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Descriptions for Symbols on Product Labels

SN	Serial Number
	Date of Manufacture
	Manufacturer
	Type BF Applied Part
	Consult Instruction For Use
	Refer to instruction manual/ booklet
	Caution, Failure to follow those instruction may cause damage to the device or harm to operator or patient
	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
EC REP	Authorized representative in the European Community/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 inspecting 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, crushed, 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 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 Magil 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 impact 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, restrict the device from clinical use and contact local dealers for support.
- Before insertion, check to make sure video image on the display screen is live 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 hard light.
- The SafeLM™ Videoscope has NOT yet been tested to operate in environment with the presence of 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 regulation regarding handling of electronical medical device wastes 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 with authorization from Magil Medical. In case of device malfunction or needing support, please contact Magil 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 damage the laryngeal mask.

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 Magil Medical's 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.

MGL-SP-E are designed for adult and compatible with SafeLM™ Disposable Video Laryngeal Mask with models of **FlexiView #3, FlexiView #4, and FlexiView #5**.

MGL-SP-C is designed for juniors and compatible with SafeLM™ Disposable Video Laryngeal Mask with models of **FlexiView #2 and FlexiView #2.5**.

The SafeLM™ Videoscope is a reusable device.

1.2 Intended Use

SafeLM™ Videoscope is intended to be operated in combination with Magill Medical's SafeLM™ Disposable Video Laryngeal Mask, to provide live visual guidance during establishment of airway. The device should ONLY be operated by a certificated health care professionals with proper training in airway management.

1.3 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.

1.4 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, hemophysis, etc.
- Patients with severe oral or laryngeal injury, or those with limited range of motion of neck due to cervical injury.
- Responsive patients with an intact gag reflex that require CPR.
- Patients requiring head or neck surgery where the surgeon cannot gain adequate access to operative site due to the presence of laryngeal mask.
- Patients with inadequate mouth opening to permit insertion of the device.

1.5 Structure and Working Principle

SafeLM™ Videoscope consists of Display Apparatus, Control Body, and Insertion Tube which includes Video Rigid Tube, Video Soft Tube, Flexible Tip, and Camera. Movement of Videoscope's Flexible Tip and distal camera is controlled by adjusting the Angulation Handle. 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.

Device Diagram		Description
	1	USB Port/Protective Cover
	2	Display Screen
	3	Image Capture Button
	4	Connecting Base of Control Body
	5	Release Button
	6	Locking Orifice
	7	Illumination Orifice
	8	Soft Insertion Tube
	9	Flexible Tip
	10	Camera
	11	Rigid Insertion Tube
	12	Control Body
	13	Angulation Handle
	14	Power Button
	15	Screen Panel
	16	Charging Indicator

1.6 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

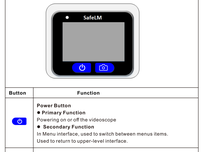
Ingress Protection: The Display Panel and Insertion Tube Parts of the device are IPX0, common appliances NOT protected against water ingression.

This is a portable hand-held device.

Technical Terms	Specifications
Camera	Field of view:100°±15°; Resolution: 1 Megapixel
Illumination	Illumination at the distal end of optic fiber (cuff of SafeLM™ Disposable Video Laryngeal Mask ：≥500 Lux
Power Consumption	≤10VA
Video Recording	Support Loop Recording
Image Capture	Support capture image snapshot
Storage Capacity	16GB
Display Screen	3.0 inches (diagonal) IPS TFT Color Display Screen
Internal Battery	Rechargeable polymer lithium battery; ● Capacity: 2000mAh; ● Discharge Time >2.5 hours Charging Time >2.5 hours(when the device is powered off, and using charger supplied by manufacturer) ● Charging Cycle >300 cycles ● Battery Charging Environment: 0 to 45℃
USB Port	USB Type-C port for accessing and transferring stored data in device and recharging its internal Lithium battery.
Material	● Display Apparatus and Control Body's enclosure is composed of acrylonitrile butadiene styrene (ABS) ● Soft insertion tube's enclosure is composed of polycarbethane （PU） ● Rigid Insertion Tube composed of steel. ● Flexible Tip's enclosure is composed of fluoronubber.
Power Adaptor	Input ： 100-240V~, 50/60Hz Output ： 5.0V/d.c./2.0A
Working Environment	Temperature:10℃ to 40℃(50°F to 104°F) Relative Humidity：30% to 90%, no condensation Atmosphere Pressure：860hPa to1060hPa
Weight	Approx.200g (0.44 lbs.)

1.7 Buttons, Display Screen and Feature

1.7.1 Buttons



Button	Function
	Power Button **★ Primary Function** Powering on or off the videoscope **★ Secondary Function** In Menu Interface, used to switch between menus items. Used to return to upper-level interface.
	Image Capture Button **★ Primary Function** take image snapshot during video recording. **★ Secondary Function** During video recording, press and hold this button to enter Menu Interface. Used to enter lower-level interface.

Note: See Chapter 3 for menu navigation and setting

1.7.2 Symbols on User Interface

Symbol	Description
	Start-up screen
	Blinking *Charge Now* symbol indicate the battery capacity is too low to sustain device working. Connect videoscope to power source for charging immediately.
	Remaining battery capacity. The battery icon turns red when there is only one bar for battery capacity.
	Videoscope is being charged
	Time Setting Menu
	Image Review Menu; Current File is image
	Video Replay Menu
	Data Export Menu
	Current file is video
	Folder/ Empty: No saved image or video in folder
	Image snapshot is being captured.
	File Damaged
	Input Current Password: Refer to Section 3.12
	New Password: Refer to Section 3.12
	Password Setting Menu. Refer to Section 3.7
	Password Verification, Refer to Section 3.11

1.7.3 Charging Indicator

Charging indicator locates at the upper left corner of the display panel.

- Blue indicator indicates videoscope is being charged.
- Green indicator indicates videoscope is fully charged.

2. Basic Operation of SafeLM™ Videoscope and Disposable Video Laryngeal Mask

As an assistive visualization device for SafeLM™ Disposable Video Laryngeal Mask, the videoscope can provide real time visual guidance during the following processes:

- Insertion and position adjustment of SafeLM™ Disposable Video Laryngeal Mask
- Intubation through inserted laryngeal mask
- Inspection of supraglottic structure and laryngeal mask positioning during surgery.

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

For sake of battery conservation, power off the videoscope after finish operating it. Do NOT leave the videoscope powered on and unattended.

Warning:

- If 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.
- When removing the videoscope from laryngeal mask, do not adjust the Angulation Handle.

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 authorized dealer if any sign of damage and 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. Hold the insertion tube of the videoscope vertically to the videoscope plain of the laryngeal mask, align the videoscope's flexible tip to the entry of laryngeal mask's video channel.

3. Insert a small segment of the videoscope' s 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 rest in the videoscope's hollow opening on the base of control body.
4. 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 fail to assemble and may cause damage to the videoscope or laryngeal mask.
- If excessive resistance is felt when inserting the Insertion Section 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.
- After assembled to laryngeal mask, press OK button on the videoscope to power on the device. The videoscope automatically activates illumination and starts video recording when powered on. Observe whether the video quality on display is sufficient. If video appears blurry or flared and causes obstacle in normal use, remove the videoscope from laryngeal mask and gently wipe the camera lens with cloth that has been dipped in cleaning agent.

2.2 Adjustment of View Angle

After videoscope is assembled with laryngeal mask, gently press the Angulation Handle to control the movement of the bending section and adjust direction of camera to observe anatomical target field.

Warning:

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

2.3 Disassembling Videoscope from Laryngeal Mask

1. Make sure the laryngeal mask is fixated in correct position and secure airway is established.
2. Press the Release Buttons on both side of the connecting base of the videoscope with one hand, while stabilize the laryngeal mask in position with another hand.
3. Gently and vertically pull the videoscope' insertion tube from laryngeal mask's video channel. Avoid moving the Angulation Handel during this process.
4. Press and hold the Power OK Button to power off the videoscope.

3. Basic Operation

3.1 Powering On

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

Figure 3.1 Startup Logo Interface

3.2 Displaying Video

When videoscope is powered on, video captured by camera is shown on Display Screen in real time.

Warning:

- If image shown on screen appears blurry, check and ensure the camera lens of videoscope and distal end of laryngeal mask's Flexible Extension are not contaminated or stained.
- Live video is not shown when the videoscope is set to Menu Interface. Exit Menu Interface to resume displaying video.

3.3 Video Recording

The videoscope automatically light up the LED light source and starts video recording after startup.

Warning

- DO NOT look directly into light orifice or point the light orifice to open eyes of others 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 live video with correct orientation, NOT replay of recorded video.
- Before videoscope operation 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

Recording video is stopped and illumination is turned off when either the Power OK Button is pressed and held to power off the videoscope or the Image Capture OK Button is pressed and hold to enter Menu Interface. Video footage recorded is automatically saved when recording is stopped.

3.5 Image Capture

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

3.6 Powering Off

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

Figure 3.6 Power Off Countdown Interface

Warning:

- If the Power OK Button is released before countdown is finished, the power off process is canceled and the device 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.

3.7 Menu Interface

When videoscope is powered-on, press and hold to enter Menu Interface. (See Figure below.) In Menu Interface, press Power OK Button to switch between menu items: press Image Capture OK Button to enter selected lower-level menu.

Figure 3.7 Menu Interface

- The lower right corner of the interface shows the version number of distributed software

3.8 System Time Setting

When displaying live video, system time is shown on the upper right corner of the screen. If system time displayed is desynchronized with local time, set system time following steps on the base of control.

Figure 3.8.1 Selected System Time Setting Menu

Press and release OK button

Figure 3.8.2 System Time Setting Interface

Steps:

Press and hold Image Capture OK Button for 2 seconds to enter Menu Interface

1. Press and release OK Button to enter Time Setting Interface.
2. Press and release Power OK Button to switch between date/time digit.
3. Press Image Capture OK Button to change the value of selected digit.
4. When finish setting, press and hold Power OK Button to save adjusted system time and return to Menu Interface.

- Range of year setting:2000-2099
- When system time is set to invalid value, system prompt setting change failed, with inappropriate value highlighted red. For example, when month is set to 14, the system will prompt this error when user attempt exiting Time Setting Interface.

3.9 Image Review

In Menu Interface, press Power OK Button to switch to the Image Review symbol, and press Image Capture OK Button to enter Image Review Interface's list of saved captured images.

Figure 3.9.1 Selected Image Review symbol

Press and release OK button

Figure 3.9.2 List of saved images

- User interface's airway images and symbols appear on figures are for illustrative purposes only and may NOT represent image shown in actual clinical use.

In interface shown in Figure 3.9.2, press Power OK Button to move between images top-down, and press Image Capture OK Button to view highlighted image, as illustrated in Figure 3.9.3.

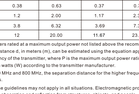


Figure 3.9.3 Image Review Interface

If there is not captured image file saved, the following symbol is displayed, as illustrated in Figure 3.9.4

Figure 3.9.4 Folder Empty

3.10 Video Replay

In Menu Interface, press Power OK Button to switch to the Video Replay symbol, and press Image Capture OK Button to enter Video Replay Interface's list of saved video footages.

Figure 3.10.1 Selected Video Replay symbol

Press and release OK button

Figure 3.10.2 List of saved video footages

- User interface's airway images and symbols appear on figures are for illustrative purposes only and may NOT represent image shown in actual clinical use.

In interface shown in Figure 3.10.2, press Power OK Button to move between video footages top-down, and press Image Capture OK Button to view highlighted video, as illustrated in Figure 3.10.3.

Figure 3.10.3 Video Replay Interface

If there is not video footage file saved, the Folder/ Empty symbol is displayed, as illustrated in Figure 3.10.4.

If saved video files are damaged, the File Damaged symbol is displayed, as illustrated in Figure 3.10.5.

Figure 3.10.4 Folder/ Empty

Figure 3.10.5 File Damaged

3.11 Data Storage and Export

Data Storage

Recorded videos and captured images are automatically saved to the internal storage of the videoscope. The videoscope employed segmented loop recording method to manage files. For live recording, it is segmented and automatically saved as a video footage every 10 minutes. If a single recording lasts less than 10 minutes, video duration is same as actual recording time.

Data Export

In Menu Interface, press Power OK Button to switch to the Data Export symbol, and press Image Capture OK Button to enter Password Verification Interface.

Data Export Interface can be displayed ONLY after providing correct password.

Figure. 3.11.1 Selected Data Export symbol

Press and release OK button

Figure 3.11.2 Password Verification Interface

Figure 3.11.3 Input correct password

Press and hold OK button

Figure 3.11.4 Data Export Interface

Steps:

1. Connect the videoscope to PC with a USB cable with Type-C port.
2. On the videoscope, press and release Image Capture OK Button to enter Password Verification Interface.
   a. Press the Image Capture OK Button to adjust the current digit by increment of 1 for each press, ranging from 0 to 9.
   b. Press and release the Power OK Button to switch to the next digit of the password, digits switch in circulation.
   c. After correct password combination is inputted, press and hold the Image Capture OK Button to enter Data Export Interface
3. On PC, visit the disk volume named MGL.
4. In MGL directory, there are two folders named *photo* and *video*, where corresponding file types are separately stored.
5. Copy, paste, cut, or delete files in these folders as needed.
6. When finished, look for the Safely *Remove Hardware and Eject* Media icon on the taskbar in PC. Click on the icon and select *Eject MGL STORAGE* in list of connected hardware. When prompted *Safe to Remove Hardware* on PC, disconnect the videoscope from connected cable.

7. Press and release Image Capture OK Button to return to Menu Interface; or Press and hold the Power OK Button to power off the device.

- The factory default password combination is ↑↑↑ as illustrated in Figure 3.11.3 User should input the current password in this interface.
- In case of password is forgotten, please contact Magil Medical or its local dealer.
- 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 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 device from PC.
- Use only accompanying USB Type-C cable supplied by the manufacturer or USB Type-C cable compliant to IEC 60950.

3.12 Data Export Password Setting

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

Interface

Figure 3.12.1 Password Setting Interface

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

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

Password Setting Steps

Enter Password Setting Interface

Press and release OK button

Setting Password:

- Press the Image Capture OK Button to adjust the current digit by increment of 1 for each press, ranging from 0 to 9.
- Press and release the Power OK Button to switch to the next digit of the password, digits switch in circulation.
- After desired password is inputted, press and hold the Image Capture OK Button to save new password and return to previous menu.
- Press and hold the Power OK Button to return to previous menu WITHOUT saving password change.

Forgotten Password

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

Incorrect Password Prompt

When current password inputted is wrong, new password cannot be saved as illustrated in figure3.12.3 below:

Figure 3.12.3 Incorrect Password Prompt

- The factory default password combination is ↑↑↑.
- Current Password illustrated in 3.12.2 is the factory default password. If user has set a new password, the user-set password should be inputted before setting a new password.

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

Purpose of the PEMS connection to an IT-Network

The purpose of the PEMS connection to an IT-Network is to export recorded video and image file stored in the videoscope.

Required Characteristics of the IT-Network Incorporating the PEMS

Desktop and Laptop Computer

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

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.

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

Operator needs to connect the videoscope to desktop or laptop computer via compatible USB cable to 1. access and export its stored data 2. copy those data to the computer or portable data storage devices (e.g. flash drive, portable hard disk, etc.) that is connected to the computer.

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 in IT-network configuration	USB Port incompatible
New device incorporated to IT Network	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	Introduce bugs in the system
Devices incorporated in IT network is upgraded	Cause software compatibility issue between devices

4. Power Supply for the Videoscope

SafeLM™ Videoscope can be powered by both 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 red and blinking, it 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, 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 on while charging, the Charging Indicator turns blue.

When the videoscope is powered on while charging, the Charging Indicator turns blue. A Charging Symbol OK 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 raise in 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 Magil 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 need cleaning and disinfection, use equipped with 70% concentration as cleaning and disinfectant agent, following steps outlined below:

1. Remove the videoscope from laryngeal mask. Make sure the videoscope is powered off and detached from USB cable before starting any cleaning and disinfectant procedure.
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 wipes if available.
3. Clean the area difficult to reach by cloth, towel, or wipe (e.g., hinges and crevices) 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 the lens or damage the flexible tip of the videoscope.
- 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 disinfection shall be performed according to local regulations regarding non-autoclaving and non-metal critical 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 followed:

Environmental Temperature Range：-20℃ to +55℃(-4℉ to 131℉);

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 differ from technical specification stated in this document. Leave the device for at least 8 hours after restoring 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.
	Damaged contact to battery or battery damaged	Please contact support
No video display after power on	Camera damaged or malfunctioned	Try restarting the videoscope. If problem persists, contact support.
	Display screen malfunctioned	
Screen freezes	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 free of electromagnetic radioactive interference. If problem persists, contact support.
	Software error	
	Camera module malfunctioned	
Video appears blurry or unrecognizable	Poor contact of wiring to the Display Screen.	Gently wipe the camera lens with sterile alcohol wipe.
	Distal end of laryngeal mask's flexible extension is contaminated or blurred	Try assembling the videoscope with another SafeLM™ Disposable Video Laryngeal mask.
Illumination appears too dark or frequent change of brightness	Light source is damaged or poor contact of wiring	Please contact support
	Driving power source for the illumination malfunctioned	
Buttons are unresponsive	System crashed or button malfunctioned	Press and