



ClearViz™ VL3D Video Laryngoscope
Operating Instructions

Guidebook

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ClearViz™ VL3D Video Laryngoscope Operating Instructions

Welcome to use VL3D handheld video laryngoscope. With its advanced module design, high resolution images, professional lighting system, and recording capabilities, this device represents a state-of-the-art solution to both average and difficult intubation procedures in different environments.

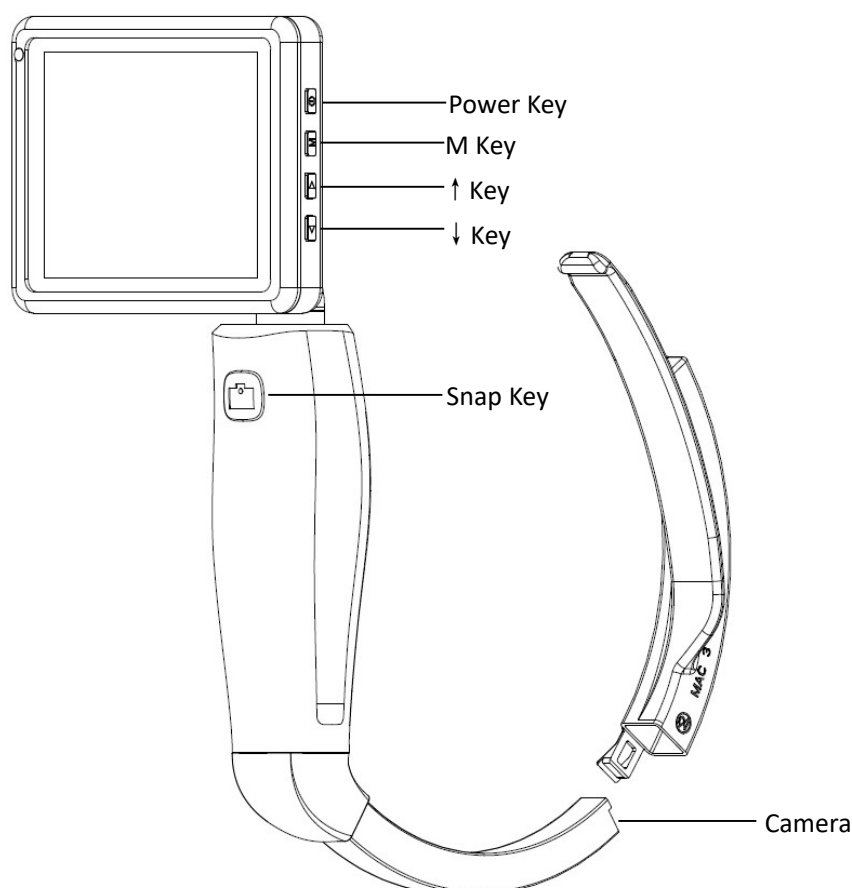
While the VL3D is fairly intuitive to assemble and operate, these instructions will serve as a reference for operation and maintenance of the device. Please read the instructions carefully before attempting to operate the VL3D.

I. Device Assembly and Disassembly

1. Select the appropriate VL3D video blade according to patient oral cavity size.
2. Assembly: Insert the camera stick into the blade and listen for a "Click" to feel the camera stick engage with the Blade.
3. Disassembly: Remove the blade from the camera stick.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radiofrequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

II. Operating the VL3D Display



1. Power Key: Switch on/off the device.
2. M Key: Menu key / video play Pause key / Enter / time selection.
 - a. ↑ key: Last image or video / increase value.
 - b. ↓ key: Next image or video / Decrease value.
5. Snapkey : Short press camera / long press video / return.
6. Camera: For filming.

1. Pressing the power button for 3.5 seconds, the system will power up and display the "SourceMark" logo for seconds. The device will then be fully functional with an image shown on the screen.
2. Upon turning on the display, in the lower left-hand corner of the screen there will be a small battery symbol icon indicating the power level of the monitor's internal rechargeable lithium battery. The date and time will also be displayed.
3. If the battery is low in power and in need of recharging, there will be reminder like "Reminder: Low battery! Please charge in time!" The system will be shut down in 15 minutes!", until the device is either recharged with the external mini-USB recharger cord, or power is eventually exhausted, and the monitor turns itself off.

III. VL3D System Operation Guidance

The VL3D is designed to be used with standard laryngoscopy technique similar to that of direct laryngoscopy. Please refer to qualified instructors who provide specialized training in endotracheal intubation techniques before attempting to use this device with human subjects. The static images and video for respiratory and tracheal intubation procedures can be recorded and automatically saved to the SD card inside the display.

1. Warming up :

- Cleaning: The blade and handle should be appropriately cleaned and/or sterilized before use (see cleaning instructions in PART IV).
- The blade electrical component generates heat to the camera lens, which helps clear lens fogging immediately after opening up, especially while in the warm and humid conditions of the airway.

2. Recording static images:

- Press short the snap key on the handle for picture shooting. When the icon  appears, images are automatically saved to the SD card under a ".JPG" file format.

NOTE: static images cannot be recorded and saved while the device is recording video.

3. Recording video loops:

- Press long (2 seconds) on the snap key to initiate recording. The action is noted by an ongoing blinking "Recording" on the display. A recording time counting will also be displayed.
- Press the same button a second time to end the recording. The video file will automatically be saved to the SD card under an ".MP4" format.

4. Reviewing images and videos:

- Both static images and video loops can be reviewed by pressing the "M" menu button for selecting "Image view" or "Video play" to preview.
- Each file is individually identified by a date/time stamp.

5. Exiting video:

- Press "M" menu button to pause video review play; press "Snap" key to end video review.

6. Setting up Time and Date

- Press "M" Menu key and select "Time Setting".
- Press Up or Down arrow buttons to amend date and time value.
- Press "M" Menu key to confirm the changes and then the upper right corner of the display will show the change.

IV. Cleaning Instruction

Please carefully follow the below operating instructions from the manufacturer before you do cleaning/sterilization.

1. Handle & Display Cleaning

- The display is not waterproof and should not be merged with or exposed to excessive amounts of fluids. The face of the unit, including the front control buttons, is sealed and can be cleaned with anti-microbial solution wipes. Cleaning of the remainder of the unit should be done carefully to avoid introducing liquids into the interior of the monitor.

2. Blade

Blade can be used only once, and it should be destroyed according to the hospital's regulations.

V. Battery use and battery maintenance

The VL3D system is equipped with rechargeable lithium-ion batteries. These batteries are designed to independently provide optimal power to the display and the video blades, and can be fully recharged many times with minimal loss in performance.

1. Charging

It is not accessible other than to connect to a charger via the mini-USB charging port on the top of the display. The LED on the upper left of the display will illuminate GREEN when the battery is charging and will cease when the battery is fully charged.

- When the power is nearly consumed up, there will be reminder 5 minutes beforehand.
- Consumption time of one full charge in continuous use: 2 hours (average)
- Time to recharge: 8 hours from fully discharged state
- Span life: up to 3 years (average)

2. Maintenance

The VL3D monitor can be continuously attached to the charger for long periods of time. Lithium-ion batteries also do not have "memory" characteristics, and do not require deep discharging and recharging to maintain peak functionality

Note: Allowing rechargeable lithium batteries to fully discharge can damage the battery and reduce performance significantly. Full discharge of the batteries should be avoided.

VI. Electromagnetic Compatibility



Notice

- VL3D conforms with IEC 60601-1-2 relevant requirements of the standard electromagnetic compatibility; user should install and use in accordance with electromagnetic Compatibility random file provided.
- Portable and mobile RF communication equipment may affect VL3D performance, so avoid the use of strong electromagnetic interference such as near cell phones, microwave ovens and the like.
- Guidelines and manufacturer's statement are detailed in the annex.



Warning

- VL3D should not be close to or stacked with other equipment; if it must be close to or stacked use, it should be observed to verify normal operation in the configuration when using.
- VL3D equipment class is designed for use in industrial environments where it meets the necessary standards for controlling electromagnetic interference (EMI), including both conducted and radiated interference. When using VL3D in non-industrial environments, be aware that potential electromagnetic compatibility (EMC) issues may occur.

- Using accessories and cables other than those specified by the manufacturer for VL3D internal components may result in increased or reduced immunity to emitted interference.

Annex:

Guidance and manufacturer's declaration - electromagnetic emissions		
VL3D is intended to be used in the electromagnetic environment specified below; the purchaser or user should ensure that it is used in such an electromagnetic environment:		
Emission test	Compliance	Electromagnetic environment - Guidelines
RF Transmitter GB4824	Group 1	VL3D operates using radio frequency energy for its internal functions. Therefore, it is a very low-radio frequency transmitter, with small risk of interference to nearby electronic equipment.
RF Transmitter GB4824	A Class	VL3D is suitable for use in non-residential and is not directly connected to all facilities for residential home in the public low-voltage power supply network.
Harmonic emission GB 17625.1	Not applicable	
Voltage fluctuations / flicker emission GB17625.2	Not applicable	

Guidance and manufacturer's declaration - electromagnetic immunity			
VL3D is intended to use in the electromagnetic environment specified below, the purchaser or user should ensure that it is used in such an electromagnetic environment:			
Immunity Test	IEC 60601 Test level	compliance level	Electromagnetic environment - Guidelines
Electrostatic discharge GB/T 17626.2	±6kV contact discharge ±8 kV air discharge	±6kV contact discharge ±8 kV air discharge	Floors should be wood, concrete or ceramic tile. If the ground is covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient burst GB/T 17626.4	±2kV to Power line	±2kV to Power line	Main power quality should have a typical commercial or hospital environment using
Surging GB/T 17626.5	±1 kV Wire to Wire ±2 kV Wire to earth	±1 kV Wire to Wire ±2 kV Wire to earth	Main power quality should have a typical commercial or hospital environment using
Power input line voltage dips, short interruptions and voltage variations GB/T 17626.11	<5 % U_T , Duration of 0.5 cycles (on the basis of U_T , >95% voltage sag) 40 % U_T , Duration of 5 cycles (on the basis of U_T , 60% voltage sag) 70 % U_T Duration of 25 cycles (on the basis of U_T , 30% voltage sag) <5 % U_T , Continued 5s (on the basis of U_T , >95% voltage sag)	<5 % U_T , Duration of 0.5 cycles (on the basis of U_T , >95% voltage sag) 40 % U_T , Duration of 5 cycles (on the basis of U_T , 60% voltage sag) 70 % U_T , Duration of 25 cycles (on the basis of U_T , 30% voltage sag) <5 % U_T , Continued 5s (on the basis of U_T , >95% voltage sag)	Main power should have the quality of a typical commercial or hospital environment use. If the user needs VL3D continuous operation during power interruption, its recommended VL3D use an uninterruptible power supply or fullbattery-power.
Power frequency magnetic field (50/60Hz) GB/T 17626.8	3A/m	3A/m, 50/60Hz	Power frequency magnetic field should have a typical commercial or hospital environment characteristic of the level of power frequency magnetic field

Remark: U_T is the AC voltage before applying the test voltage

Guidance and Statement of Electromagnetic Immunity

The VL3D should be used under the stipulated electromagnetic environment. Customer or user shall ensure using VL3D under the following stipulated electromagnetic environment.

Immunity test	IEC 60601Test Level	Compliance Level	Electromagnetic environment - Guide
Conduction immunity GB/T 17626.6	3 V (Valid Value) 150 kHz ~ 80 MHz	3 V (Valid Value)	Portable and mobile RF communications equipment must be used outside the equipment and / or systems (including cable) of any parts the prescribed distance. The separation distance is based on the transmitter frequency to choose the right formula calculated. The suggested calculation formula of isolation distance is: $d = 1.2\sqrt{P} \quad 80M \sim 800MHz$ $d = 2.3\sqrt{P} \quad 800M \sim 2.5GHz$
Radiation immunity GB/T 17626.3	3 V/m 80 MHz ~ 2.5 GHz	3 V/m	Among them, P is the Nominal maximum output power of transmitters, its unit is watt; d is the recommended isolation distance, its unit is meter. The field strength of RF transmitter is obtained via electromagnetic field measurements a , in every frequency range b must be less than line level. Interference may occur with other equipment marked by the following sign: 

Note 1: Use higher frequency band formula between 80 MHz and 800 MHz

Note 2: The above guidance does not apply to all cases, because material structure, objects and persons can absorb and reflect the electromagnetic wave and then affect the electromagnetic transmission.

^aThe field strength of Radio (honeycomb and wireless) mobile phone's base stations and ground mobile radio receivers, the antenna devices, FM and AM radio, television broadcast is unable to use pure theory for the accurate estimation. In order to evaluate the electromagnetic environment produced by fixed RF transmitters, one should consider method of electromagnetic field measurement. If the measured field strength of working environment of VL3D exceeded the stipulated RF level, one must observe whether VL3D can work normally. Once abnormal situation was found, one must take corresponding measures, such as changing the direction of VL3D or moving it to other places.

^bWhen the frequency range is between 150 k and 80 Mhz, the field strength shall be less than 3 V/m.

Recommended Distance Between VL3D and Portable/Mobile RF Communication Equipment

The VL3D can be used in the electromagnetic environment where RF interference can be controlled. In order to avoid electromagnetic interference, the customer or user should ensure that the VL3D and portable/mobile RF communications equipment maintain the minimum recommended distance. The following recommended distance is calculated according to the maximum output power of communication equipment.

The transmitter's maximum output power (W)	Calculate isolation distance according to the transmitter frequency (m)		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ~ 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

If the transmitter's maximum output power is not within the above range, one can estimate isolation distance by corresponding equation in column. P in the equation is the maximum output power given by transmitter manufacturer. The unit is watt.

Note 1: Use the higher frequency band formula between 80 M and 800 MHz.

Note 2: The above guidance does not apply to all cases, because material structure, objects and persons can absorb and reflect the electromagnetic wave and then affect the electromagnetic transmission.

VII. Troubleshooting

ClearViz™ VL3D systems are generally reliable and simple to operate, requiring minimal maintenance for extended periods. However, the following is offered to help deal with unexpected device conditions:

1) Display is non-functional, shows no sign of power

- Check for proper power
- Restart if necessary

2) Image appears on screen, but is grainy or dim

- Ensure that handle battery is adequately charged
- Check all blade and handle connections
- Ensure that lenses on camera and LEDs on blade are clean, and not contaminated

VIII. ClearViz™ VL3D Limited Quality Warranty

SourceMark warrants its ClearViz™ VL3D Products to be free of defects in materials or production and offer 12 months guarantee under normal use from date of purchase. Details are as follows:

What is Covered: Replacement of All Parts.

What is Not Covered: Transportation charges to and from SourceMark; damage caused by abuse, misuse, accident or negligence.

To Obtain Warranty Service: Please contact SourceMark Customer Support which will check and evaluate the situation. If it is appropriate, SourceMark will issue an RGA authorization and number. A form will be sent to be completed and returned with the defective product.

An RGA number is valid for 30 days after issuance. Any returns beyond 30-day period will expire and will not be authorized and will not be accepted.

Manufacturer For: SourceMark Medical

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Made in China