



OneScope[®] Pro *Video Laryngoscope*

Instructions for Use (IFU)

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INTRODUCTION

Before using the Curaplex® OneScope® Pro Video Laryngoscope (the device), it's essential to train the user about the uses and the applicable medical procedures. Please read this manual thoroughly before using the product and keep the manual properly for future reference. Please follow the appropriate Cautions and Warnings as indicated in this manual.

INTENDED USE

The Curaplex® OneScope® Pro Video Laryngoscope (the device) is intended to be used by trained and licensed individuals to obtain a view of the airway and vocal cords during medical procedures, typically laryngoscopy.

INDICATIONS

- General laryngoscopy
- Endotracheal intubation
- Visualization of the hypopharynx, larynx and vocal cords

PRODUCT DESCRIPTION

The Curaplex® OneScope® Pro Video Laryngoscope (the device) is a handheld medical device used to aid the intubation of the trachea. The device incorporates a light source (LED) and miniature camera (camera) to indirectly visualize the glottis and larynx during the procedure of laryngoscopy. The image is displayed on an LCD screen contained within a display mounted to the handle of the device.

COMPONENT LIST AND TECHNICAL SPECIFICATIONS

| Curaplex® OneScope® Pro Video Laryngoscope | | |
|--|--------------------------------------|-----|
| No. | Description | Qty |
| 1 | OneScope® Pro Display | 1 |
| 2 | Video Laryngoscope Handle | 1 |
| 3 | Rugged Custom Storage Case | 1 |
| 4 | Power Adaptor | 1 |
| 5 | USB-C Cable | 1 |
| 6 | Curaplex® Silicone Display Protector | 1 |

Unpack and check for any visible signs of damage that may have occurred during shipment. In the event of signs of damage do not use the device and inform your local distributor.

OneScope® Pro Display

The reusable display is a high-resolution HD monitor that has an image quality of over 2 million pixels. With innovative IPS technology, images are received from the distal tip of the video adapter and displayed in real-time on the full-color 3.5" LCD screen.

OneScope® Pro Display Detail



OneScope® Pro Display Specifications

| Parameter | Specification |
|-----------------------------|---|
| Screen | 3.5" IPS LCD Medical grade touch screen suitable for doctors to use when wearing gloves, supports up to 4 additional external displays |
| Resolution | >1.2MP |
| Rotating angle | Up/Down \geq 130°, L/R \geq 330° |
| Viewing angle | IPS 170 degree |
| Capacity / Recording | 32 GB internal memory. Case photos, video/sound recording; photos and videos can be read and played back on the monitor. This amount of storage can hold up to 4 hours of video, and/or 16,000 photos. |
| Connector | Standard USB-C for power / data and USB-C to HDMI for external display connection |
| Battery | Rechargeable lithium battery, 5-7 years life, a single charge can support up to ~400 intubations; Need 2-3 hours to charge from 0 to 100%. Battery volume displayed on monitor (White 100%-80%; Yellow <20%; Red <5%) |



CAUTION:

The display has a 270°-360° rotating range. For normal function of the device, there should be obvious resistance force when the rotating range is reached. Do not over force the rotation against the resistance force. Manipulation of more than above range will damage the circuit inside and lead to LED light or image malfunction.

OneScope® Pro Handle & Blades

The reusable handle houses the camera and LCD light source and connects to the display monitor. The single-use blades come in 8 size options to fit all patients ranging from neonatal to adult. When attached to the handle, the single-use blade covers the handle completely, reducing risk of cross-contamination.



CAUTION:

The disposable blades are packaged sterile and ready to use. Do not attempt to reuse or reprocess blades after use.

OneScope® Pro Handle Specifications

| Parameter | Specification |
|----------------------------|---|
| Camera type and resolution | CMOS, HD digital imaging technology, imaging pixels: ~2M pixels |
| Depth of field | 2~100mm |
| Spatial Resolution | ≥10.10lp/mm |
| Angle of camera view | 80°+/- 10° |
| Light source | 2 White LED light source, luminance: 1000 LUX, not fiber-optic illumination |
| Blades | 8 sizes; 0/00 neonatal, 1/2 pediatric, 3A/4A adult angulated, 3D/4D adult direct |
| Handle | One handle to support all 8 sizes of blades, easy to use and maintain |
| Durability | Anti-drop from 2 meters, wearable, water-resistant IPX1 material, suitable for varied environment use |

Total System Weight = 8.6 OZ

Product Safety Specifications

| Parameter | Specification |
|---|-----------------------------------|
| Type of Protection Against | II (Internally powered equipment) |
| Degree of Protection Against Electric Shock | Type B Applied part |
| Degree of EMC | Class A |
| Degree of Protection Against Hazards of Explosion | Ordinary equipment, not protected |
| Equipment Type | Handheld |

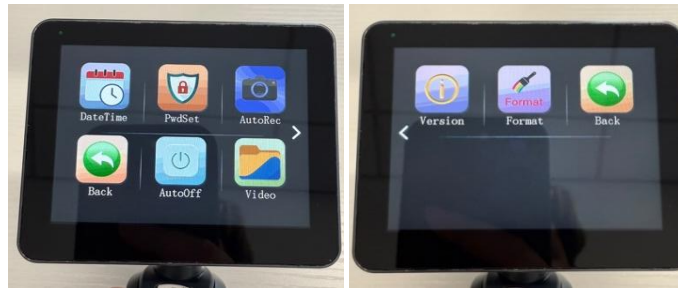
Environmental Specifications


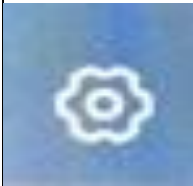
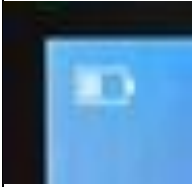
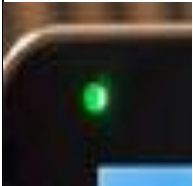
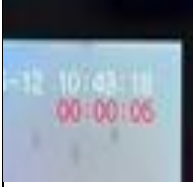

| Parameter | Specification | |
|----------------------------------|----------------------|------------------------------------|
| Operating Conditions | Temperature | 5°C ~ 40°C |
| | Humidity | ≤80%, non-condensing |
| | Atmospheric Pressure | 646.7 ~ 797.1mmHg (86.0~ 106.0kPa) |
| Transport and Storage Conditions | Temperature | -20°C ~ 60°C |
| | Humidity | ≤95%, non-condensing |
| | Atmospheric Pressure | 564.0 ~ 797.1mmHg (75.0~ 106.0kPa) |

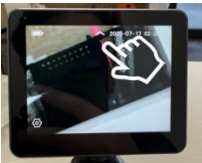







Power Specifications

| Parameter | Specification | |
|------------------|-----------------|------------------------|
| AC Adapter | Input Voltage | AC100 - 240V |
| | Input Frequency | 50/60Hz |
| | Input Current | 0.33-0.16A |
| | Output voltage | DC5V |
| | Output Current | 2A |
| | Fuse | T2A, 250V |
| Built-in Battery | Type | Lithium Battery 2500MA |
| | Voltage | DC3.7V |

OneScope® Pro Display Menu Description



| | | |
|--|----------------|--|
|  | Power Button | Press and hold for 2-3 seconds to turn on, press for 3-4 seconds to turn off |
|  | Menu | Click to enter Menu |
|  | Battery volume | The 3 colors show different volumes left in the battery. White, Yellow, and Red. When it's red, you need to charge it. |
|  | Charging light | A green light shows that the battery is charging |
|  | Operating time | This feature shows how long you have used this device per procedure |
|  | Photo/Video | Review and manage the videos taken |

| | |
|--|---|
|  <p>Reverse camera view (1)</p> | <p>The ability to reverse the camera from both angles. Applicable to use cases for creating alternative viewpoints when working with larger bodies.</p> |
|  <p>Reverse camera view (2)</p> | <p>(Same as above)</p> |
|  <p>Date and Time</p> | <p>Set recording date and time</p> |
|  <p>AutoRec</p> | <p>Enable auto recording</p> |
|  <p>Format</p> | <p>Delete all data</p> |
|  <p>Version</p> | <p>View version type</p> |
|  <p>Automatic Shutdown</p> | <p>Enable time for shutdown when not in use</p> |
|  <p>Password Set</p> | <p>Set password for videos</p> |

CONTRAINDICATIONS

None known.

CLINICAL BENEFITS

Clear visualization of the patient's airway

Single-use blades minimize the risk of cross contamination of the patient

RESIDUAL RISKS AND SIDE EFFECTS

Potential side effects associated with laryngoscopy include, but are not limited to:

- Laryngeal / airway trauma
- Bleeding
- Sore throat
- Hoarseness
- Dental trauma
- Dysphagia

PRECAUTIONS / CAUTIONS

- The Curaplex® OneScope® Pro video laryngoscope should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, observe the system to verify normal operation in the configuration in which it will be used.
- This device can radiate radio frequency energy and is very unlikely to cause harmful interference with other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation. Evidence of interference may include degradation of performance in this device or other devices when operated simultaneously. If this occurs, try to correct the interference by using the following measures: Turn devices on and off within the vicinity to determine the source of interference. Reorient or relocate this device or other devices. Increase the separation between devices.
- Federal (USA) law restricts this device to sale by or on the order of a physician.

WARNINGS

- Blades are single-use only. Do not attempt to reprocess, clean or disinfect the blades.
- The device must be used only with OneScope® Pro disposable laryngoscope blades.
- Do not use the blades with any other type of laryngoscope. Blades are designed to be used with the OneScope® Pro video laryngoscope only.
- Do not use if any components become loose, physically damaged, or fit poorly.
- Ensure the device is completely dry before use.
- Do not use ultrasonic cleaning method.
- Do not use hydrogen peroxide.
- Do not autoclave this device.
- Always check that the device is working correctly before each patient use.

- Do not use with Magnetic Resonance Imaging (MR/MRI).
- Operating temperature of blades up to 40°C (104°F) maximum.
- Do not use after expiry.

OPERATING INSTRUCTIONS FOR USE

Before Use / Setup

- Use the **Power** button to turn on the display to check battery capacity and ensure sufficient battery life for the procedure.
- Connect the display and handle to check if the LED light and image are displayed properly on the display before operation.
- Check if the sterile pouch containing the disposable blade is intact before opening.
- Open the sterile pouch and carefully remove the blade. Slide the blade in an upward motion over the flexible camera channel until it clicks into place on the handle.
- ET tube shaping: Use a sterile stylet guide to adjust the ET tube to the same curve as the blade before intubation. We recommend pre-shaped OneScope® Disposable Rigid Stylet, but any available stylet with similar shape may be adopted.



NOTE:

OneScope® Pro video laryngoscope handle supports multiple blade sizes and shapes due to the flexible camera channel.

After Use

- Clean / disinfect entire device immediately after use.
- Detach the disposable blade from the handle and dispose of according to your local hospital procedures.
- Once the device is completely dry, place the device in the approved storage container in accordance with local practice guidelines.

Photo and video recording, capturing, and reviewing

To take a photo, press on the button with the camera icon once. A camera icon will flash in the upper left part of the screen, indicating that a photo has been taken. To record video on your device, press and hold on the same button for 2 seconds. A timer with a red color will appear in the top right of the screen, indicating that the video is being recorded. To stop recording, press again on the same button. The timer will disappear, and the recording will have stopped.

To review your photos and videos, follow the instructions above or listed here:

1. Press the menu button on the bottom left of the screen.
2. You will see 6 icons displayed on the main menu.
3. Select the Video icon (middle icon on the second row).
4. From there, go through the folder(s) to access everything. Image files will have a .jpg extension, and video files will have a .mov extension.









Erasing Data from OneScope® Pro


There are two methods to erase data from the OneScope® Pro:

1. Directly on the device
2. Using a Mac, iPad or PC

Method 1: Deleting individual files from device

| | | | | | |
|--|---|---|---|---|---|
| Step 1: Choose Settings on the bottom left of screen |  | Step 2: Choose Video folder icon |  | Step 3: Choose folder for deletion |  |
| Step 4: Choose video or picture file for deletion |  | Step 5: Press the Trash icon on top left |  | Step 6: Select "Delete" to confirm and erase the file |  |

Method 2: Connecting to Mac, iPad or PC

| | | | |
|--|---|--|---|
|  | Step 1: Using the white USB-C to USB data/power cable, connect USB-C to OneScope® Pro and USB to a Mac, iPad or PC | Step 2: OneScope® Pro folder will appear just like any external thumb drive connected | Step 3: Open the folder on your Mac, iPad or PC and delete files similar to using Mac, iPad or PC delete functions |
|--|---|--|---|



Connecting the OneScope® Pro to an external display

You can easily connect your OneScope® Pro to an external monitor or display using a USB-C to HDMI dongle and a two-way HDMI cable. Follow the steps below to ensure proper connection and video output.

What you'll need:

- OneScope® Pro Video Laryngoscope
- USB-C to HDMI dongle (sold separately)
- Two-way HDMI cable (commercially available)
- External display (monitor, TV, projector, etc.)



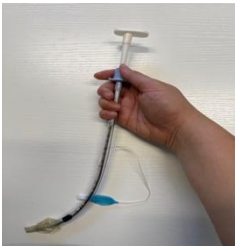
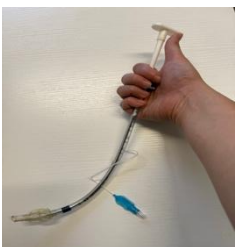


Instructions to connect to an external display:

| | |
|---|---|
|  <p>Step 1: Position the Dongle</p> <ul style="list-style-type: none"> • Hold the USB-C to HDMI dongle so that the “Up” label on the dongle is facing upward. • Locate the arrow on the left side of your OneScope® Pro device. • Align the arrow on the dongle with the arrow on the device. This ensures correct orientation. |  <p>Step 2: Connect the Dongle to OneScope® Pro</p> <ul style="list-style-type: none"> • Firmly insert the USB-C connector into the USB-C port on the left side of the device. • Ensure the dongle is fully seated and the arrows are still aligned. |
| <p>Step 3: Connect to External Display</p> <ul style="list-style-type: none"> • Plug one end of the HDMI cable into the HDMI port on the dongle. • Plug the other end into an available HDMI input on your external display. | <p>Step 4: Select the Correct Input</p> <ul style="list-style-type: none"> • Use the input/source button on your external display to select the corresponding HDMI input. |
| <p>Step 5: Power On</p> <ul style="list-style-type: none"> • Power on the OneScope® Pro (if not already on). • The display should automatically mirror or extend depending on system settings. | |

Troubleshooting tips:

- Make sure all connections are secure.
- Double-check that the “Up” label and arrow alignment is correct.
- Try a different HDMI cable or input if no signal appears.
- Restart the OneScope Pro with the HDMI cable already connected.

OneScope® Pro Video Laryngoscope Accessories**Using the OneStylet® Disposable Rigid Stylet (sold separately):**

| | | | |
|---|--|--|--|
| <p>Step 1:</p> <p>Insert the stylet into the ET tube</p> |  | <p>Step 2:</p> <p>Position the ET tube at the opening of the vocal cords</p> |  |
| <p>Step 3 (Removal):</p> <p>Apply gentle upward pressure on the stylet near the upper tab with your thumb.</p> |  | <p>Step 4:</p> <p>Keep moving the thumb up to gently remove the stylet near the upper tab with your thumb.</p> |  |
| <p>Step 5:</p> <p>Keep moving your thumb up to gently remove the stylet while advancing the soft end of the ET tube into the vocal chords.</p> |  | <p>Step 6:</p> <p>After the stylet is fully retracted, put the used stylet back in its pouch and dispose of the packaging according to your facility procedure.</p> |  |

CLEANING AND DISINFECTION INSTRUCTIONS

General Guidelines

The Curaplex® OneScope® Pro Video Laryngoscope must be cleaned, disinfected, or sterilized prior to the first use and after each use to prevent cross contamination. The device can be cleaned with low-level disinfectant and can be wiped down between procedures. Cleaning, disinfection, and sterilization methods listed in this manual are recommended by the manufacturer based on the efficacy of disinfectants and their compatibility with the device materials. Always follow the instructions on the cleaner's label to ensure safety and efficacy. Sterilization is not required for the handle, but the handle is compatible with sterilization.

Sterilization Methods

| Product Component | Autoclave | Sterilization | |
|---|-----------|--------------------|--------------------------------------|
| | | Ethylene Oxide Gas | Low Temperature Plasma Sterilization |
| OneScope® Pro Display | ⊘ | ⊘ | ⊘ |
| OneScope® Pro Video Laryngoscope Handle | ⊘ | ✓ | ✓ |



CAUTION:

DO NOT AUTOCLAVE. Do not attempt disinfection/sterilization at a temperature above 60°C.

Separate the handle from the display for sterilization. Do not attempt to sterilize the display.

The single-use blades are for one-time use only. Do not reprocess.



NOTE:

Handle must be cleaned and dried before sterilization.

The distal end of the handle can attract lint and/or other particles. Use lint-free cloth or lens cleaner to gently wipe any debris. Avoid touching the camera lens.

Equipment and Accessories for Cleaning

| Product Component | Equipment and Accessories |
|---|---|
| OneScope® Pro Display | Soft lint-free cloth 70% isopropyl alcohol Clean covered tray/container |
| OneScope® Pro Video Laryngoscope Handle | Soft lint-free cloth 70% isopropyl alcohol Clean covered tray/container |







Tested and Approved Disinfectants




The following disinfectants have been tested and approved for regular use:

| Product Name | Product Type | Manufacturer |
|-------------------------|--------------|----------------|
| CaviWipes | Wipes | Metrex |
| Super Sani-Cloth | Wipes | PDI, Inc. |
| Sani-Cloth HB | Wipes | PDI, Inc. |
| Sani-Cloth Plus | Wipes | PDI, Inc. |
| Oxivir TB Wipes | Wipes | Diversey |
| Clorox Healthcare Wipes | Wipes | Clorox Company |

Manual Disinfecting / Cleaning for OneScope® Pro

Clean equipment before disinfecting. OneScope® Pro can be disinfected with standard hospital wipes between procedures, and it is recommended to clean the unit with the disposable blade attached after the completion of a procedure. After the display and handle are wiped down along with the blade, detach the blade and dispose of it in the sterilized packaging. The following is the recommended procedure for disinfecting:

| | |
|--|---|
| Step 1: Cover the entire unit with the cleaning wipe  | Step 2: Begin at the top of the display and wipe it down clean  |
| Step 3: Continue with a smooth wiping down motion on to the handle  | Step 4: With a smooth down motion continue cleaning down the handle  |
| Step 5: Continue to wipe down on the blade  | Step 6: With a smooth motion, complete the blade cleaning and dispose of the wipe  |

| | | | |
|--|---|--|---|
| <p>Step 7:</p> <p>Carefully detach the blade from the handle</p> |  | <p>Step 8:</p> <p>Carefully completely detach the blade from the handle</p> |  |
| <p>Step 9:</p> <p>Carefully place the detached blade back in its sterilized package</p> |  | <p>Step 10:</p> <p>After placing the blade back in its packaging, dispose of the package according to your hospital procedure</p> | |

STORAGE

The device should be cleaned immediately after use and be stored in suitable containers in accordance with local practice guidelines.

Store in a cool, dry place out of direct sunlight. Do not expose the device to excessive heat or corrosive substances during storage.



NOTE:

If the device is in long-term standby, charge the battery at least once every 3 months.

DISPOSAL INSTRUCTIONS

1. Completely detach the blade from the handle.
2. Place the detached blade back in its original sterilized package.
3. After placing the blade back in its original packaging, dispose of the package according to your hospital procedure.

TROUBLESHOOTING

The device is generally reliable and simple to use, requiring minimal maintenance for extended periods. However, the following is provided to help deal with unexpected device conditions:

| | |
|--------------------------------------|--|
| Will not turn on | <ul style="list-style-type: none"> • Ensure the battery is charged. • Press and hold the power button for at least 5 seconds. • Press reset button located on top of the power button • Ensure USB-C is plugged into the power/data port. • If issue persists, contact technical support. |
| SD card not found | <ul style="list-style-type: none"> • Contact support for troubleshooting. |
| Unexpected video interruption | <ul style="list-style-type: none"> • Ensure the device has sufficient battery or is properly connected to power. • Restart the device and attempt recording again. |
| HDMI output not functioning | <ul style="list-style-type: none"> • Ensure the HDMI cable is properly connected to both the device and display (refer to page 12). • Try a different HDMI cable and input port on the display. • Make sure the display is set to the correct HDMI input source. • If issue continues, consult the user manual or support. |
| Password lockout | <ul style="list-style-type: none"> • Make sure to store your password in a secure location. Forgotten passwords may require a full device replacement. |

If problem remains, please contact One-AI customer service for further diagnostics and repair.



CAUTION:

Do not disassemble the device without manufacturer's authorization. Doing so will impair patients' safety and void the warranty.













To prevent infection and to ensure the safety of maintenance personnel, all equipment should be completely cleaned and properly disinfected before returning to our customer service.

WARRANTY

The device is supplied with a 3-year manufacturer's warranty from the date of purchase and includes a free replacement of the device to cover any manufacturing defects.

- Only products purchased from One-AI or an authorized distributor of One-AI are covered by the manufacturer's warranty.
- The use of accessories (blades, stylet) that are not supplied by One-AI or an authorized distributor of One-AI may be incompatible and can cause damage to the device and void the warranty.
- Before returning the device under a warranty claim, disinfect the device per the instructions in this document.

SYMBOLS USED

| | |
|---|---|
|  | Lot number |
|  | Catalog number |
|  | Date of manufacture |
|  | Sterilized using ethylene oxide |
|  | Manufacturer |
|  | Product must be collected separately |
|  | Do not reuse |
| Rx Only | Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner |
|  | Consult instructions for use |
|  | Do not use if package damaged |
|  | Distributor |
|  | Use by date |
|  | Caution |