

MedRx.

INSTALLATION

MANUAL



External
Light Source



Battery Operated
Light Source

*Camera, Probe and
Lightsource*

VIDEO OTOSCOPES



www.medrx-int.com

Contents

Using The Video Otoscope	3
The Battery Operated LED Light Source	4
Wiring Diagram - Battery Operated LED Light Source	5
Wiring Diagram - External Light Source.....	6
Wiring Diagram – USB Camera with LED Light Source	7
Wiring Diagram – USB Camera with External Light Source	8
Trouble Shooting Guide	9
Cleaning & Disinfecting	10
Transportation & Storage	10
Safety.....	11
Limited Warranty	12



MedRx.

www.medrx-int.com

DISTRIBUTOR

MAICO Diagnostics GmbH
MedRx International Sales
Sickingenstr. 70-71, 10553 Berlin, Germany
Tel.:+49 30/70 71 46-50, Fax: -99
E-mail: medrx-sales@maico.biz
Web: www.medrx-int.com

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. Also used to assist the 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: Since the Video Otoscope incorporates glass lenses for image transmission 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.

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



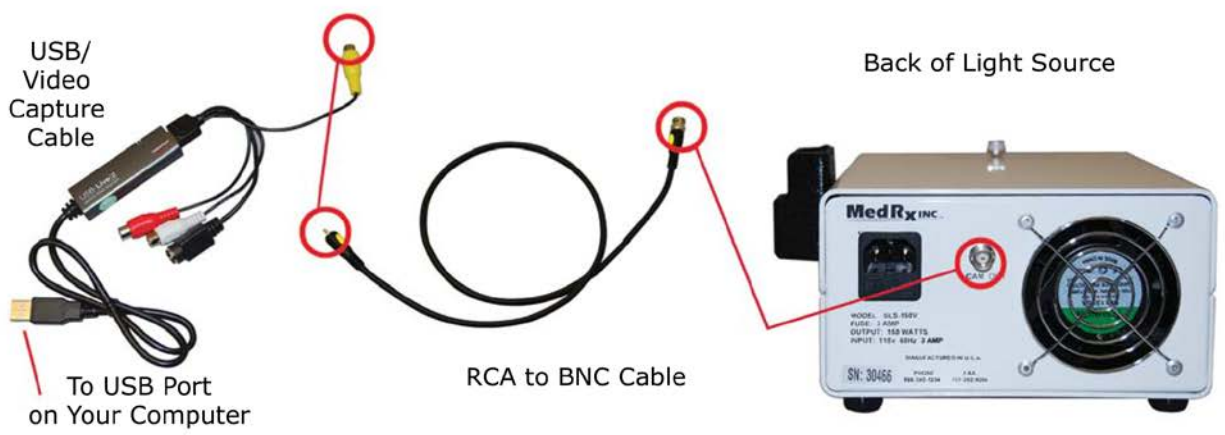
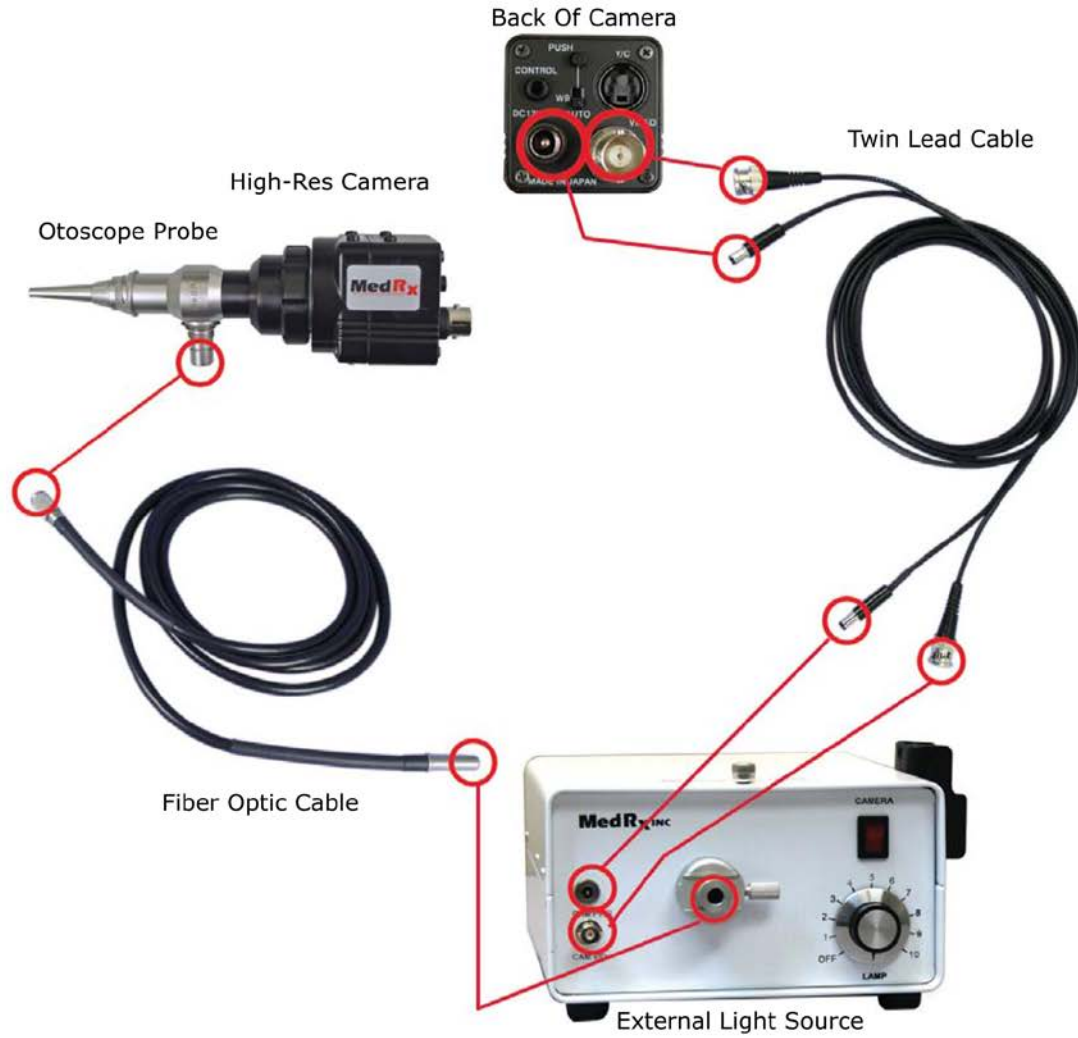
Right Way

Wiring Diagram

Battery Operated LED Light Source



Wiring Diagram - External Light Source



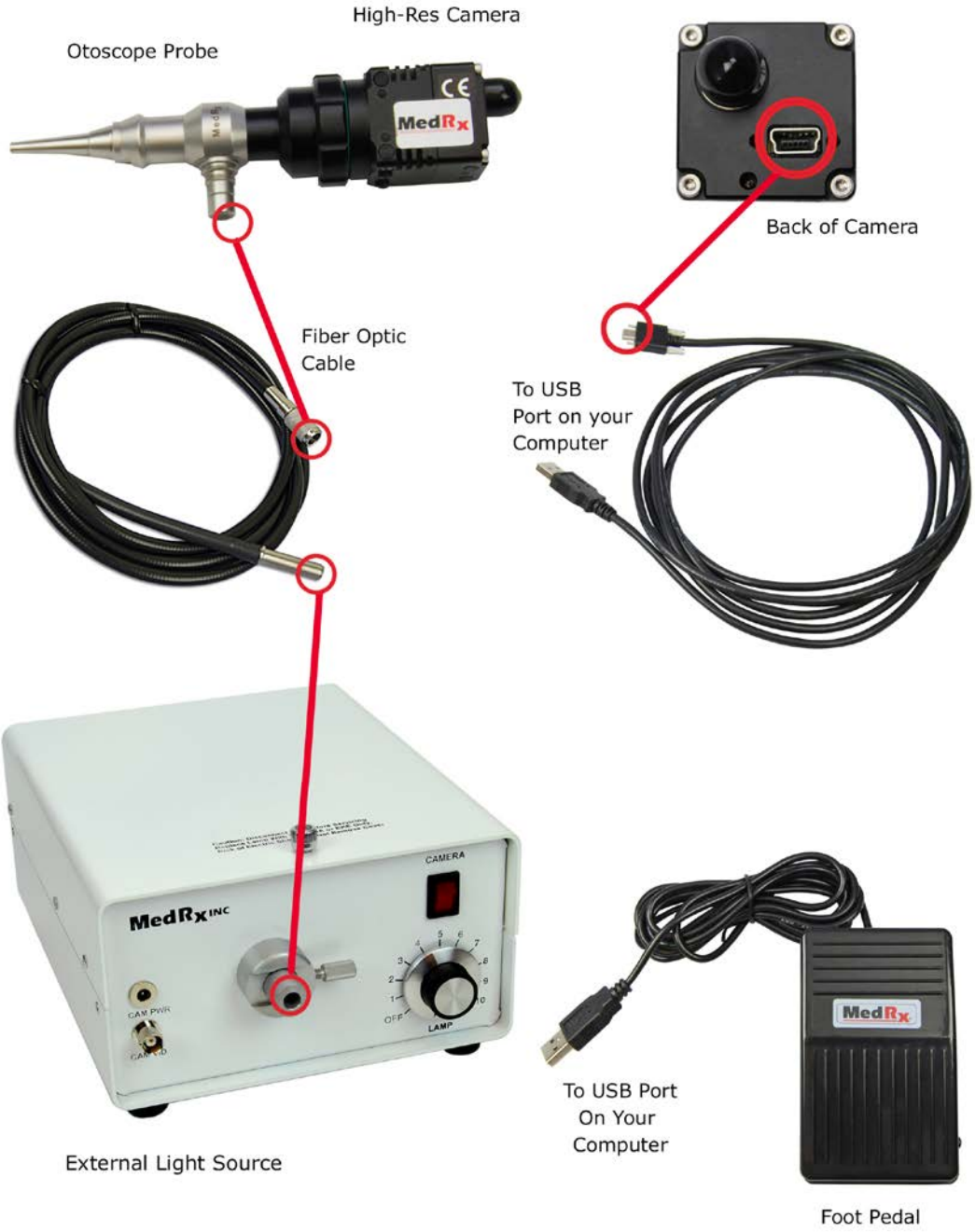
Wiring Diagram

USB Camera with LED Light Source



Wiring Diagram

USB Camera with External Light Source



Trouble Shooting Guide

External Light Source

Problem	Main Cause	Solution
Fuzzy or out of focus picture	Dirty probe tip (dried cerumen)	Carefully clean probe tip with an alcohol wipe
	Short in twin lead cable	Replace twin lead cable
No picture on display	Light Source not turned on	Turn light source on
	Loose wire connection	Re-check wire connection
Indicator light switch on light source not on	Power supply not plugged in	Plug in power supply
	Short in twin lead cable	Unplug twin cable from light source; see if light comes on, if so replace twin lead cable
No light from probe tip	Light source not on	Turn on light source
	Bulb burnt out	Replace bulb
Picture is dark	Switch on back of camera in wrong position	Move camera shutter switch to off position
	Light source too low	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 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; 75% Alcohol • Chlorhexiderm • Cidex • Nolvasan • Parvocide • Parvosol • Roccal • 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


The probe tip cover should be retained and used for additional transportation protection of the video otoscope optics while in or out of the case.

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 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. If supplied with the External Lightsource, it is Class I, where power is supplied by the grounded mains power cable. 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, except bulb replacement in the External Lightsource, should be sent to MedRx for evaluation and / or repair. Unplug the External Lightsource before attempting bulb replacement.

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 +49 30 70 71 46 43. The company's representative will advise the owner to either return specific components or the entire system to:

MAICO Diagnostics GmbH
MedRx International TCS
Sickingenstr. 70-71
10553 Berlin Germany

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 37,78° 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 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.