UESCOPE°



User's Manual

VL400 Series
Video Laryngoscope

Please read this manual thoroughly and follow the procedures. Keep this manual properly for future reference. Information in this manual may change at any time without prior notice. Please visit www.uescope.com for the most updated User's Manual and contact information.

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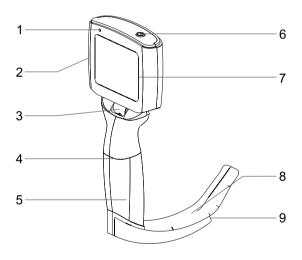
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1 Introduction

1.1 Description

The UESCOPE® VL400 video laryngoscope system (the device) is a handheld medical device that uses video camera to allow the operator to indirectly visualize the glottis and larynx on the monitor. The device is an ideal tool for examination of the interior of the larynx and for placement of an tracheal tube. It is also very helpful for teaching and clinical training of tracheal intubation in both regular and difficult airway.



- 1. Power Indicator
- 2. USB Port
- 3. Two-Way Axis
- Twist-N-Lock™
- 5. Handle
- 6. Power Switch
- 7. LCD Screen
- 8 Blade
- 9. Camera

1.2 Components and Specifications

The UESCOPE[®] VL400 video laryngoscope system consists of one LCD monitor mounted directly on top of another reusable component such as video baton, video blade, and video stylet.

Monitor

Display 2.5" LCD

Tilt and Rotation 65° forward, 65° backward, 90° left, 180° right Recording (optional) 100,000 photos (JPEG), 4.5 hour video (AVI)

 $\begin{array}{lll} \mbox{Video Output} & \mbox{Yes} \\ \mbox{Power Consumption} & < 2 \ \mbox{W} \\ \mbox{Weight} & 120 \ \mbox{g} \\ \end{array}$

Battery Lithium-Ion rechargeable, 1000 mAh

Working Time \geq 90 min Charging Time \leq 3 hour

Charge Cycles > 300 charge/discharge cycles

There are two models available: standard monitor, and monitor with on-board recording capability. The optional recording function can take photos and videos, and store them in its internal memory. Saved image files can then be transferred to a computer through established USB connection.



Standard Monitor



Monitor with Recording Integration

Monitor can be tilted 130 degree and turned 270 degree, allowing visualization from every direction. However, operators should note that monitor is *not* able to spin 360 degree. Spinning may twist the internal electrical wiring and damage the monitor.

Video Blade

Camera CMOS Angle of View 60°

Light Source High intensity LED

Illuminance \geq 150 LUX

Sizes Miller 0, Mac 1, Mac 2, Mac 3, Mac 4

Weight 60-100 g

Video blade's design is based on conventional laryngoscope blade shape, with a slight angulation at the end. Video blades are available in various sizes for pediatric and adult patient usage. Video blades are reusable. They need to be reprocessed between uses.



Video Baton & Disposable Cover

Camera CMOS Angle of View 60°

Light Source High intensity LED

Illuminance ≥ 150 LUX

Sizes Mac 2, Mac 3, Mac 4

Weight 60-100 g

Video baton needs to be loaded with single-use plastic cover (blade) that protect them. There are different sizes of video batons, corresponding to different sizes of single-use covers. Each disposable plastic cover has anti-fogging technology, and has been sterilized using Ethylene Oxide (EO) and packaged in individual peel pouch for single use only.

After loaded with disposable cover, video baton has the exactly same shape as the corresponding video blade.

Video Stylet

Camera CMOS Angle of View 80°

Light Source High intensity LED

 $\begin{array}{ll} \text{Illuminance} & \geq 200 \text{ LUX} \\ \text{Stylet Length} & 360 \text{ mm} \\ \text{Stylet OD} & 5.2 \text{ mm} \\ \text{Tracheal Tube Size} & 5.5-9.0 \text{ mm} \end{array}$

Weight 80 g

Video stylet is a lighted stylet with digital camera at the tip. The camera located at the tip will provide much wider view compared to conventional fiber optic stylet. Video Stylet is either rigid or malleable. Its adjustable tube stop can accommodate different sizes of tracheal tube. Like video blades, video stylet is reusable and need to be reprocessed between uses.

Charger & Cable

Charger Input 110-240 VAC, 50/60 Hz

Charger Output 5 V 1000 mA

Charging Cable USB, Composite video output, micro-USB

The device shall only be charged using the provided charger. The device shall not be used during the charging.

Environmental and Operating Conditions

Operating Temperature -5-50 °C (23-122 °F) Storage/Transit Temp. -40-55 °C (-40-131 °F)

Humidity 10-90%

The device is designed for medical applications. Always respect the conditions specified for storage and operating environments.

The device must be prevented from adverse external effects such as strong electromagnetic radiation, excessive force, or high temperature. The device shall not be used in places where there are fire hazards. The device shall not be used in the presence of flammable anesthetic mixture.

1.3 Warnings and Cautions



Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.



Do not disassemble the device without manufacturer's authorization. To do so will impair patient safety and void the warranty.

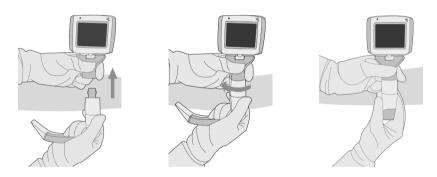
2 Operating Instructions

2.1 Getting Started

Please note that the devices are supplied *non-sterile*. Refer to Chapter 3 to clean the device and accessories before using on patient for the first time. Disposable laryngoscope blades are supplied sterile and ready for single use only.

Twist-N-Lock™

The device's Twist-N-Lock™ Connector is designed for quick and easy swapping of video components such as video blades, video batons, and video stylets. It helps to secure these components in place and prevent accidental disconnection during use.



Hold steady the lower portion of the monitor, not the screen itself. Insert the handle in such a direction that the handle looks like a **Letter J** with the blade tip pointing towards left. Turn the handle counter-clockwise to tighten and lock the connection. Conversely, hold steady the lower portion of the monitor, turn the handle clockwise to unlock and separate the handle from the monitor.

Charge the Battery

The device is powered by an internal rechargeable Lithium-ion battery. It is highly recommended to fully charge the battery before first use, using the provided charger and cable.

During charging, a *flashing green* power indicator indicates that charging is in progress, while a *steady green* power indicator indicates that charging has completed. It may take up to 3 hours to fully charge the battery when no charge remains.



During the long-term standby, the battery shall be checked and recharged if necessary once every 2–3 months.

Load Disposable Blade

Open the peel pouch and slide the disposable blade over the VL400 Video Baton. The blade is securely loaded when it is firmly latched to the anchor point with a *click* sound.

Power Up

Press and briefly hold the power switch for 2–4 seconds to turn on the device. A bright LED light should appear from the front end of the video component, where the camera locates. The company logo should appear on the screen for a few seconds. Then the scene taken by a high definition camera will be shown. Observe the monitor screen to verify that a clear image is being displayed.



A steady *green* power indicator means the device is in normal working state. A *red* power indicator means the battery is running low and needs to be recharged immediately.

Record Images and Video

For monitors with recording integration, photos and videos of the operations can be recorded and automatically saved in its internal memory. Files can then be transferred to a computer through established USB connection.

Take a Snapshot	Press and release the recording button. A snapshot			
	icon appears briefly at the upper of the screen, indi-			
	cating a still photo has been taken and saved.			

Record a Video

Press and hold the recording button until you see
a red dot appearing at the upper left corner of the
screen, indicating a video recording is in process.
Press and hold again to exit video recording.

2.2 Intubation Procedure

The procedures of the intubation using the UESCOPE® VL400 video laryngoscopeare basically the same as those of doing direct laryngoscopy.

- When intubating difficult way, it is recommended to insert a well lubricated stylet into the tracheal tube. The distal end of intubating stylet is bent anteriorly to follow the specially designed 45° blade angle of UE video laryngoscope.
- Check to make sure the patient is in the optimal position for direct laryngoscopy.
- **3.** Look directly into the patient's mouth. Hold the device in the left hand and introduce the blade into the patient's mouth along the midline.
- 4. Look at the screen. While gliding downwards on the surface of the tongue following the anatomical curvature of the oral cavity and pharynx, manipulate the device to visualize the palate, uvula, and epiglottis sequentially on the screen. Advance the blade tip to the vallecula and gently lift the

tip upwards to expose the vocal cords in the central upper section of the monitor (i.e., Grade 2 view). If you see the vocal cords almost occupy the whole screen (i.e., Grade 1 view), it's better to withdraw the blade a little backward.

- Look directly into the patient's mouth. Gently insert the precurved styletted tracheal tube into the oropharynx along with the right side of the blade.
- 6. Look at the screen. You should visualize the tip of the tracheal tube in the lower right corner of the screen. Angle or rotate the tracheal tube to align its tip with the glottis. Withdraw the stylet slightly if necessary, and advance the tracheal tube to pass the glottis. Do not allow the stylet to enter the glottis.
- 7. After gently withdraw the stylet from tracheal tube, advance the tracheal tube further into the trachea until the entire cuff disappears from the view.
- 8. After confirming correct placement of the tracheal tube into the trachea, hold the tracheal tube in place and withdraw the video laryngoscope from the mouth. Inflate the cuff of the tracheal tube to appropriate cuff pressure. Tightly secure the tracheal tube in place.
- **9.** Press and briefly hold the power switch button for 2–4 seconds to turn off the device.
- 10. Unload the disposable blade from the video baton and discard the blade. Twist and unlock to separate the monitor from the handle. Clean and decontaminate the monitor and handle according to the cleaning guidelines in chapter 3.

2.3 Factors that Influence Successful Intubation

Because the procedures of the UESCOPE® video laryngoscope are basically the same as those of direct laryngoscopy, the operator experienced in the direct

laryngoscopy can use it successfully after reading this manual, without the need for any special training. However, there are a few factors worth paying attention to:

• Use precurved rigid stylet

It is highly recommended to use rigid UESCOPE[®] Intubating Stylet, or a similar one whose distal end is bent anteriorly to an angle of 45°. This helps to make the tracheal tube conform better to the upper airway anatomy and facilitate successful intubation, specifically when dealing difficult airways.

Do not place the blade too deeply into the airway

When the device is in the optimal position the glottis should be viewed in the central upper section of the screen. Inserting the video blade too deeply will make it extremely difficult to pass the tracheal tube into the glottis despite a good view. If the glottic exposure is inadequate, the external laryngeal compression is suggested to improve the laryngeal view.

· Pre-heat reusable video blade to defog if necessarily

If the ambient temperature is too low, the reusable video blade or video stylet should *not* be inserted into the patient's mouth immediately after the power is turned on. A one-minute preheating period, or immersing in warm saline, are recommended to overcome the fogging issue.

After removal of the stylet from the tracheal tube, if the difficulty on advancement of the tracheal tube downward into the trachea occurs, the following measures are suggested:

- Withdraw the video laryngoscope blade 1–2 cm backwards to allow the glottis draw down.
- Reduce the upward lifting force of the video laryngoscope so that the
 patient's head will be returned to the neutral position and the tracheal
 tube tip can be away from the anterior tracheal wall.

- Rotate the tracheal tube 90° clockwise and then further advance the tube into the trachea.
- The patient's head is lifted (flexed) slowly when the tracheal tube is advanced, which makes long axis of tube to be more parallel to that of trachea so as to advance the tracheal tube downward much easier.

3 Cleaning and Maintenance

3.1 General Guideline

The UESCOPE[®] VL400 video laryngoscope must be decontaminated prior to first use and as soon as feasible after each use. Decontamination should be carried out in accordance with local regulations and your facility's policy.

Commonly used aldehyde disinfectants including 2% glutaraldehyde, and 0.55% *ortho*-pathalaldehyde (Cidex OPA), have been verified as compatible and will cause no physical degradation to the device. Other types of disinfectant like peracetic acid and sodium hypochlorite are also effective but may be corrosive to pin connectors and plastic handle.

UE Medical make no claims regarding the efficacy of the detergents, disinfectants, and equipment. It remains the responsibility of the operator to ensure that the reprocessing procedures performed following the chemical and equipment manufacturer's instructions and guidelines to achieve the desired result. This normally requires validation and routine monitoring of the process.



Do not autoclave. Do not attempt disinfection/sterilization in a temperature above 60 °C. Doing so will permanently damage the components and will void the warranty.



Always follow the detergents, disinfectants, and instrument manufacturer's written instructions.

Before cleaning, power off the monitor and detach from the handle. Ensure video baton, video blade, and video stylet are properly fitted into the provided end caps and secured to protect pin connectors. The eligible cleaning methods for components are summarized in **Table 1**.

Table 1 Eligible decontamination levels and methods for UESCOPE[®] VL400 video laryngoscope components and accessories. Recommended methods are in *shaded* area with double checkmarks. However, the level of disinfection or sterilization required may vary according to local regulations.

Component &	Low-Level Disinfection	High-Level Disinfection		Sterilization	
Accessory	Disinfectant Wipes ¹	Manual Soaking ²	AERs ³	STERRAD Gas Plasma	Ethylene Oxide
Monitor	√√				✓
Video Baton	√√4	✓	✓	✓	✓
Video Blade	√	✓	√ √		✓
Video Stylet	✓	✓	√ √	✓	✓
Disposable Blade	For single use only. Do Not Reprocess				

Recommended disinfectant wipes include 70% Isopropyl alcohol, CaviWipes, and Super Sani-Cloth wipe.

3.2 Cleaning Monitor

Wipe clean the monitor in between uses and as needed, using 70% Isopropyl alcohol, CaviWipes, or Super Sani-Cloth wipe. If there is concern about the level of disinfection or if it is exposed to contamination, the monitor can be sterilized using Ethylene Oxide (EO) gas method (see Table 1).



Monitor is *not* waterproof and should not be submerged or exposed to excessive amounts of fluids.

² Completely submerged in 2% glutaraldehyde for 20 minutes, or Cidex OPA for 12 minutes at room temperature, per chemical manufacturer's instructions.

³ Automated Endoscope Reprocessors implementing Cidex OPA and Rapicide OPA/28 as disinfectants, e.g., Medivators DSD-201.

⁴ Low-level disinfection process may be considered where high level disinfection and sterilization processes are not practical.

3.3 Cleaning Video Baton

To clean, remove the disposable blade from the baton and dispose of properly. Wipe clean the baton thoroughly to remove any soil from all exposed surfaces. Then wipe down using 70% Isopropyl alcohol, CaviWipes, or Super Sani-Cloth wips, per manufacturer's instructions.

If there is concern about its level of contamination or if it is exposed to contamination, video baton should be reprocessed by glutaraldehyde or Cidex OPA method, STERRAD gas plasma sterilization, or EO gas method (see Table 1).

3.4 Cleaning Video Blade

To clean reusable video blade, use water and appropriate enzymatic detergent to wash. Repeat until no visible soil remains. Then rinse and rough dry all surfaces of the component. Manually soak the blade in 2% glutaraldehyde or Cidex OPA solution per manufacturer's instructions. Alternatively, reprocess with automatic reprocessors using Cidex OPA or Rapicide OPA/28 disinfectant, e.g., Medivators DSD-201 (See Table 1).

3.5 Cleaning Video Stylet

To clean reusable video stylet, use water and appropriate enzymatic detergent to wash. Repeat until no visible soil remains. Then rinse and rough dry all surfaces of the component. Manually soak video stylet in 2% glutaraldehyde or Cidex OPA solution per manufacturer's instructions. Alternatively, use Medivators AER with Rapicide OPA/28 disinfectant, or use STERRAD gas plasma processor (See Table 1).

4 Troubleshooting

UESCOPE® VL400 video laryngoscope systems are generally reliable and simple to use, requiring minimal maintenance for extended periods. However, the following is provided to help dealing with unexpected device conditions:

Blurred Image

If the image displayed on the screen is blurred or fuzzy, remove the disposable blade and check if the image is clear. Wipe the camera with a clean, soft wipe if necessary. If this blurred image is caused by fogging, preheating the reusable video blade or video stylet for one minute will help defogging.

Will Not Turn On

Recharge battery, or contact local distributor to replace the battery.

Black Screen

No video signals captured. Re-connect the monitor and handle, double check the electrical connection between handle and monitor. Ensure the pin connectors are clean.

If problem remains, please contact your local distributor or our customer service for further diagnostics and repair.



CAUTION: Devices returned for repair MUST be decontaminated to a high-level disinfection state before transportation.

5 Warranty

UE Medical warrants the original purchaser that the device will be free from defects in material and workmanship. This warranty applies for one year from the date of shipment from UE Medical Devices, Inc. This warranty does not apply if the product has been damaged due to improper cleaning and handling, neglect, misuse, accident, or unauthorized repair.

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