

MedRx

INSTALLATION

MANUAL



*Hearing Instrument
Test Chamber*

**AVANT™
HIT+**



www.medrx-usa.com

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Getting to Know Your AVANT HIT+

Intended Use Statement:

The MedRx Avant series of HIT devices are acoustic chambers utilizing loudspeakers and measurement microphones that are used in the verification of overall performance of hearing aids for adults and children. The measurements are made without the hearing instrument being worn. These devices are to be operated by professionals with education and/or training in the field of audiometry.

Indication For Use Statement:

The Avant HIT Chambers are for use by professionals with education and/or training in the field of audiometry to evaluate the overall performance of hearing aids for adults and children utilizing loudspeakers and measurement microphones. The measurements are made without the hearing instrument being worn.

The AVANT HIT+ represents a new era of precision Hearing Instrument Testing for your office. Compact yet rugged, this PC-Based system is USB powered and performs all required ANSI and IEC tests. The following section of this manual will familiarize you with the physical features and accessories of the HIT+ system.



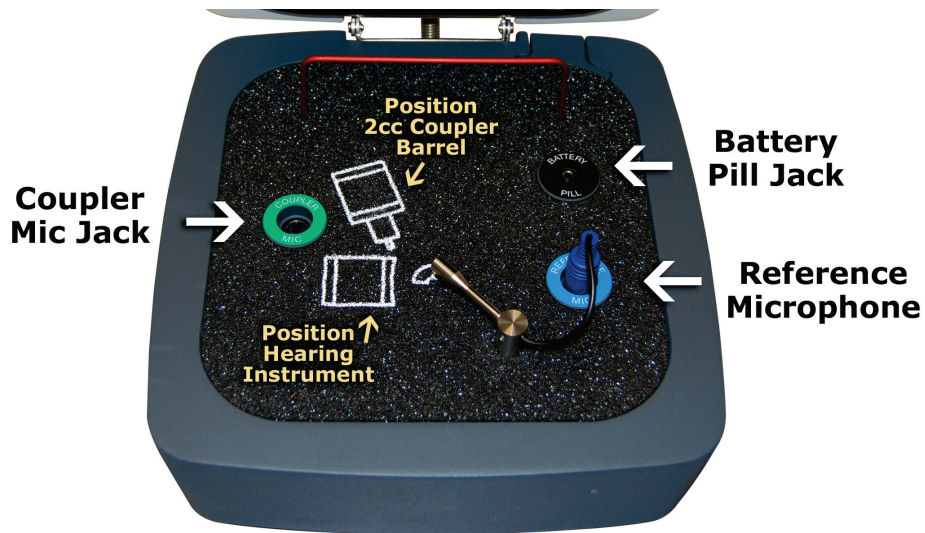
Computer Requirements

MedRx Minimum Computer Specs:
Windows®-PC compatible computer
Intel™ Dual Core, 1.8 GHz or better
2 GB RAM
5 GB free hard drive space
Available 2.0 USB port
CD-ROM or DVD-ROM drive
Windows 7, 8 or 10 (32 or 64-bit)
MedRx Recommended Computer Specs:
Windows®-PC compatible computer
Intel™ Dual Core, 2.0 GHz or better
3 GB RAM or more ° 20 GB or more free hard drive space
Available 2.0 USB port
Graphics Adapter with Dedicated Video Memory
DVD-ROM Drive
High Speed Internet Connection (DSL, Cable)
Windows 7, 8 or 10 (32 or 64-bit)



Setting up the System

The Reference Microphone (blue) is pre-installed at the factory.



Inside the Test Chamber



Carefully install the coupler microphone (green) as shown in the image above. Take care when handling these components as they are delicate precision calibrated instruments.

NOTE: Both of the microphone plugs, blue and green, are “keyed”. The arrowhead molded into the two plugs must facing towards the front on the Avant HIT+ when the plug is installed.

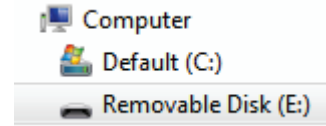
Once the microphones are installed you must install the HIT Software and Drivers. This procedure is detailed in the next section of this manual. Should you need assistance with these steps, contact MedRx Technical Support at (888) 392-1234 or 727-584-9600.

Software Installation



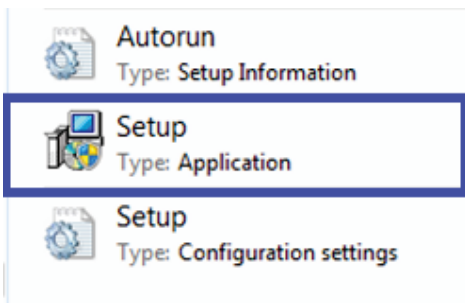
1. Insert the MedRx USB Flash Drive into USB port:

- Launch **My Computer**
- Locate USB Drive



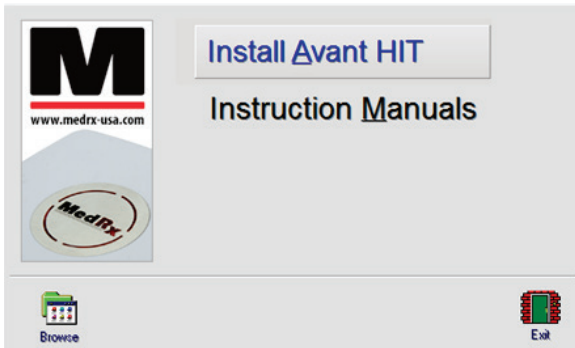
(E:) may vary depending on the USB port selected. Consult your computer's documentation.

2. Double Click on **Setup** to launch:
NOTE: If requested, Accept Permission to Install Software.

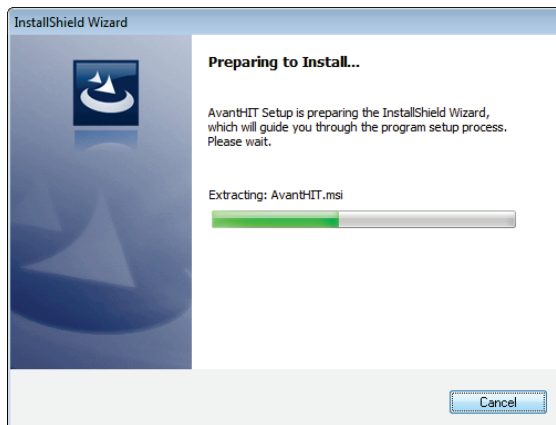


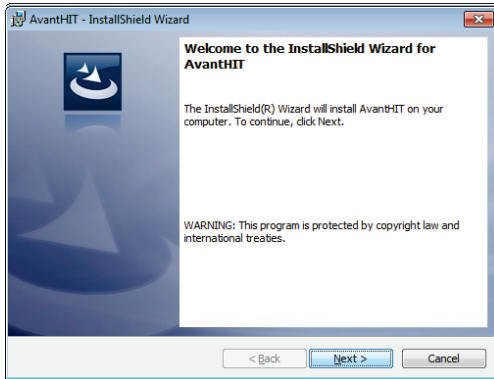
3. On the Setup screen, choose **Install Avant HIT**.

Also, the Electronic Copy of this Manual is located under **Manual**.



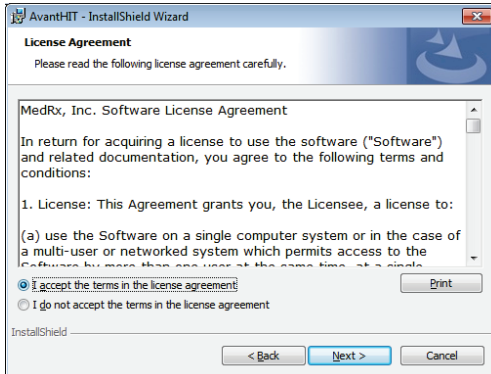
4. Wait for the program to setup the InstallShield Wizard.





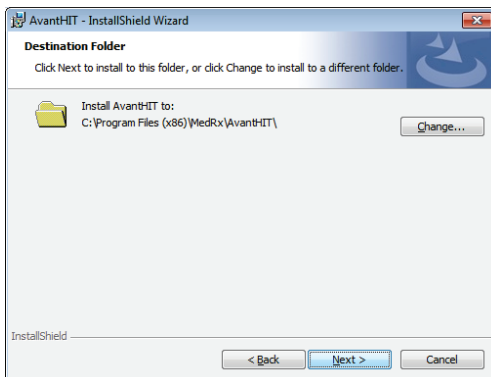
5. This is the Welcome screen

- Click **Next**.



6. Read the Software License Agreement. This important document defines the acceptable usage of the HIT.

- After reading the Agreement, Click **I accept...**
- Click **Next**.



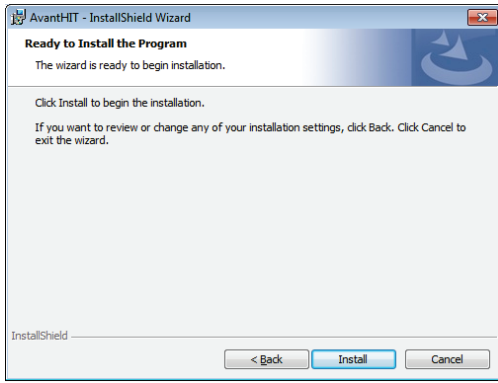
7. This screen indicates the location of the program files.

- Click **Next**.

NOTE: You can install the Software to a different location, but it is not recommended.

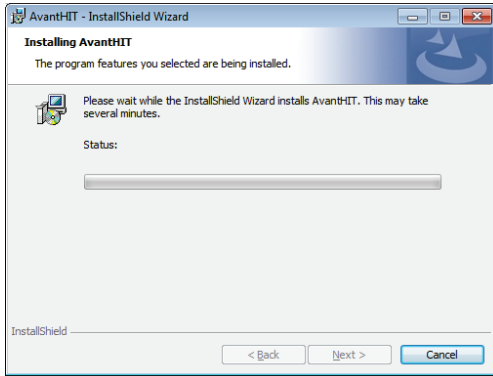
8. Choose desired Locale

- Click **Next**.



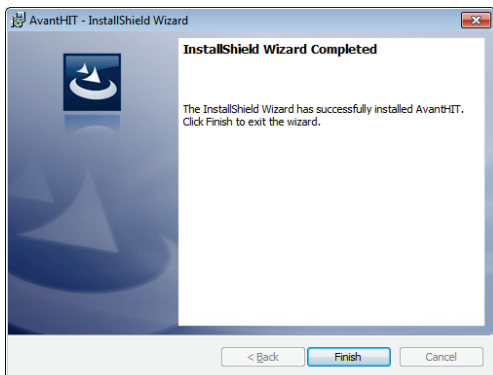
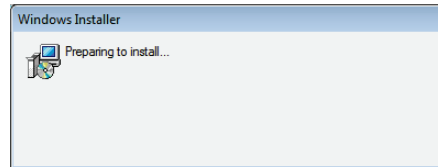
9. Ready to Install Program.

- Click **Install**.



10. Wait while the InstallShield Wizard installs the Avant HIT program.

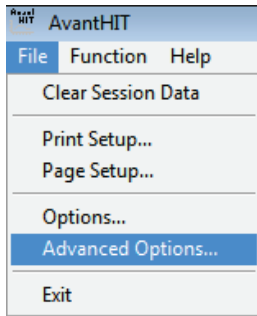
- Click **Next**.



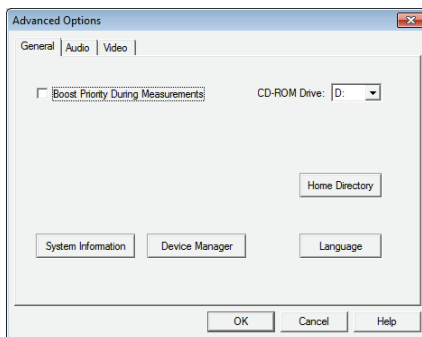
11. When the installation is complete, click **Finish**.

Sound Card Settings

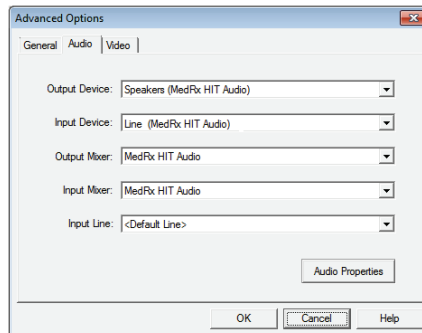
Next you need to set the Default Windows sound card settings. This will route all non-AVANT™ Windows sounds to the internal sound card of your computer. These sounds include event notifications such as new e-mail and error warnings as well as audio and video playback.



1. Launch the **AVANT HIT** software.
2. Open the **Advanced Options** from File menu as shown.



3. Open **Audio tab**.



4. When the audio properties are configured properly, during driver installation, the **Audio Tab** will appear like the image on the left. If not, use the pull-down lists to adjust the settings to match the image.
(Names May Vary Depending on Operating System)



5. Click **Audio Properties**.
 - In Windows Sound control panel, make sure the MedRx Audio Device is not set as default. If it is default, change this by clicking on your system (non-MedRx) audio device and then choose **Set Default**.

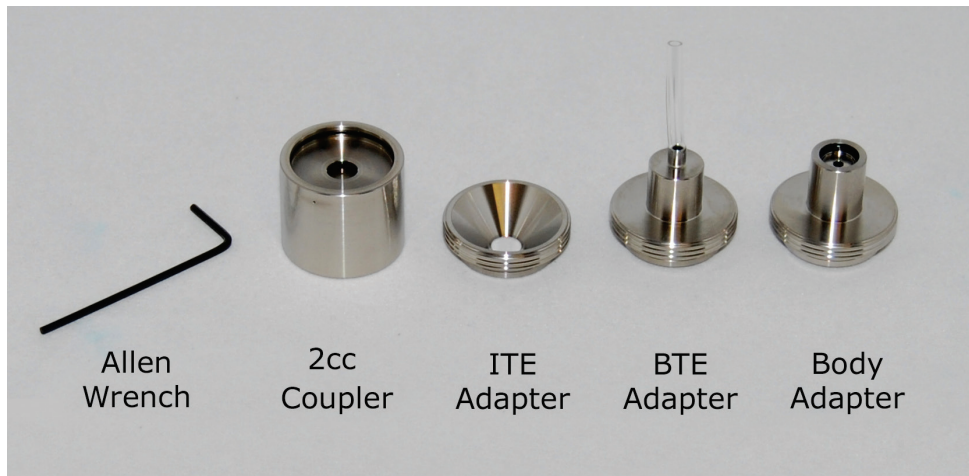
NOTE: The internal sound card on your computer will likely not have the same name as this screen shot. Consult your computer's documentation for the name of the internal sound card and set this control accordingly.

Accessories

Couplers

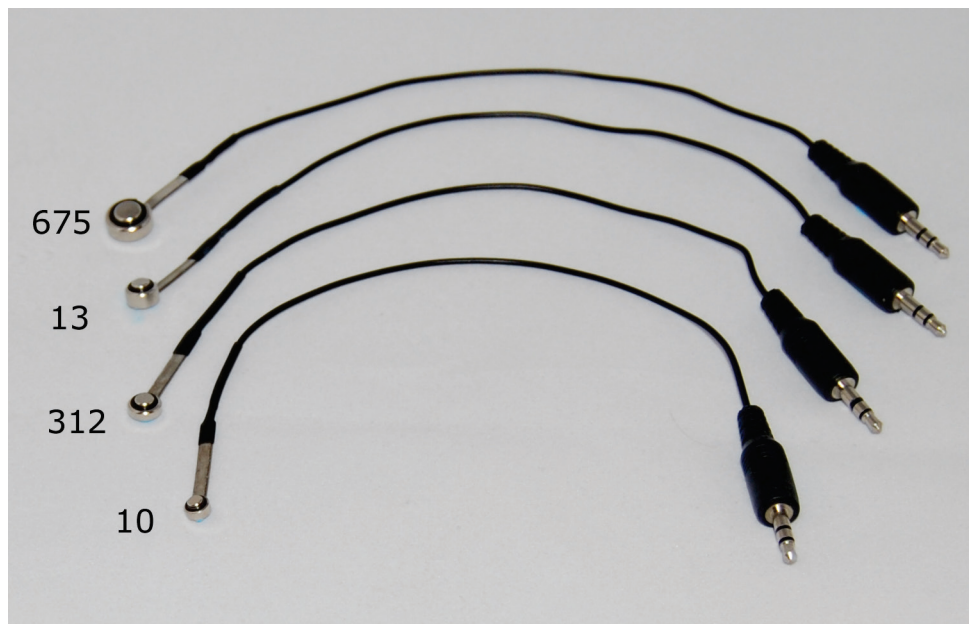
The system includes the couplers and adapters shown below. These will allow you to perform all ANSI and IEC Hearing Instrument Tests.

NOTE: There is a flexible O-ring inside both the 2cc Coupler and the Body Adapter. These must remain in place for the couplers to function properly. Replacement O-rings are available from MedRx. The Allen Wrench is used when removing the Reference Microphone for re-calibration or replacement.



Battery Pills

Battery Pills, also known as Battery Simulators, provide power to the hearing instrument during testing. The system includes a complete set of Battery Pills as shown below.



EMC Precautions

The Avant Hearing Instrument Test (HIT) box needs special precautions regarding EMC and needs to be installed 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	2.9 meters
Battery Simulators (All Versions)	0.3 meters
Microphones (All Versions)	0.3 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 Avant Hearing Instrument Test box as replacement parts for internal components, may result in increased emissions or decreased immunity of the Avant Hearing Instrument Test Box.
- The Avant Hearing Instrument Test Box should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Avant Hearing Instrument Test box should be observed to verify normal operation in the configuration in which it will be used.
- The Avant Hearing Instrument Test Box may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.
- The Avant Hearing Instrument Test Box does not have life supporting function
- Portable and mobile RF communications equipment can affect the Avant Hearing Instrument Test Box.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Avant Hearing Instrument Test box is intended for use in electromagnetic environment specific below. The customer or the user of the Avant Hearing Instrument Test box should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Avant Hearing Instrument Test box 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 Avant Hearing Instrument Test box 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 Avant Hearing Instrument Test box is intended for use in electromagnetic environment specific below. The customer or the user of the Avant Hearing Instrument Test box 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	+/- 6 kV contact +/- 8 kV air	+/- 6 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 +/- 1 kV for input / output lines	+/- 2 kV for power supply lines +/- 1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Avant Hearing Instrument Test box is intended for use in electromagnetic environment specific below. The customer or the user of the Avant Hearing Instrument Test box 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 Avant Hearing Instrument Test box, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	$3 V_{\text{eff}}$	$3 V_{\text{eff}}$	$d = 1,17 \times \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,17 \times \sqrt{P}$ 80 to 800 MHz $d = 2,33 \times \sqrt{P}$ 800 MHz to 2,5 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: 
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 Avant Hearing Instrument Test box is used exceeds the applicable RF compliance level above, the Avant Hearing Instrument Test box			

should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Avant Hearing Instrument Test box.

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 Avant Hearing Instrument Test box			
The Avant Hearing Instrument Test box is intended to use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Avant Hearing Instrument Test box can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Avant Hearing Instrument Test box 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 $d = 1,17 \times \sqrt{P}$	80 MHz to 800 MHz $d = 1,17 \times \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,33 \times \sqrt{P}$
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 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.

Power is supplied by the USB cable connected to a computer. An in-line optical isolator with medical power supply is recommended to achieve optimum safety. A medical grade computer is recommended and a medical grade isolation transformer will help minimize ground current. It is recommended that powered speakers are connected to an isolation transformer. The use environment should be between 10°C and 35°C, humidity within 30% to 90%. All components with operator contact are made of bio-compatible materials.

The green “ready” light on the front of the device indicates that the device and software are ready for use. Mild soapy water on a clean cloth 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.

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

Symbols that may be used:



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



or **SN** Indicates that the device serial number will follow.



Type B applied part.



Manufacturer (Medrx)



Authorized Representative in Europe

Congratulations

Your MedRx system is now set up and ready for use. Please consult the Training Manual and the Interactive Help Files within the software for instructions and procedures. The Training Manual is available in PDF format on a USB flash drive and at www.medrx-usa.com in our Download Section.

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.
1200 Starkey Road #105
Largo, FL 33771 USA**

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.