SafeLM™ Videoscope

(models : A8, B8)

Instruction For Use

Changsha Magill Medical Technology Co. Ltd.

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Descriptions for Symbols on Product Labels

	Universal Serial Bus (USB) Port
	Serial Number
	Date of Manufacture
	Manufacturer
	Type BF Applied Part
	Consult Instruction For Use
	Refer to instruction manual/ booklet
	Caution: Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Advice and explanation regarding use of the device.
	Separate Collection for Waste of Electrical and Electronic Equipment.
	Fragile, Handle with Care
	Keep Dry
	Temperature Limit
	Humidity Limitation
	Atmosphere Pressure Limitation
UDI	Unique Device Identifier
EU REP	Authorized representative in the European Union
CE	CE mark
	Keep Away from Sunlight
	This Way Up
	Stacking limit by number:5

Warning and Cautionary Notice

- SafeLM™ Videoscope shall only be operated by trained and certificated health care personnel.
- Avoid injecting or allowing any foreign body entering the video channel of the SafeLM™ Disposable Video Laryngeal Mask, image quality may be affected by contamination.
- This device is not designed to be waterproof, DO NOT flush or soak in liquid.
- This device shall be handled and store with care. Avoid the device from been dropped, crashed, under strong vibration, or sustaining other mechanical force.
- DO NOT fold or apply excessive force to the video soft tube of the videoscope as it may cause damage to it.
- DO NOT insert the SafeLM™ Videoscope alone into the patient's body cavity WITHOUT being assembled to a SafeLM™ Disposable Video Laryngeal Mask.
- DO NOT forcefully bend the support stand on the back of the Displayer.
- DO NOT modify the name of folders or files stored in SafeLM™ Videoscope when connected PC.
- DO NOT manually fold or rotate the Flexible Tip of the videoscope .
- DO NOT attempt to disassemble this device without written authorization from Magill Medical.
- It is recommended to charge the device in the environment temperature range of 0 to 45℃. Charging the device in environment beyond abovementioned temperature may impair battery performance.
- ONLY assemble SafeLM™ Videoscope model with its compatible SafeLM™ Disposable Video Laryngeal Mask model listed later in this manual. Mismatching will result in the devices fail to assemble and may cause damage to the videoscope or laryngeal mask, and delay in treatment.
- Check each component of SafeLM™ Videoscope and verify they are functioning properly before initial and every use of the device. If any sign of damage is found, remove the device from clinical use and contact local dealers for support.
- Before insertion, check to make sure video image on the display screen is real-time video with correct orientation, NOT replay of recorded video.
- In case of illumination system LED malfunctioned, the videoscope must be returned to manufacturer for component replacement. Model of LED: XM-L2.
- When storing SafeLM™ Videoscope after use, make sure the insertion tube part of the videoscope is naturally straight and NOT twisted forcefully.
- The Videoscope is designed with a mechanical limit in view angle adjustment. Do not forcefully move the angulation handle beyond its range of rotation.
- Under environment with high brightness, contents on the display screen may become difficult to observe and less recognizable to the operator. Avoid operating the videoscope under strong ambient light.

- The SafeLM™ Videoscope has NOT yet been tested to operate in environment with the presence of air, oxygen, nitrous oxide or other flammable anesthetics or mixed vapor or gas containing flammable anesthetics.Therefore, use of flammable anesthetics while in the presence of this device should be restricted.
- The SafeLM™ Videoscope is NOT compatible with environment with the presence of strong magnetic field, such as operating with Magnetic Resonance Imaging (MRI). Therefore, use of this device under such environment should be restricted.
- DO NOT store or operate SafeLM™ Videoscope near any sensitive electronic medical system, keep it away from mobile phone or other source of radiated emission.
- At the end of its service life, this device should be recycled or discarded in accordance with regulations regarding handling of electronic medical device waste in local institute or region.
- Before each use, user should inspect the device's compatibility with other accessories or active medical devices according to relevant IFUs.
- User interface's airway images and symbols appear on figures of this Instruction for Use are for illustrative purposes only and may NOT represent image shown in actual clinical use.
- This device should only be repaired or maintained by professional service staff in case of device malfunction or needing support, please contact Magill Medical or its local dealer.
- When this product is used with other energized endotherapy devices, patient leakage currents may be additive.
- Before each use, inspect the surface of the insertion tube to ensure it has no sharpen edge, spike, rough surface, or bump that may cause damage to the patient or operator.

1 Product Description

1.1 Introduction

SafeLM™ Videoscope (also referred as 'videoscope' or 'device' in this manual) is an assistive device designed to operate in couple with Changsha Magill Medical Technology Co., Ltd. (also referred as 'Magill Medical' or 'manufacturer' in this manual) SafeLM™ Disposable Video Laryngeal Mask (also referred as 'laryngeal mask' in this manual) to allow visualization during the processes of laryngeal mask insertion and post-insertion inspection. SafeLM™ Videoscope is only a visualizing tool and does not serve for diagnostic and therapeutic purpose.

1.2 Product Model

Videoscope with model of A8 is compatible with adult size SafeLM™ Disposable Video Laryngeal Mask.

Videoscope with model of B8 is compatible with junior size SafeLM™ Disposable Video Laryngeal Mask.

The Videoscope is a reusable device.

1.3 Intended Use

SafeLM™ Videoscope is intended to be operated in combination with Magill Medical's SafeLM™ Disposable Video Laryngeal Mask, to provide real-time visual guidance during establishing artificial airway. This device should ONLY be operated by certificated health care professionals with proper training in airway management.

1.4 Intended Situation/Scenario

SafeLM™ Videoscope is a hand portable device to allow visualization during airway establishment and management under in-hospital and pre-hospital scenario. The models of A8 and B8 are specifically designed for the clinical situation where continuous observation is required after laryngeal mask insertion in extended medical procedures.

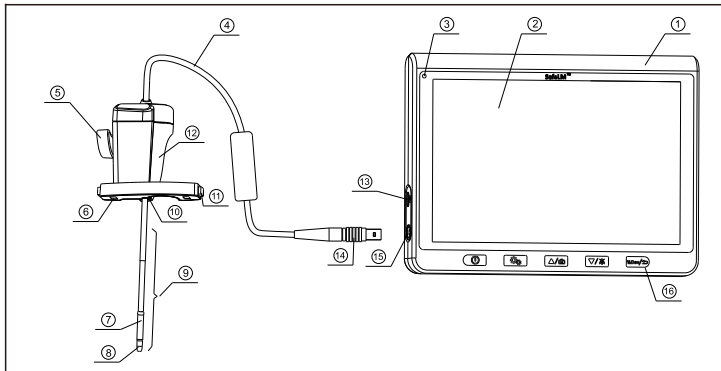
1.5 Contraindications

- Patients at high risk of regurgitation and aspiration, for instance, full stomach, pyloric or intestinal obstacle, etc.
- Patients with high airway resistance, for instance, asthma, hemoptysis, etc.
- Patients with severe oral or pharyngeal injury, or those with limited range of motion of neck due to cervical injury.
- Responsive patients with an intact gag reflex that require CPR(Cardiopulmonary Resuscitation).
- Patients require head or neck surgery where the surgeon cannot gain adequate access to operative site due to the presence of laryngeal mask.
- Patients with inadequate interdental gap to permit insertion of the device.

1.6 Structure and Working Principle

SafeLM™ Videoscope with models of A8 and B8 consist of two major parts: Displayer and Video Component. Video Component include Control Body, Insertion Tube, and Video & Power Cable. SafeLM Videoscope ships with accessories of a power adaptor and USB Type-C cable for changing and data transferring.

Movement of Videoscope's Flexible Tip and distal camera is controlled by adjusting the Angulation Hande. The Insertion Tube of the videoscope is shielded by the laryngeal mask and insulated from directly contacting patient's tissue. Light emitted from the illumination Orifice is transmitted to the cuff of laryngeal mask through Optic Fiber embedded in the Airway Tube, providing illumination for camera.



①	Displayer	⑨	Insertion Tube
②	Display Screen	⑩	Illumination Orifice
③	Charging Indicator	⑪	Release Button
④	Video & Power Cable	⑫	Control Body
⑤	Angulation Handle	⑬	USB Port (Type C)
⑥	Locking Orifice	⑭	Cable Plug
⑦	Flexible Tip	⑮	Video & Power Socket
⑧	Camera	⑯	Operating Buttons

1.7 Device Specification

According to classification of electronic medical device specified in IEC 60601-1, this device belongs to

1.Internally Powered Equipment

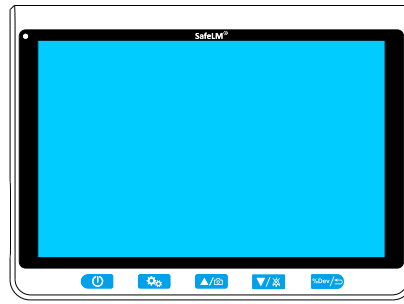
2.Externally Powered Equipment: Class II.

Type BF Applied Parts
Continuous Operation
Device Applied Part: Disposable Video Laryngeal Mask
Ingress Protection: IPX0
This is a portable hand-held device.

Technical Terms	Specifications
Camera Module	1 Megapixel
Power Consumption	≤10VA
Video Recording	Support loop recording video files
Image Capture	Support capture and storage of still images
Storage Capacity	8GB
Illumination	illumination at the distal end of optic fiber /cuff of SafeLM™ Disposable Video Laryngeal Mask＞ 500 Lux
Display Screen	8.0 inches (diagonal) IPS TFT Color Display Screen
Internal Battery	Rechargeable polymer lithium battery； ● Capacity:5000mAh ● Discharge Time >5 hours ● Charging Time > Approx. 5 hours (when the device is powered off, and using power adapter supplied by manufacturer) ● Charging Cycle >300 cycles
USB Port	USB Type-C port for accessing stored data in device and recharging its internal Lithium battery.
Power Adapter	Input: 100-240V~, 50/60Hz Output: 5V/2A
Material	● Displayer and Control Body's enclosure is composed of acrylonitrile butadiene styrene (ABS) ● Soft insertion tube's enclosure is composed of polyurethane(PU) ● Rigid Insertion Tube composed of steel. ● Flexible Tip's enclosure is composed of fluororubber.
Working Environment	Temperature: 10℃ to 40℃(50° F to 104° F) Relative Humidity：30% to 90%, no condensation Atmosphere Pressure：860hPa to 1060hPa
Weight	Approx. 0.65 kg (1.43 lb.)

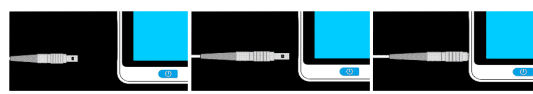
1.8 Buttons, Display Screen and Feature

1.8.1 Buttons



Button	Function
	Power Button
	Multifunction Button, functionalities include setting, confirm and switch selection.
	Increase Value/Image Capture Button
	Decrease Value/Mute Button
	Return/Activate (Deactivate) Image Deviation Comparison Button

1.8.2 Symbols on User Interface

Symbol	Description
	Start-up screen
	Prompt that Video Component is not connected. The moving plug prompt user to plug the Video Component into the Displayer. 

Symbol	Description
	Blinking *Charge Now* symbol indicate the battery capacity is too low to sustain device working. Connect Displayer to power source for charging immediately.
	Remaining battery capacity. The battery icon turns red when there is only one bar remaining for battery capacity.
	Videoscope is being charged
	Time Setting Menu
	Video Replay Menu
	Data Export Menu
	Video Replay Indicator
	Image Review Menu; Indication of Image Review Interface
	Folder Empty: No saved image or video in folder
	Image snapshot is being captured.
	File Damaged
	Input Current Password. Refer to Section 3.13
	New Password. Refer to Section 3.13
	Password Setting Menu. Refer to Section 3.13
	Password Verification, Refer to Section 3.9
%Dev	Percentage Deviation Notice Threshold Setting, Refer to Section 3.6

1.8.3 Charging Indicator

Charging Indicator is located at the upper left corner of the Display Screen.

 : Blue indicator indicates videoscope is being charged.

 : Green indicator indicates videoscope is fully charged.

2. Basic Operation of SafeLM™ Videoscope

2.1 Assembling Videoscope to Laryngeal Mask

⚠	**Warning:** • Inspect the integrity of videoscope's insertion tube before operating it. Remove the device from clinical service and contact Magill Medical or its authorized dealer if any sign of damage or wear is sighted.

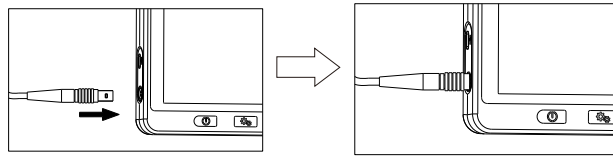
Assembling Steps:

1. The protective sheath assembled to the Videoscope shall be removed before use. To remove the sheath, hold the two Release Buttons on the Videoscope while pulling it away from the Insertion Tube.

2. Unfold the support stand of the Displayer to its rotary limit and place it on a flat surface.

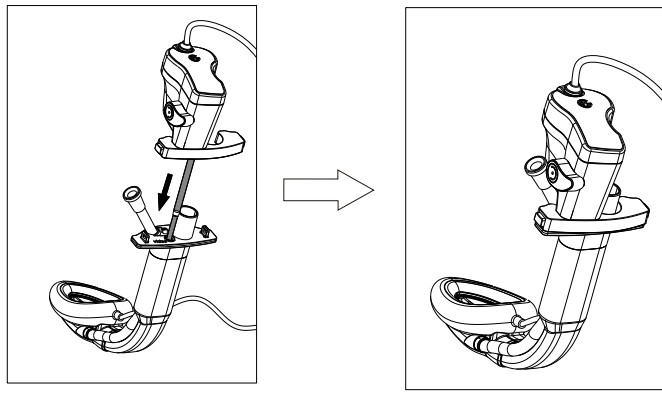
⚠	**Warning:** • To maintain stability of the device during use, the Displayer should be placed on a flat surface with its support stand rotated to maximum allowed angle. • Leaving the device on tilted or uneven surface may cause the Displayer to fall off during normal use.

3. Plug the Video Signal Connector of the Video Component into the Video & Power Socket on the Displayer, as illustrated below.



⚠	**Warning:** • Before plugging in the connector, ensure the red marker on the Cable Plug aligns with the red marker on Video & Power Socket. DO NOT force in the plug into the socket as it may damage the pins in the connector
ℹ	**Information:** • When plug and socket are aligned, push in the plug until a 'click' sound is heard, which indicates a secure assembly.

4. Hold the Insertion Tube perpendicularly to laryngeal mask's Videoscope Plain and insert a short segment of Insertion Tube into the Video Channel of the laryngeal mask. Rotate the videoscope or laryngeal mask to a correct orientation so, when fully inserted, the Ventilator Connector of laryngeal mask rests in the videoscope`s Hollow Opening on the base of Control Body. When alignment is correct, gently push the videoscope's Insertion Tube into Laryngeal Mask until videoscope's Connecting Base contacts with the laryngeal mask's Videoscope Plain. A 'click' sound indicates the videoscope is successfully fixated to the laryngeal mask.



Warning:

- Check that the videoscope model is compatible with SafeLM™ Disposable Video Laryngeal Mask model before assembling. Mismatching will result in the devices failing to assemble and may cause damage to the videoscope or laryngeal mask. Refer to section 1.2 Product Model for matching instructions.
- If excessive resistance is felt when inserting the Insertion Tube along the Video Channel of laryngeal mask, do not press in with excessive force. Pull out the videoscope and inspect the Insertion Tube or Flexible Tip for any bump or tearing. Remove the device from clinical service if any sign of damage or wear is sighted.

3. Basic Operation

After the videoscope is assembled with laryngeal mask, gently adjust the Angulation Handle to control the movement of the Flexible Tip to adjust direction of camera and observe visual field.

⚠	**Warning:** • Mechanical design has limited videoscope's range of bending. If significant physical resistance is sensed when adjusting the Angulation Handle, it may be due to Flexible Tip has reached its adjusting limit or it has been pressed against patient's anatomical structure. In this case, do not move Angulation Handle with excessive force. Instead, inspect and resolve the cause of resistance before continuing procedure.

3.1 Powering On

Press and hold the Power ⏻ Button, wait until the display screen shows the following startup screen, then release the button.

ⓘ	• The lower right corner of the interface shows the version number of distributed software.

3.2 Displaying Video

When Video Component is correctly plugged-in, video captured by camera is shown on Display Screen in real time.

⚠	**Warning:** • If prompted Video Component is not connected, please try reconnecting the Cable Plug. • After the videoscope is assembled to laryngeal mask, press Power ⏻ Button to power on the Displayer. The videoscope automatically activates illumination and starts video recording when powered on. Observe whether the video quality on display is optimal. If video appears blurry or flared and causes obstacle in normal use, ensure the Camera lens of the videoscope and distal end of laryngeal mask's Flexible Extension are not contaminated or stained. Remove the videoscope from laryngeal mask and gently wipe the camera lens with cloth that has been dipped in cleaning agent.

Information:
Real-time video is not shown when the videoscope is set to Menu Interface. Exit Menu Interface to resume displaying real-time recording.

3.3 Video Recording

The videoscope automatically light up the LED light source embedded in the Illumination Orifice when powered on. When Camera is detected, it starts video recording and display real-time video on the Display Screen.

Warning:
- DO NOT look directly into the Illumination Orifice or point it to open eyes of other personnel within proximity when the illumination is ON. Shining intense light to eyes may cause temporary flash blindness.
- Check to ensure video image on the display screen is real-time video with correct orientation, NOT replay of recorded video.
- When powered on for long duration, the temperature at the Illumination Orifice may raise above 41℃（106℉）, operator should avoid touching the Illumination Orifice.

3.4 Stopping Video Recording

Video recording is stopped when either the Power Button is pressed and hold to power off the videoscope or Multifunction Button is pressed to enter Menu Interface. Video footage recorded is automatically saved when recording is stopped.

3.5 Image Capture

When video recording is in progress, press Image Capture Button once to take an image snapshot. A Camera symbol flashes on the upper right corner of the user interface when image snapshot is captured.

3.6 Image Deviation Comparison Function

During use, when laryngeal mask dispositioning or regurgitation occur, deviation of real-time image captured by Videoscope’s camera may take place. This function assists in recognizing such deviation and provides notifying signals, thereby helping the operator to identify laryngeal mask dispositioning or regurgitation.

Information:
- This function only serves assistive and notifying purposes. Users should set parameters and take appropriate measures complying with relevant safety guidelines and regulations base on clinical needs when using this function.

3.6.1 Activating and Deactivating Image Deviation Comparison

- Ensure the laryngeal mask is positioned in patient's airway correctly and the videoscope is in working interface.
- Press Image Deviation Comparison %Dev Button to activate this function.

When Image Deviation Comparison function is activated, an initial image is displayed picture-in-picture at the upper left corner of the screen, while the rest of the screen displays real-time video. The figure displayed above the initial image is the percentage deviation of real time image from the initial image. See Figure below.

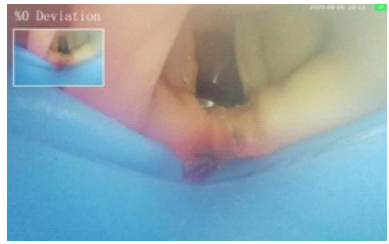


Fig 3.6.1 Image Deviation Comparison Activated

- Press Image Deviation Comparison %Dev/⮌ Button again to deactivate this function.

Information:
User should deactivate the Image Deviation Comparison function before performing following operation:
- Adjust the position of the laryngeal mask or the Videoscope's view angle.
- Remove the Videoscope from laryngeal mask.
- Remove the Videoscope with laryngeal mask from patient.

3.6.2 Parameter Setting

- In working interface, press Multifunction ⚙ Button to enter Menu Interface.
- Use ▲/📷 Button and ▼/✱ Button to switch to the Percentage Deviation Notice Threshold Setting % Dev symbol, and press Multifunction ⚙ Button to enter the Percentage Deviation Notice Threshold Setting Interface:

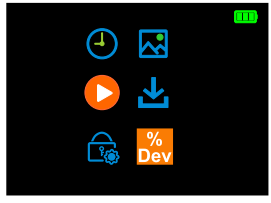


Figure. 3.6.2 Selected Percentage Deviation Notice Threshold Setting symbol

Press and release ⚙ button

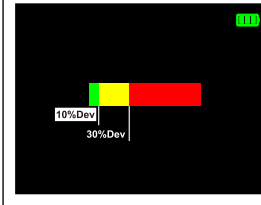


Figure. 3.6.3 Percentage Deviation Notice Threshold Setting Interface

- Use Increase Value ▲/📷 and Decrease Value ▼/✱ Buttons to adjust the threshold of percentage deviation for triggering notice, and press Multifunction ⚙ Button to switch between the setting of yellow-color and red-color notices
- After finishing setting, press Return %Dev/⮌ Buttons to return to Menu Interface.

3.6.3 Explanation on Image Deviation Notice

When the percent deviation is beyond the configured threshold value for yellow-color notice, the edge of the image display area and the percentage deviation figure will blink in yellow, accompanied by auditorial signal.

When the percentage deviation is beyond the configured threshold value for red-color notice, the edge of image display area and the percent deviation figure will blink in red , accompanied by auditorial signal.

3.6.4 Handling of Image Deviation Notice

- When the percentage deviation notice appears, users may handle it as proper clinically.
- User may also press Mute ▼/🔕 Button to temporarily mute the auditorial signal of the active notice. When muted, a Mute 🔕 symbol appears on the upper left corner of the display screen. The auditorial signal for the active notice is automatically resumed after 120 seconds. When muted, the auditorial signal can be unmuted by pressing Mute ▼/🔕 Button again.
- Users may also press Image Deviation Comparison %Dev/⇆ Button to deactivate this function directly.

3.7 Powering Off

- Press and hold Power ⏻ Button to power off the videoscope. Screen displays a power off countdown. When the display screen is darkened, release the Power ⏻ Button to complete the process.

ⓘ	• If the Power ⏻ Button is released before countdown is finished, the power off process is canceled and the videoscope returns to its previous interface.

Before storing the Videoscope, the protective sheath is recommended to be reassembled. To reassemble the sheath, insert the Videoscope's Insertion Tube into the Sheath until its latch is pushed into the Locking Orifice on the Videoscope and a 'click' sound is heard.

3.8 Assisting Procedures for Disposable Video Laryngeal Mask

As an assistive visualization device for Disposable Video Laryngeal Mask, the videoscope can be utilized for the following medical procedures with its real-time video guidance.

- Insertion and position adjustment of Disposable Video Laryngeal Mask
- Intubation through inserted laryngeal mask
- Visualization or continuous inspection of supraglottic structure and laryngeal mask positioning during procedure.

Refer to Instruction for User Manual of SafeLM™ Disposable Video Laryngeal Mask for detailed information regarding its clinical applications.

	**Information:** • If excessive resistance is felt when inserting the Insertion Tube along the video channel of laryngeal mask, do not press in with excessive force. Pull out the videoscope and inspect the Soft Insertion Tube or Flexible Tip for any bump or tearing. Remove the device from clinical service if any sign of damage or wear is sighted. • For sake of battery conservation, power off the Displayer after finish operating the device.
	**Warning:** • When removing the videoscope from laryngeal mask, do not apply any force to the Angulation Handle.

3.9 Data Storage and Export

3.9.1 Data Storage

Recorded videos and captured image snapshots are automatically saved to the internal storage of the videoscope. For video recorded, it is automatically segmented and saved as video footages. The videoscope employed loop recording method to manage files. When internal storage is full, the earliest stored images and video footages are overwritten by latest save files. Files are named according to the time at the start of recording for video footages and time the snapshoot is taken for images.

3.9.2 Data Export

Press Multifunction Button to enter Menu Interface. In Menu Interface, use Button and Button to switch to the Data Export symbol, and press Multifunction Button to enter Password Verification Interface. Data Export Interface can be displayed ONLY after providing correct preset password.

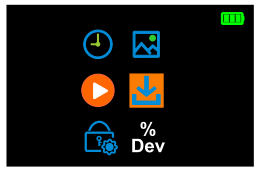


Figure. 3.9.1 Selected Data Export symbol

Press and release button

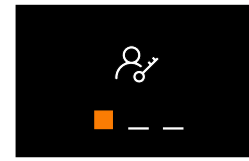


Figure 3.9.2 Provide user password

To provide password in Password Verification Interface as illustrated in Figure. 3.9.2:

- In Password Verification Interface, use Increase Value Button and Decrease Value Button to adjust value of current digit by increment of 1. Number ranges from 0 to 9.
- Press Multifunction Button to switch to next digit. Digits switch in circulation.
- When all three digits of password have been input, press Return Button once to Enter Data Export Interface.

To return from Password Verification Interface, press and hold Return Button

Figure 3.9.3 Input correct password

Press and release button

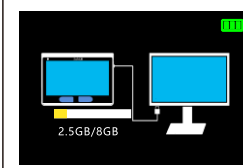


Figure 3.9.4 Data Export Interface

1. Make sure the videoscope remain in Data Export Interface when connected to PC via a USB Type-C Cable.
2. On PC, visit the disk volume named *MGL*.
3. Two folders, named *photo* and *video,* exist in M*GL* directory, where corresponding file types are separately stored.
4. Copy, paste, cut, or delete files in these folders as needed.
5. After finish accessing data stored in the device, eject the device's disk volume from PC. Then unplug the USB Type-C Cable.
6. On the videoscope, press Return Button from Data Export Interface to return to previous interface.

⚠	**Warning:** • Data Export Interface also display storage usage in x GB/y GB, where x is used storage space and y is total storage space. • There is still a small amount of storage space occupied for system files despite image or video folders is empty. • Make sure the data transport is not in progress and file in the videoscope is not in use before disconnecting the videoscope from PC. When finished, Right click on the Disk Volume named *MGL*, then select eject the device.
ⓘ	**Information:** • For convenience of use, remove the Video Component from Displayer when connecting it to PC. • The factory default password combination is *111* as illustrated in Figure 3.9.3. User should input user-designated password in this interface. Refer to *section 3.13* for setting password.

3.10 System Time Setting

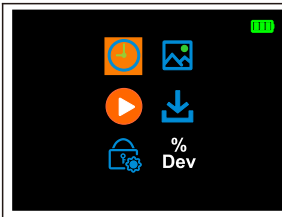


Figure 3.10.1 Selected System Time Setting Menu

Press and release button

Figure 3.10.2 System Time Setting Interface

1. Press Multifunction Button to enter Menu Interface. In Menu Interface, use ▲/📷 Button and ▼/✱ Button to switch to the Time Setting Menu symbol, and press Multifunction Button to enter Password Verification Interface.
2. Press Multifunction Button once to switch between time digits.
3. Use Increase Value ▲/📷 and Decrease Value ▼/✱ Buttons to adjust time.
4. After finish setting, press Return %Dev/⮌ Button to save set time and return to Menu Interface.

⚠	**Warning:** • Press and hold Return %Dev/⮌ Button to return to Menu Interface WITHOUT saving system time change.
ⓘ	**Information:** • Range of year setting:2000-2099

3.11 Video Replay

1. Press Multifunction Button to enter Menu Interface. In Menu Interface, use ▲/📷 Button and ▼/✂ Button to switch to the Video Replay Menu symbol, and press Multifunction Button to enter Video Replay Interface's list of saved video footages.

Figure 3.11.1 Selected Video Replay symbol

Press and release button

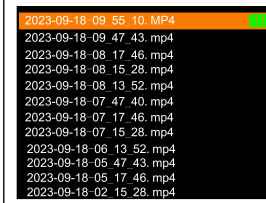
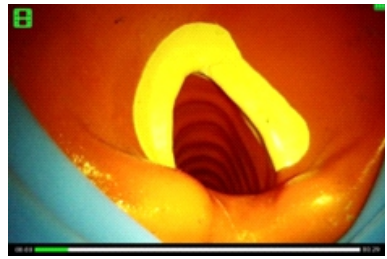


Figure 3.11.2 List of saved video footages

2. Use ▲/📷 Button and ▼/✂ Button to move between video footages, press Return %Dev/⮌ to return to Menu Interface.
3. Press Multifunction Button to view video, as illustrated below.



4. Press Return %Dev/⮌ Button to return to list of saved videos.

Warning:

- User should distinguish replay of recorded video footage from real-time video.

3.12 Image Review

1. Press Multifunction Button to enter Menu Interface. In Menu Interface, use ▲/ Button and ▼/ Button to switch to the Image Review symbol, and press Multifunction Button to enter Image Review Interface's list of saved captured images.

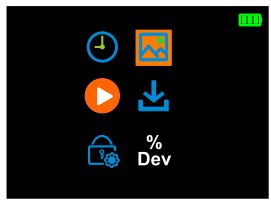


Figure 3.12.1 Selected Image Review symbol

Press and release button

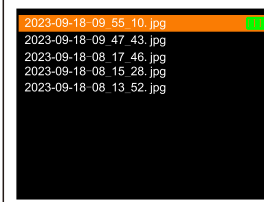
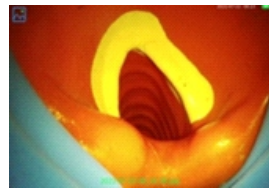


Figure 3.12.2 List of saved images

2. Use ▲/ Button and ▼/ Button to move between captured images, press Return %Dev/ to return to Menu Interface.
3. Press Multifunction Button to view captured images, as illustrated below.



4. Press Return %Dev/ Button to return to list of captured images.

3.13 Data Export Password Setting

A password is required to enter Data Export Interface, user may change this password as needed.

- **3.13.1 Interface**

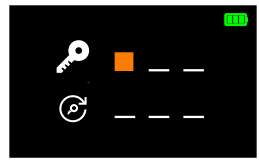


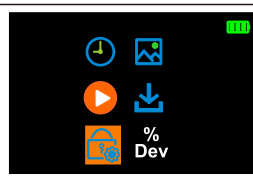
Figure 3.13.1 Password Setting Interface

: Current Password: Before password changing password, user should verify current password by inputting it on this line.

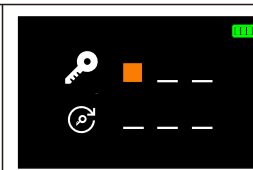
: New Password: Input desired new password on this line.

- **3.13.2 Password Setting Steps**

Enter Password Setting Interface

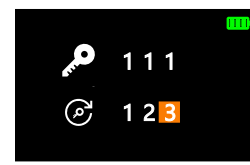


Press and release button



Setting Password:

1. Use Increase Value ▲/📷 and Decrease Value ▼/✱ Buttons to adjust the current digit by increment of 1 for each press.
2. Press and release the Multifunction ⚙ Button to switch to the next digit of the password, digits switch in circulation.
3. After desired password is inputted, press Return %Dev/⮌ Button to return to save new password and return to Menu Interface.
4. Press and hold Return %Dev/⮌ Button to return to Menu Interface WITHOUT saving password change.



- **3.13.3 Forgotten Password**

In case of password is forgotten, please contact Magill Medical or its local dealer.

- **3.13.4 Incorrect Password Prompt**

When current password inputted is wrong, new password cannot be saved as illustrated in figure3.13.3 below.

Figure 3.13.3 Incorrect Password Prompt

	• The factory default password combination is *111*. • Current Password illustrated in 3.13.2 is the factory default password. If user has set a new password, the user-set password should be inputted before setting a new password.

3.14 PEMS (Programmable Electrical Medical Systems) Intended to be Incorporated into an IT-Network

3.14.1 Purpose of the PEMS connection to an IT-Network

The purpose of the PEMS connection to an IT-Network is to update device software and access recorded video and image files stored in the videoscope.

3.14.2 Required Characteristics of the IT-Network Incorporating the PEMS

Desktop and laptop computer

3.14.3 The Required Configuration of the IT-Network Incorporating the PEMS

Connecting port supporting USB 2.0 with corresponding driver.

Hard Disk:80 GB

RAM:4 GB

Operating System: Windows XP or later

3.14.4 The Technical Specifications of the PEMS- Incorporated Network

Video and image data Transported though PEMS and IT network does not contain private personal data of patient or operator.

3.14.5 The Information Stream between PEMS, IT Network and Other IT Network Incorporating Equipment, and Their Expected Routes

To access stored recordings and images in videoscope user needs to connect it to desktop or laptop computer via compatible USB cable, and pass password authentication。

3.14.6 Hazardous Situation in IT-Network Failure

- IT Network's USB port that is damaged or insufficiently powered may lead to operator unable to access video and image data stored in the videoscope.

⚠	**Warning:** • Connecting the PEMS with IT-Network containing other devices may introduce additional unrecognized risks to the patients, operators or other third parties. • Operator should recognize, analyze, evaluate, and control these risks.

Further modification to IT Network may introduce new risk, which include:

Modification	Potentially Introduced Risk
Changes of IT network configuration	USB Port incompatible
New device incorporated in IT Network Connection	Cause existing USB port insufficiently powered
Devices incorporated in IT network is disconnected	Cause instability of IT Network or system crash
Devices incorporated in IT network is updated	Introduces bugs to the system
Devices incorporated in IT network is upgraded	Cause software compatibility issues between devices

4. Power Supply for the Videoscope

SafeLM™ Videoscope can be powered by internal rechargeable lithium battery and external power adaptor.

When the videoscope is working on internal battery, remaining battery capacity is indicated by the symbol on the upper right corner of the user interface.

: Three bars battery symbol indicates battery capacity is full.

: Two bars battery symbol indicates partial of the videoscope's battery has been drained. When this symbol is shown, remaining battery capacity can support working for at least 30 minutes.

: One bar battery symbol is blinking in red indicates battery capacity is running low.

When battery capacity is too low to sustain expected functions, the screen displays a blinking *Charge Now* symbol (see below). When this symbol is shown, the user should connect the videoscope to power supply for charging intermediately. If the videoscope is not connected to power supply when this symbol is displayed, the videoscope will automatically power off after 3 minutes.

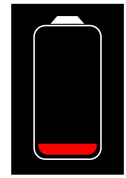


Figure 4 Charge Now symbols

When the videoscope is powered off while charging, the Charging Indicator turns blue.

When the videoscope is powered on while charging, the Charging Indicator turns blue. A Charing Symbol  is displayed on the upper right corner of the UI.

When the battery of the videoscope is fully charged, the Charging Indicator turns from blue to green. The fully charged videoscope should be unplugged from power supply to avoid impairing battery life.

When the Charging Indicator flashes between blue and green, the charging process is not working properly.

Warning:

- Only charge the videoscope using power adaptor supplied by the manufacturer.
- When battery symbol is shown as  , user should connect the videoscope for charging in time.
- When the charging indicator turns green, videoscope should be unplugged from power source to prevent battery overcharge.
- When plug in the videoscope for charging, avoid leaving the device in location inaccessible for disconnecting power source.
- During charging, plug of the power adaptor serve as circuit breaking device between the videoscope and main power supply.
- Surface temperature of the power adaptor will rise during extended charging session. The operation of unplugging power adaptor from main power supply should be completed in 10 seconds.

5. Cleaning and Disinfection

The SafeLM™ Videoscope needed to be assembled correctly with Magill Medical's SafeLM™ Disposable Video Laryngeal Mask to achieve its intended purpose. The videoscope is insulated by the SafeLM™ Disposable Video Laryngeal Mask from directly contacting the patient's tissue during routine use. In case the videoscope is accidentally contaminated and needs cleaning and disinfection, use isopropanol with 70% concentration as cleaning and disinfectant agent, following steps outlined below:

1. Remove the videoscope's insertion tube from laryngeal mask.
2. Wipe the surface of the videoscope with a piece of cotton cloth or sterile surgical towel that has been soaked in cleaning and disinfection agent. Use commercial 70% isopropanol wipe if available.
3. Clean the area difficult to reach by cloth, towel, or wipe (e.g., hinges and groves) with a brush dipped with cleaning and disinfectant agent. Make sure all contamination is removed.

Warning:

- Make sure no flowing or dripping liquid remains on the device surface when cleaning or disinfecting.
- Do not apply excessive force when wiping the distal end of videoscope's Insertion Section, as it may scrape or damage the component.
- Do not disinfect the device by autoclaving, flushing, or soaking in liquid, as steam or liquid may leak into and cause damage to the device.
- Cleaning and disinfecting shall be performed according to local regulations regarding non-autoclaving and non-metal cleaning procedures before the initial and after each use of the device.

6. Storage and Transportation

The SafeLM™ Videoscope should remain clean, free from source of contamination, and protected against by rain or snow during transportation. Storage location should be indoor and well-ventilated, and free of biohazards. Environmental requirements for storage are as follows:

Environmental Temperature Range :-20℃to +55℃ (-4°F to 131°F)

Relative Humidity : 0% to 93% no condensation

Barometric Pressure Range : 500hPa to 1060hPa.

Warning:

- Putting the videoscope into intermediate clinical use after removing it from environment beyond abovementioned storage temperature range may lead to the device's performance differing from technical specification stated in this document. Leave the device for at least 8 hours after restocking the device to its proper storage temperature to allow it to resume its functionality.

7. Troubleshooting

Symptoms	Potential Causes	Solution
The videoscope fails to power on	Battery of the videoscope is depleted	Try charging the videoscope with specified charger. If problem persist, contact support or local dealer.
	Defective contact to battery or battery damaged	Please contact support or local dealer.
No video is displayed after power on	Camera damaged or malfunctioned	Try restarting videoscope. If problem persists, contact support or local dealer.
	Display screen malfunctioned	
	Cable Plug has not been plugged into Video & Power Socket correctly	Try plugging off and plugging in the Cable Plug and restarting the videoscope. If problem persists, contact support or local dealer.
	Pins in the connector or socket have defective contact.	
Screen display is frozen and not responsive	The videoscope is under electromagnetic radioactive interference.	Press and hold the power button at least 6 seconds to force shutdown the videoscope. Restart the device in environment away from electromagnetic radioactive interference. If problem persists, contact support or local dealer.
	Software error	
	Camera module malfunctioned	
Video appears blurry or unrecognizable	Camera lens of the videoscope is contaminated.	Gently wipe the camera lens with clean isopropanol wipe.
	Distal end of laryngeal mask's flexible extension is contaminated or blurred	Try assembling the videoscope with another Disposable Video Laryngeal mask.
illumination apparently dimmed or frequent change of brightness	Light source is damaged or poor contact of wiring	Please contract support or local dealer
	Driving power source for the illumination malfunctioned	
Buttons is not responsive	System crashed or button malfunctioned	Press and hold Power Button to force shutdown and restart the device. If problem persists, please contact support or local dealer.
Videoscope cannot be charged when connected to power source	The USB connector is not plugged correctly into the port.	Check whether the connector of the cable is plugged into the USB port securely. Try reconnecting the USB cable, contact support or local dealer if problem persist.
	The charging circuit of the videoscope malfunctioned	Please contract support or local dealer

Charging Indicator does not light up, or blink when videoscope is plugged in.	The USB connector is not plugged correctly into the USB port.	Check whether the connector of the cable is plugged into the USB port securely. Try reconnecting the USB cable, contact support if problem persist.
	The charging circuit malfunctioned	Please contact support or local dealer.
	The charging indicator light malfunctioned.	Please contact support or local dealer.
Unable to access stored recorded files when connected to PC	Driver for Type-C port on the PC does not function properly	Check whether the PC can recognize other Type-C port devices. If not, update the corresponding driver for PC
	Port for USB cable has poor contact or did not plug in securely.	If the driver for Type-C port functions normally and no USB device is found on PC when connected to videoscope, try reconnecting the device and power it on again.
Insertion Tube is twisted irregularly	Spring tube position fixating components have loosened or fall off.	Please contact support or local dealer
Bending Section has irresponsive range or apparent decreased range of angles adjustment	Steel wire controlling angulation is elongated due to metal fatigue or damaged.	Please contact support or local dealer
Flexible Tip cannot be controlled by Angulation Handle or decrease in range of angle adjustment range	Steel wire which controls the Flexible Tip is loosened or fallen off. Angulation handle malfunction.	Please contact support or local dealer
Surface of video soft tube or flexible tip is seen cracked or glue loosen at bonding site	Surface material is aged or scratched by sharp object.	Please contact support or local dealer
The connecting body of the videoscope cannot be secured to laryngeal mask	Locking mechanism in the locking orifice of the videoscope is worn. Locking latch on the laryngeal mask is cracked or missing.	Try replacing with another disposable video laryngeal mask. If problem persist, contact support or local dealer.

8. Accessories

Name	Count	Description
Power Adaptor	1	Input:100-240V~; 50/60Hz; Output: DC5V, 2A; Model: LXCP12X-050200BG(EU plug) LXCP12X-050200CG(UK plug) LXCP12X-050200DG(US plug) LXCP12X-050200IG(JIS plug) LXCP12X-050200KG(Brazil plug) LXCP12X-050200LG(KR plug) LXCP12X-050200OG(AUS plug).
Protective Sheath	1	Protect the Insertion Tube and Camera from external force.
USB Cable	1	USB to Type-C cable for charging the videoscope and accessing media data stored in the device.
Instruction For Use	1	Instruction For Use for SafeLM™ Videoscope
Certificate of Warranty	1	Warranty policy and contact information for return and service for SafeLM™ Videoscope

9. Maintenance and Service

9.1 Maintenance

9.1.1 Regular Inspection

To ensure the Videoscope remains in optimal condition for clinical operation, its condition and performance should be inspected regularly at least once per year.

Inspected Parts	Criteria
Lithium Battery	Videoscope' s battery life has not deteriorated significantly.
Plastic External Enclosure	• Plastic enclosure has no visible sign of cracking. • Screws in the enclosure remain tight.
Angulation Handle	• Angulation Handel remain tightly attached to Control Body. Flexible tip is responsive when handle is moving. • Angulation Handle's surface is not scratched or cracked. • Mechanical limitation in view angle adjustment remains effective.
Insertion Tube	• No sign of crack or loosen at the adhesive site of Soft Insertion Tube/Rigid Insertion Tube. • No sign of scratch or crack on the surface of insertion tube. • No apparent impairment in bending range and capability at the Flexible Tip.
Buttons	• Symbols imprinted on the buttons is clearly recognizable. • Buttons are not stuck or lagged when pressed and rebound normally when released.
USB Port	• Connection of USB ports not loose.
Display Screen	• Screen panel show no sign of crack. • The image on screen should remain intact with no flickering or blurring.
USB Cable	• No sign of cracking on the cable surface • The connector is intact without been bent
Camera	Check for any stained contamination attached on the camera lens. If displayed image appears blurry, wipe with cotton swab or cloth that has been dipped in disinfecting alcohol.

9.1.2 Battery

The SafeLM™ Videoscope is integrated with rechargeable Lithium battery. If the videoscope is stored away and not used for over three month, it should be fully charged at least once every three months.

	**Warning:** • User should NOT attempt to replace the internal Lithium battery. Battery replacement performed by inadequately trained personnel may cause fire hazard or electrical shock to the operator. In need of replacing internal battery, please contact Magill Medical or its authorized dealer.

9.2 Product Lifetime

The designed product lifetime for SafeLM™ Videoscope is five years from the date of manufacture. Operating this device beyond its product lifetime could pose risk of injury to its operator or patient. The device's off-power data storage time is 20 years.

9.3 Waste Disposal

	**Warning:** • Medical device beyond its product lifespan or battery removed from the medical device shall be handled in accordance with local laws and regulations regarding disposal of medical and electronic wastes. • Improper disposal of abovementioned items poses risks of environmental contamination and health-harming effects to the public or waste-disposal workers.

9.4 Warranty

The warranty for SafeLM™ Videoscope is one year from the date of purchase. Warranty is void in case of damage to the device due to following causes: irresistible natural disasters such as fire, earthquake, or floods; intentional tempering; failure of following instructions stated in this IFU operating or maintaining this device. In case of any quality issues or need support need, please contact Magill Medical or its local dealers.

10. Manufacturer Information

Manufacturer: Changsha Magill Medical Technology Co., Ltd

Address: Room 101-201, Bldg. 1, No. 41, Yannong Road, Hi-Tech Development Zone Changsha, 410205, Hunan , China

Tel:+86-731-85585005 Email:support@magillmed.com

Software version applicable to this IFU is V1.0

IFU Version: V1.4

EU REP Share Info GmbH
Am Schulzentrum 12, 41564 Kaarst, Germany

CE

- **Appendix-EMC**

Warning:

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this the **SafeLM™ Videoscope** could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- 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.
- 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 **SafeLM™ Videoscope**, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Using power adaptor other than specification provided by Magill Medical may cause the videoscope's radiate power to increase or electromagnetic immunity to decrease.
- Operator should try to move the **SafeLM™ videoscope** to another place or restart the device due to ESSENTIAL PERFORMANCE is lost or degraded caused by EM DISTURBANCES.
- **The SafeLM™ Videoscope** is NOT compatible with environment with the presence of strong magnetic field, such as working with Magnetic Resonance Imaging (MRI). Therefore, use of this device under strong radio magnetic field should be restricted.
- This device shall be shielded against electromagnetic radiation and should be assembled, operated, and repaired in the electromagnetic environment which meet the following criteria.
- Portable and mobile RF communication equipment may interfere the performance of this device.
- **The SafeLM™ Videoscope** shall not be used in HOME HEALTHCARE environment.

Essential performance:

- The OPERATOR is viewing the real-time video during an endoscope procedure.
- **The SafeLM™ Videoscope** Support internal battery and external Class II .
- The angulation handle of **The SafeLM™ Videoscope** can control the bending section to adjust camera angle, then, the bending section drives the laryngeal mask's flexible extension to bend.

Guidance and manufacturer´s declaration-electromagnetic emission-for all equipment and systems.

<table>
<tr><th colspan="3">Guidance and manufacturer´s declaration-electromagnetic emission</th></tr>
<tr><td colspan="3">SafeLM™ Videoscope is intended for use in the electromagnetic environment specified below. The customer or the user of SafeLM™ Videoscope should assure that it is being used in such environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The SafeLM™ Videoscope uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The SafeLM™ Videoscope is suitable for use in all establishments other than domestic setting that are directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration electromagnetic immunity for all Equipment and Systems

Guidance and manufacturer´s declaration-- electromagnetic immunity			
SafeLM™ Videoscope is intended for use in the electromagnetic environment specified below. The customer or user of the device should assure that it is being operated in such environment.			
Immunity Test	**Test Level**	**Compliance Level**	**Electromagnetic environment -guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ± 8 kV Air: ±15 kV	Contact: ± 8 kV Air: ±15 kV	Floor material should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic transient / burst IEC 61000-4-4	Power supply line: ± 2 kV ,100kHz repetition frequency	Power supply line: ± 2 kV ,100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Line-to-line: ±0.5kV, ±1kV	Line-to-line: ±0.5kV, ±1kV	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	0 %U_T; 0.5 cycle At 0°,45°,90°,135°, 180°,225°,270°,and 315° 0 %U_T; 1 cycle and 70% U_T; 25 and 30 cycles Single phase: at 0° 0 %U_T; 250 and 300 cycle	0 %U_T; 0.5 cycle At 0°,45°,90°,135°, 180°,225°,270°,and 315° 0 %U_T; 1 cycle and 70% U_T; 25 and 30 cycles Single phase: at 0° 0 %U_T; 250 and 300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **SafeLM™ Videoscope** requires continued operation during power mains interruptions, it is recommended that the **SafeLM™ Videoscope** be powered from an uninterruptible power supply or a battery.
Power Frequency Magnetic Field (50Hz/60Hz) IEC 61000-4-8	30 A/m	30 A/m	Power Frequency (50Hz) Magnetic Field should be equivalent to the strength that is typical in business or hospital environment.
Proximity magnetic fields 9kHz to 13.56MHz IEC 61000-4-39	30kHz:8A/m 134.2kHz:65A/m 13.56MHz:7.5A/m	30kHz:8A/m 134.2kHz:65A/m 13.56MHz:7.5A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer´s declaration electromagnetic immunity to NON-LIFE SUPPORTING EQUIPMENT and SYSTEMS

<table>
<tr><th colspan="4">Guidance and manufacturer´s declaration electromagnetic immunity</th></tr>
<tr><td colspan="4">Videoscope is intended for use in the electromagnetic environment specified below. The customer or the user of Videoscope should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity Test</th><th>Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment -Guidance</th></tr>
<tr><td>Conducted RF IEC 61000-4-6</td><td>3 Vr.m.s 150kHz～80MHz

6Vr.m.s ISM and amateur radio bands between 0.15 MHz and 80MHz[a]</td><td>3 Vr.m.s 150kHz～80MHz

6Vr.m.s ISM and amateur radio bands between 0.15 MHz and 80MHz[a]</td><td rowspan="3">Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d=[\frac{3.5}{V_1}]\sqrt{P}$
$d=[\frac{12}{V_2}]\sqrt{P}$
$d=[\frac{3.5}{E_1}]\sqrt{P}$ 80MHz to 800 MHz
$d=[\frac{7}{E_1}]\sqrt{P}$ 800MHz to 2.7 GHz
Where:
P- the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer;
d – recommended separation distance in meters (m).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[b] should be less than the compliance. level in each frequency range. [c]
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF IEC 61000-4-3</td><td>3V/m 80MHz to 2.7 GHz

385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)</td><td>3V/m 80MHz to 2.7 GHz

385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)</td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.</td></tr>
</table>

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

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

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

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for NON-LIFE SUPPORTING EQUIPMENT and SYSTEMS

Recommended separation distances between portable and mobile RF communications equipment and the SafeLM™ Videoscope

The SafeLM™ Videoscope is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output of transmitter [W]	Separation distance [m] according to frequency of transmitter			
	150 kHz to 80 MHz outside ISM and amateur radio bands $d=[\frac{3.5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM and amateur radio bands $d=[\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d=[\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.20	0.12	0.23
0.1	0.38	0.63	0.37	0.74
1	1.2	2.00	1.17	2.33
10	3.8	6.32	3.69	7.38
100	12	20.00	11.67	23.33

For transmitters rated at a maximum output power not listed above the recommended separation distance d, in meters (m), can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

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