INSTALLATION MANUAL







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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.

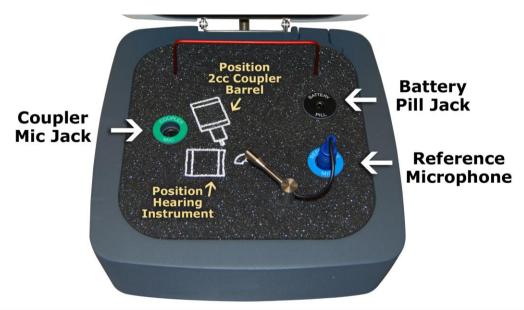




Rear View

Front View

Note the single high-speed USB 2.0 (backward compatible to USB 1.1) connector, which supplies the unit with power and transmits software control and data acquisition.



Inside the Test Chamber

Setting up the System

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



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 that both of the microphone plugs, blue and green, are "keyed" so that the arrowhead molded into the two plugs must be towards the front on the Avant HIT+ when the plug is installed.

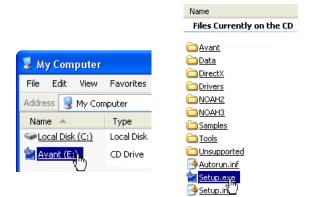
Once the microphones are installed, you must install the HIT Software and Drivers. This procedure is detailed in the next sections of this manual. If you have difficulty with these steps, contact MedRx Technical Support at (888) 392-1234 or 727-584-9600.

Software Installation

Do Not Plug in the AVANT HIT+™ USB Cable yet



- Insert the AVANT HIT[™] CD-ROM into the CD drive. Wait until the Setup program starts
- 2. On the Setup screen, choose **Install Avant HIT**.



If the Setup program does not start automatically:

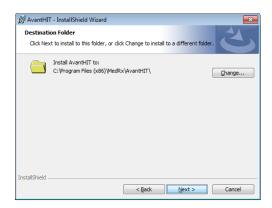
- Open Computer explorer from Windows Start menu.
- Double Click on the CD Drive icon.
 This should open the AVANTTM Setup screen shown at the top left.
- If it does not, Windows will display a list of files on the CD ROM.
- Double Click Setup.exe

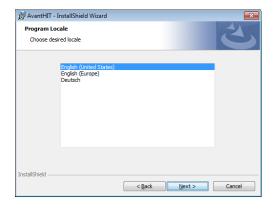


3. Wait for the program to setup the InstallShield Wizard.







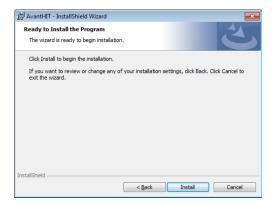


- 4. This is the Welcome screen
 - Click Next.

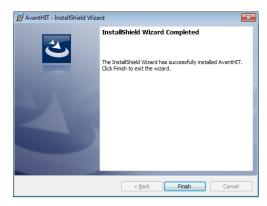
- 5. Read the Software License Agreement. This important document defines the acceptable usage of the HIT.
 - After reading the Agreement, click
 I accept...
 - Click Next.
- 6. This screen indicates the location of the program files.
 - · Click Next.

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

- 7. Choose desired Locale
 - Click Next.

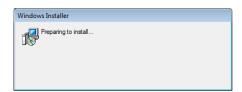






- 8. Ready to Install Program.
 - Click Install.

- 9. Wait while the InstallShield Wizard installs the Avant HIT program.
 - Click Next.



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

Driver Installation on Windows 7

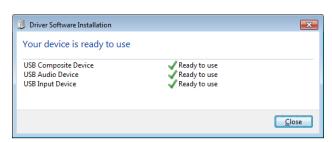
(see page 13 for Windows XP Driver Installation)

Because drivers are loaded to specific USB ports, it is essential that the HIT+ cable be connected to the same USB port on your computer each time it is used. It is advisable to mark this port with a label to assist with identifying it should the cable need to be disconnected.





- 1. Connect the USB cable from the AVANT HIT+ [™] to your computer as shown above.
- 2. Wait for the system to copy and install <u>default</u> drivers. During this process, you will see the following screen.



3. When this screen appears and all devices are "Ready to use", click **Close.**



4. On the Avant HIT Setup screen, click **Install Drivers.**



5. When this screen appears, click Ok.



6. When this window appears and all devices are "Ready to use", click **Close.**



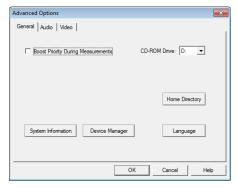
7. If this warning screen appears, click **Install** this driver software anyway.

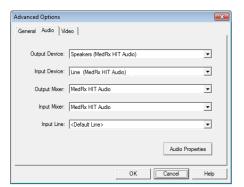


8. On Setup Window click Exit

Next you need to set the Default Windows sound card settings. This will route all non-AVANTTM 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.
- 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.
- 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 <u>not</u> 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.

Driver Installation on Windows XP

Because drivers are loaded to specific USB ports, it is essential that the HIT+ cable be connected to the same USB port on your computer each time it is used. It is advisable to mark this port with a label to assist with identifying it should the cable need to be disconnected.





- 1. Connect the USB cable from the AVANT HIT+ [™] to your computer as shown above.
- 2. Wait for the system to copy and install default drivers. During this process, you will see the following prompts in your system tray (lower right corner of the screen).

















- 3. After the Window drivers have been installed, insert the Avant HIT installation CD into the CD Drive.
- **4.** When this screen appears, click **Install Drivers.**



The software you are installing for this hardware:

MedRx HIT Composite USB-Device

has not passed Windows Logo testing to verify its compatibility with Windows XP. (Tell me why this testing is important.)

Continuing your installation of this software may impair or destabilize the correct operation of your system either immediately or in the future. Microsoft strongly recommends that you stop this installation now and contact the hardware vendor for software that has passed Windows Logo testing.

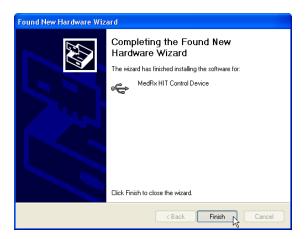




- 5. When this screen appears, click **OK**.
- 6. When the driver signature check screen appears, click **Continue Anyway.**

- 7. When this window appears,
- 8. Select No, not at this time.
- 9. Click Next.

- 10. When this screen appears,
- 11. Select Install the software automatically (recommended).
- 12. Click Next.



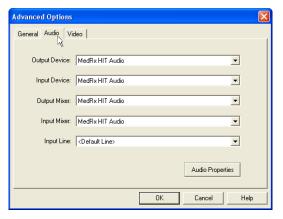
- 13. When this screen appears,
- 14. Click Finish.

Exit the Setup screen when the driver installation is finished.

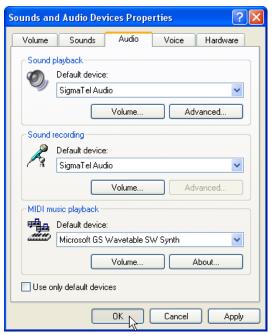
Next you need to set the Default Windows sound card settings. This will route all non-AVANTTM Windows sounds to the internal sound card of your computer. These sounds include event notifications such as new e-mail and error warnings as well as audio and video playback.



- 1. Launch the AVANT HIT software.
- 2. Open the **Advanced Options** as shown.



- 3. Click on the Audio Tab
- 4. When the audio properties are configured properly, 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.
- 5. Click the Audio Properties button



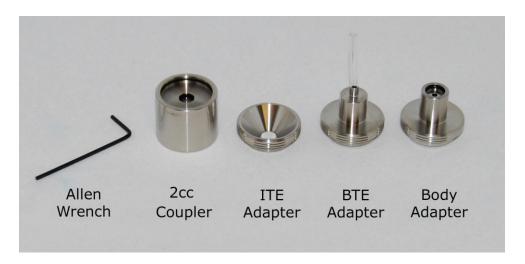
- Using the pull downs, set the Sound Playback and Sound Recording Default devices to the <u>internal sound card</u> of your computer.
- NOTE: The internal sound card on your computer will likely <u>not</u> have the same name as this screen shot (SigmaTelAudio). Consult your computer's documentation for the name of your internal sound card and set this control accordingly.

Accessories

Couplers

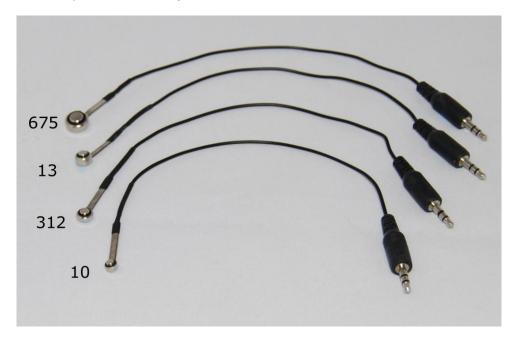
The system includes the couplers and adapters shown below. These will allow you to perform all ANSI and IEC Hearing Instrument Tests.

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	
Harmonic emissions IEC 61000-3-2	Non applicable	domestic establishments and those directly connected to the public low - voltage power	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Non applicable	supply network that supplies buildings used for domestic purposes.	

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.		
Conducted RF			Recommended separation distance:		
Conducted RF	3 V _{eff}	3 V _{eff}			
IEC 61000-4-6	O V eπ	o v em	$d = 1.17 \times \sqrt{P}$		
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		
	00 12 to 2,0 0. 12				
			$d = 2.33 \times \sqrt{P}$ 800 MHz to 2.5 GHz		
			0 = 2,55 × V 1		
			Where D is the maximum output name		
			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		
			Interference may occur in the vicinity of		
			equipment marked with the following		
			symbol:		
			$((\omega))$		

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.

- 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	Separation distance according to frequency of transmitter		
maximum	meters		
output power of transmitter W	150 kHz to 80 MHz $\mathrm{d} = \mathrm{1,17} \times \sqrt{P}$	80 MHz to 800 MHz $\mathrm{d} = 1,17 \times \sqrt{P}$	800 MHz to 2,5 GHz $\mathrm{d} = 2,33 \times \sqrt{P}$
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.

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 CD 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.