

"LET OUR IMAGE ENHANCE YOUR IMAGE"

Operating Instructions MedRx Digitally Enhanced Video OtoScope System



Digital Video Otoscope Manual Rev 1

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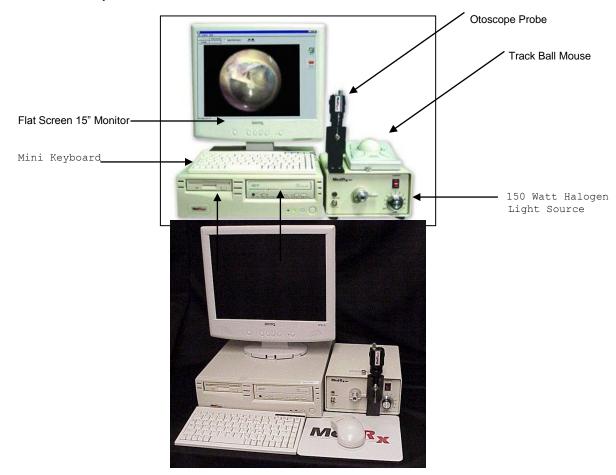
Introduction to the MedRx Digitally Enhanced Video OtoScope System

The Digital Video OtoScope System:

- MedRx Patented OtoScope Probe
- MedRx High Resolution Camera
- High Resolution Sony Color Video Monitor
- High Resolution Sony Color Video Printer with Stop Action Foot Pedal
- 0 150 Watt Halogen Light Source
- Universal Fiber Optic Cable
- 3mm Specula
- All Necessary Cables and Attachments
- One Year Warranty

Options:

- Full Image/Radiograph Lens with Adjustable IRIS
- Extended Warranty



Accessories and System Components

Camera/Probe Assembly

This hand held assembly part includes the custom designed and patented optical probe and high resolution color video camera. These are the key components to the system. The camera operates on 12V DC provided from the light source.

Color Monitor

Monitor features auto-adjustment, of full-screen images no matter what resolution, giving you the best display image without the hassle of changing settings manually.

Light Source

This high quality 150-watt variable intensity light source is designed to provide a small spot of high intensity light which enhances the quality of the image. A fiber optic cable transfers the light from the light source to the probe. A 3/4 rotation of the dial is usually appropriate. However, some adjustment may be necessary for optimum image clarity.

Fiber Optic Cable

The cable, containing thousands of high-grade glass fibers, connects the light source to the probe. The connection to the probe uses a connector, which pushes on and locks in place on the probes optical socket. The connector is released from the probe by pulling firmly on the connector.

Twin Lead Power Cable

This cable is bi-directional so either end can be connected to the camera. The other end connects to the front of the light source.

Power Module

This is a 2" (w) x 1 1/2" (h) x 2 1/4" (d) black cube with a 120V AC power plug on one side and an attached cord on the other side which plugs into the rear of the light source. This power module supplies a constant power of 12V DC to the camera/probe and provides a high degree of voltage regulation.

Should the power module fail, replace it with one from MedRx. A lower quality replacement could cause the camera power supply voltage to fluctuate, resulting in <u>camera damage</u>. (The camera warranty is voided if the proper power module is not used)

Cerumen Management Tools (Curettes) – Accessory

Replace the speculum on the tapered tip of the probe with a curette, and insert into the canal to remove cerumen.

Speculum - Accessory

A reusable 3mm-speculum cover is used to protect the probe tip. Welsh Allyn 3mm (Part Number: 24303)

Lamp EJA 150 - Accessory

This bulb, used in the light source, lasts approximately 200 hours. We suggest you keep a spare bulb on hand.

Digital Image Storage Drive

Allows for electronic storage and recall of diagnostic video images. Video images are easily downloaded to a standard 3.5" floppy disk or a CDWR rewriteable CD drive as a JPEG or BMP file. These images can be labeled and stored or attached to e-mail for diagnostic image forwarding.

Computer

Intel Celeron 1.7, 20GB Hard Drive

Assembly and Installation

Although no specific order is required for connecting the Video OtoScope System, it is sometimes helpful to understand the flow of the signal from the camera to the monitor. The following instructions follow the path of the video signal flow. Before you put the system together, please refer to page 5 for connecting instructions, and page 5 for the wiring diagram.

After unpacking the individual components, the interconnecting wires can be installed. Connect the camera to the light source with the 8' twin lead cable, which plugs into the back of the camera and the front of the light source. One of the plugs, called a BNC, plugs in and turns 1/8 of a turn to lock the plug in place. The power plugs straight into the camera and the light source.

The power module plugs into the power strip and into the back of the light source. The 18" long cable that comes out of the back of the control box with the BNC connector on the end plugs into the video input on the back of the computer. The monitor, and light source need to be plugged into the power strip. (The fiber optic cable needs to be attached into the light source and the probe.)

Caution: Take care to avoid the following circumstances that could cause extensive damage to your fiber optic cable:

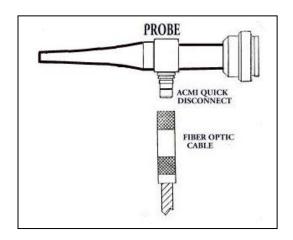
- Do not roll chairs or carts over the cable.
- Do not close the carrying case on the cable.
- Do not pull or yank the cable to disconnect it from the camera.

Instructions for Attaching/Disconnecting Fiber Optic Cable to Probe

To Connect

Push the connector end into the probe as shown in figure 1.

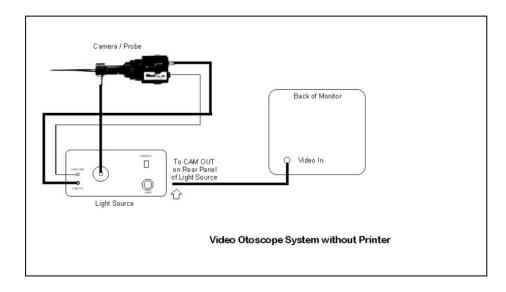
To Disconnect With thumb and forefinger, gently pull the connector away from the probe.



Fuzzy Video Images

Cerumen and/or fog on the lens tip most often cause fuzzy video images. You can correct or prevent either condition by using an alcohol wipe on the lens tip before and after each use.

Medrx Wiring Diagram



Operating Instructions for Using the MedRx Video OtoScope System

Turning on the Video OtoScope System

Master Switch

The master switch is located on the power strip. Before turning off the master switch you must shutdown the computer.

Video Monitor

The video monitor power switch is located on the front of the monitor. An indicator light on the front of the monitor turns green when the power is on.

Light Source

The light source intensity is controlled by rotating a knob located on the front of the light box. The light source should be turned to 3/4 intensity. Once the probe is in the ear, you may need to adjust the intensity control to achieve an optimum picture. When in the standby mode, leave the light on but turn the intensity down to the lowest setting.

<u>Camera</u>

The camera power switch is located on the top of the Light Source. An indicator light turns red when the power is on. If no picture is showing, check to see that the monitor is turned on and that all connections are correct.

Suggested Operating Procedure

- * Leave the monitor, camera, and the printer in the on position and control all pieces of equipment with the master switch on a power strip.
- * The light source can be left on for long periods of time, but the lamp intensity should be turned down except when being used. Following this guideline will greatly extend the bulb life, which is estimated to be about 200 hours. We suggest you keep a spare bulb on hand at all times.

Video Otoscopy



MedRx Video Otoscopy

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

Always perform an otoscopic examination of the ear canal prior 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 the hearing instrument is fitted.

The Video Otoscope function can be accessed from any screen displaying the camera icon.

NOAH Installation

Install the NOAH module

NOAH must be already installed prior to installing the MedRx NOAH Module.

The MedRx module is compatible with both NOAH 2 and NOAH 3 systems.

Installing from CD-ROM:

- Insert MedRx Setup disk into CD drive.
- Start NOAH.
- Choose **Setup** from the NOAH main screen menu (In NOAH 3 choose **Tools** | **Setup**).
- Choose Install Module.
- In NOAH 2 type *D*:*NOAH* (replacing A:\, where D: is the name of your CD drive.) in the box and click **OK**. In NOAH 3 browse to the NOAH directory located on the CD-ROM, choose **Install.ini**, and click **Open**.

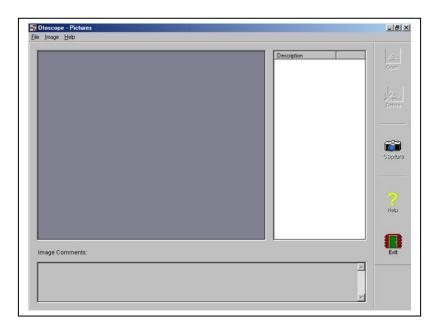
Installing from floppy disk:

- Insert MedRx NOAH Module floppy disk into drive A:
- Start NOAH.
- Choose **Setup** from the NOAH main screen menu (In NOAH 3 choose **Tools** | **Setup**).
- Choose Install Module
- In NOAH 2 make sure that A: is displayed in the box and click **OK**.
- In NOAH 3 browse to the A: drive, choose **Install.ini**, and click **Open**.

Video Otoscope Capture

To begin using your Digital Video Otoscope click on the NOAH Icon. Select a Client Select Medrx Otoscope Module

This screen will appear



Using the probe or the full-face lens select the image you want and hit Capture.

Video Otoscopy - Capture

The Capture screen allows you to take pictures with the Video Otoscope, view them, and prepare them for storing in the patient database.

Before taking pictures, adjust the light source. Use a clean speculum tip for each new patient. From the drop-down box choose appropriate picture description, or type your own. The description can be changed later.

To take a picture, click on the **Capture** icon.

Single Click Mode

If checked, the capturing will operate differently. Once the Capture icon is clicked, instead of immediately taking a picture, the program switches to the Single Click mode. All the icons will turn gray, indicating that they are inactive. At that moment a picture can be taken by pressing *any* key on the keyboard or the *left* mouse button. The advantage of this mode is that you do not have to watch the mouse pointer on the screen during the picture taking procedure but rather concentrate on the patient.

To end the Single Click Capture mode, hit the Esc key or the right mouse button.

Sequence

If selected, a sequence of pictures can be taken by using the Capture icon (or any key in Single Click mode). If not selected, a single picture will be taken and the capturing screen will close every time you choose the Capture icon.

The icons at the top left of the display configure your hardware for use in this task. Your MedRx representative will install the appropriate configuration on the system and should be consulted when problems arise with displaying an image.

Video Otoscope Preview

Video Otoscopy - Preview

The Video Preview screen allows you to perform an otoscopic examination and to place the probe microphone in the ear canal.

Before taking pictures, adjust the light source. Use a clean speculum tip for each new patient.

To freeze or run a picture, click on the **Run/Freeze** button. To take a picture and view it, click on the **Open** button.

Single Click Mode

If checked, the capturing will operate differently. Once the Run/Freeze or Open button is clicked, instead of immediately freezing or taking a picture, the program switches to the Single Click mode. All the icons will turn gray, indicating that they are inactive. At that moment a picture can be frozen by pressing *any* key on the keyboard or the *left* mouse button. The advantage of this mode is that you do not have to watch the mouse pointer on the screen during the picture taking procedure but rather concentrate on the patient.

To end the Single Click mode, hit the *Esc* key or the *right* mouse button.

Open

The Open option allows to take a picture view it on a separate screen where it can be zoomed-in or enhanced for better viewing. On that screen is will be also possible to add the taken picture to the list of pictures prepared for storing in the patient database. When using the Single Click mode, to use the Open option the picture has to be frozen by Run/Freeze icon, and the Single Click mode inactive (i.e. activate the mode, click on the Run/Freeze button to freeze the picture, end the Single Click mode by using the Esc key or right mouse button, and then click on the Open button).

The icons at the top left of the display configure your hardware for use in this task. Your MedRx representative will install the appropriate configuration on the system and should be consulted when problems arise with displaying an image.

Video Otoscope Record

Video Otoscopy Record

The Video Otoscopy Record can be accessed from the main (first) program screen by selecting the Pictures button.

The screen shows the list of captured pictures, comments, and a preview of the selected image. To preview a picture, select it in the list. An image in the list can be renamed by selecting it, clicking the *right* mouse button, and choosing the Rename option from the menu.



Open Click on the Open button to open the selected picture and view it on a separate screen where it can be zoomed-in or enhanced for viewing.

Delete Click on the Delete button to remove the selected picture from the record.

Capture Click on the Capture button to take a new picture.

Using the pull down windows on the top of the screen permits you to perform other functions as needed.

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Video Otoscopy View

This screen allows you to view a picture, zoom it in, and enhance for viewing.

Tool Bar

- \bigcirc Use this button to enlarge the image.
- Use this button to restore the image to its the original size.
- Use this button to maximize the image so that it occupies all available screen space.

Use this button to undo the last processing operation performed on the image.

Enhancing



Use this function to emphasize the details on the image.



Use this function to blur the details on the image.

Smooth



Use this function to create a shadow effect on the image. Best when used with monochrome pictures.

Shadow

The **Store** option is available only for new (just taken) pictures captured in the preview mode, and allows you to add this picture to the patient database.

Using the Deluxe Hand Held Camera Probe

CAUTION: The deluxe hand held camera probe/assembly is only to be used by a person qualified in the use of an OtoScope. Misuse can cause a patient pain and possible injury.

CAUTION: The deluxe hand held camera probe/assembly is only to be used by a person qualified in the use an Otoscope. Misuse can cause a patient pain and possible ear damage. The speculum cover is always to be used with the system. The speculum cover must be cleaned or replaced between usage per accepted medical practice procedures.

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.

The monitor should be observed as the probe is inserted into the ear. Once the desired image is obtained, follow instructions for image capture.

Practice is essential to achieving optimum picture quality. Cerumen and/or fog on the lens tip most often cause fuzzy video images. You can correct or prevent either condition by using an alcohol wipe on the lens tip before and after each use.

Care, Maintenance, and Storage

Your MedRx Video OtoScope has been designed to provide years of trouble-free service. Do not remove or open the cabinets of the equipment, 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 in the components.

Use an alcohol wipe to clean the lens on the end of the OtoScope probe, or a common disinfectant.

Operational Tips

When using the camera be sure camera is in the upright position – so you can read the horizontal writing on the side. This helps orientation of the UP/DOWN on video screen.

IMPORTANT:

- THE PROBE TIP COVER SHOULD BE RETAINED AND USED FOR ADDITIONAL TRANSPORTATION PROTECTION OF THE VIDEO SCOPE OPTICS WHILE IN OR OUT OF THE FOAM CASE
- MEDRX SUGGESTS THAT AFTER USING THE LIGHT SOURCE, TO REDUCE INTENSITY ON THE DIMMER TO LOWEST POINT AND LET THE BULB COOL FOR 1 – 2 MINUTES PRIOR TO TURNING THE LIGHT SOURCE OFF.

Since the Video Otoscope incorporates glass lenses for image transmission and fibers for illumination it is breakable. Although the tip is tapered to improve durability, any impact or crushing to the tip may cause serious damage to the instrument.

Video Otoscope Disinfecting

The Video Otoscope is sealed so that it may be wiped with the following surface cleaners to disinfect:

75% alcohol Chlorhexiderm Cidex Nolvasan Parvocide Parvosol Roccal Synphenol

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

Transportation and 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. Remove the batteries from any wireless remote controls if they are not going to be used for extended periods of time.

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

Trouble Shooting Guide

Problem	<u>Main Cause</u>	Solution
Fuzzy or out of focus picture	Dirty probe tip (dried cerumen) When changing adapters on camera, make sure space ring is removed with adapters.	Vigorously clean probe tip with an alcohol wipe
No picture on monitor	Short in twin lead cable Source/Memory button in memory	Replace twin lead cable Push to Source on printer or memory
Indicator light switch on light source not on	Power supply not plugged in Short in twin leads cable	Plug in power supply Unplug twin cable from light source; see if light comes on, if so replace twin leads cable
No light from probe tip	Light source not on Bulb burnt out	Turn on light source Replace bulb
Picture is dark	Switch on back of camera in wrong position Light source too low	Move camera shutter switch to off position Turn up intensity of light source
Cleaning probe does not improve picture	Probe dropped and physically damaged	Call MedRx for service

This guide was designed to assist you in diagnosing minor problems. Should service be needed, please call MedRx for Technical Support Monday-Friday, EST 9:00 a.m.-5:00 p.m. at 1(888) 392-1234.

Limited Warranty

MedRx, Inc. warrants the MedRx Video OtoScope System 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. The company's representative will advise the owner to either return specific components or the entire system to:

MedRx, Inc. 1200 Starkey Road #105 Largo, FL 33771

MedRx will repair or replace any defective parts, fully test and calibrate the system and/or components and ship the system promptly back to the owner. There is no cost for this warranty service, 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 degrees 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 components at the purchaser's request, charging for parts and labor as necessary.

Components Registration for Customer Information

Probe Serial Number: _____

Printer Serial Number:

Monitor Serial Number: _____

Camera Serial Number: ______

Date Purchased

MedRx Video OtoScope System Technical Specifications

Computer

Windows ME or above Intel Celeron 1.7 or above 1.44 Floppy Drive CDRW 52x24x52 rewritable drive USB 2 Sound Card Network Card !5" LED Monitor

Fiber Optic Light Source

- 150 watt
- Infinitely variable
- Thermal overload protected
- Fan cooled
- 3 amp circuit breaker
- EPA or EKE reflector lamp
- 115 VA. or 220 VA. (special)
- 9-1/2" long, 4-3/4" wide, 6-1/4" high
- On/off switch incorporated in intensity control

<u>Handset</u>

- High grade lens elements
- Anti-reflective coatings
- 60 degree field of view
- High resolution color camera
- 0-3" depth of field
- 203 gram total weight, balanced design · 5.5" total length
- Tapered conical Stainless Steel probe for durability

Additional System Features Include:

- High quality glass fiber optic cable
- Custom light source with handset holder
- Camera power/signal cable
- Instructions/wiring diagram
- Alcohol swabs
- Full image lens
- Specula

MedRx Video OtoScope Handset Technical Specifications

THE HANDSET CONSISTS OF TWO PRIMARY COMPONENTS, THE VIDEO CAMERA AND THE PROBE.

Video Camera

- 1/3 inch pick-up element
- 420K pixels
- Horizontal resolution 420 TV lines
- 5 lux minimum illumination interchangeable to a 3 lux
- CS lens mount
- 153 grams total weight
- Adjustable white balance
- -10" to +40"C operating temperature
- 42mm (W) x42mm (H)x 53mm (L)
- BNC video output socket
- 12V DC +/- 10% voltage requirement

Deluxe Probe

- Field of view 60 degree + 10-5 degree
- Focal plane from tip .25" (+/- .125")
- 360 degree glass fiber light at tip
- Conventional optical elements, color corrected
- Minimum intensity 750 FC at 1"
- Working length 1.125" from shoulder
- Tip diameter .120"
- Tapered tip
- Stainless steel body
- Serialized
- Integral glare reduction filter
- 50 grams total weight
- Normal erect image orientation
- Overall length 3.22"
- Body diameter .7"
- Maximum diameter 1.225" dia.
- Swivel mount
- FFA.OS fiber optic socket
- CS mount
- Impervious to alcohol cleaning

<u>Note:</u> The camera and probe are sold as a matched system with MedRx proprietary coupling and focusing techniques. Should either the camera or probe become defective either part can be replaced; however, the process must be accomplished at the MedRx USA manufacturing facility. Neither the probe nor the camera can be sold separately.

Comment: While system specifications may serve some benefit in comparing various products, discretion must be used in determining overall system performance. It is suggested that a logical system test might involve the comparison of color printouts of the same subject, such as a known ear canal, using various systems. The MedRx system has been optimized with respect to each specified component. Claims of specifications of individual components do not reflect the overall optimization of the system as will be evidenced through such a test. System optimization provides the end user with the best value for the investment. That is the MedRx commitment.