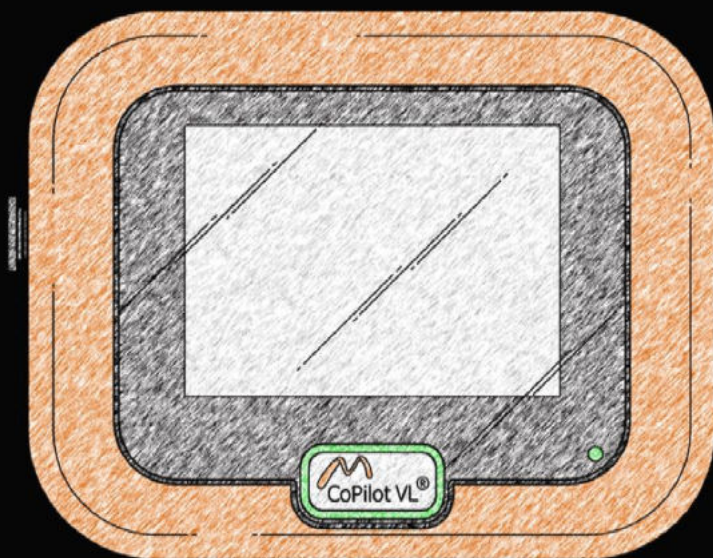




CoPilot VL[®]

CoPilot Video Laryngoscope System



Instructions for Use

Magaw Medical
1120 South Freeway
Fort Worth, Texas 76104
855-CoPilot

www.CoPilotVL.com



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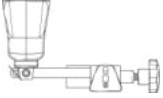





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Introduction

The CoPilot Video Laryngoscope (CoPilot VL[®]) was developed from the ground up, by practitioners who believe that video laryngoscopy should be the standard of care for all intubations. Every patient. Every single time. Our affordable video laryngoscope makes video laryngoscopy available for ALL your patients.

What's Included?

The CoPilot VL[®] system comes with everything you need to start using it right out of the box. All components must be inspected, prior to use, for any obvious physical damage that may have occurred during shipping.

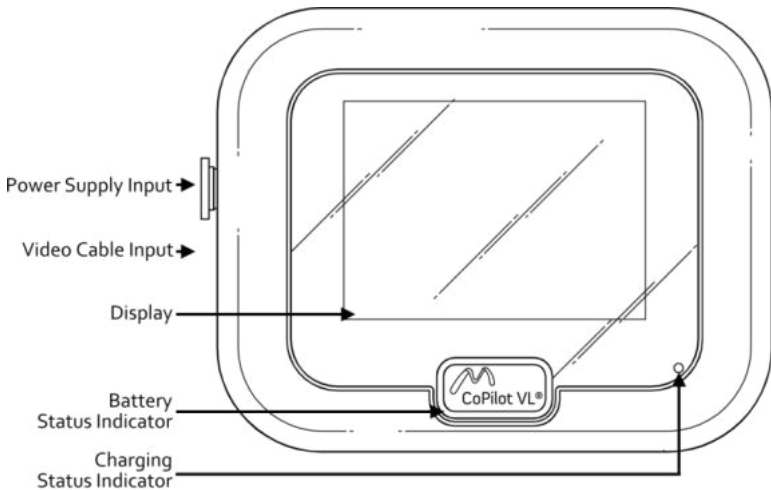
Part:	Description:	Part No:
	Display	1100
	Handle	1120
	Adult Video Blade	1140
	IV Pole Clamp	1160
	CoPilot VL [®] Rigid Stylet	1300
	CoPilot VL [®] Disposable Bougies	1510
	CoPilot VL [®] Disposable Sheaths <ul style="list-style-type: none"> • Adult Size 3 • Adult Size 4 	1730 1740
	Power Supply (AC Adapter)	1400
	Emergency Backup Battery Pack *Optional accessory	1440

Features of the CoPilot VL®

The CoPilot VL® system consists of three main components: the display, the handle and video blade assembly, and the disposable sheaths. The CoPilot VL® is compact and can be used in a variety of environments; it goes easily from the operating room to the ambulance and other health care settings.

Display – Front View

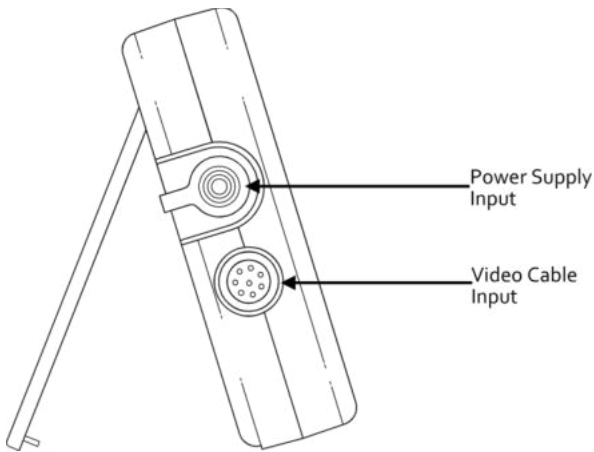
The CoPilot VL® was designed with simplicity in mind. There are no buttons to push, no settings to change. When the video blade is fully opened, the display will turn on and the battery status indicator will illuminate.



Features of the CoPilot VL[®]

Display – Side View

There are two inputs on the side of the display: the first is for the power supply and the second is for the video cable input. The power supply is used to charge the built-in internal battery. The video cable is used to attach the handle to the display. Do not twist or screw the video cable into or out of the connector.

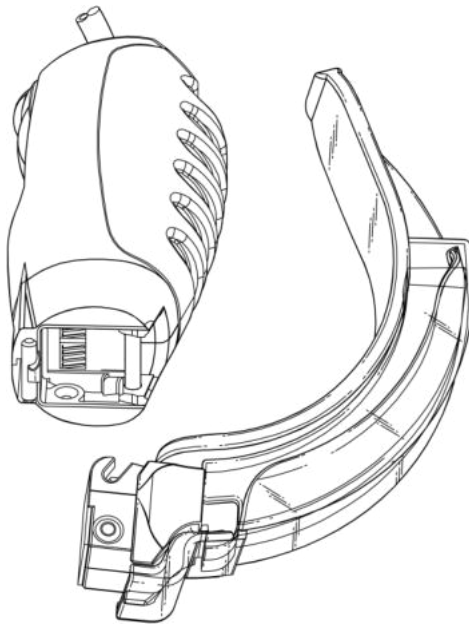


Note: You may use the CoPilot VL[®] while it is charging.

Features of the CoPilot VL[®]

Handle and Video Blade

The video blade attaches to the handle in the same fashion as a traditional laryngoscope. To power on the system, simply attach the video blade to the handle in the same manner as a traditional laryngoscope and open the video blade. When the system is on, an antifog heating mechanism in the distal tip of the blade is activated. To prevent fog, allow the sheath to heat for at least 30 seconds prior to laryngoscopy.

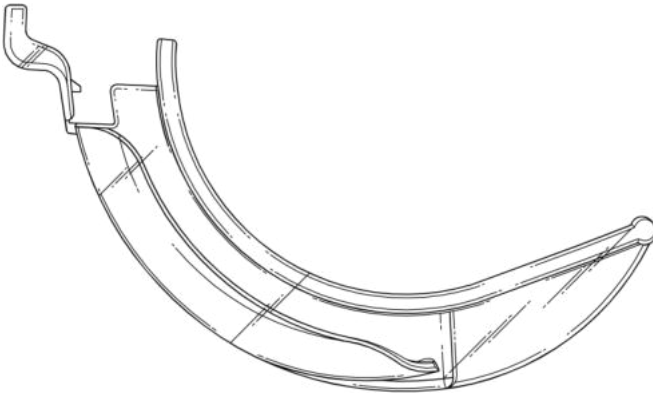


Note: Prior to use, confirm full functionality of the device by connecting the video blade to the handle and the handle to the display. Open the video blade to engage the unit and verify that the LED's on the end of the blade are illuminated and that the display is showing a clear image.

Features of the CoPilot VL[®]

Disposable Sheaths

One of the primary benefits of the CoPilot VL[®] is that it uses disposable sheaths. Sheaths are easily removed with the eject mechanism and can be quickly replaced with a new one, eliminating down time. Sheaths are single use only and *must* be disposed of after every use in accordance with hospital procedures for general refuse.

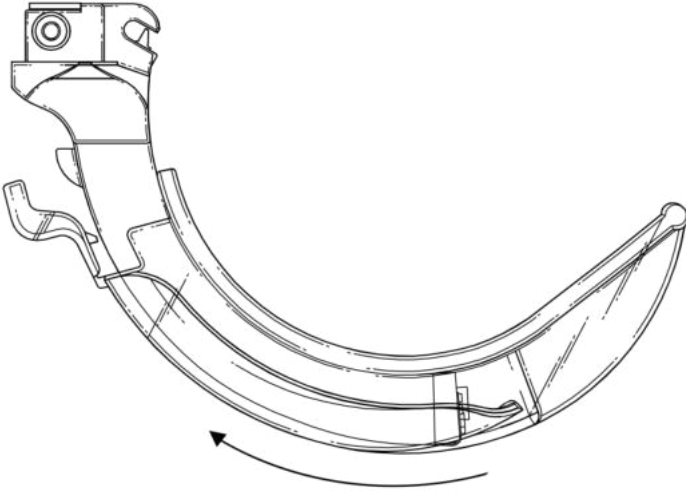


Note: Sheaths are provided in sealed pouches. Examine pouch for damage, including breach of seal, prior to use. Do not use if seal is damaged or breached.

Features of the CoPilot VL[®]

Install the Disposable Sheath

With the video blade open, slide a new CoPilot VL[®] disposable sheath over the end of the video blade until it snaps in place.

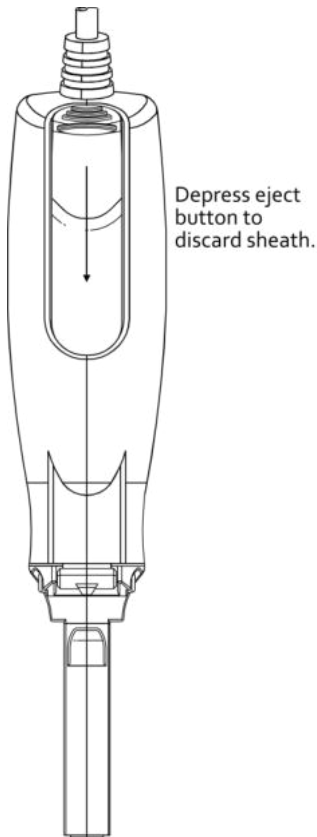


Note: Examine the sheath for any visible signs of damage prior to use.

Features of the CoPilot VL[®]

Eject the Disposable Sheath

Each CoPilot VL[®] disposable sheath is intended for a single intubation only and must be disposed of immediately following use. To remove the CoPilot VL[®] disposable sheath from the video blade, depress the eject button on the back of the handle until the sheath is released. This mechanism allows the contaminated sheath to be disposed of without requiring the user to touch the sheath.



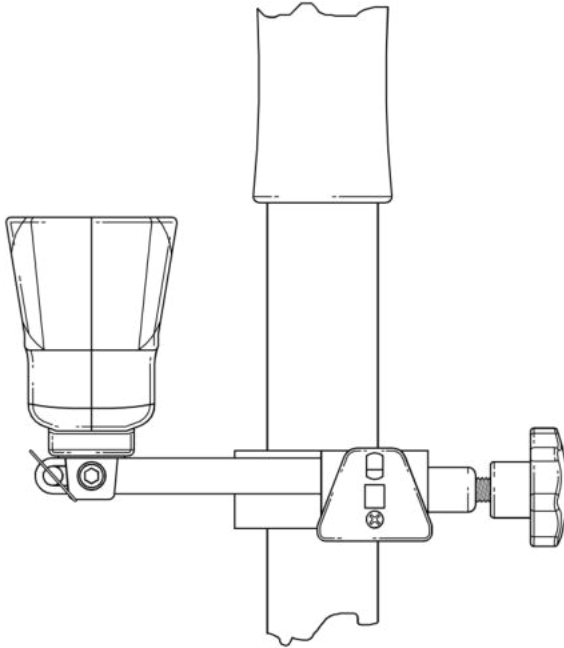
Note: The unsheathed tip of the video blade may be warm to the touch. Take care to avoid contact with the skin.

Features of the CoPilot VL[®]

IV Pole Clamp Use

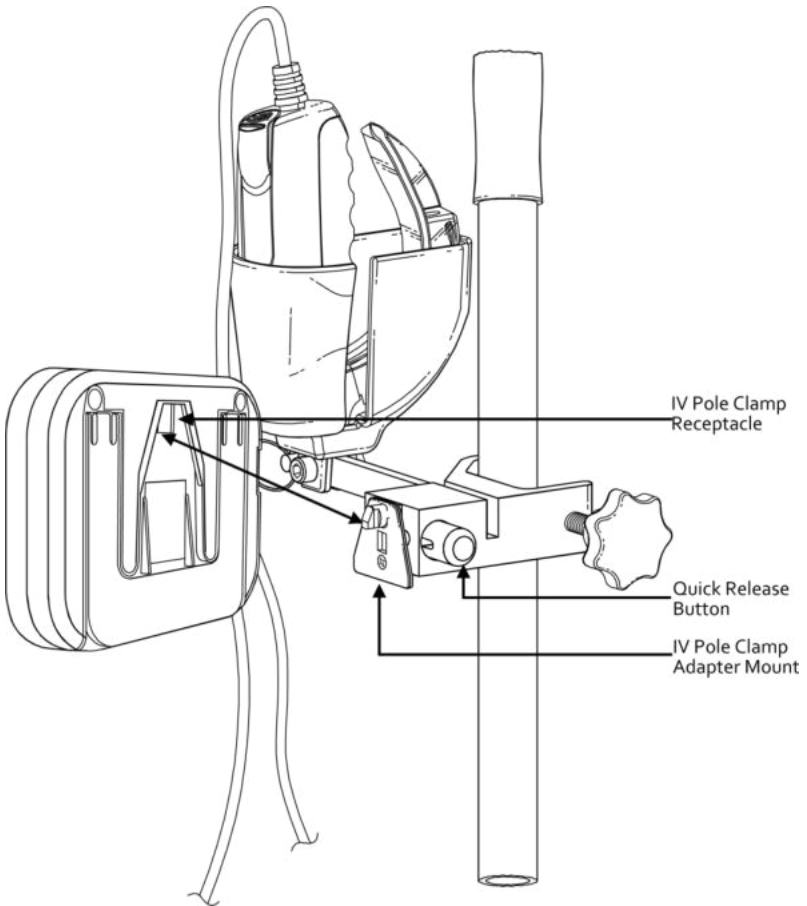
The CoPilot VL[®] display can be mounted to an IV pole at a position that is convenient for the user. Alternatively, the display can be quickly released from the IV pole clamp and may be placed on a table or other flat surface using the built in stand.

To use the IV pole clamp, position the clamp at the desired level. Tighten the threaded mounting screw in a clockwise fashion until the clamp is firmly secured to the IV pole. Hand-tighten only. Do not use tools to tighten the knob. Do not use the clamp to support any other device.



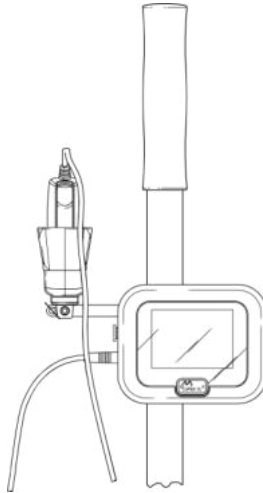
Features of the CoPilot VL[®]

Next, slide the display unit onto the IV pole mount until it locks into place.



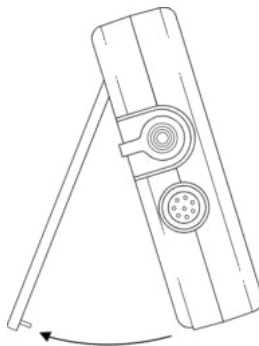
Features of the CoPilot VL[®]

The IV pole clamp also provides a convenient place to store the laryngoscope when not in use.



Using the Built-In Stand




The CoPilot VL[®] can be used independent of the IV pole clamp. You may place the display on a table or other flat surface using the stand built into the back of the unit. To remove the CoPilot VL[®] from the IV pole clamp, press the quick release button and lift the CoPilot VL[®] straight up. Place the display on the flat surface and pull out the bottom of the built-in stand to the desired viewing position.



Features of the CoPilot VL[®]

Powering the CoPilot VL[®]

The CoPilot VL[®] can be powered by the included external power supply or by the internal battery. A battery status indicator is built into the logo on the front of the display. A green LED around the CoPilot VL[®] logo indicates sufficient charge for use. When the unit needs to be recharged, the LED around the CoPilot VL[®] logo will change from green, to orange, and then to red. The charge status indicators are only approximate; the CoPilot VL[®] power supply should be kept immediately available for charging.

	Green: Charged.
	Orange: Approximately 20% battery life remaining. Recharge before use.
	Red: Less than 10% battery life remaining. Charge immediately!



A fully charged battery will provide over two hours of continuous use. To recharge the device, plug the power adaptor into the side of the display housing and tighten the locking washer. Plug into a standard power outlet.

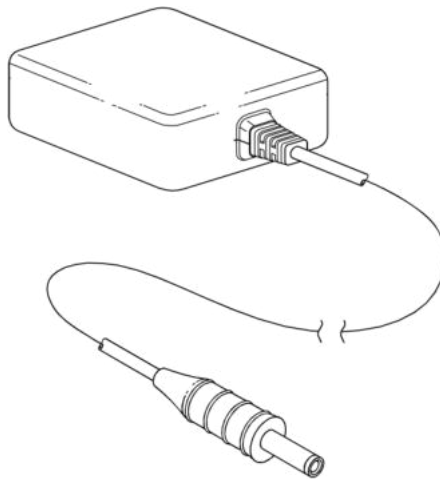
The battery charge status light will illuminate, indicating that the device is charging. A depleted battery can be completely recharged in four hours. When the unit is fully charged, the battery charge status light will change from orange to green. You may use the CoPilot VL[®] while it is recharging. To remove the power adaptor from the side of the display, loosen the locking washer by unscrewing it and pull.

Note: The device may only be recharged using the included power supply; the power supply may not be used to recharge any other device.

Features of the CoPilot VL®

Optional Power Sources for the CoPilot VL®

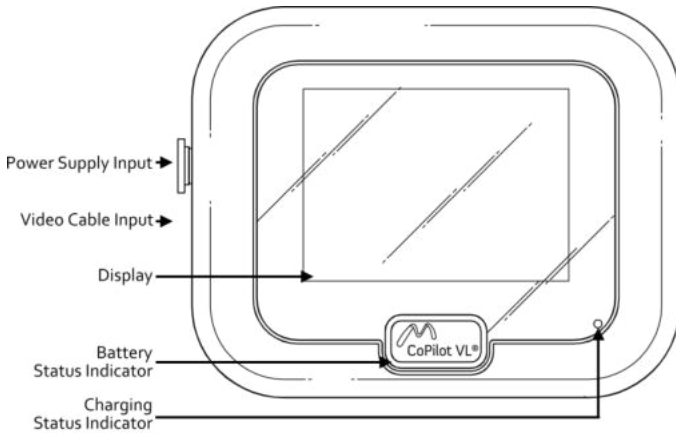
An “emergency” battery pack is available as an optional accessory. This is used for cases when the internal battery is completely depleted and there is no access to AC power. This provides sufficient power for a single intubation. The battery pack is considered single-use only and is not intended to be the primary power source for continued use or for recharging the internal battery. The emergency battery connects in the same way as the AC power supply.



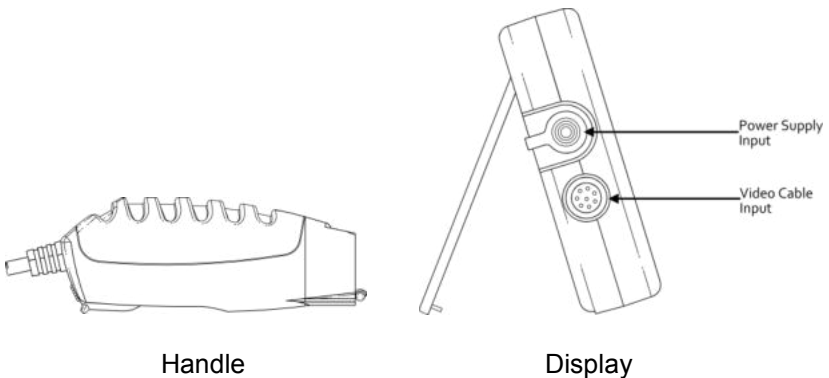
Using the CoPilot VL®

Assemble the CoPilot VL®

1. Fully charge the CoPilot VL® before first use. To do this, attach the adapter side of the included power supply to the side of the display and plug the other end into a power outlet. The charging status indicator will light up. If the unit is fully charged, this light will be green. An orange light indicates that the unit is actively charging.

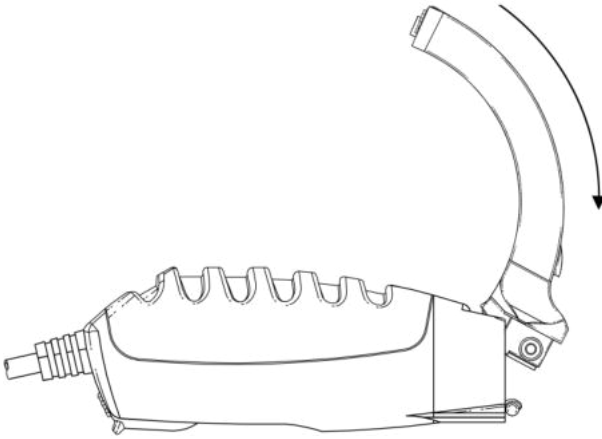


2. Next, locate the handle and plug the attached cable into the Video Cable Input on the side of the display unit. The plug and receptacle are shaped to fit only one way. DO NOT force or twist the plug into place.

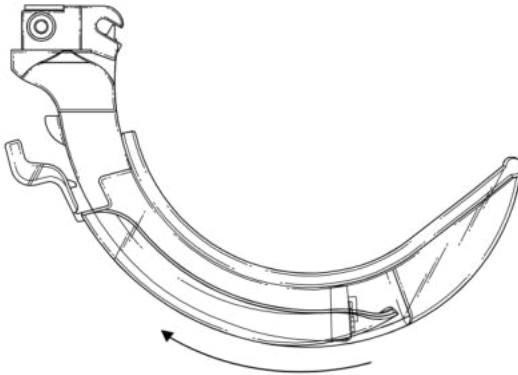


Using the CoPilot VL®

3. Attach the video blade to the handle. The video blade attaches to the handle in the same fashion as a traditional laryngoscope. Slide the hook end of the video blade onto the bar on the handle until it clicks into place. To turn the device on, simply open the video blade. The LEDs will illuminate and an image will appear on the display.



4. Finally, attach a new CoPilot VL® disposable sheath to the video blade. With the video blade open, slide the disposable sheath over the end of the video blade until it snaps in place. Allow the sheath to heat for at least 30 seconds prior to laryngoscopy to prevent fog.



Check the Operational Status

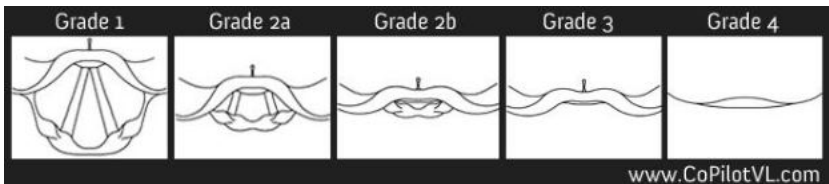
The CoPilot VL[®] must be inspected for proper functioning prior to every use. This is accomplished in the same manner as you would with a traditional laryngoscope.

1. Visually inspect the unit to ensure that it is free from damage.
2. Attach the video blade to the handle and open the video blade. In doing so, the display, camera, video blade, LEDs, heater and battery status indicator will turn on.
3. While the device is powered on, you should note the battery status indicator on the front of the display and recharge if necessary.

Using the CoPilot VL[®]

Tips for Intubating with the CoPilot VL[®]

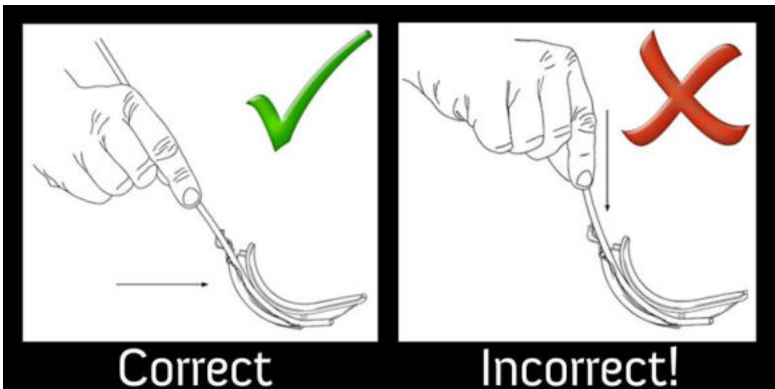
1. After ensuring proper operational status and sufficient battery charge, open a new CoPilot VL[®] disposable sheath and place it over the video blade until it snaps securely in place.
2. Keep your eyes on the PATIENT when inserting the sheathed video blade into the mouth. Observe the sheath passing into the oropharynx. **Then** locate the vocal cords on the display.
3. Only insert the video blade and sheath deep enough to just visualize the epiglottis. Advance the tip of the sheath into the vallecula. Then gently tilt the tip of the sheath upwards until the vocal cords can be visualized. Inserting the video blade too deeply will make it MORE difficult to pass the endotracheal tube into the glottis despite a good view. This is the **most important** tip for ensuring success with video laryngoscopy. Often, a grade 2a or 2b can be easier to intubate than a grade 1.



4. A small amount of water soluble lubricant applied to the distal tip of the endotracheal tube and / or bougie can facilitate intubation.

Using the CoPilot VL®

5. The Bougie Port Method: Pass a bougie through the Bougie Port and into the glottis.
 - a. The bougie should be taken straight from its packaging and inserted, **coudé tip first**, into the Bougie Port. Keep your eyes on the PATIENT when advancing the bougie into the Bougie Port. Alternatively, pre-load the bougie into the bougie port prior to introducing the disposable sheath into the patient's mouth. **Then** advance the bougie and observe the bougie passing through the glottis on the display.
 - b. Pass an endotracheal tube over the bougie in the usual fashion.
 - c. Ensure that the bougie is dislodged from the Bougie Port as the endotracheal tube is advanced.
 - d. Observe the endotracheal tube pass through the glottis on the display.
 - e. Remove the bougie while stabilizing the endotracheal tube and verify proper tube placement.
 - f. If the endotracheal tube does not enter easily into the trachea, you may try turning the endotracheal tube 90 degrees counter clockwise and gently advance into the trachea.



6. The Stylet Method: An alternative to intubating with a bougie is to intubate using a styleted endotracheal tube. Our rigid stylet is the recommended choice but you may use an appropriately shaped malleable stylet as well.
 - a. Ensure that the distal tip of the stylet DOES NOT extend past the distal tip of the endotracheal tube.
 - b. After locating the vocal cords on the display, keep your eyes on the PATIENT when inserting the styleted endotracheal tube into the mouth. Observe the endotracheal tube passing into the oropharynx. **Then** look at the display. Watch for the distal tip of the endotracheal tube to enter the lower right hand corner of the display. Once you see it, then steer the endotracheal tube toward the glottis.
 - c. Withdraw the stylet slightly if necessary to pass the tip of the endotracheal tube into the glottis. DO NOT allow the stylet to enter the glottis.
 - d. Remove the stylet and verify proper endotracheal tube placement.
 - e. The reusable rigid stylet must be cleaned via the method below after every use.

Cleaning and Maintenance

Note: Refer to the APIC Guidelines (Association for Professionals in Infections Control and Epidemiology) for Selection and Use of Disinfectants

Note: Do not attempt sterilize/disinfect the CoPilot VL[®] using Steris[®] Systems that use steam. Do not autoclave. Doing so will permanently damage the components and will void the warranty.

The CoPilot VL[®] was designed in such a way that the single-use disposable sheath is the only component that should come into direct contact with the patient when used as intended. Magaw Medical recommends the development of a policy/routine to decrease the incidence of cross contamination. This may include exercising care when handling the video laryngoscope or other medical devices when there is potential for contamination (i.e., contact with other bodily fluids or potentially contaminated surfaces). The CoPilot VL[®] must be properly handled, cleaned and/or disinfected before use and between uses. To do otherwise presents an infection-control risk to both medical personnel and the patient.

Note: Clean the CoPilot VL[®] as soon as feasible after use. Patient debris can harden and become difficult to remove if not immediately cleaned. This could inhibit the subsequent cleaning processes.

CoPilot VL[®] Video Blade

The CoPilot VL[®] Video Blade is protected by the single-use, disposable sheath during intubation. To clean, remove the blade from the handle. Then remove any particulate matter using a soft cloth or wipe and a mild detergent or enzymatic cleaner (in accordance with the disinfectant manufacturer's written instructions.) Then the blade should be cleaned with 70% isopropyl alcohol.

Cleaning and Maintenance

CoPilot VL[®] Rigid Stylet

The CoPilot VL[®] Rigid Stylet should be High Level disinfected between uses.

1. Manually wash the Rigid Stylet using water and an appropriate surgical instrument detergent.
2. Immerse in chosen disinfectant, according to the manufacturer's instructions. Examples of appropriate high-level disinfectants include 2.4% glutaraldehyde (Cidex[®]), 7.5% hydrogen peroxide, 0.55% *ortho*-phthalaldehyde, and 7.0% peracetic acid with 8.3% hydrogen peroxide.
3. Rinse with sterile, filtered, or tap water (i.e. high-quality potable water that meets federal clean water standards at the point of use) per the disinfectant manufacturer's instructions.
4. Dry thoroughly.
5. Inspect the stylet after cleaning. Discard if damage or corrosion observed.

Alternatively, the Rigid Stylet may be cleaned and dried as above and then placed in Steris System 1E[®] or Sterrad[®] according to the manufacturer's specifications.

CoPilot VL[®] Handle

Warning: Always ensure the handle is unplugged from the display before cleaning!

Remove any particulate matter using a soft cloth or wipe and a mild detergent or enzymatic cleaner (in accordance with the disinfectant manufacturer's written instructions).

The CoPilot VL[®] handle may be cleaned by wiping with an intermediate level disinfectant; e.g., 70% isopropyl alcohol or a 10% bleach solution.

Cleaning and Maintenance

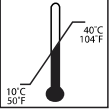
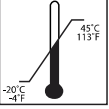
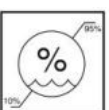
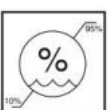
CoPilot VL[®] Display / IV Pole Clamp / Power Supply

Warning: Always ensure the display is unplugged from the power supply before cleaning!

Wipe the CoPilot VL[®] display, IV pole clamp and power supply in between uses and as needed with an EPA registered hospital disinfectant, according to the disinfectant manufacturer's written instructions. Alternatively, these components may be wiped with 70% isopropyl alcohol.

Specifications

Temperature Guidelines

Operating Conditions:	Storage and Transport Conditions
 <p>(10°C – 40°C)</p>	 <p>(-20°C - 45°C)</p>
 <p>(Relative Humidity 10% - 95%)</p>	 <p>(Relative Humidity 10% - 95%)</p>

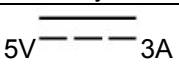














Operating the CoPilot VL[®] outside the recommended operating temperature environment may negatively impact device performance, may cause damage to the device and will void the warranty.

Specifications

General Cautions

1. Always have an alternate method for performing laryngoscopy and intubation available in case of device failure.
2. Inspect all components for any damage prior to use.
3. Confirm full functionality of the device prior to use by connecting the blade to the handle and the handle to the display and confirming that the device is operational and has sufficient battery life to perform intubation.
4. Ensure that the display provides a clear image before use.
5. Sheaths and bougies are single use disposables and may not be reused.
6. Sheaths and bougies are provided in individually sealed packaging. Inspect packaging for damage or breach of seal prior to opening. Do not use if the packaging has been damaged or breached.
7. Inspect sheaths and bougies prior to use to ensure that they have not been damaged, chipped or cracked during transport. Do not use if the item has been damaged.
8. The tip of the video blade may be warm during use when a sheath is not engaged (may exceed 42°C / 107°F during use). Do not allow the tip of the video blade to come into direct prolonged contact with skin.
9. If the battery status indicator is yellow or red, connect to power supply before use.
10. Do not attempt to perform any service or maintenance on any part of the device. The end user cannot replace the battery.
11. Never attempt to intubate without using a disposable sheath on the video blade.
12. There are no known EMI/EMC issues with the CoPilot VL[®].
13. Do not touch electrical contacts between handle and blade.

Icons and Specifications

Icon / Symbol	Description / Specifications
	The power requirements are 5 volts DC at 3 amps max.
IPX2 IP25	Fluid ingress protection. Handle (IPX2) is protected against falling water when tilted up to 15 degrees. Blade (IP25) is protected against water jets and has no opening large enough to insert a finger.
	IEC 60601 Class II device
	IEC 60601 Type BF shock protection
	Consult the Instructions For Use (this manual) for further information
	No components of the CoPilot VL [®] contain latex
	Symbol for use by. This symbol is accompanied by a date to indicate that the device should not be used after the date indicated.
	Indication that disposables delivered are non-sterile
	Indication to not use if packaging is open or damaged.
	Indication of single use for disposables
	Shipping and storage temperature range. Symbol is accompanied by lower and upper limits.
	Shipping and storage humidity range. Symbol is accompanied by lower and upper limits.
	Contents are fragile
	Keep dry
	Meets or exceeds UL STD 60601-1 emissions and immunities standards
	Component sterilized using ethylene oxide.

Limited Warranty

A. **Limited 1 Year Manufacturers Warranty**

Magaw Hardware Limited Warranty

IMPORTANT: PLEASE READ THIS LIMITED WARRANTY CAREFULLY TO UNDERSTAND YOUR RIGHTS AND OBLIGATIONS! Magaw Medical, LLC (Company) warrants the Magaw hardware you have purchased from Magaw (the hardware) to be free from defects in materials or workmanship under normal use during the warranty period from the date of purchase. Your original purchase invoice (sales receipt), showing the date of purchase of the hardware, is your proof of purchase. The warranty period applicable to the hardware is ONE year Parts and Labor. Only the reusable components of the device are covered under the warranty. Single use, disposable components are not covered under the warranty. This warranty extends only to you, the original Purchaser. Any representation or warranty made by any other person, including distributors, resellers, dealers, employees and representatives of Magaw, which are inconsistent or in conflict with or in addition to the terms of this Warranty, shall not be binding on Magaw unless approved in writing by an officer of Magaw. This warranty is not transferable to anyone who subsequently purchases, leases or otherwise obtains the hardware from you. The warranty does not apply to any expendable, disposable or consumable items supplied with the hardware. During the warranty period, Magaw will repair or replace defective hardware with new or factory refurbished parts and products. Hardware may be serviced or manufactured with parts, components, or subassemblies that originate from returned hardware and that have been tested as meeting applicable specifications for equivalent new material and hardware. All exchanged parts and hardware replaced under this warranty will become the property of Magaw. In the event the hardware exhibits a defect in material or workmanship within the warranty period, Magaw will provide the warranty services according to the following terms and conditions:

B. **Warranty Limitation; Exclusions; Exclusive Remedies**

This Limited Warranty does not extend to any hardware not purchased from Magaw. This Limited Warranty also does not extend to any hardware that has been damaged or rendered defective (a) as a result of use of the hardware other than for its normal intended use, failure to use the hardware in accordance with the instructions for use, which is available for download from Magaw, failure to clean the device in a manner described in the instructions for use, misuse, abuse or negligent care, handling, or operation of the hardware or forces or exposure beyond normal use within the specified operational and environmental parameters set forth in the applicable hardware specification; (b) by the use of parts or accessories not approved or supplied by Magaw; (c) by modification of the hardware; (d) as a result of service by anyone other than Magaw or Magaw's Authorized Service Provider; (e) improper transportation or packing when returning the hardware to Magaw; or (f) unusual physical or electrical stress or interference, failure or fluctuation of electrical power, lightning, static electricity, fire, improper storage, water or other liquids, battery leakage, accidental damage or acts of God. NO OTHER WARRANTIES ARE MADE WITH RESPECT TO THE HARDWARE, AND EXCEPT FOR THE WARRANTIES SET FORTH HEREIN, MAGAW DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED OR STATUTORY, INCLUDING BUT NOT LIMITED TO, TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. MAGAW MAKES NO REPRESENTATIONS THAT THE HARDWARE IS FREE OF THE RIGHTFUL CLAIM OF ANY THIRD PERSON BY WAY OF INFRINGEMENT OR OF INFRINGEMENT OF PATENT OR TRADEMARK OR THE LIKE, AND DISCLAIMS ANY WARRANTY AGAINST INFRINGEMENT WITH RESPECT TO THE HARDWARE. IN NO EVENT SHALL MAGAW BE LIABLE FOR ANY INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES, INCLUDING BUT NOT LIMITED TO LOSS OF BUSINESS, PROFITS, DATA OR USE, WHETHER IN AN ACTION IN CONTRACT OR TORT BASED ON A WARRANTY, ARISING OUT OF OR IN CONNECTION WITH THE USE, PERFORMANCE OR MAINTENANCE OF THE HARDWARE, EVEN IF MAGAW HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. YOU AGREE THAT REPAIR, REPLACEMENT OR REFUND, AS APPLICABLE, UNDER THE WARRANTY SERVICES DESCRIBED HEREIN ARE YOUR SOLE AND EXCLUSIVE REMEDIES WITH RESPECT TO ANY BREACH OF THE MAGAW LIMITED WARRANTY SET FORTH HEREIN.

B. **Warranty Limitation; Exclusions; Exclusive Remedies, cont'd**

Some states, provinces, or jurisdictions may not allow the exclusion or limitation of incidental or consequential damages for the type of product sold by Magaw, and some states, jurisdictions, or provinces may not allow limitations on how long an implied warranty lasts. In such states, and provinces, and jurisdictions, the exclusions or limitations of this Limited Warranty may not apply to you. This Limited Warranty gives you specific legal rights. You may also have other rights that vary from state to state. You are advised to consult applicable state or provincial laws for a full determination of your rights.

C. **Obtaining Mail-In, Return to Service Depot, Warranty Service**

If you purchased Magaw hardware in the continental United States, Alaska and Hawaii, you are entitled to mail-in, return to service depot, repair service during the applicable warranty period subject to the following terms and conditions: 1. Mail-in repair service is available for Magaw hardware purchased and located in the continental United States and limited areas of Alaska and Hawaii. 2. During the warranty period, you must first contact Magaw Customer Service Center prior to obtaining any repair service. Please visit www.CoPilotVL.com for contact information. 3. Magaw will attempt to resolve all technical issues over the phone with your assistance. If the problem cannot be resolved, you will be issued a Return Materials Authorization (RMA) Number to be used to identify the hardware that you are authorized to return for service. 4. You must send in the hardware to the Magaw Customer Service Center for mail-in service. Magaw will provide you with a pre-paid return-shipping label for you to return your defective hardware. Buyer shall be responsible for return shipment charges for Product returned where Magaw determines there is no defect ("No Defect Found"), or for Product returned that Magaw determines is not eligible for warranty repair. 5. The Return Materials Authorization (RMA) Number must be placed on the exterior shipping container. Use the original shipping and packing materials and include a description of the hardware problem along with the RMA number on the inside of the package.

D. **Technical Support**

Please visit our website at www.CoPilotVL.com for information on receiving Magaw technical support.

Note: All terms and conditions subject to change without notice.

Ordering Replacement Sheaths & Bougies

Contact Magaw Medical to order replacement or extra parts.

855-CoPilot

<http://www.CoPilotVL.com>



CoPilot VL[®] *The first time. Every time.*