## **INSTALLATION MANUAL**





Clinical Audiometer



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# **Getting To Know Your AVANT Stealth Audiometer**

Intended Use Statement: The MedRx Avant series of audiometers are electronic instruments intended to diagnose hearing loss in adults and children. Audiograms are created and used to set the correct gain levels of the hearing aid for various frequencies. These devices should be operated by trained professionals with education and/or training in the field of audiometry.

Indication for Use Statement: This device is an audiometer. For use by professionals with education and/or training in the field of audiometry to conduct diagnostic hearing evaluations, evaluate basic hearing function and aid in the diagnosis of otologic disorders in adults and children.



Top View

Type 1 HFAE Audiometer



**Bottom View** 

The Avant Stealth Audiometer represents a new era of ultra compact diagnostic audiometry for your office. Compact yet rugged, this PC-Based system is USB or externally powered\* and performs all required ANSI and IEC audiometric tests.

The following section of this manual will familiarize you with the physical features and accessories of the system.

The Avant Stealth complies with the requirements of: ANSI S3.6-2010, IEC 60645-1:2012, IEC 60645-2:1993 and IEC 60645-4:1994.

\* External Power is required to utilize the built-in 2x20 Watt Amplifiers and the Optional High Frequency Feature. (See safety page for power supply specification).

The Red & Blue adapters are included and must be removed to attach FF speaker wires and then reinstalled as shown at left. Refer to page 6 for additional instructions

### **Transducers and Accessories**







**3A Insert Earphones** 

**TDH-39 or DD45 Earphones** 

HDA 200 (Optional)\*
High Frequency

**NOTE:** The Avant Stealth Audiometer supports 3A Insert earphones, TDH-39 or DD45 earphones and HDA 200 extended high frequency earphones. The standard configuration includes either 3A Inserts or TDH-39 or DD45 earphones.

\* HDA 200 earphones must be ordered with the High Frequency Option Upgrade.







**Operator Mic and Monitor** 

**Speakers (Optional)** 

**Bone Conductor** 



**Power Supply** 



**USB Cable** 



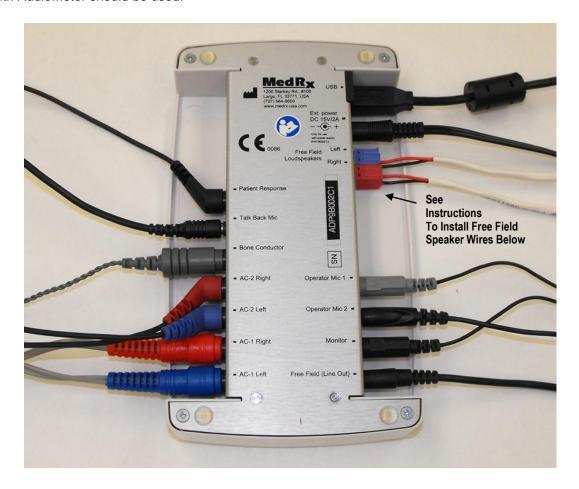
**Patient Response Switch** 



**Talkback Microphone** 

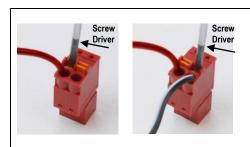
The AVANT Stealth may be located inside or outside of a sound booth.

Refer to the Certificate of Calibration for transducer characteristics and the date of the next required transducer calibration. Only transducers supplied by MedRx and specifically calibrated for each AVANT Stealth Audiometer should be used.



There are two sets of air conduction transducer connections, AC-1 and AC-2 and two Operator Microphone connections 1 and 2.

- \* High frequency transducers, such as HDA 200, can be plugged to either AC-1 or AC-2 output.
- \* Either amplified or non-amplified speakers can be used. Amplified speakers are connected to the Free Field (Line-Out) output. Non-amplified speakers are connected to the Free Field Loudspeaker outputs.



#### To Install Free Field Speaker Wires:

Unplug both the Red & Blue connectors. (see above)

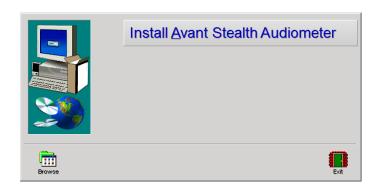
Place a small flat head screw driver on the small orange tabs and push down while inserting a wire into the opening then remove the screw driver. Be sure the wire is secure.

Repeat until all the speaker wires are secured, then plug both connectors into the device as indicated above.

Make sure that the correct transducers are set in the software by right-clicking any transducer button on the Audiometry screen and left-clicking to change the transducer.

<sup>\*</sup>External power is required for non-amplified speakers and high frequency audiometry.

### **Software Installation**





 Insert the AVANT TM Audiometer CD-ROM into the CD drive. Wait until the Setup program starts.

If Setup does not start automatically, press Win+R on the keyboard, in the box type D:\text{lsetup.exe} (where D is the letter of your CD-ROM drive), and press Enter.

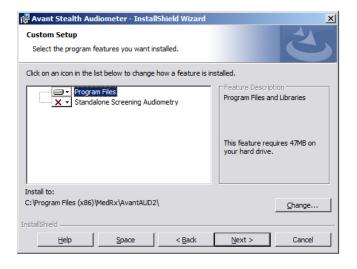
- On the Setup screen, choose
   Install Avant Stealth
   Audiometer.
- 3. This is the Welcome screen.
  - To continue, click Next.



- Read the Software License
   Agreement. This important document defines the acceptable usage of the AVANT Stealth Audiometer.
  - After reading the Agreement, choose the Accept option and click Next.



- 5. This screen indicates the software language of the program. Choose the appropriate language option.
  - To continue with the default settings, click Next.



- This screen indicates the location of the program files. The default location is recommended for most users. If necessary, this location can be changed.
  - To continue with the default settings, click **Next.**
  - To change the location of the files (advanced users or system administrators only) click **Change**.



- 7. This screen summarizes the installation configuration.
  - To continue, click Install.
  - To make changes, click Back.



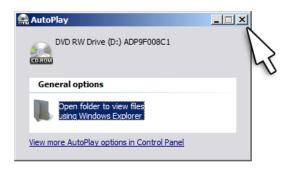
8. When the installation is complete, click **Finish**.

#### The Installation is finished.

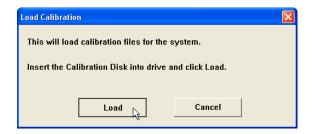
### Drivers are not required with the Stealth.

## **Loading the Calibration**











Each Avant Stealth Audiometer is calibrated in compliance with the ANSI S3.6 standard. This calibration procedure results in accessing a series of files that the software reads to keep the hardware in calibration. These files are supplied on a CD bearing the same serial number as your device.

The final step before using your Avant to evaluate hearing is to load these device-specific calibration files onto the computer used to control the device.

- Depending on your computer settings you may see this screen
  - Click the X to close out of this window.
- 2. With the Calibration CD in the drive, open the Avant software and click:
  - Function
  - Calibrate
  - Load Calibration
- 3. After a few seconds, the CD will "spin up" and this message will appear.
  - Click Load.
- 4. When the files are finished being loaded, this message will appear.
  - Click **OK** to complete loading the calibration.

#### **EMC Precautions**

The Avant Stealth Audiometer 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 from transducers and accessories:

Transducer / Accessories	Maximum Cable length	
Power Cord	2,0 meters	
USB Cable	2,0 meters	
All Transducers	2,0 meters	
Monitor Headset	2,0 meters	
Patient Microphone	2,0 meters	
Patient switch	2,0 meters	

#### Warnings!

- The Avant Stealth Audiometer generates high frequency for its own use.
- The Avant Stealth Audiometer is intended to create a medical system.
- 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 Stealth Audiometer as replacement parts for internal components, may result in increased emissions or decreased immunity of the Avant Stealth Audiometer.
- The Avant Stealth Audiometer should not be used adjacent to or stacked with other equipment
  and if adjacent or stacked use is necessary, the Avant Stealth Audiometer should be observed to
  verify normal operation in the configuration in which it will be used.
- The Avant Stealth Audiometer may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.
- The Avant Stealth Audiometer does not have life supporting function.
- Portable and mobile RF communications equipment can affect the Avant Stealth Audiometer.

Guidance and manufacturer's declaration – electromagnetic emissions  The Avant Stealth Audiometer is intended for use in electromagnetic environment specific below. The customer or the user of the Avant Stealth Audiometer should assure that it is used in such an environment.			
RF emissions CISPR 11	Group 1	The Avant Stealth Audiometer 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 Stealth Audiometer 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	Class 1.Not applicable
IEC 61000-3-2	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Passed

#### Guidance and manufacturer's declaration - electromagnetic immunity

The Avant Stealth Audiometer is intended for use in electromagnetic environment specific below. The customer or the user of the Avant Stealth Audiometer should assure that it is used in such an environment.

	IEC 60601		Electromagnetic
Immunity test	test level	Compliance level	environment - guidance
Electrostatic discharge (ESD)	+/- 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
IEC 61000-4-2			at least 30%.
Electrical fast transient / burst	+/- 2 kV for power supply lines	+/- 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital
IEC 61000-4-4	+/- 1 kV for input / output lines	+/- 1 kV for input / output lines	environment.
Surge	+/- 1 kV	+/- 1 kV	Mains power quality should
	differential mode	differential mode	be that of a typical commercial or hospital environment.
IEC 61000-4-5	+/- 2 kV	+/- 2 kV	
	common mode	common mode	
Voltage dips, short interruptions and voltage variations on power supply	< 5 % U <sub>T</sub> (> 95 % dip in U <sub>T</sub> )	passed	Mains power quality should be that of a typical commercial or hospital
input lines	for ½ cycle		environment. If the user of the Avant Stealth Audiometer requires continued operation during
IEC 61000-4-11	40 % U <sub>T</sub>		power main interruptions, it is recommended that the Avant Stealth Audiometer be
	(60 % dip in U <sub>T</sub> )	passed	powered from an uninterruptible power supply
	for 5 cycles		or a battery.
	70 % U <sub>T</sub>	passed	
	(30 % dip in U <sub>T</sub> )		
	for 25 cycles		
	10. 20 0yolo3		
	< 5 % U <sub>T</sub>	passed criteria B	

	(> 95 % dip in $U_T$ ) for 5 s		
Power frequency (50/60 Hz)	3 A/m	3 A/m	Power frequency magnetic fields should be at levels
Magnetic field			characteristic of a typical location in a typical commercial or hospital environment.
IEC 61000-4-8			
NOTE U <sub>T</sub> is the a.c. mains voltage prior to application of the test level			

### Guidance and manufacturer's declaration – electromagnetic immunity

The Avant Stealth Audiometer is intended for use in electromagnetic environment specific below. The customer or the user of the Avant Stealth Audiometer 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 Stealth Audiometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  Recommended separation distance:
Conducted RF			
	3 V <sub>eff</sub>	3 V <sub>eff</sub>	$d = 1,17 \times \sqrt{P}$
IEC 61000-4-6			
Radiated RF			
	3 V/m	3 V/m	$d = 1.17 \times \sqrt{P}$ 80 to 800 MHz
IEC 61000-4-3	80 MHz to 2,5 GHz		
			d = 2,33 $ imes \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 <sup>a</sup> , should be less than the compliance level in each frequency range <sup>b</sup> .

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.

- 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 Stealth Audiometer is used exceeds the applicable RF compliance level above, the Avant Stealth Audiometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Avant Stealth Audiometer.
- 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 Stealth Audiometer

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

Rated	Separation distance according to frequency of transmitter			
maximum output power	meters			
of transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz	
W	d = 1,17 $ imes \sqrt{P}$	$d=1,17\times \sqrt{P}$	$d=2,33\times\sqrt{P}$	
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. This audiometer conforms to the requirements of IEC 60601-1.

It is Class II Medical Electrical (ME) equipment that is part of an ME system.



Power is supplied by an un-grounded mains power cable to a medical grade power supply, and by the USB connection to a computer. 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 within 30% to 90%, ambient pressure of 1013 +/- 10% mbar. All components with patient contact are made of bio-compatible materials. The IP code is IP22.

The colored lights on the device only signify that the device is operational. The color does not signify any dangerous or faulty condition. Mild soapy water or 70% isopropyl alcohol are the preferred cleaning solutions.

Maximum warm-up time needed is 5 minutes.

Use only the 15 VDC, 2A medical power supply supplied with your Avant Stealth: ETMA150200UD-P5P-IC.

Mains power 100 – 240 VAC 50/60 Hz. The operator should periodically inspect the power supply and cables for any signs of wear or damage. Contact MedRx for replacement parts.

The power supply cable should always be accessible in order to disconnect it from the supply mains.

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<sup>™</sup> 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.