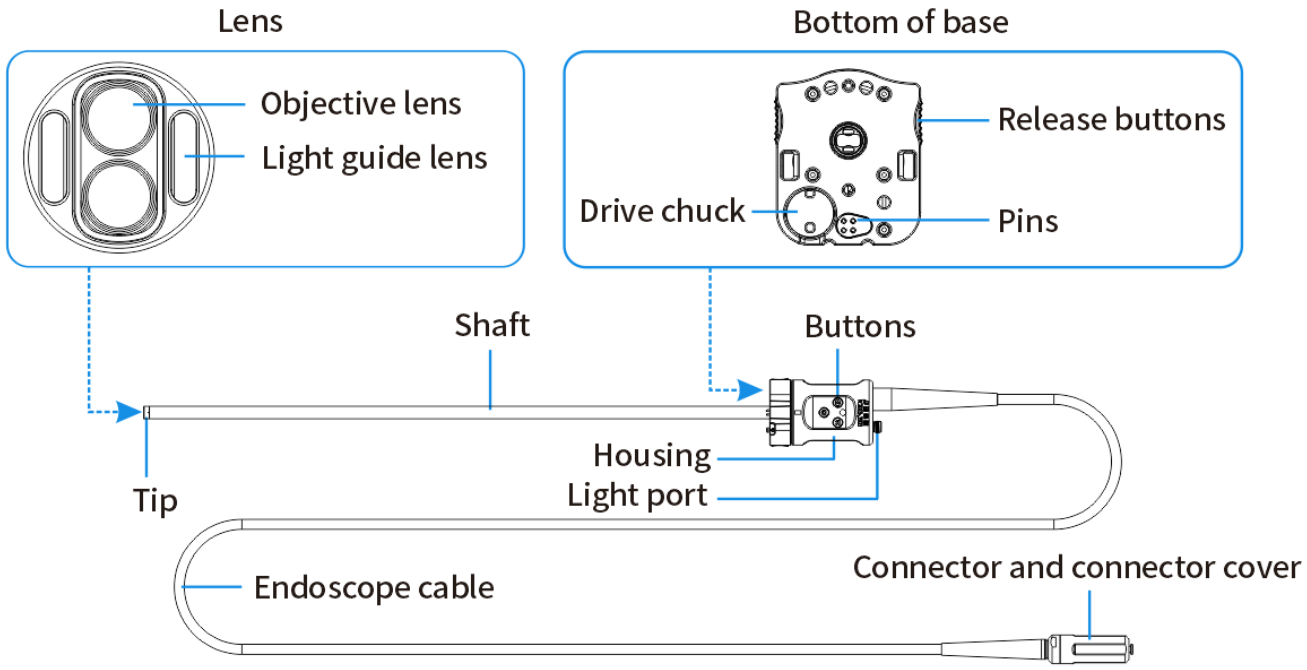


Figure 2.1 Endoscope Components (MP1212)

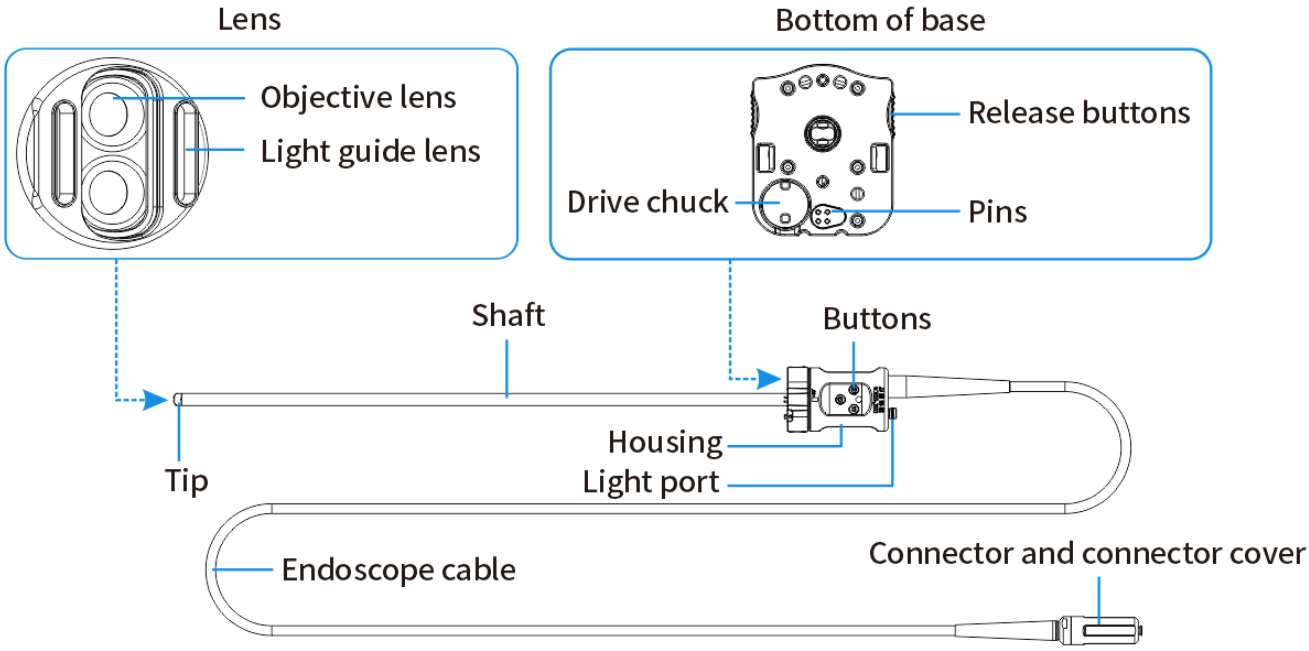


Figure 2.2 Endoscope Components (MP1213)

- Connector cover: Protect the connector of the endoscope cable during cleaning and sterilization, and avoid liquids contact with the connector to prevent endoscope damage.
- Endoscope cable: Connect the endoscope to the Camera Control Unit for signal transmission.

- Light port: Connect the light guide bundles, which in turn connects to the Endoscope Illuminator. After the endoscope is connected to the Endoscope Illuminator (Model: HE1003), the Endoscope Illuminator will provide light output through light guide lens of the endoscope.
- Housing: There are three functional buttons, a LED indicator, and a hash mark on the housing. For further information, see 2.2.1 Endoscope Housing.
- Base: There are two **Release** buttons on both sides of the base, pins and a drive chuck at the bottom of the base, and a hash mark on the top of the base. For further information, see 2.2.2 Endoscope Base.
- Shaft: After being inserted through the cannula, the endoscope is rotated controlled by the Surgeon Console.
- Tip: Located at the distal end of the endoscope, including two objective lens and two light guide lens.

2.2.1 Endoscope Housing

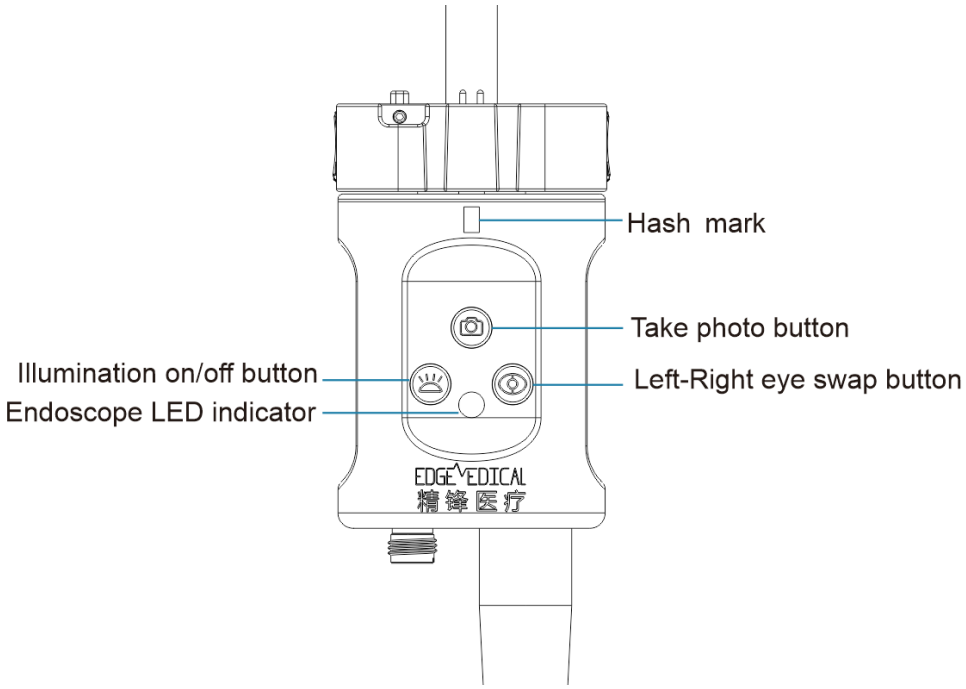


Figure 2.3 Endoscope Housing

LED Indicator

The LED indicator indicates the status of the connection between the endoscope and the system.

Table 2.1 LED Indicator

Indicator Status	Meaning
Off	Not connected
Flashing blue	Restoring
Solid blue	Connected and ready

Buttons

The buttons can be used after the endoscope is connected to the system.

Table 2.2 Buttons

Buttons		Description
	Left-Right eye swap	Press to swap the left-eye or right-eye endoscope image
	Take photo	Press to capture an image from the endoscope view
	Illumination on/off	Press to turn illumination on or off

2.2.2 Endoscope Base

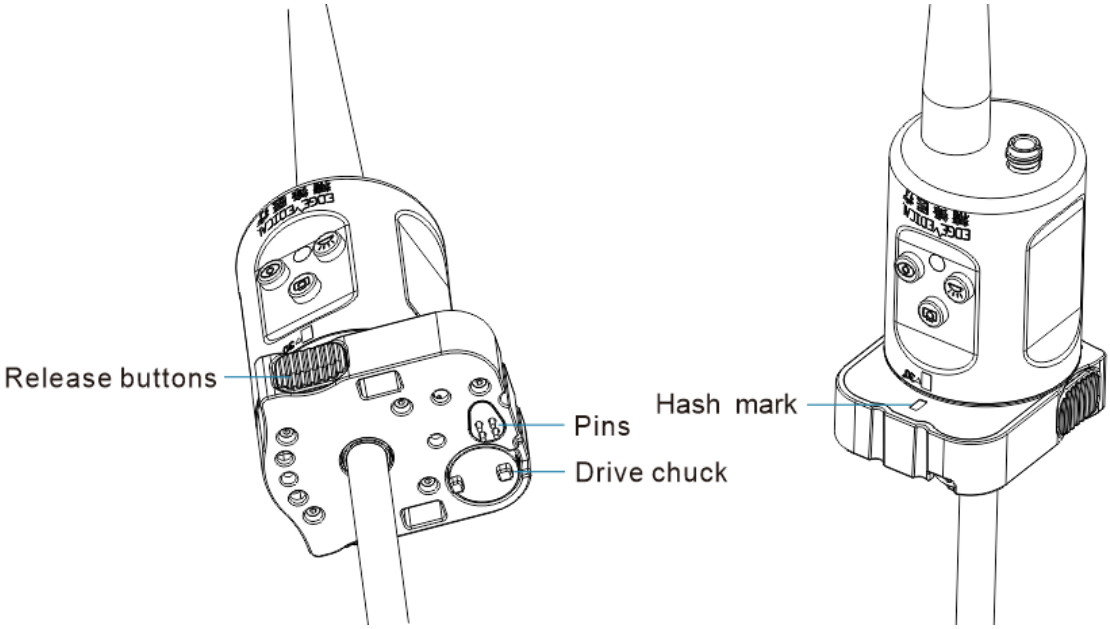


Figure 2.4 Endoscope Base

- **Release** buttons: Used to remove the endoscope from the instrument arm of the Patient Cart by squeezing both **Release** buttons on two sides of the base.
- Pins: Used to communicate with the Patient Cart and for endoscope identification.
- Drive chuck: Used to translate the movements from the Surgeon Console master controls.

- Hash mark: Used to align with the hash mark on the housing after mounting the endoscope on the instrument arm and completing the self-test.

3. Preparation before Use

3.1 Visually Inspecting the Endoscope

Warning: Do not use endoscopes with any defects or signs of damage. Otherwise, serious injury or surgical complications may occur to the patient.

- Inspect the endoscope for any defects or damage, including breaks, bends, cracks, rough surfaces, sharp edges, burrs, protrusions, etc.
- Inspect the endoscope for mechanical or optical defects.
- Inspect the exterior of the endoscope for cleanliness, paying special attention to the tip. There should be no visual contamination.
- Inspect the glass surfaces at the distal end. There should be no deposits, residues or haze.
- Inspect the endoscope cable sheath for any cuts, damage or defects.
- Inspect the cable fiber surfaces for any deposits or residues.
- Inspect the light port and connector for loosening, distortion, damage, smudges or soiling that can affect connections, and there should be no debris in the port.
- Ensure that only compatible equipment and accessories can be connected to the endoscope.

3.2 Connecting to the Camera Control Unit

The endoscope is connected to the Camera Control Unit through the endoscope cable. The image signals from the endoscope are processed and transmitted by the Camera Control Unit.

1. Remove the connector cover from the endoscope cable connector.

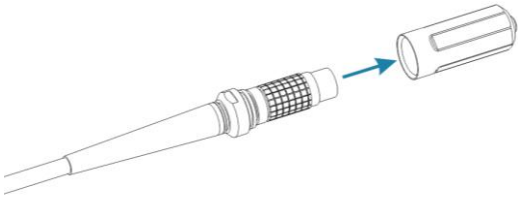


Figure 3.1 Remove the Connector Cover

Note: Reattach the connector cover to the connector when the endoscope cable is not in use or before reprocessing the endoscope.

Note: The part of the connector under the cover is not sterile. Sterile users should not handle the end of the connector once the cover has been removed.

2. Align the red dot on the endoscope cable connector with the red dot on the Camera Control Unit receptacle and insert the connector. An audible sound indicates a correct cable connection. Gently pull on the connector to verify the cable is fully seated.

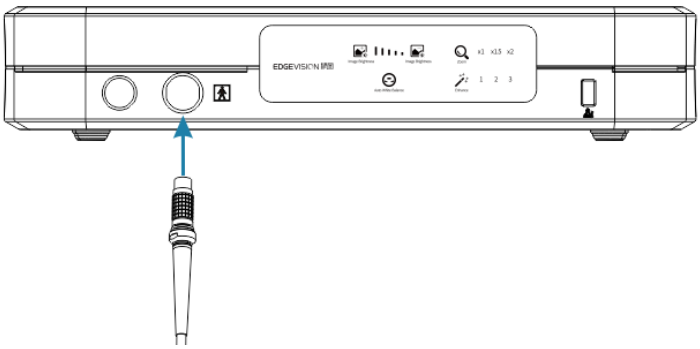


Figure 3.2 Connect to the Camera Control Unit

3.3 Connecting the Light Guide Bundles

The endoscope is connected to the Endoscope Illuminator through the light guide bundles, which provides illumination for endoscopy and endoscopic surgery.

Warning: Power off the Endoscope Illuminator or deactivate the light output before connecting or removing the light guide bundles or endoscope.

1. Connect the light guide bundles to the light port, and tighten by twisting the knurled screw on the endoscope base clockwise.

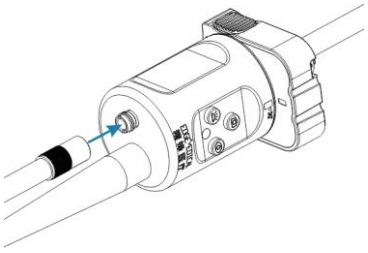


Figure 3.3 Connect to the Light Port

2. Insert the light guide bundles into the light cable port of the Endoscope Illuminator until it engages. Note that hold the connector only by the plastic part, never by the metal part.

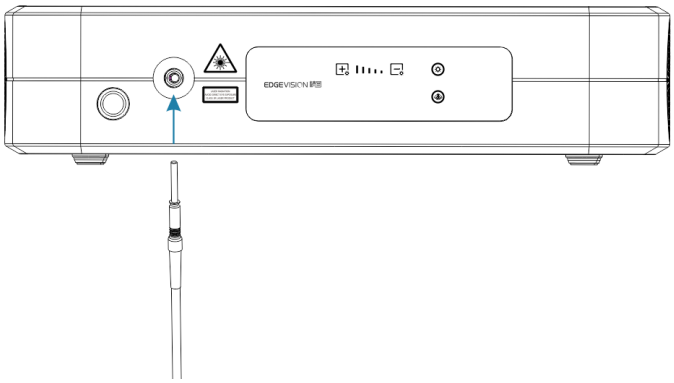


Figure 3.4 Connect to the Endoscope Illuminator

Note: To maintain optimal light transmission, always keep the light input and output surfaces of the light guide bundles and the endoscope clean.

Caution: Be careful with the light guide bundles. Serious bends or kinks can damage the internal fiber materials and increase the transmission loss of fiber.

3.4 Handheld Endoscope Use

The endoscope can be used handheld when connected to the Camera Control Unit before it is mounted to the instrument arm of the Patient Cart. The endoscope image is displayed to aid with visualizing when used handheld. After handheld use, the endoscope is then installed on the instrument arm of the Patient Cart.

0° Endoscope (MP1212)

The angular field of the endoscope (MP1212) is 0°. Hold the endoscope with the base and buttons facing up so that the image is displayed in the positive direction in the monitor.

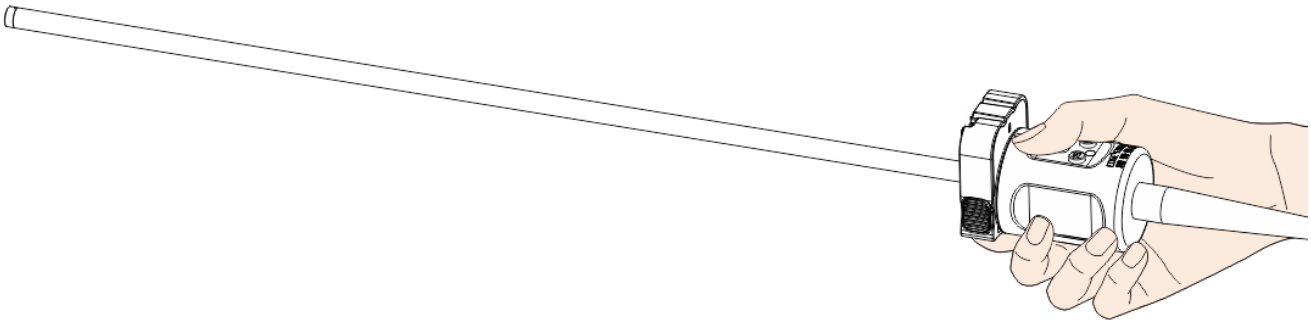


Figure 3.5 Handheld Orientation of 0° Endoscope

30° Endoscope (MP1213)

The angular field of the endoscope (MP1213) is 30°. The endoscope provides two tip orientations: upward and downward. If the base is facing down, the image is displayed upside-down.

- Hold the endoscope with the base and buttons facing up, the 30° tip orientated downward, with the hash mark on the base aligned with the 30° down marking on the housing.

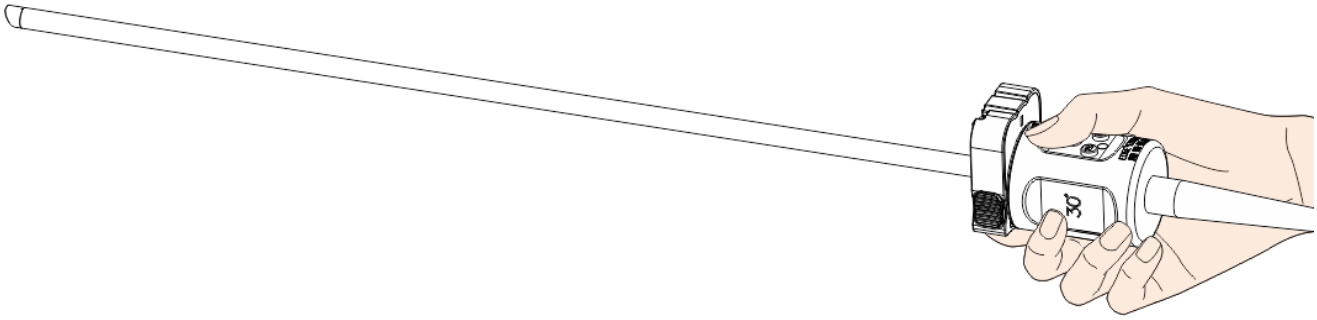


Figure 3.6 Down Orientation of 30° Endoscope

- Hold the endoscope with the base and buttons facing down, the 30° tip orientated upward, with the hash mark on the base aligned with the 30° up marking on the housing.

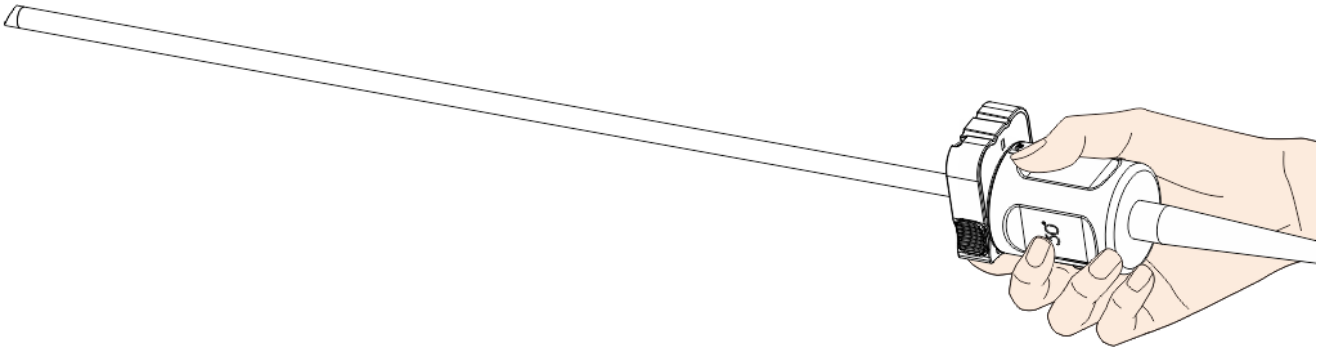


Figure 3.7 Up Orientation of 30° Endoscope

3.5 Endoscope Installation

Warning: Do not look into the light at the tip of the endoscope or Endoscope Illuminator when the illumination is on, and do not point the tip toward other people's eyes. As with any bright light, permanent eye injury can result.

Warning: Ensure the endoscope cable is properly managed according to 3.7 Endoscope Cable Management. Failing to do so could lead to patient harm resulting from inadvertent movement of the endoscope or loss of endoscope visualization.

1. Confirm the orientation.
   - Install 0° endoscope with the buttons facing the instrument arm.
   - Install 30° endoscope with the buttons facing the instrument arm for the down orientation, and the buttons facing away from the instrument arm for the up orientation.

2. Hold the endoscope base, and place the cable between the endoscope shaft and the instrument arm and the hash mark against the inside of the instrument arm.
3. Insert the endoscope tip into the cannula and press the endoscope base into the adaptor of the instrument arm.

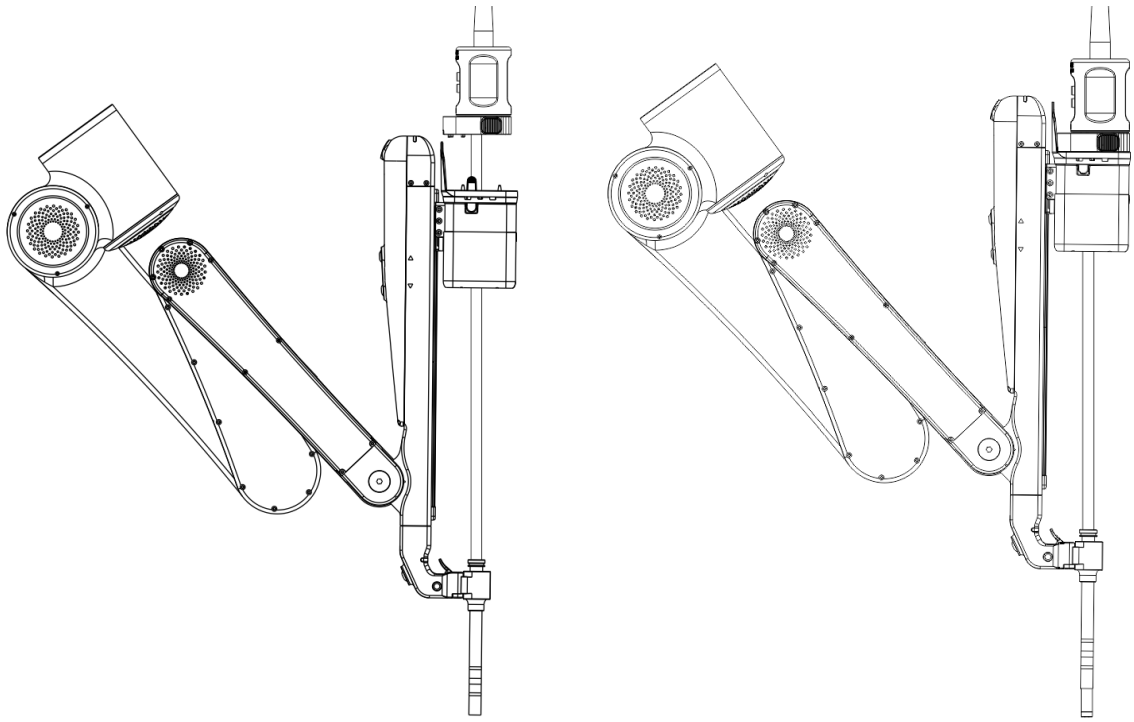


Figure 3.8 Insert the Endoscope into the Cannula and Adaptor

4. After the endoscope is installed on the instrument arm, the system will identify endoscope information, which can be displayed on the system.
5. Use the **Instrument Clutch** button on the instrument arm to manually advance the endoscope. Position the endoscope to view the operative field and the target anatomy.

3.6 Endoscope Removal and Replacement

Remove the endoscope from the instrument arm by squeezing both **Release** buttons on the endoscope base and pulling the endoscope up and away from the instrument arm.

If the endoscope needs to be replaced during the procedure, do as follows:

1. Remove the endoscope:
   a. Squeeze both **Release** buttons on the endoscope base.
   b. Pull the endoscope up and away from the instrument arm.
   c. Put the endoscope on a sterile table.
   d. Unplug the endoscope cable from the Camera Control Unit.

2. Install a new endoscope:

   a. Connect the endoscope cable to the Camera Control Unit.

   b. Attach the endoscope to the instrument arm. See 3.5.

Note: When the endoscope is re-installed or replaced, the memory function may be activated automatically. At this time, the LED indicator of the instrument arm flashes green, indicating the endoscope can be advanced into memory position.

Note: In order to prevent tissue hardening and deposits caused by high temperature, wipe the tip and lens immediately after removing the endoscope from the instrument arm.

Warning: To avoid burns or flammation, always turn off the Endoscope Illuminator when removing the light guide bundles, replacing or stopping using the endoscope. Do not allow high-temperature parts of the endoscope to come into contact with the operator, patient, drapes or flammable materials without turning off the Endoscope Illuminator.

3.7 Endoscope Cable Management

For improving cable management throughout the procedure, place the cable between the endoscope shaft and the arm before inserting the endoscope into the cannula. This minimizes the length of cable that is free to swing around during the procedure. Do not hang the endoscope cable over the arm as it may get caught or damaged and limit the motion range of the arm.

Caution: There is pulling and swinging of the endoscope cable, which may cause abnormal image display or even cable damage if the condition is serious.

Caution: Handle the endoscope cable carefully. If severe bending or kinking occurs, especially at the connectors and handles at each end of the cable, the cable may be damaged.

4. Endoscope Use

4.1 Operation Guidelines

- To avoid permanent eye injury, observe the following cautions:
  - Do not look directly at the emitting light when the endoscope is connected to the system.
  - Do not use an optical instrument (magnifying glass or similar) to examine the optical fibers at the tip of the endoscope when the endoscope is connected.
  - Adjustments, settings and maintenance other than those specified and allowed herein and on the specification label and in the user manual may result in eye injury.
  - Do not attempt to perform any repair or maintenance on any of the optical components in the system.
- In order to avoid excessive heating of the cannula, do not leave the endoscope tip inside the cannula for a prolonged period while the Endoscope Illuminator is on.
- Ensure the vision system can provide the ability of adequate visualization to complete operative tasks safely.
- Avoid excessively long and continuous direct tissue contact with the shaft during procedures, which may cause permanent tissue injury or burns.
- Be careful with the light guide bundles. Serious bends or kinks can damage the internal optical materials and increase the transmission loss of fiber.
- Take care to avoid sharply bending or kinking the cable, as it can damage the cable. Do not step on the cable, since this can damage it.
- The endoscope is delicate and can be broken if dropped or struck. Adhere to the sterilization, inspection, and connection requirements.
- Prior to each procedure, the endoscope should be cleaned and sterilized, and only can be used by personnel in sterile field. Refer to the Fluorescence Endoscopes Reprocessing Instructions Manual for detailed instructions.
- Reattach the connector cover to the connector when the endoscope cable is not in use or before reprocessing the endoscope. Failure to secure the connector cover during reprocessing may result in endoscope damage.

4.2 Feature Settings

After the endoscope is installed on the system properly, the image, display and fluorescence parameters can be set via the touchscreen of the Surgeon Console.

For the instructions of feature settings, see the Endoscopic Instrument Control System User Manual.

4.3 Live Image and Orientation

Each time an endoscope is installed, and after changing visualization modes or settings during a procedure, view the screen to confirm live image and desired orientation. Adjust 30° endoscope upward and downward orientation by the Surgeon Console if necessary.

4.4 3D Calibration and White Balance

Warning: Be careful when performing the white balance. Direct eye exposure to emitted light can cause permanent eye injury.

Warning: Do not touch the distal end of the endoscope after performing the white balance because continued illumination will cause the distal end to become hot and could cause burns.

Note: Failure to follow the instructions below on performing the white balance can cause incorrect image color.

The endoscope is calibrated at the factory. Usually no special treatment is required.

Before each surgical procedure, it is necessary to perform white balance to adjust the perception of white and the ability to display colors properly. Follow the steps to perform white balance:

1. Turn illumination on.
2. Point the tip of the endoscope at any clean white surface (such as white gauze).
3. Press the button on the Camera Control Unit.

White balance can be also set on the touchscreen of the Surgeon Console. For details, see the Endoscopic Instrument Control System User Manual.

4.5 Take Photo

Press the button on the housing of the endoscope, images can be captured from the endoscopic view. The system can save the images to a specified USB flash drive which is connected to the Camera Control Unit. The system records the left or right image based on which image is currently displayed on the touchscreen.

Note: Use the USB flash drive specified or allowed by the company. Otherwise, the system may be unable to identify it.

4.6 Left-Right Eye Swap

Press the button on the housing of the endoscope. Then the endoscope can swap the left or right eye video image displayed on the monitor.

4.7 Illumination

Press the button on the housing of the endoscope to turn illumination on or off.

- When near-infrared imaging is activated and only the fluorescence endoscope is removed from the instrument arm, press the button to turn off near-infrared light or turn on/off visible light.
- When visible light imaging is activated with the near-infrared imaging inactivated, regardless of removal of the fluorescence endoscope from the instrument arm, press the button to turn on/off visible light.

After turning off illumination, press the button again to turn on illumination and activate visible light imaging. Instead of being activated by the button, near-infrared imaging can only be turned on and activated by the Surgeon Console.

4.8 Imaging Toggling

Users can toggle between visible light and near-infrared light imaging at the Surgeon Console or Endoscope Illuminator for the fluorescence endoscope.

For more instructions, see the Endoscopic Instrument Control System User Manual and Endoscope Illuminator User Manual.

Warning: To minimize exposure to laser energy that could result in injury to operator or patient, deactivate fluorescence imaging when removing the endoscope from the patient.

Note: Before delivering the ICG into the patient, locate the target anatomy in visible light mode and then activate fluorescence imaging.

4.9 Endoscope Fogging and Cleaning

4.9.1 Endoscope Fogging

Caution: When the endoscope is connected to the Endoscope Illuminator, do not use methods that heat the endoscope for a long time, which may cause overheating and damage to the endoscope.

When the endoscope tip is inserted into the body, the lens may fog up due to temperature difference between inside and outside the body, thus affecting the surgical filed of endoscope view. The electronics in the distal tip of the endoscope generate heat, which reduces fogging to a large extent.

The following methods can be used to prevent fogging before a procedure:

- Clean any residual detergent solution.
- When the endoscope is outside the patient and waiting to be used, it can be placed in an endoscope warming device (the temperature inside less than 55℃).
- Apply antifogging agent evenly to the endoscope tip.

If endoscope fogging appears during a procedure, it needs to remove the endoscope and carefully wipe the tip and lens with moistened sterile gauze. If necessary, briefly (less than 15 seconds) submerge the tip of the endoscope in sterilized water for injection (the temperature is less than 55℃) and dry with sterile gauze.

4.9.2 Endoscope Cleaning

If endoscope contamination appears during a procedure, it needs to remove the endoscope and carefully wipe the tip and lens with moistened sterile gauze. The following methods can be used to confirm cleanliness:

- Point the tip of the endoscope at an adjacent object, and the image is viewed through the monitor to confirm whether it is clearly visible.
- Turn off illumination, observe the tip directly to confirm cleanliness, and then turn the illumination back on.

5. Maintenance, Storage and Disposal

5.1 Maintenance

Warning: The endoscope does not contain any user-serviceable parts. Do not disassemble, modify, or attempt to repair it; patient or operator injury and/or device damage may result.

Note: Repairs and equipment modifications shall be performed only by Edge Medical or by persons authorized by Edge Medical.

To maximize the lifetime of the endoscope, perform proper routine maintenance or service as following:

- Avoid tightly looping, sharply bending or kinking the cables during storage or use.
- When connecting cables, make sure that the connectors are completely dry and free of any debris. If needed, use a clean low-lint cloth to dry off any residual moisture or residue before using.
- Do not lift the endoscope directly by cable.
- Place the endoscope properly to avoid potential collisions with other objects and reduce the risk of contamination and damage.
- Handle with care to avoid mechanical shock or stress on the endoscope.
- Do not touch the tip of the endoscope and avoid the tip colliding with other objects. Otherwise, roughness or damage may cause blurred images.
- Before and after each use, inspect the endoscope for damage or abnormalities. Do not use an endoscope if it has visible damage or abnormalities.
- Do not handle or maintain the endoscope when in use.
- Regularly inspect the lifetime of the endoscope, and replace it once it runs out of the lifetime.
- Endoscope maintenance is necessary and should be performed by authorized personnel at least once every 6 months.

5.2 Storage and Transport

- To prevent endoscope damage during transportation, take appropriate measures to protect the endoscope (for example: place the endoscope in a special container).
- Place entire endoscope in position in the appropriate container, avoiding tip or lens damage.

- When transportation, make sure to place the endoscope properly and handle with care. Protect the endoscope from being cracked by heavy load, being scratched by hard objects, and being exposed to direct sunlight or water. Do not transport with volatile solvent or corrosive materials.
- Transport and storage conditions:
  - Temperature: -20℃ ~ 55℃
  - Relative humidity: Transport 5% ~ 93%, storage 10% ~ 85%, non-condensing
  - Atmospheric pressure: 700 hPa ~ 1060 hPa

5.3 Disposal

When the reusable endoscope expires, it cannot be used any more.

Expired endoscopes must be properly disposed of following all applicable national and local laws and guidelines. Contact your local Edge Medical representative for disposal information.

Warning: The endoscope must be disposed of as hazardous biological waste.

Caution: Before disposing of damaged endoscope or components, be careful of possible sharp edges that may cause scratches.

6. Reprocessing

For complete reprocessing information, refer to the Fluorescence Endoscopes Reprocessing Instructions Manual. The endoscope is shipped non-sterile and should be cleaned and sterilized thoroughly before first use and after every use.

6.1 Reprocessing Workflow

Operating Room

1. Remove Accessories
2. Clean Connector and Cover
3. Wipe
4. Pre-cleaning and Wet
5. Pack Tray
6. Transport

Decontamination Area

1. Inspection
2. Rinse
3. Prepare Multi-enzymatic Cleaner
4. Soak
5. Manually Brush
6. Spray with Pressurized Water
7. Automated Cleaning
8. Dry
9. Transfer

Inspection, Packing and Sterilization Area

1. Final Inspection
2. Pack Tray
3. Wrap Tray
4. Sterilization

Store Area

1. Sterilized Storage

Note: If the “Pre-cleaning and Wet” step in the operating room is not possible within 60 minutes, start cleaning in the decontamination area within 60 minutes.

Caution: If the endoscope is equipped with a connector cover, confirm that the connector cover is secured to the connector before reprocessing. Failure to follow the instruction may result in liquids leakage and endoscope damage.

6.2 Sterilization Method and Parameter

The fluorescence endoscope is sterilized by pre-vacuum steam sterilization.

Validated Steam Sterilizer	
Manufacturer	**Model**
STERIS	AMSCO Century

Parameters	
Temperature and exposure time	134℃, for 3 minutes
Dry time	30 minutes Based on the packing system, steam quality, load capacity of the sterilizer and environment conditions, the dry time may be different, 30 minutes recommended by the company. Dry time should be determined according to hospital policy.

Warning: Only sterilization machines, methods, parameters and cycles verified by the company can be used, and follow instructions in entirety. Unverified sterilization machines, sterilization methods (such as chemical sterilization), parameters (such as too high or too low sterilization temperature) or cycles may cause damage or incomplete sterilization.

Caution: Following steam sterilization, allow all parts to cool to room temperature. Sudden changes in temperature may damage the parts.

Note: Dry time depends on the packing materials and load capacity of the sterilizer.

Note: Please refer to sterilization system manufacturers' instructions for proper use of the system and recommendations for sterilization.

7. Troubleshooting

Fault	Possible Cause	Solution
Image too bright or dark	The glass surfaces on the endoscope are smudged or soiled.	Clean the glass surfaces after removing the endoscope and turning off the illumination.
	The image brightness set too high or low.	Set image brightness at the system.
Image flickering	Flickering happens during cautery	Keep away from or replace high frequency equipment, and restart the system.
Image blurring	The glass surfaces on the endoscope are smudged or soiled.	Clean the glass surfaces after removing the endoscope and turning off the illumination.
	The image is zoomed out too much.	Set digital zoom at the system.
Color cast	The system needs white balancing manually.	Perform manual white balance. See 4.4 3D Calibration and White Balance.
3D images displayed improperly	The system needs manual 3D calibration.	Perform manual 3D calibration by technical support.
No image	No illumination.	Connect the endoscope to the Endoscope Illuminator.
	The endoscope cable connector or the matching receptacle of the Camera Control Unit has dirt or moisture.	Clean the connector and the matching receptacle after disconnecting the endoscope cable.
No or weak fluorescence image in the expected time after ICG injection	Clinical factors related to ICG dosage and administration.	Use ICG properly according to the manufacturer’s instructions while in combination with clinically relevant information.

Fault	Possible Cause	Solution
	The fluorescence intensity needs adjustment.	Adjust fluorescence intensity at the system.
No light is emitted from the endoscope when it is connected to the Endoscope Illuminator	The light guide bundles is not connected properly.	Connect the light guide bundles to its matching receptacle and confirm that the endoscope and the Endoscope Illuminator are connected correctly.
Surgical image appears dark or there are too many image artifacts	The administration of ICG is inadequate or is completed incorrectly.	Confirm that the administration of ICG is completed correctly.

Note: If the above solutions cannot clear the faults, the endoscope may be damaged. The system is equipped with backup endoscope for replacement. If any fault still exists after endoscope replacement, contact the company for technical support.

Warning: Do not use the endoscope if any part of the vision equipment is damaged. Failure to follow the warning may cause injury to the operator or patient.

Appendix A Product Specifications

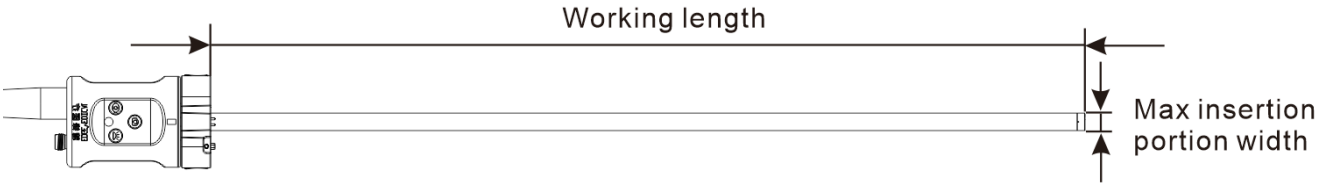
A.1 Environmental Specifications

Operating Conditions	
Temperature	10℃～40℃
Relative humidity	30%～75%, non-condensing
Atmospheric pressure	700 hPa～1060 hPa
Storage and Transport Conditions	
Temperature	-20℃～55℃
Relative humidity	● Transport: 5%～93%, non-condensing ● Storage: 10%～85%, non-condensing
Atmospheric pressure	700 hPa～1060 hPa

A.2 Electrical Safety Classification

- Type of protection against electric shock: Not applicable
- Degree of protection against electric shock: BF applied part
- Ingress protection: IPX7
- Safety classification when using in environments with flammable anesthetic mixture of air, oxygen and/or nitrous oxide: Not applicable
- Mode of operation: Continuous
- Power supply and operating frequency: Intended to be connected with Camera Control Unit.
- Power input: Not applicable
- No defibrillation-proof applied part
- Equipped with signal output or input part
- Non-permanently installed equipment

A.3 Dimensions



Product	Model Number	Max Insertion Portion Width	Working Length (Tolerance ±3%)	Weight
Fluorescence endoscope	MP1212	≤10.5 mm	500 mm	Approx. 855 g
Fluorescence endoscope	MP1213	≤10.5 mm	500 mm	Approx. 855 g

A.4 Optical and Illumination Properties

Parameter	Value
View field (2 W)	80°, tolerance ±15%
View direction	MP1212: 0°, tolerance ±3°
	MP1213: 30°, tolerance ±3°
IL_{eR}(Relative self-effect of illumination light luminosity)	At the working distance of 5 cm, the nominal value of IL_{eR} at 90% of view field is 0.56, and the measured value is not less than the nominal value
Brightness response characteristic	The linear fitting coefficient of EOTF (Electro-optical Transfer Function) is not less than 0.98
Signal-to-noise ratio	50 dB, tolerance -20%, no upper limit
SFR (Spatial frequency response)	At the working distance of 5cm, the corresponding objective spatial angular frequency is 3.0 C/(°) and 4.0 C/(°) when the SFR is 50% and 30%, tolerance -20%, no upper limit
Static image tolerance	180, tolerance -20%, no upper limit
Effective luminosity rate	The image surface of the endoscope displays that the minimum surface brightness of critical noticeable grayscale difference is 30 cd/m^2

Parameter	Value
Image resolution (frames per second)	No less than 60 fps
Color rendering index	No less than 70
Correlated color temperature	In the range of 5000 K～7000 K
Radiation flux ratio of red, green and blue light	Based on the green radiation flux φ_{eg} in the wavelength range of 515 nm～545 nm, the ratio of the red radiation flux φ_{er} and φ_{eg} in the wavelength range of 630 nm～660 nm is 0.35, tolerance ±20% And the nominal value of the ratio of the blue radiation flux φ_{eb} and φ_{eg} in the wavelength range of 435 nm～465 nm is 1.70, tolerance ±20%
Infrared cut properties	The ratio of radiation and luminous flux in the wavelength range of 300 nm～1700 nm is not more than 6 mW/lm
Radiation properties	The nominal value of total luminous flux is 12 lm，tolerance -10%, no upper limit
Lux	No less than 4500 lx

Appendix B Electromagnetic Compatibility

The fluorescence endoscope was tested according to the recommendations of Technical Report IEC TR 60601-4-2: Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

Note:

- The customer or the user should use the endoscope in the electromagnetic environment as specified in Tables B.2, B.3, B.4, and B.5, otherwise the endoscope may not work properly.
- Portable and mobile RF communications equipment may affect the use of the endoscope, so the endoscope should be used in the recommended electromagnetic environment.
- The system is suitable for professional healthcare facility environment (such as hospital).
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Warning:

- Due to the intended purpose in the electromagnetic environment, the endoscope is Class A equipment. The endoscope cannot provide sufficient protection for radio communications when the equipment is operated in a residential area.
- Except the accessories and cables provided by the company (see the table below for details), the use of unspecified accessories and cables can lead to an increase in radiated emissions or a decrease in immunity of the endoscope.
- The fluorescence endoscope should not be used adjacent to or stacked with other equipment. However, if adjacent or stacked use is necessary, the endoscope should be observed to verify normal operation in the configuration in which it is used.
- Don’t near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The system is not life-supporting equipment of CISPR 11 Group 1 Class A.

The essential performance for the system is defined as follows: Endoscopic real-time image can be transmitted normally.

Table B.1 Table of Cables

No.	Cable Name	Cable Length	Shield	Note
1	Endoscope cable	5.0 m	Yes	Used for the connection of the endoscope and the Camera Control Unit.

Table B.2 Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Guidance and Manufacturer's Declaration - Electromagnetic Emissions	
Emissions Test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Not Applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable

Table B.3 Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV power supply lines ±1 kV signal input/output 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle	0 % UT; 0.5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz/60 Hz	30 A/m 50 Hz/60 Hz
Conducted RF IEC61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
NOTE: UT is the AC mains voltage prior to application of the test level.		

Table B.4 Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Guidance and Manufacturer's Declaration - Electromagnetic Immunity						
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to	**Test Frequency** (MHz)	**Band** (MHz)	**Service**	**Modulation**	**IEC 60601-1-2 Test Level** (V/m)	**Compliance Level** (V/m)

Guidance and Manufacturer's Declaration - Electromagnetic Immunity						
RF wireless communications equipment)	385	380 – 390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	9	9
	745					
	780					
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28
	870					
	930					
	1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28	28
	1845					
	1970					
	2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
	5500					
	5785					

Table B.5 Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity				
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	**Test Frequency**	**Modulation**	**IEC 60601-1-2 Test Level** (A/m)	**Compliance Level** (A/m)
	30 kHz	CW	8	Not applicable

Guidance and Manufacturer's Declaration – Electromagnetic Immunity				
	134.2 kHz	Pulse modulation 2.1 kHz	65	65
	13.56 MHz	Pulse modulation 50 kHz	7.5	7.5

Appendix C Glossary

Term	Meaning
3D	Three-dimensional.
AC	Alternating Current, also represented by the AC symbol ～.
BF	An IEC 60601-1 classification for patient applied parts, which is protectively earthed, connected to earth but not protectively earthed, or floating but not isolated from earth to the degree that would be required for a type BF applied part, but is not suitable for direct cardiac application.
HD	High Definition.
ICG	Indocyanine Green. A cyanine dye is used for near-infrared imaging in medical diagnostics
Laser Aperture	A symbol is used for orientation only, indicating the direction of laser emission when using with Endoscope Illuminator.
LED	Light Emitting Diode. A light-emitting diode is a semiconductor device that emits light when current flows through it.
ME	Medical Electrical Equipment.
SFR	Spatial frequency response.
Target anatomy	The center of the surgical workspace boundary.
USB	Universal Serial Bus. An industry standard that specifies the physical interfaces and protocols for connecting, data transferring and powering of hosts.

Shenzhen Edge Medical Co., Ltd.
Manufacturer Address: 2B 1901, Phase II, Smart Home, No.76, Baohe Avenue, Baolong Community, Baolong Street, Longgang District, 518116, Shenzhen, P.R.China
Manufacturer Site Address: 2B 0401, 1901, 2001, 2101, Phase II, Smart Home, No.76, Baohe Avenue, Baolong Community, Baolong Street, Longgang District, 518116, Shenzhen, P.R.China
E-Mail: contact@edgemed.cn
Web: www.edgemedicalrobotics.com

EC REP
Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
E-Mail: shholding@hotmail.com

CE 0123