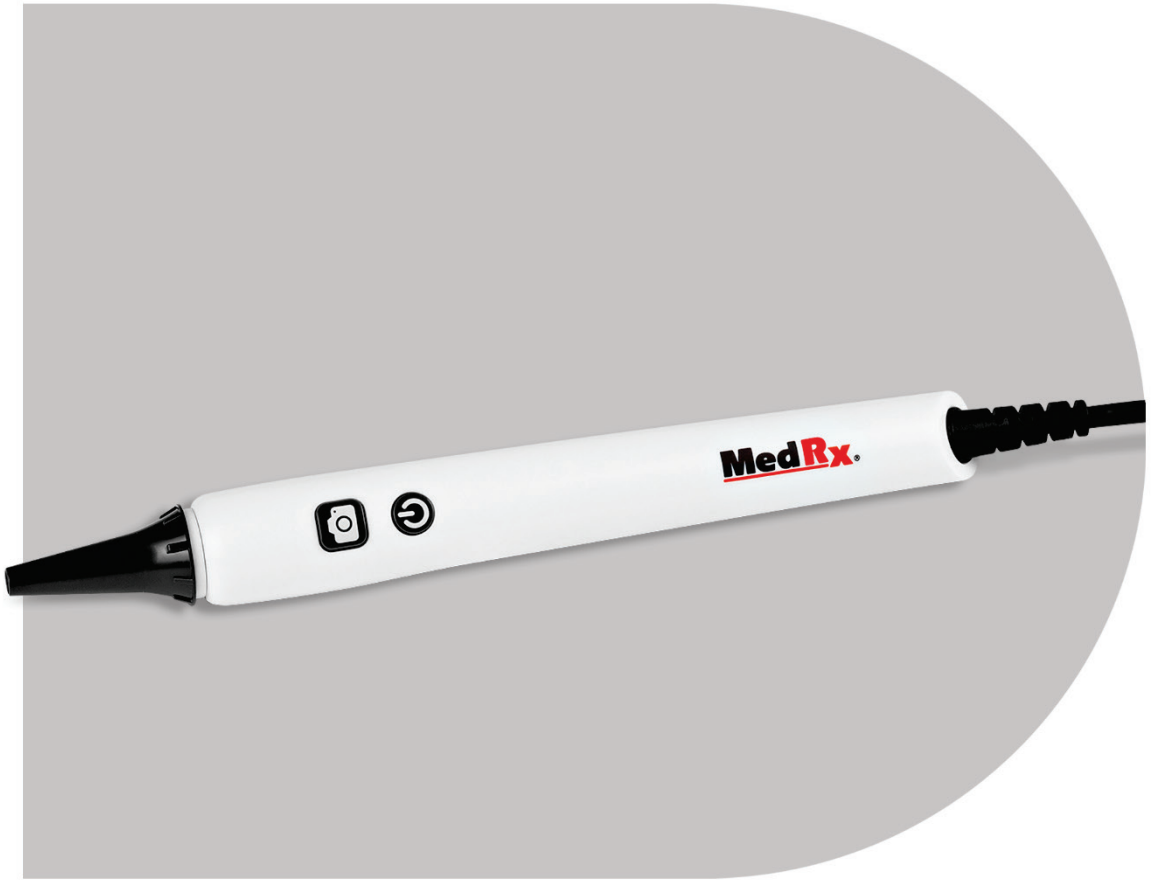


STUDIO Software

VIDEO OTOSCOPE
CAMERA, PROBE
& LIGHTSOURCE

MedRx

Studio Software Video Otoscope Training Manual

CE

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MedRx's Archived manuals are available at www.medrx-diagnostics.com/support/manuals-studio-software/archive

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The MedRx Video Otoscope represents a new era of otoscopic examination in your office. The clear resolution of the MedRx Video Otoscope is particularly helpful when comparing a clean ear canal with normal eardrum to a canal that has excessive cerumen, foreign bodies, external otitis, PE Tube status, cholesteatoma, TM perforations or other abnormalities.

Getting to Know Your Video Otoscope

Intended Use Statement:

The MedRx Video Otoscope is used to perform otoscopic examination of the outer ear and tympanic membrane. The MedRx Video Otoscope is an endoscope designed to perform video otoscopic evaluations. 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. The MedRx Video Otoscope is an endoscope designed to perform video otoscopic evaluations. 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:

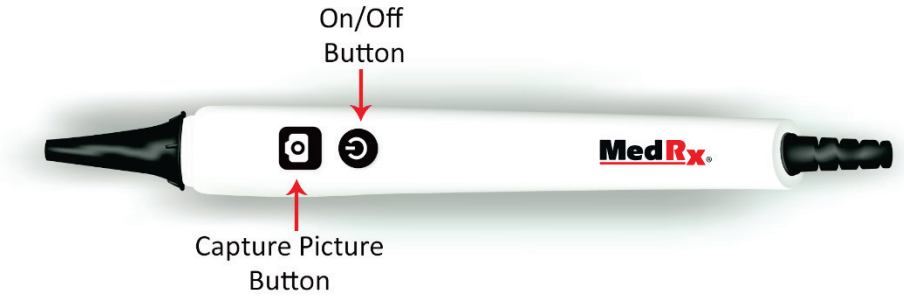
- Performing the initial otoscopic examination prior to testing.
- Capturing and storing images to the Noah patient database.
- Troubleshooting problems with the hearing aid, such as blocked receivers and microphones.
- Probe microphone placement for Live Speech Mapping or Real Ear Measurements.

Always perform an otoscopic examination of the ear canal prior to testing to determine if earwax or other foreign matter will interfere with inserts and 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. Remove the speculum and use an alcohol pad to clean the video otoscope lens. The speculum must be cleaned or replaced between patients per accepted medical practice procedures. (Reference section: “Cleaning and Disinfecting” for more information)

⚠ 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.

This manual will familiarize you with the features and software for the MedRx Video Otoscope system.



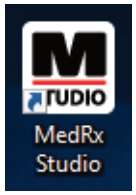


Plug your video otoscope into any USB port on your computer and turn it on, this will automatically load your drivers.

The MedRx Studio Software Overview

The MedRx Studio software can run stand-alone, from Noah system or the TIMS® Noah-compatible office system.

Launching the MedRx Studio Software



Stand Alone

- Double click the MedRx Studio shortcut on your Windows desktop.





Noah

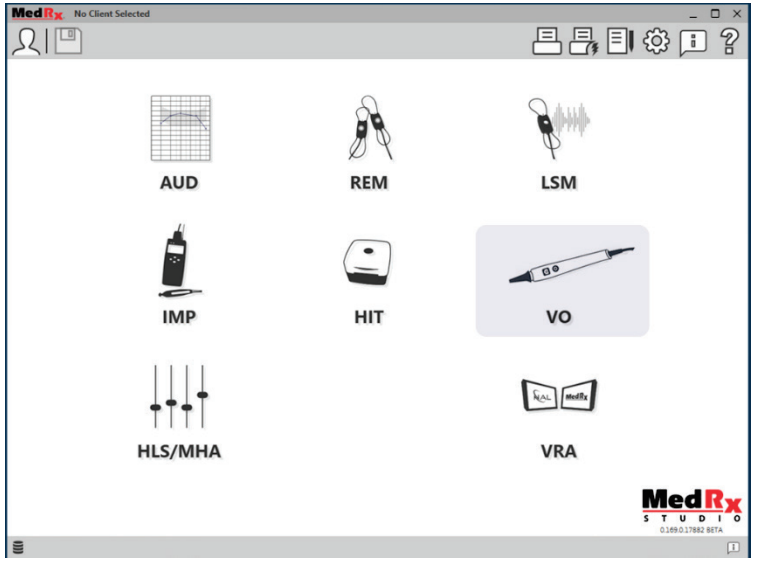
- Launch Noah.
- Select a patient.
- Launch MedRx Studio module following Noah procedures.

Basic Software Options

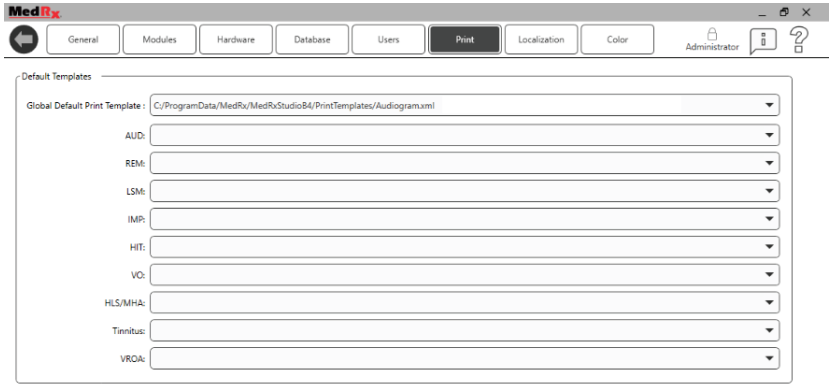
Several options are available which allow the user to customize the MedRx Studio software to meet their needs.



Access these options by clicking the settings wheel in the top right menu bar.



The MedRx Studio software main screen. (Icons will vary depending on your equipment).



The Main Screen settings allow you to set the default modules, database, print templates defaults and more.



If you have more than one MedRx product you can show/hide modules in the Main Screen settings.

NOTE: Remember, more information is always available in the Interactive Help System by clicking the "?" Icon in the top right corner of the software or pressing the F1 key

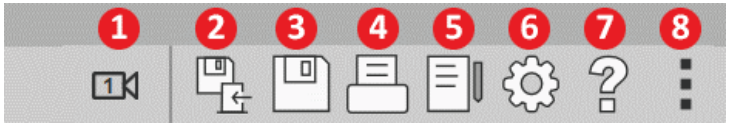
Video Otoscopy



Select VO from the main menu.

Top Tool Bar

The **Tool Bar** icons have the following functions:



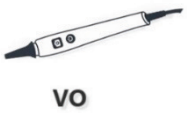
1. Switch Between 2 Video Capture Devices
2. Save Session and Exit
3. Save Session
4. Print
5. Show Journal
6. Show Settings
7. Show Help
8. More Options

The **More Options** icons have the following functions:



1. Save the current session to a file
2. Open session from a file
3. Clear Data from Current Test
4. Video Properties

Configuring the Otoscope Software



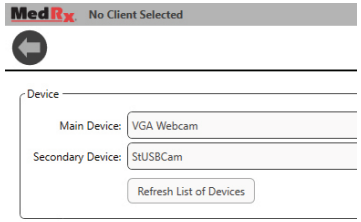
It is important to note that each module will have different settings available for customization.

Once you plug-in and turn on your video otoscope, the drivers are automatically installed, you must then configure the software to recognize the USB capture device as follows:



Enter the VO module and click the settings wheel to customize.

VO Settings Screen



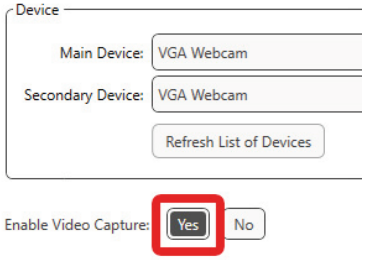
From the Main Device Tab:

- Click the device pull-down.
- Select the name of your video capture device.

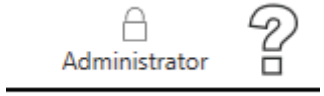
To add the Record Video Option



- Click the lock icon in the top right until it displays Supervisor



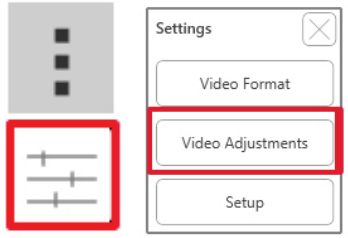
- Under the Device options, click **Yes** next to Enable Video Capture



- Be sure to click the lock icon until it is back to Administrator



Go back to the Video Otoscope main screen by clicking the back arrow on the menu bar top left.

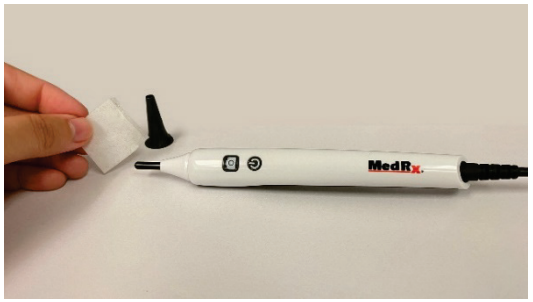


Click on the Video Properties Icon which is located under the more icon (3 dots).

Click on Video Adjustments and make any changes.

Taking Pictures

Always use a clean speculum tip for each new patient.



It is recommended
to remove the speculum and
wipe the video otoscope lens
between patients and ears
if the image is not clear.



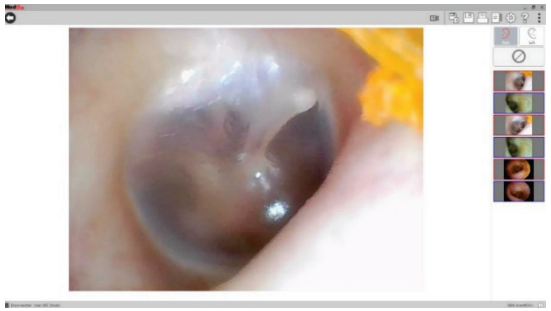
- Make sure your video otoscope is turned on.



- Click the VO Icon on the MedRx Studio software main screen.

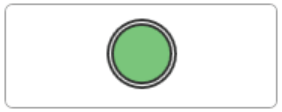


- You can switch between 2 video capture devices by clicking the camera icon in the top toolbar.



- The capture screen appears.

There are four ways to capture pictures:



1. Left click on the green circle capture Icon to take one picture.

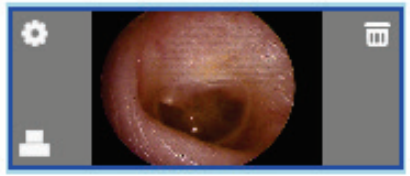
2. Capture a picture by simply pressing the spacebar on your keyboard or the F2 key.



3. Capture a picture by pressing the camera button on your video otoscope

4. Capture a picture by using an optional foot pedal.

Prior to taking the picture press the R or L key to assign the images to a particular ear. The L key will switch to the left ear and R key will switch to the right ear. G key will toggle between ears.



Hover the mouse over any image in the sidebar, three icons show up on the image:

a. Click the trash can icon to delete the image.

b. Right click on any image in the side bar or click the settings icon to select what type of picture it is, write a comment or assign the image to a particular ear.

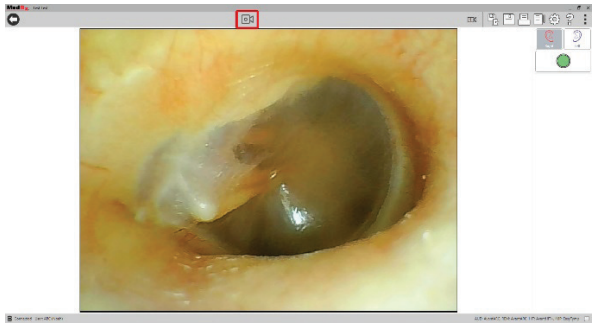
c. Click the printer icon to add the image to the print template or shift click to add more than one image to the template.

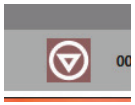
Recording a Video

Be sure to turn the video option on as described in the “Configuring the Otoscope Software” section.

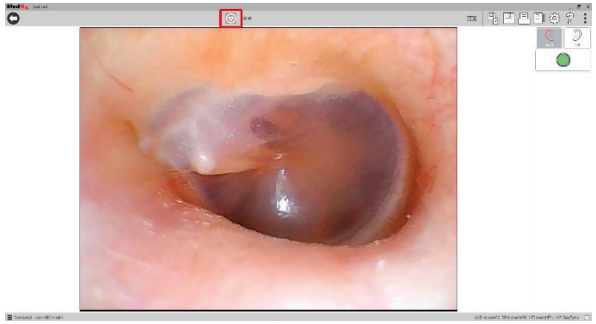


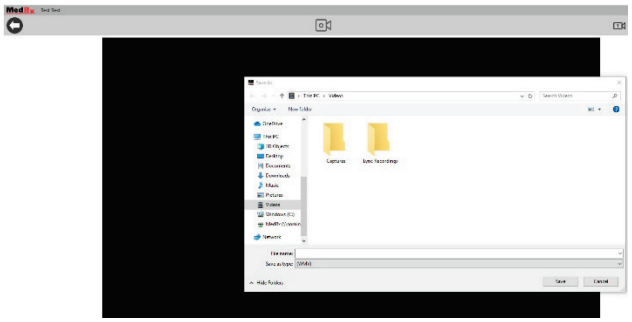
To record a video, select the video icon at the top of the screen.





Once you are done recording, select the stop button at the top of the screen.





Once you hit stop, the Save As screen will appear. Select a location and click save. The video will be saved as a WMV.

*Note: It is important to save in this screen as a WMV file because most databases including Noah, OtoAccess, and MS SQL Express do not have ways of saving videos to patient’s files.

To record a video in the Otoscope module you can also click “Ctrl + Alt + Shift + M” to start the recording.

Saving Images and Session Data



Click on the save session icon located in the top right menu bar. It will prompt you to save the current session to your patient file.

Saving Images as JPEGs

To save an image as a JPEG instead of a JSON file:

- Click on the image you want to save as a jpg.
- Press “Ctrl + S” on your keyboard and a save as dialog box will appear.
- Save the image to your computer.

Click “Ctrl+O” to open an image

Click “Ctrl+C” to copy the image to clipboard

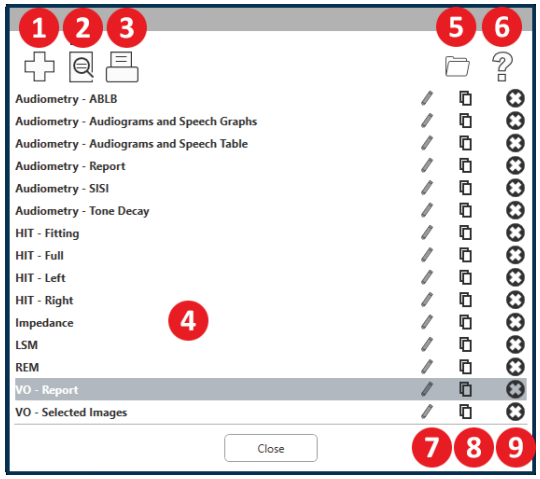
Click “Ctrl+V” to paste the image in Word, Paint, PowerPoint, etc.

Turn-off your video otoscope when you exit the VO module by pressing the on/off button located on the top side of your video otoscope.

Printing

Printing within the MedRx Studio software. You can use the templates provided at installation or create your own templates to suit your needs.

Icons in the Print Window

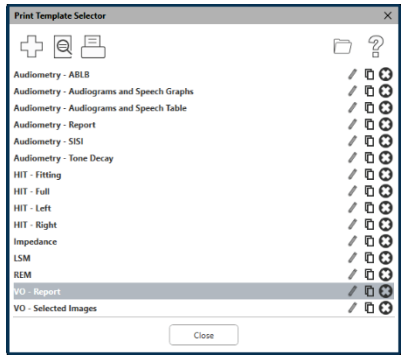


1. Create a new template.
2. Preview template icon.
3. Print template icon.
4. Select the template you would like to use.
5. Shortcut to templates folder on your desktop.
6. Studio Help icon.
7. Edit the template with the pencil icon. Editing a template will open the print editor and allow you to adjust print elements.
8. Duplicate existing templates icon.
9. Delete template icon.

To Use an Existing Print Template



1. Click the print icon in the top tool bar or hold down the Ctrl key and click the P key on your keyboard.

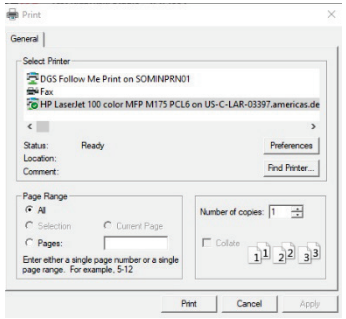


2. Select the template you would like to use.

3. Click the print preview icon to see the patient's data & images on the template before printing.



4. Click the print icon.



5. The printer options box will pop-up.

6. Click print.

7. Or click Ctrl+Shift+P to print the modules default template.

Create New Print Templates



1. Select the printer icon.



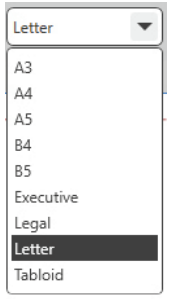
2. Select the + icon to create a new template.



3. Name the template you are creating.

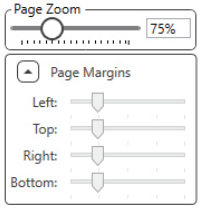


4. Choose page orientation.

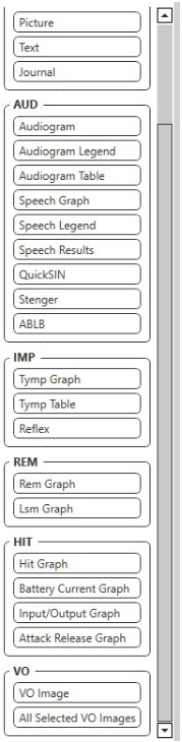


5. Use the drop-down menu to choose the size of paper you will be using.

6. In the bottom left, Page Zoom will allow you to zoom in/out of the template for easier editing.



7. In the bottom left, the Page Margin is set by default to the ideal level. Adjusting this will determine how far items will print from the edges.



8. Drag and drop elements onto the page to create your template.

   a. You can combine data from multiple modules into a single template.
   b. Elements may overlap and will stack/cover previously added elements.
   c. Certain elements will have settings that can be adjusted after dropping onto the page.
   d. You can resize all elements. The contents of each element will resize within the box depending on the amount of data in the element.



9. Use the + button to add additional pages if needed.



10. After template completion, use the Save, Save As, Preview and Print Icons for your template.
    a. Saved templates will be available for future sessions.
    b. Print a template to ensure that all elements print as expected.

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. Remove the speculum and use an alcohol pad 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 Replacement

The speculum is always to be 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.

EMC Precautions

The MedRx Video Otoscope needs special precautions regarding EMC and needs to be installed and put into service according to the following EMC information.

List of all cables and maximum lengths of cables, transducers and accessories:

Transducer / Accessories	**Maximum Cable length**
USB Cable	2.6 meters

Warnings!

- The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the MedRx Video Otoscope as replacement parts for internal components, may result in increased emissions or decreased immunity of the MedRx Video Otoscope.
- The MedRx Video Otoscope should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the MedRx Video Otoscope should be observed to verify normal operation in the configuration in which it will be used.
- The MedRx Video Otoscope may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.
- The MedRx Video Otoscope does not have life supporting function
- Portable and mobile RF communications equipment can affect the MedRx Video Otoscope.
- WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the MedRx Video Otoscope, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.”

Guidance and manufacturer's declaration – electromagnetic emissions		
The MedRx Video Otoscope is intended for use in electromagnetic environment specific below. The customer or the user of the MedRx Video Otoscope should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The MedRx Video Otoscope uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby Electronic equipment.
RF emissions CISPR 11	Class B	The MedRx Video Otoscope is suitable for use in all establishments, including domestic establishments and those directly connected to the public low - voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Non applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Non applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The MedRx Video Otoscope is intended for use in electromagnetic environment specific below. The customer or the user of the MedRx Video Otoscope should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV contact +/- 8 kV air	+/- 8 kV contact +/- 15 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	+/- 2 kV for power supply lines	+/- 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The MedRx Video Otoscope is intended for use in electromagnetic environment specific below. The customer or the user of the MedRx Video Otoscope should assure that it is used in such an environment.			
Immunity test	**IEC 60601- test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the MedRx Video Otoscope ,including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V_{eff} 6V in ISM Bands between 0.15 Mhz and 80 Mhz	3 V_{eff} 6V in ISM Bands between 0.15 Mhz and 80 Mhz	d = 30 cm (12 inches)
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz 80 % AM at 1kHz	3 V/m 80 MHz to 2,7 GHz 80 % AM at 1kHz	d = 30 cm (12 inches) 80 to 800 MHz d = 30 cm (12 inches) 800 MHz to 2,7 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Surge	+/- 1kV for Line-to-Line +/- 2kV for Line-to-ground	+/- 1kV for Line-to-Line +/- 2kV for Line-to-ground	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency ranges applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MedRx Video Otoscope is used exceeds the applicable RF compliance level above, the MedRx Video Otoscope should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MedRx Video Otoscope .

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between
Portable and mobile RF communications equipment and the MedRx Video Otoscope

The MedRx Video Otoscope is intended to use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MedRx Video Otoscope can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MedRx Video Otoscope as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter meters		
	150 kHz to 80 MHz d = 30 cm (12 inches)	80 MHz to 800 MHz d = 30 cm (12 inches)	800 MHz to 2,5 GHz d = 30 cm (12 inches)
0,01	0,12	0,12	0,233
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,7	3,7	7,40
100	11,7	11,7	23,3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Safety

- Regarding electrical safety, this device is designed to be used only by professionals in the hearing healthcare industry.
- It is Class II Medical Electrical (ME) equipment that is part of an ME system.  This device provides Type B protection  (Type B equipment, Type B applied part)
- This device is not protected from ingress of water. The USB computer power must be able to supply at least 500mA at the standard USB voltage.
- Power is supplied by the USB cable connected to a computer.
- The device provides 2 MOPP per IEC 60601-1.
- This device is to be operated on non-conductive surfaces only.
- The computer used with this device should conform to the requirements of IEC 60601-1.
- The device warm-up time is less than 5 minutes.
- Do not connect items that are not specified as part of the system.
- The use environment should be between 10°C and 35°C 

, humidity within 30% to 90% 

and an atmospheric pressure range from 80 kPa to 104 kPa.
- Storage temperature range at least from -20°C to 50°C and humidity level from 10% to 90%.
- All components with patient contact are made of bio-compatible materials.
- This device does not produce any adverse physiological effects.
- Install the device as directed by this manual to achieve optimal use. Clean accessories per the cleaning instructions prior to use.
- The device is not intended to be operated in an environment with anesthetics, oxygen or NO. It is not an AP or APG device. This ME System is not intended for use with flammable anesthetics.
- This device uses Type B application parts temporarily placed on the patient during testing. They are nonconductive and can be immediately withdrawn from the patient at any time.
- The device is intended for continuous operation.
- The computer and the MedRx device or accessories may be located in the patient environment if required.
- Contact the local MedRx distributor for safe and proper disposal of this equipment. Proper disposal may require that it be sent to collection facilities for recovery and recycling. 
- All repairs should be sent to MedRx for evaluation and/or repair. However, necessary diagrams and repair instruction will upon request be provided to authorized repair personnel.
- There are no known contraindications for the use of this equipment.
- Mild soapy water is the preferred cleaning solution.
- 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.
- Refer to the Training manual and Help files for test options and descriptions.

Complaints/Safety Reporting

Please contact your local distributor in case of any incidents related to product defects (hardware defects or software bugs) or adverse events (which does not necessarily have a causal association to the product). It is recommended for a user to report all the known facts about the incident. Upon receipt of any serious incident with serious health impact for the patient or user (serious adverse events), local distributor shall report to MedRx through its appropriate vigilance system. MedRx shall ensure that the regulatory authority in patient's home country is informed according to the vigilance requirements. MedRx shall handle all the product complaints and adverse events as per the internal procedure.

Symbols that may be used



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



Indicates that the device serial number will follow



Type B applied part. (Type B equipment)



Manufacturer (MedRx)



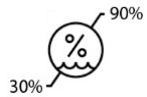
Authorized Representative in Europe



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



Special Disposal Required



Humidity Limitation



Caution, General warning sign



Temperature limitation



Class II equipment



Single use only

Technical Specifications

- Image Sensor: 1/10” High Color Sensor
- Camera diameter: 4.2mm
- Pixel Size: 2.25µm x 2.25µm
- Effective Picture Element: 1280(H) x 720(V)
- AGC: Auto AES: Auto AWB: Auto
- Dynamic Range: 68dB
- S/N Ratio: 37dB
- Lens Construction: 1G +2P + IR
- Lens F/NO: F3.8
- Depth of Field: 10mm – 30mm
- Light Source: 6pcs High Luminous White Color LED
- Power input: DC 3.6 ~ 5V
- Output System: USB Output
- Power Consumption: 0.5W
- Operating Temperature: -10°C to +35°C
- Operating Humidity: 30%~90%Rh
- TV Distortion: < 5%

Otoscope Software

- Capture, View and Store Digital Images
- Perform an Otoscopic Examination
- Place the Probe Microphone Tube in the Ear Canal
- Conveniently Shows a List of Captured Pictures, Comments and Previews of the Selected Images
- View a Picture then Zoom In and Enhance it
- User Friendly, Noah & TIMS Compatible
- An Integrated Video Module is Standard in all
- MedRx Software
- Designed for Cerumen Management

Limited Warranty

MedRx warrants this product to be free from defects in material and workmanship for two years from the time of purchase. If this system fails to perform as specified during this period, the purchaser is responsible for calling MedRx at +48 91 835 63 00. The company's representative will advise the owner to either return specific components or the entire system to:

MedRx International
DGS Diagnostics Sp. z o.o.
Rosówek 43
72-001 Kołbaskowo
Poland

MedRx International 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 two years 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 37,78º C 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 International 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 international 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.