



Endoscopes



## Introduction

VisionScope is an endoscopic imaging system designed to enable pre-operative and post-operative diagnosis in physician examination rooms. The device can also be used in intra-operative procedures in operating rooms where smaller gauge endoscopes are important for minimally invasive surgical procedures. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.

The key component of the VisionScope is a 1.4 mm diameter semi-rigid fiber-lens endoscope that fits within a disposable sterile 1.7 mm diameter endoscope sheath (patented), which in turn is small enough to fit through a 2 mm portal or cannula. The disposable endoscope sheath, consisting of an illumination sheath with an integrated camera drape, also acts as a sterile barrier, thereby eliminating the need for full sterilization of the endoscope and camera handpiece following each procedure. VisionScope Technologies is able to miniaturize the endoscope diameter while still providing true High Definition (HD 1080) anatomical visualization, enabling Surgeons to obtain direct visual clinical assessment in a physician examination room without requiring sterilization or bio-hazard processing infrastructure when used as an imaging device alone and without any resection instrument.

### Indications for Use

The VisionScope High Definition Endoscopy Camera System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of an interior cavity of the body through a natural or surgical opening. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.

Additionally, when used in conjunction with an appropriately indicated and FDA 510(k)-cleared endoscope and light source, the VisionScope High Definition Endoscopy Camera Control Unit and Camera Handpiece are indicated for use in arthroscopic and endoscopic surgical procedures to provide illumination, visualization and capture of still and motion pictures of articular cavities, body cavities, hollow organs and canals.

### Intended Users

The VisionScope line of Endoscopes is designed for use by licensed physicians for performing diagnostic or surgical procedures. Physician assistants may assist in the setup of the equipment and preparation of patients.

### Contraindications

None Known.

### Warnings

- Read this *Instructions for Use* (PN 01113) completely prior to use.
- Read the *Instructions for Use* for the VisionScope System (PN 01112), VisionScope Camera Handpiece (PN 01115), and Sterile Procedure Kit with Disposable Endoscope Sheath, Cannula, and Trocar (PN 01114) completely prior to use.
- It is the Surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
- The VisionScope family of Camera Control Unit, Camera Handpiece, and Endoscope are designed to be used together with one-time use sterile Illumination Sheath with Camera Drape, Cannula, and Trocar to ensure safety and effectiveness. Never mix or substitute any component with any other unauthorized product from any other unauthorized manufacturer.
- This product is shipped non-sterile. It must be used in conjunction of a matching piece of sterile disposable Endoscope Sheath manufactured by VisionScope to ensure sterility.
- WARNING: Disregarding the information on safety of this device is considered ABNORMAL USE.

### Precautions

- U.S. Federal law restricts this device to sale by or on the order of a physician.
- When used for diagnostic imaging in a physician examination room singly without accompanying resection or surgical instrument, the Endoscope and the Camera Handpiece must be sheathed with a disposable sterile Illumination Sheath and Camera Drape to avoid infection.
- When used for intra-operative surgical procedure in an Operating Room, the Camera Handpiece and the Endoscope must be sterilized with chemical sterilants (100% Ethylene Oxide (ETO), Sterrad 100S, Sterrad NX, or Sterrad 100 NX). This is to ensure that in the unlikely event that the exterior sterile Endoscope Sheath is accidentally damaged by resection or surgical instruments, the Endoscope and Camera Handpiece will not result in infection.
- Do not autoclave the Camera Handpiece or the Endoscope.
- Prior to each use and insertion into a patient, ensure the system is functioning properly and is producing live video. Inspect the Endoscope, the disposable Endoscope Sheath, Cannula, and Trocar to ensure that the tubes are not bent, the windows are not damaged, and there are no unintended rough surfaces, sharp edges or protrusions which may cause HARM. Do not use a damaged device.
- Handle any exposed sharp needle point at the distal tip of the Trocar, Cannula, and Endoscope with care to avoid accidental injury or contamination.
- To avoid fogging during surgery, the Camera Handpiece and the Endoscope must be dry prior to attaching the one-time-use sterile Illumination Sheath and Camera Drape.
- Do not operate or sterilize an Endoscope that is damaged. Use authorized hospital decontamination procedures to clean the Camera Handpiece and the Endoscope optics prior to returning to the factory for service.
- Review the live video images to ensure that there is no deposit on the optical surfaces prior to a procedure.
- The Endoscope contains plastics, metals, glass, and epoxy material. At the end of the useful life of the Endoscope it should be disposed of in accordance with any applicable national, local or institutional regulation and environmental policy.

### Glossary of Symbols

Attention, Please Read Instructions for Use

This WEEE symbol indicates that when the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling

Cardiac Floating Symbol, signifying that the equipment has a leakage current of less than 10 µA per IEC60601-1

Split Illumination Icon for aiding alignment of the Illumination Sheath to Camera Handpiece

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CE Mark issued by TUV Rheinland

Electrical Safety Testing Mark by TUV Rheinland of North America, Inc., a test laboratory and notified body

European Representative

## Device Description

VisionScope Endoscopes are designed to be used with the VisionScope Camera Handpiece and matched line of Sterile Procedure Kits to provide illumination and access to articular cavities, body cavities, hollow organs, and canals.

Five Endoscopes (60 mm, 95 mm, 125 mm, 160 mm, or 220 mm operating lengths) are available. Endoscopes and Sterile Procedure Kits are color-coded to ensure that the correct components are selected.

Part Number	Description	Functions
50006-060	VisionScope Endoscopes with working lengths of 60 mm, 95 mm, 125 mm, 160 mm and 220 mm Non-Sterile	A family of five 17-gauge needle Endoscopes with working lengths of 60 mm, 95 mm, 125 mm, 160 mm and 220 mm, optimized for visualization of articular or body cavities of different sizes. Surgeons make the choice of working length for each procedure based on the clinical need.
50006-095		
50006-125	The innovative optics, working in conjunction with the Camera Handpiece and integrated Camera Control Unit, offers unprecedented light collecting efficiency, contrast resolution, and image clarity. VisionScope endoscopes are compatible with the following sterilization methods: ETO, Sterrad 100S, Sterrad NX. Do not autoclave.	
50006-160		
50006-220		

## Unpacking and Inspection

Prior to using the Endoscopes, inspect the Endoscope for signs of damage, including bent shaft, dented shaft, loose needles, missing glass windows on the distal tip and proximal end. Inspection should include all equipment to be used in performance an imaging procedure, including the Camera Control Unit, the Camera Handpiece, the camera cable and the Endoscopes. Inspection of the disposable devices may be carried out separately by examining the exterior of the Sterile Procedure Kit prior to use.

Check that the O-ring at the base of the Endoscope is in place and undamaged. If damaged or missing, a new O-ring can be ordered through VisionScope Customer Service.

Examine the shipping containers for any sign of external damage. Open the packing boxes containing the Endoscopes and standard accessories. Set up the equipment following the instructions in this document to ensure that they are functional. Contact VisionScope or its authorized sales representatives to report any missing, damaged or non-functional items. Save the carton and packing material in the event that the equipment needs to be returned for repair or exchange.

Figure 1 Marking on Endoscope with Part Number and Serial Number



## Performing a Patient Procedure

If VisionScope is prescribed to be used in a diagnostic imaging procedure without any resection tool, the one-time use sterile Illumination Sheath and Camera Drape may be used for protecting the patient as well as the Endoscope and Camera Handpiece from contamination.

### Warning

#### Reprocessing Requirements of the Endoscope and Camera Handpiece

**Procedures with an accompanying in vivo resection tool:** If VisionScope is prescribed to be used in a surgical procedure with an in vivo resection tool, the entire Camera Handpiece and the Endoscope must be sterilized before and after each procedure, using one of the sterilization methods specified in the Instructions for Use for the Camera Handpiece and the Endoscope (PN 01113, PN01115), to assure sterility in the unlikely event that the sterile Illumination Sheath or Camera Drape is accidentally damaged by the resection tool.

**Diagnostic Imaging Procedures without any other tool:** If VisionScope is prescribed to be used in a diagnostic imaging procedure without an in vivo resection tool or any other tool, and if used in conjunction with the VisionScope Disposable Sterile Procedure Kit in accordance with the Instructions for Use (PN 01114), the entire Camera Handpiece and the Endoscope may be used without sterilization but must be disinfected by wiping with a 70% isopropyl alcohol soaked gauze pad before and after each procedure.

#### Assembling the Endoscope and Camera Handpiece

Use the appropriate Endoscope (60 mm, 95 mm, 125 mm, 160 mm, or 220 mm operating length) for the intended patient procedure (see *Device Description* for part numbers).

### Warning

The Endoscope and Camera Handpiece are non-sterile. Do not handle the Endoscope or Camera Handpiece with gloves that will be used for sterile procedures.



Figure 2 Connecting the Endoscope to the Camera Handpiece

#### To connect the Endoscope to the Camera Handpiece:

- Inspect the Camera Handpiece and cable connectors to make sure they are dry.
- Inspect the window on the Camera Handpiece to make sure it is clean and dry. If necessary, use a lint free cotton cloth, lens tissue paper, or a Q-tip wetted with isopropyl alcohol to remove any dirt and smudge.
- Select the appropriate Endoscope model with the desired working length.
- Inspect the Endoscope to make sure that it is dry, the needle is not bent, and the windows on both ends are clean and free of dirt and smudge. Clean if necessary with a lint free cotton wipe or a Q-tip wetted with isopropyl alcohol.
- Thread the Endoscope into the C-mount on the Camera Handpiece (Figure 2). Hand-tighten the Endoscope to ensure that the O-ring seal is compressed securely. Do not use hand tools to tighten the Endoscope.

### Warning

#### To verify correct viewing mode and image orientation:

Before each use or after a change of viewing modes/settings, the Operator should check to ensure the view observed through the Endoscope provides a live image (rather than a stored one) and has the correct image orientation. Instructions for changing from a stored image to a live image and instructions for inverting the image orientation are provided in the Instructions for Use for the VisionScope System (PN 01112).

#### Installing the Endoscope Sheath

The Sterile Procedure Kit includes a Endoscope Sheath to provide illumination for arthroscopic imaging. The Endoscope Sheath is made up of an Illumination Sheath with an integrated Camera Drape to enclose the Camera Handpiece and camera cable in a sterile environment.

Physicians, Nurses and Physician Assistants should use their training and preferred surgical techniques for manipulating both sterile and non-sterile components when connecting the Illumination Sheath to the Endoscope and deploying the Camera Drape. In some cases, it may be helpful to lay the camera in a sterile field or have an assistant remove the outer glove.

**You must select the correct Sterile Procedure Kit for the installed Endoscope (see *Device Description* for part numbers). All components are color-coded to indicate their working length.**



Figure 3 Sterile Procedure Kit

#### To connect the Illumination Sheath to the Endoscope:

- Select a Sterile Procedure Kit (Figure 3) with a disposable Illumination Sheath that has the same working length as the installed Endoscope.
- Examine the Sterile Procedure Kit to ensure that the seal is not broken and the expiration date has not arrived. Discard the kit if either condition is true.
- Wear two sterile gloves on the hand that will be used to handle the non-sterile Camera Handpiece. Wear a single sterile glove on the other hand that will be used to handle the Sterile Illumination Sheath.
- Peel off the lid of the Sterile Procedure Kit.
- While holding the non-sterile Camera Handpiece in the double-gloved hand, pick up the sterile Illumination Sheath in the single-gloved hand. Make sure the non-sterile (double-gloved) hand does not touch any sterile component, such as the needle on the Illumination Sheath, which will enter the patient.
- Carefully insert the needle of the Endoscope into the funnel of the Illumination Sheath (Figure 4).
- Orient the Illumination Sheath so that the Illumination icon on the Illumination Sheath aligns with the Half-Circle icon on the Camera Handpiece and engage the threaded mount.
- Rotate the Illumination Sheath one-quarter turn in the clockwise direction (Figure 5) until the two Illumination icons align. The fiber optic light guide on the Illumination Sheath is now aligned with the light port on the Camera Handpiece.
- Confirm that a bright light spot is seen at the distal tip of the Endoscope and that an adequately bright image appears on the touch screen LCD or an external monitor (if connected) when the Endoscope is placed within 50 mm of a light color object.



Figure 4 Inserting the Endoscope into the Illumination Sheath



Figure 5 Rotating the Illumination Sheath 1/4

**Note:** Make sure the Light Control is set to full power (Normal) when verifying the image from the Endoscope.

#### To deploy the Camera Drape:

- Using the hand with the single sterile glove, hold the Camera Handpiece/Endoscope assembly by the Illumination Sheath.
- Using the double-gloved hand, pull back on the deployment cord of the Camera Drape (Figure 6). Continue pulling the cord until the Camera Drape is fully extended and covers both the Camera Handpiece and the camera cable.
- Peel off the outer glove on the double-gloved hand, touching only the upper part of the glove that has not been contaminated by the Camera Handpiece.
- Inspect the drape for any sign of tear or hole. Replace the entire Illumination Sheath if there is any sign of damage.

#### To white balance the camera:

- Point the Camera Handpiece at a white piece of cotton gauze or bandage. Press the middle button on the Camera Handpiece (pre-programmed by default, unless otherwise changed by the user) that has been pre-programmed to produce a color-balanced image such that the white background is white.

- The white balance process may take 1-2 seconds. During this time, hold the handpiece steady at the white background. Confirm that the On Screen Display indicates that the white balance is completed successfully.

Note: The middle button of the Camera Handpiece is the default setting for white balance. If picture settings have been customized, you may need to use another button to start white balance.

**To confirm image clarity of the Endoscope for suitability of re-use prior to each use:**

- After successful white balance, point the Endoscope at a piece of white cotton gauze or bandage at a distance between 4 mm to 25 mm.
- Confirm that the illumination level is bright, the color is correct, the fabric or threads are in sharp focus, and there is no foreign, nebulous object in the field of view.
- If the image is not clear or is obstructed, replace the Illumination Sheath and Endoscope until a clear image is observed.

The Camera Handpiece/Endoscope/Illumination Sheath assembly is now ready for surgical insertion. A Cannula and a Trocar with matched working length is provided for Surgeons to gain access to the anatomy.

**Inserting the Cannula and Endoscope Assembly**

Inserting the Endoscope into a patient requires the disposable sterile Cannula and Trocar included in the Sterile Procedure Kit. The Cannula and the Trocar should be inserted by qualified physicians only.

The Cannula is equipped with a fluid entry port for introducing a small volume (up to 50 ml) of liquid for flushing or drug delivery. An internal O-ring prevents release of fluid through the Cannula. If necessary, loosen the Cannula collar slightly to relax the O-ring seal before inserting the Illumination Sheath and Endoscope.

**Warnings**

Prior to each use and insertion into a patient, ensure the system is functioning properly and is producing live video. Inspect the Endoscope, the disposable Illumination Sheath, Cannula and Trocar, to ensure that the tubes are not bent, the windows are not damaged, the drape is not torn, and there are no unintended rough surfaces, sharp edges or protrusions which may cause HARM. Do not use a damaged device.

Before starting this procedure, verify that the Cannula and Trocar have the same working length as the installed Endoscope and Illumination Sheath. In addition, verify that you are wearing sterile gloves and that the sterile Camera Drape is installed over the Endoscope and Camera Handpiece.

**To insert the Cannula and Endoscope:**

- Surgically insert the Cannula/Trocar combination into the patient cavity.
- Remove the Trocar and discard.
- Carefully insert the needle of the Endoscope/Illumination Sheath assembly into the funnel of the Cannula (Figure 7). Continue inserting until the entire length of the needle is inserted and the base of the Illumination Sheath fits snugly into the Cannula collar.
- Rotate the collar on the Cannula until the collar fits snugly on the Cannula body. Tightening this threaded connection compresses an internal O-Ring to prevent any leakage of fluid during the procedure.
- If the procedure requires fluid injection, connect a syringe to the Cannula via the Luer-Lock port and inject.

**Finishing a Patient Procedure**

If the proper procedure is followed during assembly and disassembly, the Camera Handpiece and attached Endoscope should be uncontaminated at the end of a procedure and ready for re-use in the next procedure.

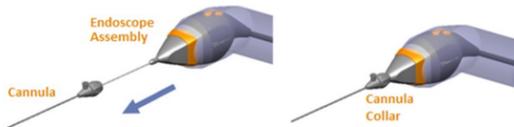


Figure 7 Inserting the Endoscope into the Cannula

**To complete a procedure:**

- Remove the Endoscope and Cannula from the patient.
- Turn the Illumination Sheath 90° counter-clockwise to disengage the bayonet mount from the Camera Handpiece C-mount. Carefully slide the Camera Handpiece and the attached Endoscope out of the Illumination Sheath.
- Carefully back the Camera Handpiece and the attached Endoscope out of the Camera Drape.
- Set the Camera Handpiece and the attached Endoscope down on a clean, uncontaminated work surface.
- Dispose of the Illumination Sheath, Camera Drape, Cannula, Trocar, and any other patient-contact accessories or supplies in a bio-hazard waste bin per the hazard waste disposal policy of the facility.
- Follow the Reprocessing Requirements of the Endoscope and Camera Handpiece stated previously in this Instructions for Use.**
- If the Camera Handpiece and attached Endoscope have been contaminated during or after a procedure, send the devices through an approved sterilization cycle per the Instructions for Use for those sub-systems (PN 01113 and PN01115). Acceptable sterilization methods include 100% ETO, Sterrad 100, Sterrad NX, or Sterrad 100 NX. Do not autoclave.

**Periodic Maintenance, Cleaning and Sterilization**

There are no user-serviceable parts inside any electronics or optical enclosure. The following periodic maintenance or cleaning tasks are recommended.

General	<b>Procedures with an accompanying in vivo resection tool:</b> If VisionScope is prescribed to be used in a surgical procedure <u>with</u> an in vivo resection tool, the entire Camera Handpiece and the Endoscope <u>must be sterilized</u> before and after each procedure, using one of the sterilization methods specified in the Instructions for Use for the Camera Handpiece and the Endoscope (PN 01113, PN01115), to assure sterility in the unlikely event that the sterile Illumination Sheath or Camera Drape is accidentally damaged by the resection tool. <b>Diagnostic Imaging Procedures without any other tool:</b> If VisionScope is prescribed to be used in a diagnostic imaging procedure <u>without</u> an in vivo resection tool or any other tool, and if used in conjunction with the VisionScope Disposable Sterile Procedure Kit in accordance with the Instructions for Use (PN 01114), the entire Camera Handpiece and the Endoscope may be used without sterilization but <u>must be disinfected</u> by wiping with a 70% isopropyl alcohol soaked gauze pad before and after each procedure.
Normal Cleaning and Inspection	The two window surfaces on the distal tip and proximal end of the Endoscopes should be dry and free of foreign objects or smudges in order to produce high quality images. These windows should be inspected in between each procedure, and cleaned with a Q-tip wetted with isopropyl alcohol when necessary.  Inspect the needle shaft of the Endoscopes between each procedure, to make sure that it is not bent or kinked.
Deep Cleaning	VisionScope Endoscopes may be immersed in water for deep cleaning. Scrub each of the window surfaces with a 4" x 4" cotton surgical gauze pad soaked in enzymatic solution recommended for reprocessing of medical Endoscopes prepared in accordance with the manufacturers' instruction, when needed to break down any organic material. Rinse thoroughly with distilled or de-ionized water. Scrub again each of the window surfaces with a 4" x 4" cotton surgical gauze pad soaked in isopropyl alcohol. Rinse thoroughly with distilled or de-ionized water. Dry thoroughly. Use a clean, dry, lint-free cotton cloth to wipe the window surfaces to remove any streak residue. Caution: do not use any ultrasonic cleaning methods, as the energy will damage seals and optical surfaces and will void the warranty.
Sterilization	If the Endoscope is contaminated with bio-fluid during any procedure, make sure that it is decontaminated and sterilized after the procedure. VisionScope Endoscopes may be sterilized with any of the following methods. <ul style="list-style-type: none"> <li>Sterrad 100S Sterilization System: Follow all directions and warnings from the Manufacturer. Put only one camera handpiece and one endoscope per tray.</li> <li>Sterrad NX and Sterrad 100 NX Sterilization System: Follow all directions and warnings from the Manufacturer. Put only one camera handpiece and one endoscope per tray.</li> <li>100% ETO - Follow standard hospital procedures maintaining the following parameters: Temperature 55° C ± 3° C (131° F ± 5° F) Relative humidity &gt;50% Gas concentration 725 mg/l Exposure time 60 minutes Aeration 11 hours minimum</li> </ul> Caution: Disinfection is not a substitute for sterilization. VisionScope Endoscopes are not designed to be autoclaved.

**Service, Troubleshooting, and Replacement**

There are no user-serviceable parts. Do not disassemble any electronics assembly or optical instrument. Some common problems may occur that the end user can easily resolve. Use the following trouble shooting guide to diagnose and correct simple problems. If the problem persists, contact your authorized VisionScope representatives for further consultation or to arrange repair or replacement at an authorized Service Center.

**Warning**

**Withdraw Endoscope if equipment loses images.**

In the unlikely event that the live image is lost during an endoscopic procedure, immediately withdraw the Endoscope and Illumination Sheath from the patient, and follow the appropriate institutional procedures for managing the patient. It is highly recommended that a backup system be available should it be necessary to continue the procedure.

**Common Problem:** Image is soft, not clear, out of focus, or fuzzy.

Probable Cause	Possible Solution
Fluid or foreign object on window of Illumination Sheath	Clean and dry the exterior window on the Illumination Sheath with sterile surgical cotton gauze.
Fluid or foreign object on window at distal tip of Endoscope	Clean and dry the distal tip window on the Endoscope with sterile surgical cotton gauze.
Fluid or foreign object on window at proximal end of Endoscope	Clean and the proximal end window on the Endoscope with sterile surgical cotton gauze.
Fluid or foreign object on window on Camera Handpiece	Clean and dry the window on the Camera Handpiece.
Endoscope not screwed all the way in C-mount	Hand-tightened the Endoscope body all the way in the C-mount until the O-ring groove is compressed. Do not over-tighten with a tool.
Endoscope is damaged	Inspect the Endoscope to ensure that there is no play or possible movement between the needle shaft and the Endoscope body.

**Common Problem:** Image is dark.

Probable Cause	Possible Solution
Fluid or foreign object on window of Illumination Sheath	Clean and dry the exterior window on the Illumination Sheath with sterile surgical cotton gauze.
Fluid or foreign object on the window at the proximal end of the Endoscope	Clean and the proximal end window on the Endoscope with sterile surgical cotton gauze.
Fluid or foreign object on window of Camera Handpiece	Clean and dry the window on the Camera Handpiece.
Endoscope is not screwed all the way in the C-mount.	Hand-tightened the Endoscope body all the way in the C-mount until the O-ring groove is compressed. Do not over-tighten with a tool.
Endoscope is damaged.	Inspect the Endoscope to ensure that there is no play or possible movement between the needle shaft and the Endoscope body.
Illumination Sheath is not attached or aligned correctly.	Attach Illumination Sheath. Check to make sure that the Illumination Sheath is aligned with the Camera Handpiece, to ensure that the light fibers on both parts are in contact with each other.
Light source is turned off.	Check that the light source is turned on from the "Light" menu page.
Camera cable is damaged.	Inspect the cable to see if it is pinched or kinked.
Brightness setting is too low.	Check the "Brightness" setting on the "Camera" tab, increase if necessary.  Check the "Brightness" or "Contrast" settings on the external monitor, make sure it is not set to a low level.
Light source is blown.	Unplug the Camera Handpiece cable connector, turn the power on, wait until the software starts. Go to the "Light" tab, turn the light source switch on and off. In the "On" position, confirm that there is a light beam exiting the Camera Handpiece connector on the front panel. Caution: do not look directly into the light source. If the light source fails to turn on, contact an authorized VisionScope representative and return the unit for repair.

**Endoscope Specifications**

Part Numbers	50006-060, 50006-095, 50006-125, 50006-160, 50006-220
Working Lengths	60 mm 95 mm 125 mm 160 mm 220 mm
Needle Diameter	1.4 mm (17 gauge)
Field of View	75° in air
Focus Distance	8.5 mm nominal from distal tip of window
Depth of Field	4 mm to 25 mm
Weight	36 g max. (1.3 oz)
Sterilization Compatibility	100% ETO, Sterrad 100S, Sterrad NX, Sterrad 100NX
Operating Environment	10° C - 40° C / 30 - 75 % Relative Humidity, non-condensing Atm. Pressure: 700 hpa -1060 hpa (525 mm Hg - 795 mm Hg)
Transport and Storage Environment	-20° to 60° C / 10 - 95 % Relative Humidity, non-condensing Atm. Pressure: 700 hpa -1060 hpa (525 mm Hg - 795 mm Hg)
Regulatory Classifications	US FDA: Class II, per FDA Product Classification Database EU: Class IIa, per "MEDDEV 2.4/1- rev. 9 Part 2, Rule 6 - Surgically invasive device for transient use.
Classification in accordance with IEC60601-2-18	Protection against electric shock: Type CF Applied Parts
Life Time	Endoscopes (50006-XXX): 3 years or 100 cycles of sterilization, whichever is earlier  Note: Obsolete or expired equipment must be disposed of in accordance

**Limited Warranty**

VisionScope warrants that the VisionScope products will be free from defects in material and workmanship, when properly installed, stored, maintained, and used for the intended purpose. The warranty period for all products except the Endoscopes is twelve (12) months, and six (6) months for Endoscopes, beginning from the date of invoice. VisionScope's warranty is extended only to the original purchaser of the products at the location where it is originally shipped.

This limited warranty is restricted to repair or replacement by VisionScope, at its option, of any product found to be defective during the warranty period without charge. Damage inflicted to a product by the user may result in additional charges, regardless of the status of warranty.

Any alteration, abuse, misuse, or modification of the product or any component thereof shall void this warranty. This warranty is null and void if the user attempts to service the product or if service is performed by unauthorized third parties. One-time use, disposable sterile products are not covered by this warranty after the first use or after the expiration date.

In no event shall VisionScope be liable for loss of profit, consequential damages, loss of time, or loss of business incurred by the buyer with the purchase or use of any product.

NO OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IS GIVEN.



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