

Video Laryngoscope

User Manual

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1. Product Name and Overview

1.1 Product name: Video Laryngoscope

1.2 Product overview: This product is a portable digital video laryngoscope with a built-in rechargeable lithium battery and consists of a main unit and a choice of blades. The laryngoscope provides reusable blades of different specifications that are exchangeable and compatible with each other and can be sterilized under high temperature and pressure. The blades are securely connected, easy to detach, portable, safe and durable. The laryngoscope makes it convenient to guide interns to learn the placement of a tracheal tube during clinical teaching.

Compared with traditional direct rigid laryngoscopes, the Video Laryngoscope has the following benefits:

- Its 3.5-inch display screen provides multi-view and high-definition images with a wide viewable angle.
- The display screen supports angle adjustment, facilitating tracheal intubation on patients with various postures.
- The laryngoscope is designed to facilitate the placement of a tracheal tube and especially suitable for use on patients with small mandible, epiglottis hypertrophy, and unclear or difficult glottis exposure.
- The laryngoscope can be connected to a PC to facilitate the establishment and storage of files.
- The laryngoscope can clearly identify the throat structure and distinguish the esophagus entrance from the airway entrance, thus avoiding blind or incorrect intubation.

2. Models and Specifications

2.1 Product models: SW-B01 and SW-B02

2.2 Introduction to the main unit of the Video Laryngoscope

Main unit of the Video Laryngoscope	
Display	3.5-inch LCD color display featuring HVGA (480×320P) resolution
Functions	Power-on/off, video recording (in AVI format), imaging (in JPG format), playback, and menu operation
Handle	Handheld
Data output	USB data cable connected to a PC
Battery	Built-in 3450 mAh non-removable lithium battery
microSD card	16 GB (customizable based on customer requirements)
Lens resolution	960×720P

2.3 The anesthetic video laryngoscope provides three types of blades of different sizes. Select a suitable blade based on the patient's actual condition. The following table lists the basic blade dimensions.

Category	Model	Blade Specifications (Length × Width × Height) Unit: mm	Deviation Unit: mm
Hook-shaped	ARC-S	114.0 × 20.0 × 42.0	±2
	ARC-M	138.0 × 20.0 × 46.5	±2
	ARC-L	151.0 × 20.0 × 62.5	±2

3. Structure

The anesthetic video laryngoscope mainly consists of a main unit, a choice of blades, and a USB data cable.

The main-unit handle and the blade are securely connected by insertion in a double structure of a hook groove and a spring locking groove, and are easy to detach.

4. Functions and Working Principles

After the Video Laryngoscope is powered on, the circuit is automatically switched on. When the blade is placed into the patient's mouth to lift the epiglottis and expose the glottis, an auxiliary illumination beam is concentrated on the throat and imaged on a COMS sensor, which converts the optical signal into an electrical signal. The signal is then transmitted to a video processor through a wire and displayed on the screen after being processed and restored.

5. Scope of Application and Intended Use

5.1 Intended use: The anesthetic video laryngoscope is intended for anesthesia or first aid. It is clinically used to lift the patient's epiglottis to expose the glottis so as to guide medical staff through accurate tracheal intubation. It can also be used for medical teaching.

5.2 Intended patients: adolescent and adult patients.

6. Performance

6.1 Buttons on the Video Laryngoscope are flexible and reliable, and all parts are securely connected. A blade can be connected tight to the laryngoscope without the risk of falling off.

6.2 Images are displayed clearly.

6.3 Bending angle of the display in the forward and backward directions: $\geq 100^\circ$.

6.4 Spatial resolution: ≥ 4.0 lp/mm.

6.5 Depth of field (DOF): 30–60 mm.

6.6 Field of view ≥ 60 degrees.

6.7 Image color reproduction level: ≥ 4 .

6.8 Images on the display are free from obvious geometric distortion.

6.9 Light intensity ≥ 900 lx.

6.10 Color temperature: ≥ 2800 K.

6.11 Electrical safety

The electrical safety of the anesthetic video laryngoscope meets the requirements of IEC 60601-1:2005+A1:2012 and IEC 60601-2-18:2009.

6.12 Electromagnetic compatibility

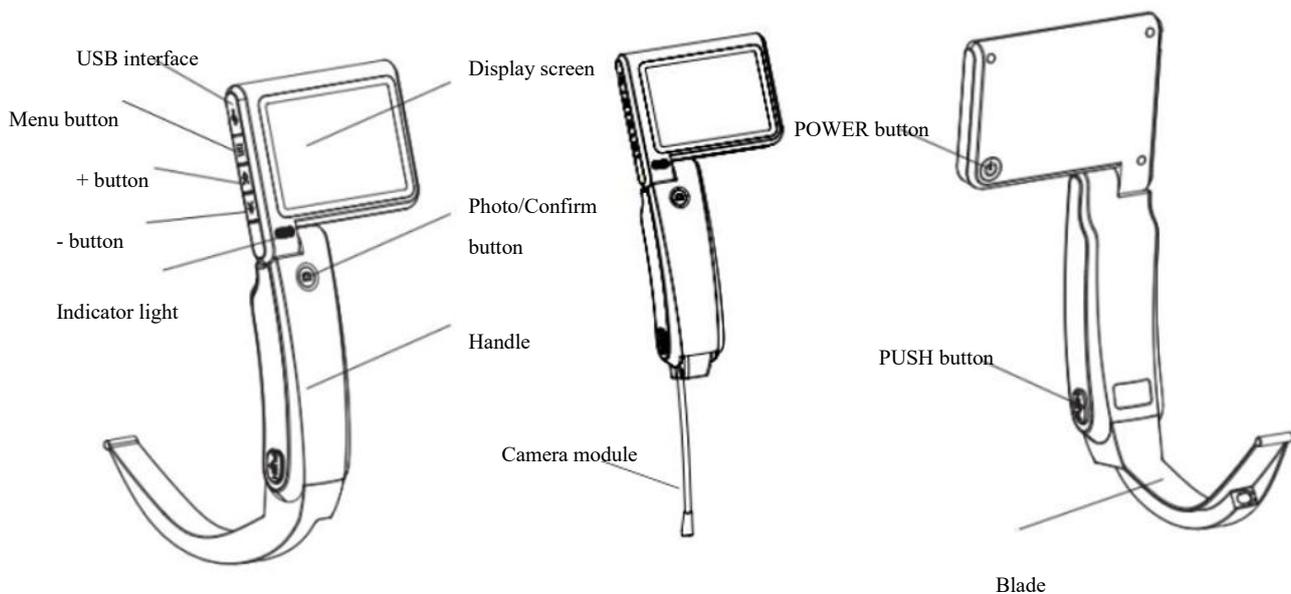
The electromagnetic compatibility of the anesthetic video laryngoscope meets the requirements of IEC 60601-1-2:2014 and the requirements of chapter 36 in IEC 60601-2-18:2009.

6.13 Description of Classification

1. Classification of the laryngoscope based on the classification for protection against electric shock: internally powered equipment.
2. Classification of the laryngoscope based on the degree of protection against electric shock: type B.
3. Classification of the laryngoscope based on the degree of protection from harmful liquid penetration: Common Equipment – IPX0.
4. For details about how to disinfect and sterilize the laryngoscope, see chapter 10 "Cleaning, Disinfection, and Sterilization" in this user manual.
5. Classification of the laryngoscope based on the safety level when it is used in the presence of flammable anesthetics mixed with air or with oxygen or nitrous oxide: Non-AP/APG type.
6. Classification of the laryngoscope based on its operating mode: continuous operation.

7. Instructions or Illustrations for Installation and Use

The following figure shows the symbols and identifiers on the panel of the laryngoscope.



7.1 Lithium battery

The anesthetic video laryngoscope has a built-in rechargeable lithium battery. Do not disassemble the body of the laryngoscope or remove the lithium battery. The lithium battery is not fully charged upon delivery and needs to be fully charged when used for the first time.

Lithium battery specifications: 3.6 V DC, 3450 mAh



Warning: Do not disassemble or replace the lithium battery by yourself; otherwise, you will bear responsibilities resulting from product damage caused by self-replacement!

7.2 Connection for charging

Open the USB interface rubber cover on the left side of the display screen, connect the USB interface to a power adapter through the USB data cable, and plug the power adapter into an electrical socket to start charging automatically.



Note: You should purchase the power adapter on your own. Please use a power adapter (output: 5 V) that is from a formal manufacturer and meets the requirements of IEC 60601-1:2005+A1:2012!

7.3 Indicator light

When the indicator light in the lower left corner next to the screen is BLUE, the laryngoscope is being charged. When the indicator light is GREEN, charging is complete or the laryngoscope is in use after power-on. When the indicator light is YELLOW, the laryngoscope has insufficient power and must be charged right away.

7.4 Power-on

When the laryngoscope is in the power-off state, press the POWER button to power it on. Then, the welcome screen appears and images are displayed properly. The following figure shows the welcome screen.



Welcome screen

7.5 Power-off

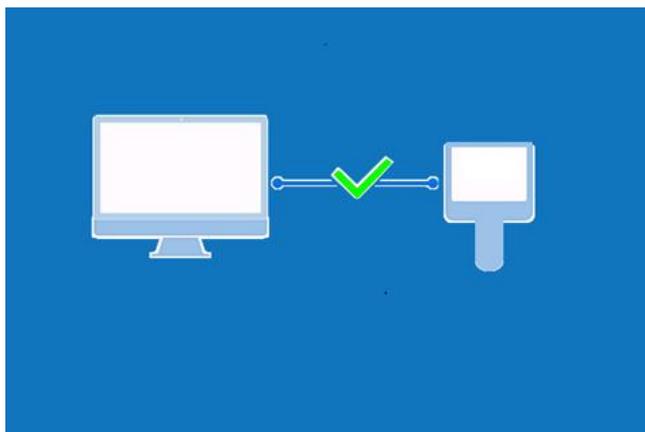
When the laryngoscope is in the running state, press and hold the POWER button for 3s to power it off.

7.6 Connection interface

1. Connect the USB interface

The laryngoscope has a USB interface for charging and connecting to a PC. The connection methods are as follows:

- 1) Connect the USB interface for charging. For details, see section 7.2.
- 2) Transmit data to a PC as follows: Start the main unit, open the USB interface cover, and connect the USB data cable between the USB interface and a PC. Then, double-click the "DATA" folder of the microSD card and select the desired images or video files. The following figure shows the connection screen.



Note: The USB interface of the laryngoscope is only used for charging and connecting to a PC for transferring images and video files!

2. Install and remove the blade

- 1) Installation: Press and hold the PUSH buttons on both sides of the handle to insert the



blade, and then release the PUSH buttons on both sides.

Warning: Do not use any other types of blades than those provided by the laryngoscope under any circumstances!

- 2) Removal: Press and hold the PUSH buttons on both sides of the handle to release and take out the blade.

7.7 Operation of function buttons

1. Photo/Confirm button

In normal display mode:

- (1) Photo taking: Press the Photo/Confirm button to take a photo. One photo is taken at a time and is automatically stored as a JPG file in the built-in microSD card.
- (2) Video recording: Press and hold the Photo/Confirm button for 3s to switch to video recording mode and start video recording. The video recording icon  and the recording duration are displayed in the upper left corner of the screen. Press the Photo button to exit video recording mode. The recorded video is automatically stored as an AVI file in the built-in microSD card and the system returns to photo taking mode.

2. POWER button

Power-off: Press and hold the POWER button for 3s to power off the laryngoscope.

3. Menu button

Press the Menu button to enter the menu list, where you can return to normal display mode, view images, play videos, and perform settings. Press the + and - buttons to select different menus, and press the Photo/Confirm button to enter the selected menu.

After you enter the menu list, you can press the Menu button to return to normal display mode. After you enter a specific menu, you can press the Menu button to return to the upper-level menu.

(1) Back

Select the Back menu and press the Photo/Confirm button to return to normal display mode.

(2) Image display

Select the image display menu and press the Photo/Confirm button to enter the image library. Press the + and - buttons to switch between different image lists. Select an image and press the Photo/Confirm button to view the image. Press the Menu button to quit viewing and press the Menu button again to return to the menu list. If no images exist in the memory, the "no data" prompt appears and the system returns to the menu list.

(3) Video playback

Select the video playback menu and press the Photo/Confirm button to enter the video library. Press the + and - buttons to switch between different video lists. Select a video and press the Photo/Confirm button to play the video. Press the Menu button to quit playing and press the Menu button again to return to the menu list. If no videos exist in the memory, the "no data" prompt appears and the system returns to the menu list.

(4) Setting

Select the setting menu and press the Photo/Confirm button to enter the setting list, where you can set the date, time, and language, restore default settings, and format the microSD card. Press the + and - buttons to switch between different settings.

- a. Date: Select the date setting mode and press the Photo/Confirm button to correct the date. Then, press the Photo/Confirm button to select different segments of the date. When numbers are highlighted, press the + and - buttons to adjust the numbers and press the Photo/Confirm button to confirm the numbers. After the date is corrected, press the Photo/Confirm button to confirm the date and manually power off the device to save the settings.
- b. Time: Select the time setting mode and press the Photo/Confirm button to correct the time. Then, press the Photo/Confirm button to select different segments of the time. When numbers are highlighted, press the + and - buttons to adjust the numbers and press the Photo/Confirm button to confirm the numbers. After the time is corrected, press the Photo/Confirm button to confirm the time and manually power off the device to save the settings.
- c. Language: Select the language setting mode and press the Photo/Confirm button repeatedly to switch between different languages. After you select a language, manually power off the device to save the settings.
- d. Default setting restoration: Select the default setting mode and press the Photo/Confirm button. When the **Yes** and **No** options appear, press the + or - button to select either option. Select **Yes** and press the Photo/Confirm button to restore default settings, and the system automatically returns to the setting list after default settings are restored. Select **No** and press the Photo/Confirm button, and the system automatically returns to the setting list without modifying settings.
- e. microSD card formatting: Select the microSD card formatting mode and press the Photo/Confirm button. When the **Yes** and **No** options appear, press the + or - button to select either option. Select **Yes** and press the Photo/Confirm button to automatically format the microSD card, and the system automatically returns to the setting list after the microSD card is formatted. Select **No** and press the Photo/Confirm button, and the system automatically returns to the setting list without formatting the microSD card.

You can also power off the device to save settings after all parameter settings of the laryngoscope are complete!

7.8 On-screen icons

The POWER icon is displayed in the upper right corner of the screen, the date and time icons are displayed in the lower right corner of the screen, and the Warning icon is displayed in the upper left corner of the screen.

1. If the camera cannot be connected, an alarm appears, as shown in the following figure. In this case, contact the after-sales personnel for repair.



2. Low battery

When voltage is too low, the indicator light is YELLOW and the battery icon  is flashing.

3. microSD card unavailable

If the microSD card fails or no microSD card is detected, the icon  indicating microSD card unavailable appears in the upper left corner of the screen. In this case, the laryngoscope still works properly but photos or videos cannot be saved.

4. microSD card full

When the remaining capacity of the microSD card is less than 20 MB, the  alarm appears, indicating that the microSD card is full. In this case, the laryngoscope still works properly but no more data can be saved to the microSD card. Please promptly cut and paste some images or video files from the microSD card to a PC, or format the microSD card.

5. Charging tips

When the laryngoscope is being charged, the dynamic charging icon appears for 5s and then the laryngoscope enters the standby state. When you press the POWER button during the charging process, the dynamic charging icon reappears for 5s and then the laryngoscope enters the standby state.

7.9 Clinical operation

1. Preparation

- (1) Check that the blades have been disinfected or sterilized.



The blades can be used only after disinfection or sterilization!

- (2) Select a suitable blade.
- (3) Connect and fix the blade and power on the laryngoscope.
- (4) Inspect the camera lens of the laryngoscope. If fogging occurs or the ambient temperature difference is greater than 10 degrees, power on the laryngoscope and preheat it for 1 minute for defogging before using the laryngoscope.

2. Placing the blade into the patient's mouth

- (1) Open the patient's mouth by using the standard technique formulated by the hospital.
- (2) In the presence of excessive secretions or blood, suction the patient's airway until it is cleaned before introducing the blade into the mouth.
- (3) Insert the blade into the mouth by following the midline. Take care to avoid pushing the tongue towards the larynx.
- (4) Avoid hurting the epiglottis when placing the blade. Point the tip of the blade to the epiglottis so that the glottis is seen on the display. Keep the vocal cords in the center of the display to observe the oral cavity most effectively.
- (5) If images cannot be displayed clearly because the lens is blocked (by secretion, blood, or something else), remove the blade from the patient's mouth and clean it, and then place it back into the mouth.



Warning: When the laryngoscope with a blade connected is working at a temperature approximating to its highest operating temperature, the temperature on the blade surface will exceed 41°C under the illuminant of the lens module. The patient's oral tissue may be injured after long-time direct contact with the blade surface at such a high temperature. Therefore, minimize the duration of direct contact between the patient's mouth and the blade under this circumstance!

3. Intubation

Select a tracheal tube of suitable specifications and place the tracheal tube into the patient's mouth by following the method and procedure formulated by the hospital.

8. Contraindications

- 8.1 Obesity, large head, short neck, and anterior glottic tumor
- 8.2 Lower micrognathia, large tongue, and larynx situated in a higher position than normal
- 8.3 Small or limited mouth opening
- 8.4 Limited mouth opening due to an injury and temporomandibular joint rigidity
- 8.5 Cervical dislocation
- 8.6 The laryngoscope should be used with caution on patients with serious illness, severe weakness,

and late pregnancy.

9. Precautions, Warnings, and Tips

9.1 Precautions for use



1. Read the instructions for use carefully and completely before using the anesthetic video laryngoscope. First check that the laryngoscope is free of cosmetic damage or deformation and that the variety and quantity of accessories are consistent with those specified in the configuration list in the user manual. If the laryngoscope is damaged due to unloading, contact the supplier or after-sales service promptly.
2. The laryngoscope can only be used with the provided choice of blades. Before use, check the outer surface of each blade for unintended sharp edges, protrusions, visible cracks, or rough surfaces, and check for lens damage and missing parts which may cause harm. If such defects are present, use a different blade.
3. Disinfect or sterilize the blades each time before using the blades on a patient.
4. The laryngoscope can be used only by professional medical staff.
5. Do not destroy or disassemble the laryngoscope and its accessories without authorization; otherwise, the laryngoscope may experience structural change, endangering the patient's safety.
6. Take care to avoid impact and dropping of the laryngoscope during use.
7. Use a sterilized tracheal tube with qualified medical equipment certification.
8. Take care to avoid direct eye contact with the luminous area when using the laryngoscope.
9. Do not use the laryngoscope when it is being charged.
10. Do not forcibly turn the main-unit display of the laryngoscope.
11. If the laryngoscope is suspected to encounter any functional errors during use, stop using it immediately, mark the errors, and contact the supplier or after-sales service promptly.
12. Do not discard the scrapped lithium battery and main unit randomly. The disposal of waste and residues should conform to local laws and regulations.
13. Do not replace parts by yourself or use components and accessories from other manufacturers; otherwise, you will bear responsibilities resulting from product damage caused by self-replacement.
14. Use only the maintenance parts and components provided by Shenzhen Century Weichuang Medical Technology Co., Ltd. Use of maintenance parts and components from other manufacturers may void the warranty.
15. Do not disassemble the laryngoscope by yourself. To perform adjustment, repair, and replacement, contact the supplier, after-sales service, or Shenzhen Century Weichuang

Medical Technology Co., Ltd.

9.2 Stop using the laryngoscope under any of the following circumstances:

1. The blade lens has cracks or smudges.
2. The LED indicator light does not turn on.
3. No image is displayed on the screen or the camera error icon appears after the laryngoscope is powered on.
4. The laryngoscope cannot be powered on or is unusable after charging.
5. The display screen is damaged or abnormal, and the camera module cannot be restored after cleaning.
6. The blade cannot be fixed when being connected.

9.3 Electronic interference

The anesthetic video laryngoscope has passed testing in compliance with applicable standards. However, other electrical medical equipment may cause interference to the laryngoscope and the laryngoscope may also interfere with other electrical medical equipment during use. If interference is present, it is recommended that you increase the physical distance between the laryngoscope and other electrical medical equipment.

10. Cleaning, Disinfection, and Sterilization

The anesthetic video laryngoscope must be cleaned and disinfected and the blades must be disinfected or sterilized before the laryngoscope is used for the first time or each time after it is used on a patient.

10.1 Disinfect the main unit (which consists of the display screen and handle) by wiping it with a piece of cloth soaked with medical alcohol.

10.2 Disinfect the camera module by wiping it with a piece of cloth soaked with medical alcohol.

10.3 Blade disinfection

- Remove the blade from the handle of the handheld main unit and inspect the lens for any damage. The user or hospital is required to rinse the blade with flowing sterile water.
- Ensure that the blade has been cleaned and rinsed before disinfection.
- Immerse the blade in 0.55% ortho-phthalaldehyde disinfectant for at least 5 minutes. After that, take out the blade and rinse it clean with flowing sterile water. During rinsing, take care to avoid secondary blade contamination. Then, dry the blade by using sterile gauze.

10.4 Blade sterilization

- Remove the blade from the handle of the handheld main unit and inspect the lens for any damage. The user or hospital is required to rinse the blade with flowing sterile water.
- Ensure that the blade has been cleaned and rinsed before disinfection.

- Sterilize the blade inside a pressure steam sterilizer at 121°C, 102.9 kPa for 20 minutes.

10.5 After the laryngoscope is used, wipe the parts that are not in direct contact with the patient by using a piece of cloth soaked with disinfectant, dry the parts, and store them in the packaging box. Disinfect or sterilize the blade that is in direct contact with the patient, dry it, and then store it in a sterile packaging box.

11. Maintenance

11.1 Perform maintenance inspection once every week.

11.2 Keep the laryngoscope clean and away from dust and protect it from contamination, shaking, and impact.

11.3 Instructions for safe use and maintenance of the lithium battery

- (1) Store and use the lithium battery within the specified temperature and humidity ranges.
- (2) Unplug the power adapter promptly when the lithium battery is fully charged to prevent overcharge.
- (3) Do not keep discharging the battery until the laryngoscope is powered off.
- (4) Do not knock, crush, heat, or burn the handle to prevent the lithium battery from being damaged.
- (5) It is recommended that the lithium battery be charged once every three months when the laryngoscope is unused for a long time, to prevent faults caused by battery self-discharge.

12. Operating Environment and Conditions of Storage and Transportation

12.1 The laryngoscope can be transported by any means provided that its package is in good condition. Ensure that the laryngoscope is clean and free of contamination during transportation and prevent exposure to sunlight and rain.

12.2 Environmental conditions for normal use

1. Ambient temperature: 5–40°C
2. Relative humidity: ≤ 80%
3. Atmospheric pressure: 86–106 kPa

12.3 Conditions of storage and transportation

1. Store the laryngoscope in a clean, dry, and ventilated place after cleaning, disinfection, and drying.
2. Ambient temperature: –20°C to +55°C
3. Relative humidity: ≤ 93%
4. Atmospheric pressure: 50–150 kPa

13. Shelf Life

Date of manufacture: See the product label.

Shelf life of the main unit: 3 years

Shelf life of the blades with disinfection via immersion: 3 years

Shelf life of the blades with sterilization under high temperature and pressure: 100 times

14. Configuration List

Item	Quantity	Item	Quantity
Main unit	1	USB data cable	1
Blade	3	User Manual	1 copy
Protective case for the module	1	Certificate of compliance	1 copy

15. Graphs, Symbols, and Acronyms and Abbreviations Used with Medical Equipment

	Attention. See the document delivered with the equipment.		Manufacturer
	Applied Part: Type B		Date of manufacture
	Manufacturer's batch code		Up
	Shelf life		Protect from rain
	Fragile. Handle with care.		Number of stacking layers
	Temperature limit		Humidity limit
	Separate handling of scrapped electrical and electronic equipment in conformance to local laws and regulations		Atmospheric Pressure Symbol indicates upper and lower limits of the atmospheric pressure for this device.

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16. Environmental Protection

The built-in lithium battery of the anesthetic video laryngoscope may cause environmental pollution after the laryngoscope reaches the end of its shelf life. Handle packaging materials, scrapped products, and products at the end of shelf life properly in accordance with local laws and regulations, and support the local practice of waste sorting and recycling if possible.

17. Registrant, Manufacturer, and After-Sales Service

Name: Shenzhen Century Weichuang Medical Technology Co., Ltd.

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18. User Manual Preparation

This user manual includes instructions for use and technical instructions.

Preparation date: August 22, 2018

Software version: V1

19. Appendix: EMC Information



Note:

- The anesthetic video laryngoscope (models: SW-B01 and SW-B02) meets the EMC requirements of the IEC 60601-1-2:2014 and IEC 60601-2-18:2009 standards.
- Install and use the laryngoscope based on the EMC information in the document that is delivered with the laryngoscope.
- Portal and mobile RF communication equipment may compromise the performance of the laryngoscope (models: SW-B01 and SW-B02), so prevent strong electromagnetic interference when using the laryngoscope, for example, keeping the laryngoscope away from mobile phones and micro ovens.
- For details about the guidelines and the manufacturer's statement, see the appendix.



Warning:

- The anesthetic video laryngoscope (models: SW-B01 and SW-B02) should not be used in proximity to or stacked with other equipment. If it must be used under such a condition, be sure to observe and verify that it can work properly with its used configuration.
- The anesthetic video laryngoscope (models: SW-B01 and SW-B02) may experience increased emission or reduced electromagnetic susceptibility when it is used with other accessories and electric cables than those sold by the laryngoscope manufacturer as spare parts for the internal components of the laryngoscope.

Cable information

No.	Name	Cable Length (m)	Shielded?	Remarks
1	USB data cable	1.0	No	/

Guidelines and Manufacturer's Statement – Electromagnetic Emission

The Video Laryngoscope (models: SW-B01 and SW-B02) is intended to be used in the following specified electromagnetic environments. Buyers or users of the laryngoscope should ensure that it is used in such electromagnetic environments.

Emission Test	Compliance	Electromagnetic Environment – Guidelines
RF emission IEC CISPR 11-2010	Group 1	The anesthetic video laryngoscope (models: SW-B01 and SW-B02) uses RF energy only for its internal functions. Therefore, the laryngoscope has extremely low RF emission and an extremely low possibility of interfering with nearby electronic equipment.
RF emission IEC CISPR 11-2010	Class B	The anesthetic video laryngoscope (models: SW-B01 and SW-B02) is suitable for use in all facilities, including domestic facilities and public low-voltage power supply networks that are directly connected to domestic residence.
Harmonic emission IEC 61000-3-2:2018	Not applicable	
Voltage fluctuation and flicker emission IEC 61000-3-2:2018	Not applicable	

Guidelines and Manufacturer's Statement – Electromagnetic Susceptibility

The Video Laryngoscope (models: SW-B01 and SW-B02) is intended to be used in the following specified electromagnetic environments. Buyers or users of the laryngoscope should ensure that it is used in such electromagnetic environments.

Electromagnetic Susceptibility Test	IEC 60601 Test Level	Coincidence Level	Electromagnetic Environment – Guidelines
Electrostatic discharge IEC61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15kV air discharge	The floor should be wood, concrete, or ceramic tiles. If the floor is covered with synthetic materials, the relative humidity should be at least 30%.
Electrical fast transient IEC61000-4-4	±2 kV pair power cable ±1 kV pair I/O cable	Not applicable	Not applicable
Surge IEC61000-4-5	±1 kV differential mode voltage ±2 kV common mode voltage	Not applicable	Not applicable
Voltage dip, short-term interruption, and voltage variation on power input cables IEC61000-4-11	< 5% U_T , lasting 0.5 cycles (On U_T , voltage dip > 95%) 40% U_T , lasting 5 cycles (On U_T , 60% voltage dip) 70% U_T , lasting 25 cycles (On U_T , 30% voltage dip) < 5% U_T , lasting 5s (On U_T , voltage dip > 95%)	Not applicable	Not applicable
Power frequency magnetic field (50/60 Hz) IEC61000-4-8	3 A/m	3 A/m, 50/60 Hz	The power frequency magnetic field 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.

Guidelines and Manufacturer's Statement – Electromagnetic Susceptibility

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Electromagnetic Susceptibility Test	IEC 60601 Test Level	Coincidence Level	Electromagnetic Environment – Guidelines
RF conduction IEC61000-4-6	3 V (valid value) 150 kHz to 80 MHz	3 V (valid value)	<p>Portable and mobile RF communication equipment should not be used closer to any parts, including cables, of the Video Laryngoscope (models: SW-B01 and SW-B02) than the recommended isolation distance. The distance should be calculated by the formula corresponding to the transmitter frequency.</p> <p align="center">Recommended isolation distance</p> $d = 1.2\sqrt{P}$ <p>$d = 1.2\sqrt{P}$ 80–800 MHz</p> <p>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>Where:</p> <p>P : the maximum rated output power of the transmitter provided by the transmitter manufacturer, in the unit of watts (W)</p> <p>d: the recommended isolation distance, in the unit^b of meters (m)</p> <p>The field strength of a fixed-type RF transmitter is determined by surveying the electromagnetic field^c and should be lower than the coincidence level in each frequency range^d.</p> <p>Interference may occur in the vicinity of equipment marked with the symbol.</p> 
RF radiation IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Note 1: From 80 MHz to 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not be applicable to all situations. Electromagnetic transmission is affected by absorption and reflection by buildings, objects, and human bodies.

a: Fixed-type transmitters, such as base stations for wireless (cellular or cordless) telephones and terrestrial mobile radios, amateur radios, AM and FM radio broadcasts, and television broadcasts,

have field strengths that cannot be predicted accurately in theory. Survey of electromagnetic sites should be considered for evaluating the electromagnetic environments of fixed-type RF transmitters. Observe and verify that the Video Laryngoscope (models: SW-B01 and SW-B02) works properly if the environment where the laryngoscope is used has field strength higher than the preceding applicable RF coincidence level. If abnormal performance is observed, supplementary measures may be necessary, such as readjusting the orientation or position of the laryngoscope.

b: In the whole frequency range of 150 kHz to 80 MHz, the field strength should be lower than 3 V/m.

Recommended Isolation Distance Between Portable and Mobile RF Equipment and the Video Laryngoscope (Models: SW-B01 and SW-B02)

The anesthetic video laryngoscope (models: SW-B01 and SW-B02) is intended to be used in electromagnetic environments with controlled RF radiation disturbance. According to the maximum rated output power of communication equipment, buyers or users of the Video Laryngoscope (models: SW-B01 and SW-B02) can prevent electromagnetic interference by maintaining the following recommended minimum distance between portable and mobile RF communication equipment (transmitter) and the laryngoscope.

Maximum Rated Output Power of the Transmitter (W)	Isolation Distance (m) Corresponding to Different Frequencies of the Transmitter		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For the maximum rated output power of the transmitter not listed above, the recommended isolation distance d , in meters (m), can be calculated by the formula in the corresponding transmitter frequency column, where P , in watts (W), is the maximum rated output power of the transmitter provided by the transmitter manufacturer.

Note 1: From 80 MHz to 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not be applicable to all situations. Electromagnetic transmission is affected by absorption and reflection by buildings, objects, and human bodies.