

MedRx.

INSTALLATION

MANUAL



*Camera, Probe and
Lightsource*

VIDEO OTOSCOPE



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Contents

Using The Video Otoscope	3
The Battery Operated LED Light Source	4
Connecting the Video Otoscope	5
Connect the LEMO Cable	6
Wiring Diagram	7
Specula Adapter	8
Trouble Shooting Guide	9
Cleaning & Disinfecting	10
Transportation & Storage	10
Safety	11
Limited Warranty.....	12



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Using the Video Otoscope

 **CAUTION:** The MedRx Video Otoscope is only to be used by a person qualified in the use of an Otoscope. Misuse can cause a patient pain and possible injury.

Intended Use Statement:

The MedRx Video Otoscope is used to perform otoscopic examination of the outer ear and tympanic membrane. It is also used to assist with hearing aid and probe microphone placement for real ear measurements. These devices are to be operated by professionals with education and/or training in the field of audiometry. The device consists of an Otoscope connected to a video camera that can present the image on a video screen. This function gives you the option to capture images for storage.

Indication For Use Statement:

The MedRx Video Otoscope is for use by professionals with education and/or training in the field of audiometry to provide detailed examinations of the outer ear canal and tympanic membrane. Also used to assist the hearing aid and probe mic placement for Real Ear Measurements. The image provided by the camera can be captured and stored as a visual record of the examination.

Video Otoscopy has multiple purposes in hearing assessment and hearing instrument fitting.

The Video Otoscope is used for:

- Performing the initial otoscopic examination prior to testing.
- Capturing and storing images to the NOAH™ patient database.
- Troubleshooting problems with the hearing aid, such as blocked receivers and microphones.
- Probe microphone placement for Live Speech Mapping measurements.

Always perform an otoscopic examination of the ear canal prior to testing to determine if earwax or other foreign matter will interfere with probe tube insertion. If this is a problem, the patient should be referred to an appropriate resource for removal of the wax or debris. If abnormal ear conditions are noticed on this examination, an appropriate medical referral is recommended before evaluating hearing or fitting hearing instruments.

The speculum is always to be used with the system. The speculum must be cleaned or replaced between patients per accepted medical practice procedures. (Reference section: "Cleaning and Disinfecting" for more information)

Prior to insertion, the probe should be held within 1/4" of a known object, such as your finger, to check the quality of the image. Sometimes the lens is smeared with cerumen or other matter and will need to be vigorously cleaned with an alcohol wipe in order to provide a clear image.

IMPORTANT: The Video Otoscope is composed of rigid glass lenses and a delicate 1/4" CCD micro-camera if either of these are treated roughly, i.e. dropped, the glass lens, video camera or cable may break.

IMPORTANT: Disconnecting the LEMO cable from the back of the Video Otoscope, or disconnecting the DC power adapter from the LEMO cable is the **ONLY** way to turn off the power to the Video Otoscope. If you do not disconnect one of these the Video Otoscope will remain on, and may burn out the image sensor.

The Battery Operated LED Light Source



The LED light handle has three components: the black light handle, the rechargeable batteries and the battery charger.



End cap removed showing batteries in holder and inserted into handle.



LED light handle in position to install on Otoscope.



LED light handle installed on Otoscope. (Note: Black button to turn the light on and off)



Battery Replacement WARNING

Grasp the upper portion of the black handle NOT the probe or camera, when unscrewing the lower section to replace the battery.

Otherwise, possible damage may occur to the probe.



Wrong Way



Right Way

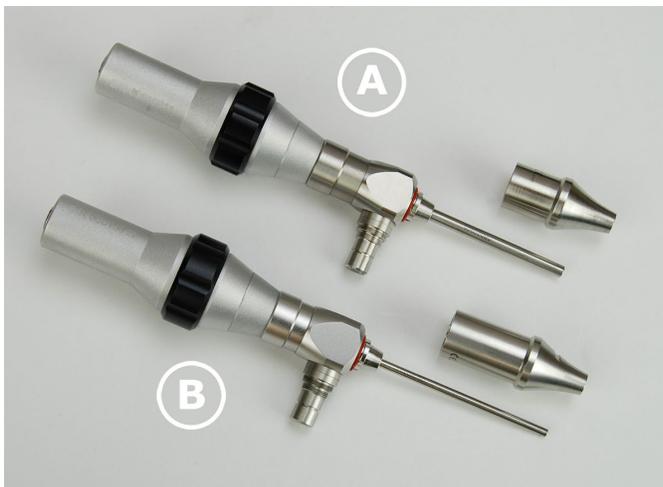
Connecting the Video Otoscope

Remove the Video Otoscope from the padded case, along with the LED light handle. These 2 units should already be connected (Figure 1), if not you can connect them by screwing the threaded end onto the Otoscope light post. The video otoscope features a manual focus wheel to adjust the focal range for better live images.

NOTE: Be careful with the Video Otoscope which is composed of rigid glass lenses and a delicate 1/4" CCD micro-camera. If either of these are treated roughly, i.e. dropped, the glass lens, video camera or cable may break.



Figure 1: Video Otoscope Set



These instructions are for both sizes of Video Otoscopes.

- A. For Adults**
0405T - 4.25mm - 45mm
- B. For Children**
0205T - 2.75mm - 54mm

Connect the LEMO Cable

Once the Video Otoscope and the LED light handle are connected, plug the 4-pin LEMO cable into the back of the Video Otoscope.

There is a red dot on the back of the camera unit and a red line on the LEMO cable. Line these marks up to properly connect the cable to the camera unit.

To disconnect the LEMO cable

you have to grip the rough area of the LEMO cable behind the red line, and pull this back.

There are little hooks on the outside of the cable, and pulling on the cable will not disconnect it. This rough silver area on the cable has to be pulled back to pull the hooks in and allow the cable to be removed.

This is a safety feature so the cable is not pulled out in the middle of an examination.



Figure 2: Connecting & Disconnecting the Lemo Cable

The LEMO cable provides the video camera unit with power and exports the live color image via an RCA video cable to your TV monitor, or to your computer via a USB capture device.

NOTE: Disconnecting the LEMO cable from the back of the Video Otoscope, or Disconnecting the DC power adapter from the LEMO cable is the ONLY way to turn off the power to the Video Otoscope. If you don't disconnect one of these the Video Otoscope will remain on, and may burn out the image sensor.

Wiring Diagram

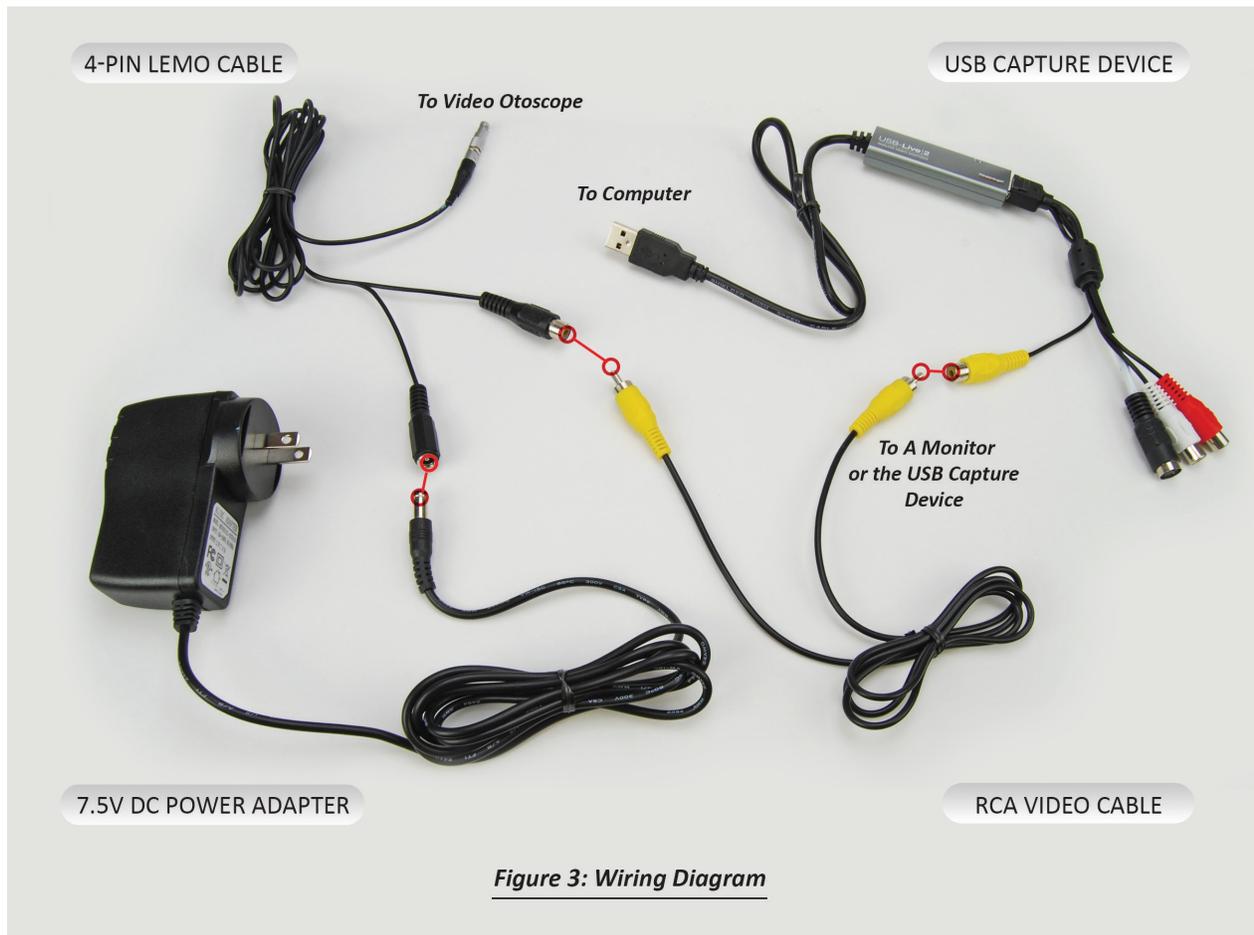


Figure 3: Wiring Diagram

Once you have connected the LEMO cable to the Video Otoscope, plug the corresponding RCA video cable plug, and the 7.5V power adapter plug to the other end of the LEMO cable (Figure 3).

Connect the Power adapter to the power plug first, and ensure that the power adapter is connected to the proper outlet. This will power the Video Otoscope. The RCA video cable plug will have the silver tip, and the power adapter plug will have the wider opening.

Connect the RCA video cable to the RCA video plug on the LEMO cable, and connect the other end of the RCA Video cable directly to the composite video input on the back, or side, of your TV monitor. If you are using the USB capture device, the RCA video cable can be connected to the yellow video input plug of the capture device.

Once the RCA cable is connected to the monitor you may need to change the input signal on your monitor to Video 1 or 2 to locate the image. This changes the signal source from Cable TV to the Video Camera.

Specula Adapter



Figure 4: Specula Adapter

Once the Video Otoscope is working attach the specula adaptor (Figure 4), and use the disposable tips to perform sanitary otoscopic exams. To do this, locate the green dot on the base. This dot acts as a reference point to ensure that the adapter is properly attached. **With the green dot facing down, slide the specula adaptor over the insertion tube, directly to the base of the locking mechanism. Twist the specula adaptor 90 degrees to the left and lock it into place over the otoscope.** You can now attach one of the disposable specula tips over the adapter.

Note: Make sure the disposable specula sticks out a bit further than the lens to insure that it protects the tip and keeps it clean. The extra length should not obstruct your view.

The video camera should now project the live image onto your monitor. To view the live color image, turn ON the attached LED light source by pressing the button once. This will cause light to illuminate from the tip of the Otoscope. To turn off the video camera after use simply detach the LEMO cable from the video camera.

The Video Otoscope is set up for close inspections, test it out on your hand rather than objects far away. There is also a focus ring located on the unit. Try adjusting this to see how it affects the image (see Figure 1).

Trouble Shooting Guide

Problem	Main Cause	Solution
Fuzzy or out of focus picture	Focus Ring not adjusted	Turn Focus Ring until image is in focus
	Dirty probe tip (dried cerumen)	Carefully clean probe tip with an alcohol wipe
	Short in cable	Replace cable
No picture on display	Light Source not turned on	Turn light source on
	Loose wire connection	Re-check wire connection
No light from probe tip	Light source not on	Turn on light source
Cleaning probe does not improve picture	Probe dropped and physically damaged	Call MedRx for service
No light from probe tip	Light source not on	Turn on light source

This guide was designed to assist you in diagnosing minor problems.

Should service be needed, please call MedRx at 888-392-1234 or 727-584-9600 for Technical Support.

Monday—Friday, EST 9AM to 5PM

Cleaning & Disinfecting

Your MedRx Video Otoscope has been designed to provide years of trouble-free service. Do not remove or open the camera housing, as there are no user serviceable components inside.

Cleaning

To keep your system looking new, wipe the exterior of the components with a soft cloth. Stubborn stains may be removed using a cloth moistened with water and mild detergent. Do not allow debris or fluid to enter into the components. Use an alcohol wipe to clean the lens on the end of the Otoscope probe, or a common disinfectant.

Video Otoscope Disinfecting

The Video Otoscope is sealed so that it may be wiped between patients with the following surface cleaners to disinfect; 70% Alcohol, Chlorhexiderm, Cidex, Nolvasan, Parvocide, Parvoso, Roccal or Synphenol. Follow instructions provided with the disinfectant.

The scope should NEVER be heat sterilized, gas sterilized or soaked in liquid because damage may result.

Speculum / Curette Disinfecting / Replacement

The speculum is always to be used with the system. The speculum and curette must always be cleaned (per accepted medical practices and instructions provided with the disinfectant) or replaced between patients.

Transportation & Storage

When transporting or storing your Video Otoscope, it is best to use the original packing case or similar packaging. Store the system in a cool, dry location and do not place your system in direct sunlight. Care must be taken to protect the system from shock, moisture damage and mishandling. Do not place heavy objects on any of the system's components.

To assure proper operation and warranty protection, use manufacturer's replacement components only.

Safety

Regarding electrical safety, this device is to be used only by professionals in the hearing healthcare industry.

The MedRx Video Otoscope is a Class II Medical Electrical (ME) equipment  that is part of an ME system. Power is supplied for video capture by the USB cable connected to a computer. A medical grade isolation transformer is recommended to achieve optimum safety. A medical grade computer is recommended and a medical grade isolation transformer will help minimize ground current. The use environment should be between 10°C and 35°C, humidity between 30% and 90%. All components with patient contact are made of bio-compatible materials.

The Instructions for Use (the Installation and Software Training manuals) are supplied as an electronic copy on a USB flash drive. Paper copies of the manuals may be also requested from the company and will be sent within one business day of the request.

Mild soapy water is the preferred cleaning solution.

All repairs should be sent to MedRx for evaluation and / or repair.

Symbols that may be used:



Caution, General warning sign



or SN Indicates that the device serial number will follow.



Read the instruction manuals for safe usage of the device.
(Operating instructions)



Type B applied part.



Manufacturer
(MedRx)



Authorized Representative in Europe

Limited Warranty

MedRx, Inc. warrants this product to be free from defects in material and workmanship for one year from the time of purchase. If this system fails to perform as specified during this period, the purchaser is responsible for calling MedRx at (888) 392-1234 or (727) 584-9600. The company's representative will advise the owner to either return specific components or the entire system to:

MedRx, Inc.
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MedRx will repair or replace any defective devices, fully test the system and/or components and ship the system promptly back to the owner. There is no cost for the repair or return shipping, provided the system is one year old or less and has not been misused, abused or damaged. Such damage includes, but is not limited to, dropping, exposure to excessive heat greater than 100°F and water/liquid damage.

Repair or replacement of the system as provided under this warranty is the sole and exclusive remedy of the purchaser. MedRx shall not be liable for any consequential or incidental damages or for breach of any express or implied warranty. Except to the extent of applicable law, any implied warranty, merchantability or fitness of this product is limited to the duration of this warranty.

MedRx will, at its discretion, service and repair out of warranty products at the purchaser's request, charging for parts and labor as necessary.

The limited warranty is deemed void if software or hardware is installed on this product which is not pre-approved by MedRx, Inc. Approved software includes NOAH™ and HIMSA approved hearing aid manufacturer programming modules for fitting hearing aids.

MedRx, Inc is not responsible for problems resulting from installation of unapproved software or hardware. In the event of unapproved software or hardware installed on the system causing a conflict, MedRx will service the product for a fee to be determined at the time of service.

Any extension of this warranty past the initial one-year warranty is subject to the following (where applicable).

1. A \$300 deductible per repair.
2. Extended warranty does not include cables, connectors or peripherals.
3. Extended warranty of the Video Otoscope covers optics only.