



Versa One System (VOS)

Instructions for Use

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IMPORTANT INFORMATION – READ BEFORE USE:

Intended Use:

The Versa One System is intended for use in otolaryngology and head and neck procedures including rhinology and endoscopic plastic and reconstructive surgery. For use by qualified physicians for the listed indications only.

Instructions for Use:

This document describes the recommended procedures for preparing and operating Versa One System Videoscope. The content herein does not constitute medical advice, nor does it describe how any medical procedure is to be performed.

Read all instructions carefully before using Versa One System.

Carefully follow all safety instructions to prevent injury to the user or patient, fire hazards, electric shock, equipment interference, and damage to the device.

To maintain this device in optimal condition, follow all recommendations in this document for cleaning, sterilizing, handling, and storage.

The current version of this document can be requested from Outlook Surgical Endoscopy Systems, LLC.

STERILE **VH202**

Processing before first use/reprocessing and storage after use:

These instruments were not cleaned, disinfected or sterilized before shipment. Before using for the first time, process according to the instructions in section 5 of this document. After use, reprocess and store equipment according to these instructions. Improper and/or incomplete reprocessing or storage can pose an infection control risk, cause equipment damage, or reduce performance.

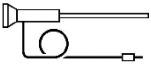


NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

1. SYMBOLS USED IN PRODUCT LABELING

SYMBOL	TITLE	REFERENCE NO.	EXPLANATORY TEXT
	REFER TO INSTRUCTION MANUAL/BOOKLET	ISO 7010-M002	To signify that the instruction manual/booklet must be read.
	PRODUCT INFORMATION; INFORMATION POINT	ISO 7000-2760	To identify a place where product information can be found.
	CAUTION	ISO 7000-043A	To indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	CAUTION, VERY BRIGHT LIGHT	IEC 60417-6069	To indicate not to watch the high level of light beam emitted.
	MANUFACTURER	ISO 7000-3082	To identify the manufacturer of a product.
	MODEL NUMBER	ISO 60417-6050	To identify the model number or type number of a product.
	BATCH CODE	ISO 7000-2492	Indicates the manufacturer's batch code so that the batch or lot can be identified
	SERIAL NUMBER	ISO 7000-2498	To identify the manufacturer's serial number on a medical device or its packaging.
	UNIQUE DEVICE IDENTIFIER	ISO 15223-1:5.7.10	To indicate a carrier that contains unique device identifier information.
	DO NOT USE IF PACKAGE IS DAMAGED	ISO 7000-2606	Indicates that the device must not be used if the package holding the device is damaged.
	TEMPERATURE LIMIT	ISO 7000-0632	To indicate the maximum and minimum temperature limits at which the item shall be stored, transported, or used.
	HUMIDITY LIMITATION	ISO 7000-2620	Indicates the acceptable upper and lower limits of relative humidity for transport and storage of the device.
	ATMOSPHERIC PRESSURE LIMITATION	ISO 7000-2621	Indicates the acceptable upper and lower limits of atmospheric pressure for transport and storage of the device.
	KEEP DRY	ISO 7000-0626	To indicate that the transport package shall be kept dry.
	KEEP AWAY FROM SUNLIGHT	ISO 7000-0624	Indicates the transport package shall not be exposed to sunlight.
	NON-STERILE	ISO 7000-2609	Indicates that the device the manufacturer intends to be sterilized has not yet been through the sterilization process.



	TO BE STERILIZED USING VAPORIZED HYDROGEN PEROXIDE	ISO 15223-5.2.10	Indicates that the medical device is to be sterilized using vaporized hydrogen peroxide
	ENDOSCOPE	IEC 60601-2-18 Annex D-101	Indicates medical device is an endoscope.
	DIRECT CURRENT	IEC 60417-5031	To indicate on the rating plate that the equipment is suitable direct current only
	ALTERNATING CURRENT	IEC 60417-5032	To indicate on the rating plate that the equipment is suitable alternating current only
	BOTH DIRECT AND ALTERNATING CURRENT	IEC 60417-5033	To indicate on the rating plate that the equipment is suitable for both direct and alternating current (universal); to identify relevant terminals
	TYPE BF APPLIED PART	IEC 60417-5333	Indicates device is classified as a TYPE BF Applied Part
	NON-IONIZING ELECTROMAGNETIC RADIATION	IEC 60417-5140	Indicates equipment or systems that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment
	PRESCRIPTION ONLY	N/A	CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN
	FCC MARK	N/A	To indicate that the electromagnetic radiation from the device is below the limits specified by the Federal Communications Commission
	NEMKO N-MARK	N/A	To indicate that the product is certified by Nemko for US/CSA.



2. WARNINGS AND PRECAUTIONS

WARNINGS

Electromagnetic disturbances may cause degradation of performance of the Versa One System such as abnormal behavior on the user interface display. If abnormal behavior is due to possible EM disturbances, relocate the system accordingly. Do not place the system in a location known to have high EM fields during the service life of the product.

Use of cables or accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- The HDMI ports provide a digital video output signal to monitors that receive HDMI input. If an adapter is connected, then monitors with other video input formats may be used. OSES does not provide the monitor or adapters. It is highly recommended to use a monitor that complies with 60601-1-2 limits for emissions.

Portable RF communications equipment (including peripherals) should be used no closer than 30 cm (12 inches) to any part of Versa One System Videoscope or WiHD Receiver, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The optics emit high-energy light at the distal end of the endoscope. Follow the instructions below to minimize the risk of injury.

- Avoid contact between the distal tip of the device and body tissue for longer than 1 minute. Under normal operating conditions the temperature is not expected to exceed 41 °C (106°F) but sustained contact may result in tissue damage.
- **DO NOT** stare at the light source. The high level of light beam emitted may cause eye damage.

Risk of injury if damaged endoscopes are used. Carry out a visual inspection and functional check prior to each use. Only use the scope if it is visually undamaged and in proper working condition.

- Ensure the outer surface intended to be inserted into the patient has no unintended rough surfaces, sharp edges, or protrusions.
- Before each use, check to ensure that the view observed through the endoscope has the correct orientation. If the image does not have the correct orientation, rotate the image by adjusting the rotating dial on the proximal end of the endoscope.

DO NOT use active endoscopic accessories such as laser probes and electrosurgical equipment with the VOS as this may result in patient injury or damage to the endoscope.

DO NOT use excessive force when advancing, operating, or withdrawing the endoscope as this may result in patient injury or damage to the endoscope.

No modification of this equipment is allowed. Unauthorized modification of this equipment can result in damages to equipment or personal injury.

PRECAUTIONS

1. Have a suitable backup system readily available in the event a malfunction should occur.
2. Take care not to damage the scope shaft or distal tip. Do not allow other objects or sharp devices such as needles to strike the endoscope.
3. **DO NOT** submerge the proximal end of the endoscope when cleaning.

3. PRODUCT DESCRIPTION

3.1. Indications for Use

The Versa One System is a hand-held, hybrid rigid/flexible, WiHD enabled scope system with high-definition imaging, and the ability to attach interchangeable surgical instruments/devices. It is intended for use in otolaryngology and head and neck procedures including rhinology and endoscopic plastic and reconstructive surgery.

3.2. Intended Use Environment

This equipment is suitable for use in residential areas or hospitals.

3.3. Contraindications

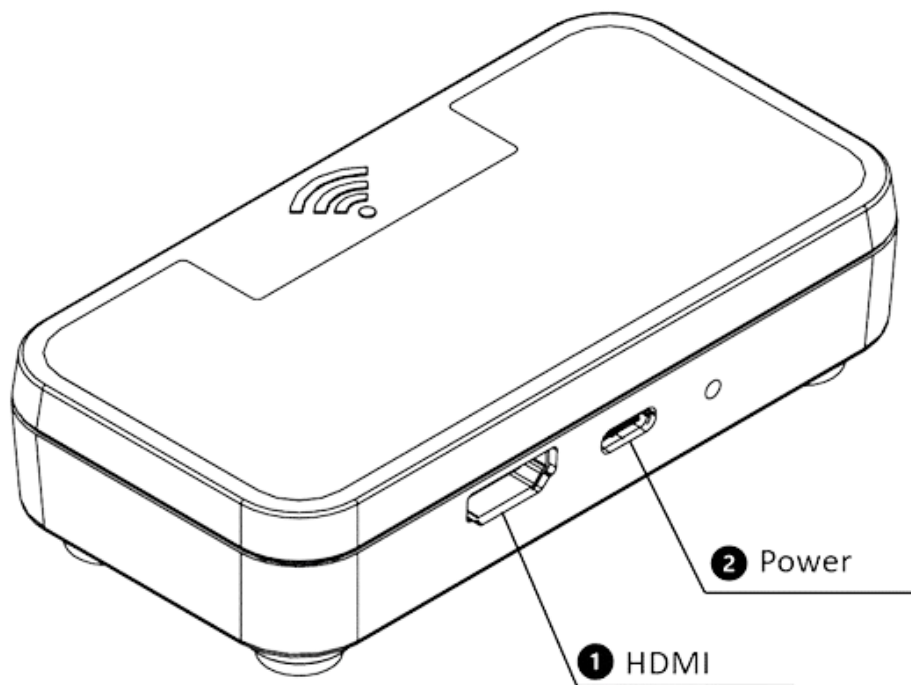
- Acute epiglottitis
- Croup
- Coagulopathies
- Craniofacial trauma

3.4. Components and Specifications

Versa One System (VOS) is comprised of four main components:

- Versa Wireless HDMI Receiver
- Versa One System Videoscope
- Versa One System Scope Cable
- Versa One System WiHD Receiver

3.4.1. Versa One System WiHD Receiver – Model No. 8101016



Mass: 110g

Size: 108mm x 55mm x 26mm

Equipment Classification: Class II

Compatible Power Supply: Globtek, GTM86100-1005-W2

Input: 100-240VAC ~ 50/60Hz, 0.6A

Output: 5.0 V --- 2.0A, 10.00W

Receiver Module:

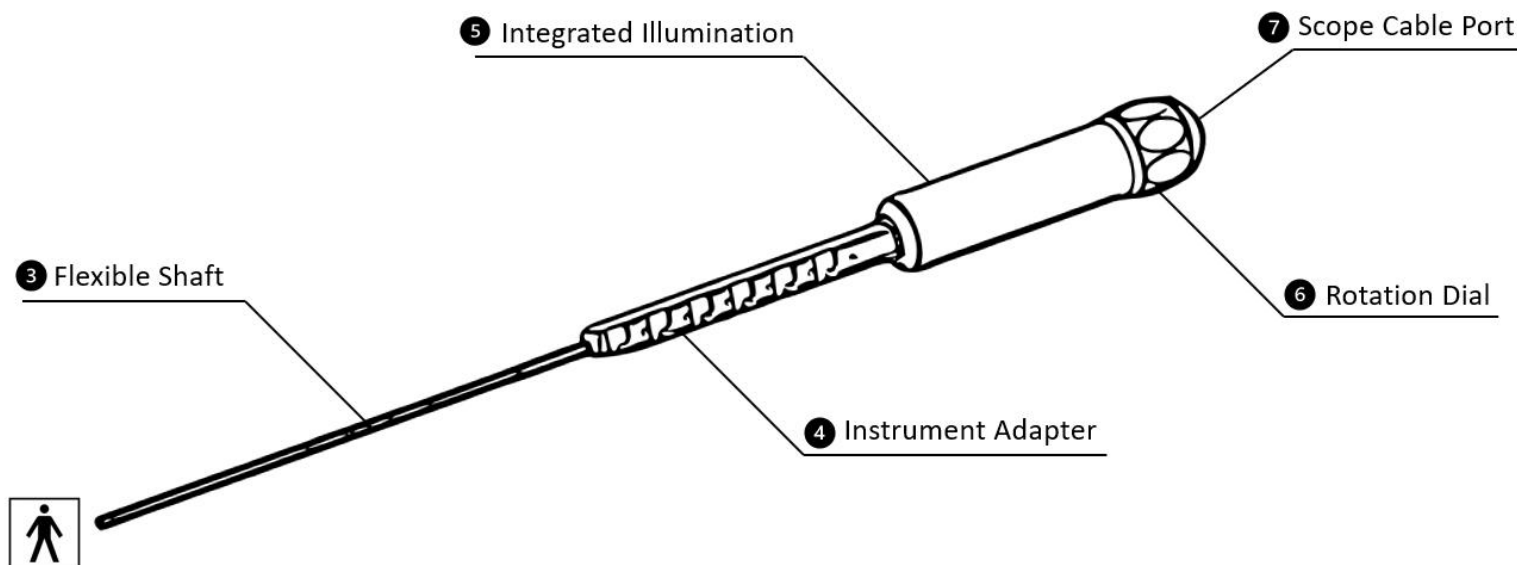
Contains FCC ID: 2ASUJ-SII-SK63101

Frequency band of reception: 59.40 GHz to 63.56 GHz

Preferred frequency: Automatic

Bandwidth: 1.6 GHz/channel

3.4.2. Versa One System Videoscope – Model No. 8100817



Flexible Shaft: 126mm, Ø2.25mm

Rigid Shaft Length: 72mm

Applied Part Classification: Type BF

LED: Luxeon Z ES DS 134

Camera Module: OmniVision OVM6946

Field of View: 120°

3.4.2.1. Endoscope Functions

- 3 Flexible shaft:** allows the camera to conform to any shape.
- 4 Instrument Adapter:** allows the scope to be attached to a variety of instrumentation
- 5 Integrated Illumination:** The built-in LED Light Engine provides excellent illumination in a lightweight and power efficient package.



Caution, very bright light: The optics emit high-energy light at the distal end of the endoscope. Do not stare directly into beam to avoid injury to the eyes.

- 6 Rotation dial:** Rotating this dial will digitally rotate the image in 30° increments clockwise or counterclockwise.
- 7 Scope cable port:** This connector allows for either length Versa Cable to connect between the display and the scope.

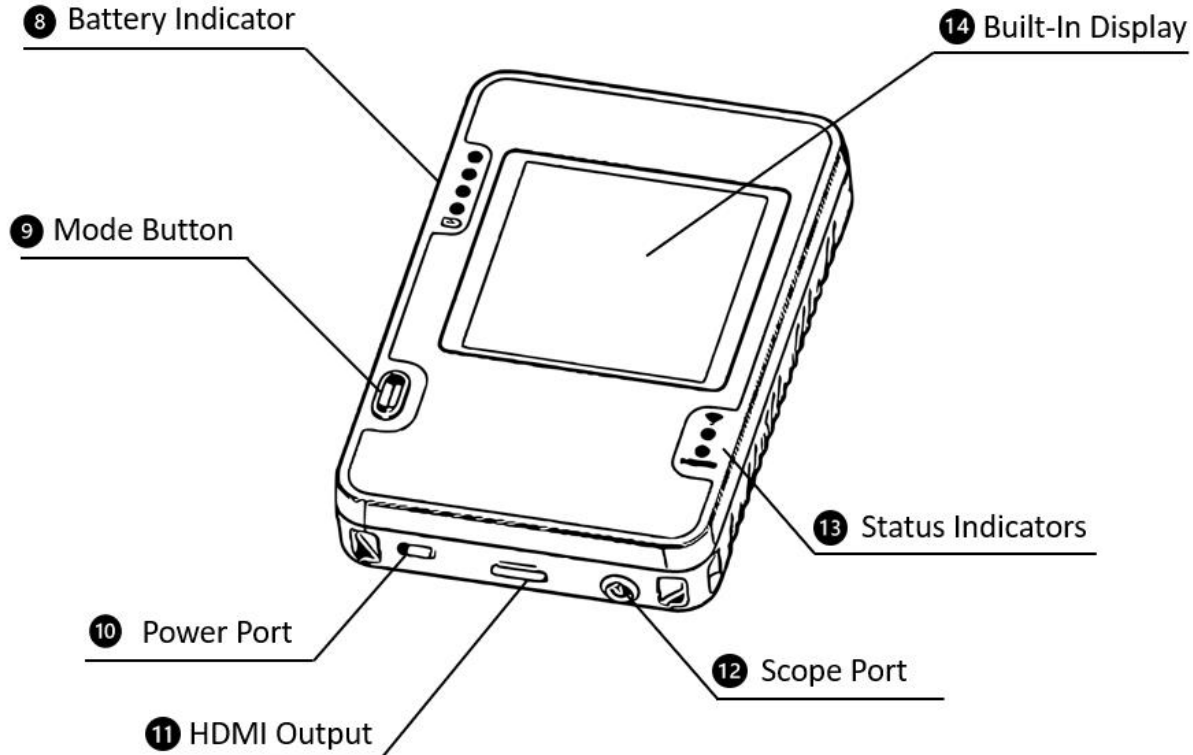
3.4.3. Versa One System Scope Cable

Model No. 8100813 – 72" length

Model No. 8100943 – 144" length



3.4.4. Versa One System Display – Model No. 8100850



Display Resolution: 400 x 400 pixels

Internally Powered: RRC1130

Secondary Battery Pack Li-Ion:
3.80V / 3.81 Ah / 14.47 Wh

Compatible Power Supply: GlobTek, GTM96183-18PD-USB1C

Input: 100-240VAC ~ 50/60Hz, 0.6A

Output: 5.0-20.0Vdc, 18W

Transmitter Module:

Contains FCC ID: 2ASUJ-SII-SK63102
Frequency band of transmission: 59.40
GHz to 63.56 GHz

Type and frequency characteristics:
WirelessHD1.1, HR2/HR3 bands
Effective Radiated Power: 26.9 dBm

3.4.4.1. Display Functions

- 8 Battery Indicator:** LEDs display charge of the battery
- 9 Mode Button:** used to control display mode
- 10 Power Port:** allows the device to charge using the provided USB-C PD charger. Note the system can charge while in use.
- 11 HDMI Output:** standard HDMI output for wired display on a larger monitor.
- 12 Scope Port:** interface to the camera
- 13 Status Indicators:** LEDs indicate the current system state. The HDMI LED indicates that the wired HDMI port is active. The WiHD LED displays the status of the WiHD link.
- 14 Built-In Display:** allows for visualization without any other equipment.

3.5. Compatible Products

The Versa One System Videoscope camera is the portion of the device that contains the imaging module and is designed to mate with OSES proprietary ENT instruments.

- Suctions
- Suction elevator
- Rigid irrigation sheaths

The endoscope connects to a handheld display module or can be wired to an HDMI compatible display monitor. The monitor is not provided by Outlook Surgical. It is highly recommended to use a monitor that complies with IEC 60601-1-2 limits for emissions.

4. INFORMATION FOR USE

4.1. Operating Conditions

Operating Temperature: 10°C to 30°C

Operating Humidity: 15% to 90% RH, non-condensing

Atmospheric Pressure: 70 to 103 kPa

4.2. Handling and Care

Endoscopes from Outlook Surgical are precision medical instruments which require careful handling.

- Do not subject the endoscope to impact
- Put the endoscope down carefully.
- Only hold the endoscope by the handle and not by the shaft.



DO NOT DROP as this can cause the flexible shaft to deform or break.

4.3. Provisioning

- Clean/disinfect and sterilize the endoscope prior to initial use as well as each subsequent use of the endoscope.
- Ensure that the proximal end of the endoscope is dry to prevent the scope from fogging up during the examination/procedure.

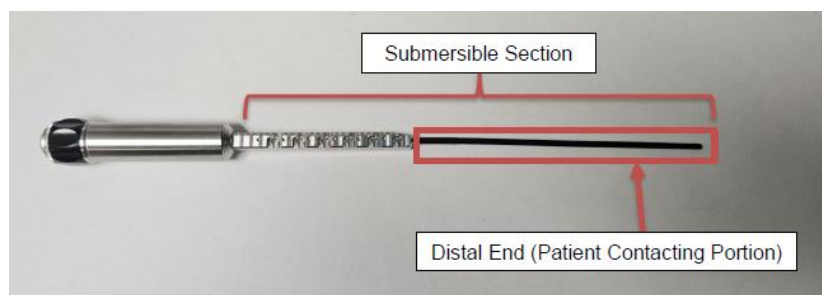
5. CLEANING AND STERILIZATION

5.1. Pre-cleaning Inspection

Perform a pre-cleaning inspection to ensure the endoscope, cable, and/or accessories are in good condition with no gross damage. Discard if there is any damage that could impact the functionality of the device.

5.2. Pre-cleaning

- Perform pre-cleaning immediately following completion of the endoscopic procedure to help prevent the formation of biofilm. Rinse the submersible section (see figure below) section of the scope under cold water and then wipe with a wetted lint-free cloth.



5.3. Manual Cleaning

- Perform manual cleaning before performing sterilization. Manual cleaning is the most critical step in the disinfection process since residual organic material can reduce the effectiveness of sterilization.
- Ensure all cables and adapters of the endoscope are detached.
- Prepare Enzol Enzymatic detergent or equivalent per manufacturer's instructions.
- Immerse the submersible section of the scope and allow it to soak for 1 minute. While device soaks brush surface with a soft bristled brush to aid in the removal of soil. Pay attention to hard to clean areas. Avoid brushing the lens at the distal end of the scope.
- Remove scope from bath and wipe scope with detergent soaked lint-free cloth, wipe handle of scope and cable to remove soil.
- Rinse the submersible section of scope under running warm water to remove detergent residue.
- Wipe the remainder of the scope and the cable with wetted lint-free cloths.
- Dry the scope and cable with clean lint-free cloths.



Do not scratch contaminants off with hard objects as this can cause damage to the optical end surfaces.

Do not clean the endoscope in an ultrasonic bath. Non-compliance with the manufacturer's specifications can result in damage to the endoscope.

5.4. Post-cleaning Inspection

- After manual cleaning, visually inspect the endoscope and accessories for debris and damage.

5.5. Sterilization



The Versa Videoscope is compatible with the STERRAD® method. Endoscopes can be sterilized with the following STERRAD® Systems:

- **STERRAD 100NX – Standard Cycle**

Observe specifications of the manufacturer (ASP) regarding the corresponding method.

5.5.1. STERRAD® Sterilization Systems

The STERRAD® Sterilization Systems, manufactured by Advances Sterilization Products (ASP), utilize a synergism between hydrogen peroxide and low temperature gas plasma to produce a rapid, low temperature, low moisture inactivation of microorganisms. It is intended for terminal sterilization of properly cleaned, rinsed and dried reusable medical devices.

The STERRAD® 100NX™ System is a large sterilizer with rectangular chamber size of 152L/93.4L (usable) and two cycles – a **Standard** cycle at approximately 47 minutes and a **Flex** cycle at approximately 42 minutes.

5.5.2. Sterilization Procedure

1. Place the instruments in a STERRAD® compatible instrument tray.
2. Place a STERRAD® indicator strip in each tray and pouch.
3. Double wrap the sterilization tray with two single layers of FDA-cleared polypropylene wrap, using a sequential double wrapping technique.
4. Load the STERRAD® sterilizer, arranging the items such that the hydrogen peroxide plasma can surround them. Do not allow any items to touch the wall of the sterilizer.
5. Select the "Standard Cycle".
6. Please refer to the STERRAD® Sterilization Systems User Guides for detailed instructions for use of any STERRAD® unit, ASP's STERRAD® Sterility Guide (SSG) at www.sterradsterilityguide.com, or contact ASP Customer service at (888) 783-7723.
7. Please contact Outlook Surgical Endoscopy Systems, LLC. for questions about STERRAD® SYSTEMS compatibility



5.6. Storage

- If possible, reprocessing endoscopes immediately after use is recommended.
- Always store endoscope securely and transport to processing in a closed container to prevent damage to the endoscope and contamination of the environment.
- Store processed flexible endoscopes in a cabinet that is either:
 1. Of sufficient height, width, and depth to allow flexible endoscopes to hang vertically without coiling and touching the bottom of the cabinet OR
 2. Designed and intended by the manufacturer for horizontal storage of flexible endoscopes.

5.7. Documentation

- Maintain documentation of adherence to these essential steps each time an endoscope is reprocessed. Documentation is essential for quality assurance purposes and for patient tracing in the event a look back is necessary.

6. PRE-OPERATIVE

6.1. Patient Preparation

- Position the patient for optimal access to target site.

6.2. Device Preparation

- Confirm the product has been sterilized in accordance with these instructions.
- Visually inspect the endoscope for any damage.



Ensure the outer surface intended to be inserted into the patient has no unintended rough surfaces, sharp edges, or protrusions.

6.3. Assembly

6.3.1. System Start-Up

Attach the Versa Vidoscope to the Versa Control One handheld display using either the 6' or 12' cable. The system will immediately turn on.



The system will take ~15 seconds to load the calibration data and will then display live video.

6.3.2. Wired Operation

- Connect the display to a monitor using the HDMI cable

Note: Any time an HDMI cable is plugged into the display the system will enable the wired output and disable wireless.

- While operating in wired mode, pressing the mode button will toggle the built-in screen on and off.
- The HDMI status light will be on while in this mode.

6.3.3. Wireless Operation

- If no HDMI cable is plugged into the system, pressing the mode button once will enable the integrated WiHD transmitter and start the pairing process.
- Once the WiHD module is powered on the WiHD light will show the transmitter status

Slow Blink	Looking for Receiver base station
Fast Blink	Connected to Receiver
Solid	Transmitting Video

- Pressing the mode button once will disable the LCD.
- Pressing the mode button again will re-enable the LCD and disable the WiHD, putting the system back into wired mode.
- The transmitter is directional. For optimal performance keep the screen of the display pointed towards the receiver



6.3.4. Pairing Procedure

- Once enabled the integrated transmitter will search for a receiver. If after 10-15 seconds, the WiHD LED is still blinking, the mode button should be held for 3 seconds to switch to a different channel.
- Depending on how many receivers are in range it may be necessary to change channels a few times.
- Holding the mode button for 10+ seconds will reset the transmitter completely and should pair to the nearest receiver.

6.3.5. System Charging

- The USB-C PD charger included with the system can be plugged into the display at any time to charge the unit.
- The system charging is automatic, and the display can remain connected to power indefinitely without risk of damage to the unit.
- After use, the system should be charged to prevent over-draining of the system.
- Never store the system with a dead battery.
- Be sure to position the equipment such that it is not difficult to disconnect from the power supply.

7. TROUBLESHOOTING

ERROR	POSSIBLE SOLUTION(S)
System will not power “On”	• Verify that the battery has been sufficiently charged.
Images are not appearing on the display.	• Verify that the Versa Cable is securely connected to the scope and the handheld display. • Verify the Receiver module is connected to power.

8. SERVICE AND MAINTENANCE

8.1. Maintenance Management

The probability of failure of the endoscope and ancillary equipment increases as the number of procedures performed and/or the total operating hours increase. In addition to the inspection before each procedure, the person in charge of medical equipment maintenance in each hospital should inspect the items specified in this manual periodically. An endoscope with an observed irregularity should not be used or serviced/maintained while in the patient.

8.2. Prohibition of improper repair and modification

This instrument does not contain any user-serviceable parts. Do not disassemble, modify, or attempt to repair it; patient or operator injury and/or equipment damage may result.

9. DISPOSAL

10. RADIO COMPLIANCE (FCC PART 15)

11. ELECTROMAGNETIC COMPATIBILITY (IEC 60601-1-2)

11.1. ESSENTIAL PERFORMANCE

Electronics essential performance: Display outputs a live video signal from the endoscope in the correct orientation. There shall be no permanent component failure. Interruption in video is acceptable if the video is self-recoverable or otherwise recovered with user intervention (re-setting the system), restoring full performance.

Guidance and Manufacturer’s Declaration – Electromagnetic Emissions
The Versa One System is intended for use in electromagnetic environment specified below. The customer or the



user of the VOS should assure that it is used in such an environment.	
Emissions Test	Compliance
Radiated Emissions CISPR 11	TBD
Conducted Emissions CISPR 11	TBD
Harmonic Current Emissions IEC 61000-3-2	TBD
Voltage fluctuation & Flicker IEC 61000-3-3	TBD

Guidance and Manufacturer's Declaration – Electromagnetic Immunity		
The Versa One System is intended for use in electromagnetic environment specified below. The customer or the user of the VOS should assure that it is used in such an environment.		
Immunity Test	IEC 60601 Test Level	Compliance Level
Electrostatic Discharge IEC 61000-4-2	±8 kV Contact ±2 kV, ±4 kV, ±8 kV, ±15 kV Air	TBD
Radiated Immunity IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	TBD
Electric Fast Transients Immunity IEC 61000-4-4	±2 kV for Input AC/DC Power Port 100 kHz repetition frequency	TBD
Surges Immunity IEC 61000-4-5	±0.5 kV, ±1 kV line to line	TBD
Conducted Immunity IEC 61000-4-6	3 Vrms 0.15 MHz - 80 MHz and 6 Vrms In ISM bands 0.15 MHz - 80 MHz 80% AM at 1 kHz	TBD
Voltage Dips IEC 61000-4-11	0 % Ut; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % Ut; 1 cycle and 70 % Ut; 25/30 cycles Single phase: at 0°	TBD
Voltage Interruptions IEC 61000-4-11	0 % Ut; 250/300 cycles	TBD