MedRx

INSTALLATION MANUAL

Revolutionary Tinnitus Assessment

MedRx TINNOMETER

www.medrx-int.com

Contents

www.medrx-int.com

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EC REP

CE
#0123

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Getting to Know Your Tinnometer

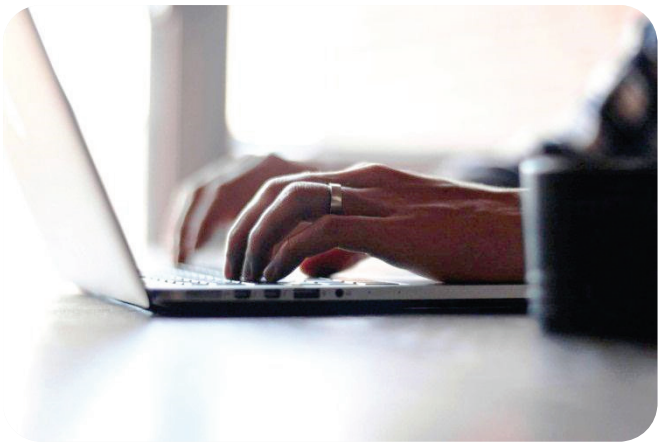
Intended Use Statement:
The MedRx Avant series of audiometers are electronic instruments intended to diagnose hearing loss in adults and children. Audiograms are created and used to set the correct gain levels of the hearing aid for various frequencies. These devices should be operated by trained professionals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

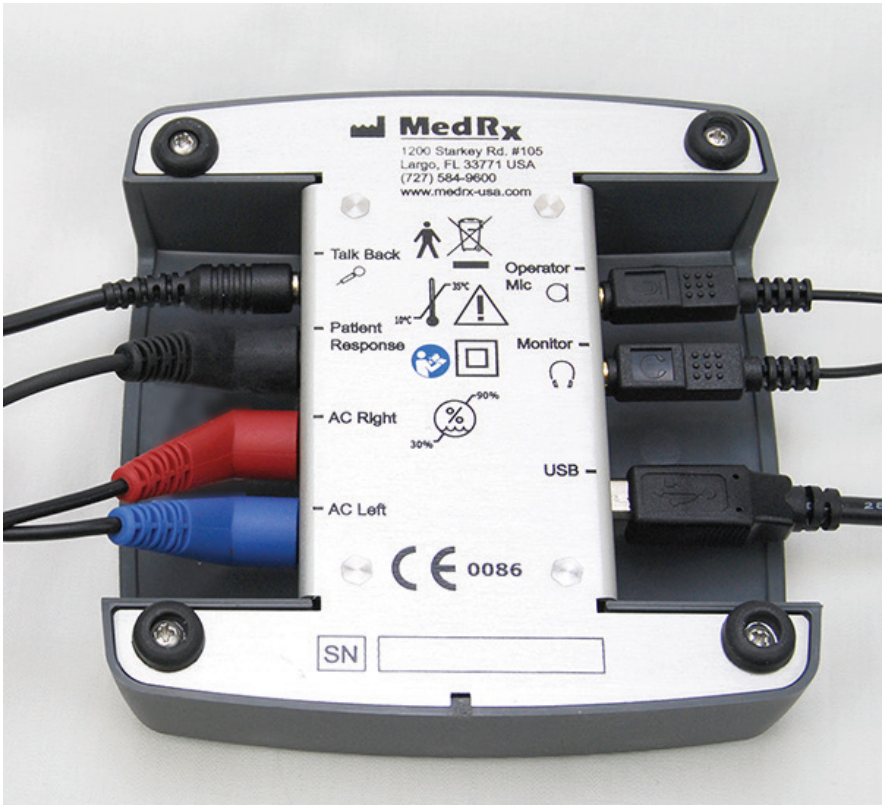
The MedRx Tinnometer represents a new era of ultra-compact screening audiometry for your office. Compact yet rugged, this PC-Based system is USB powered and supports ANSI and IEC audiometric tests. The following section of this manual will familiarize you with the physical features and accessories of the Audiometer system.

Computer Requirements

MedRx Minimum Computer Specs:
Windows®-PC compatible computer
Intel™ i5 Dual Core, 2.0 GHz or better
4 GB RAM
20 GB free hard drive space
Available 2.0 USB port
Windows 7, 8 or 10 Professional (32 or 64-bit)
MedRx Recommended Computer Specs:
Windows®-PC Computer
Intel™ i5 Dual Core, 3.2 GHz or better
8 GB RAM or more • 50 GB or more free hard drive space
Available 2.0 USB port
Graphics Adapter with 2GB Dedicated Video Memory
DVD-ROM Drive
High Speed Internet Connection
Windows 10 Professional 64-bit



MedRx Tinnometer



Bottom View – with Connectors

Transducers and Accessories

Talkback Mic

Patient Response Switch

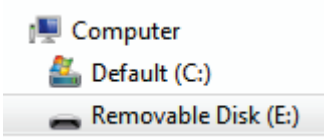
Operator Mic and Monitor (may vary)

DD450 Headset

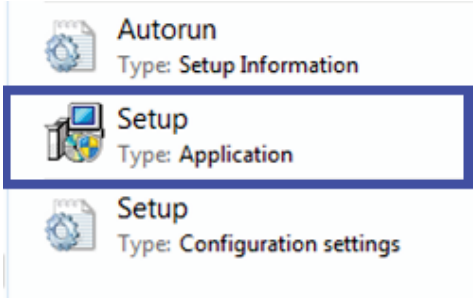
Speaker Adapter (Optional)

Software Installation

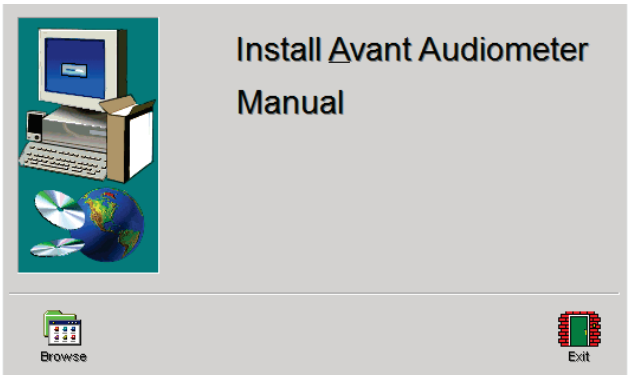
1. Insert the AVANT Audiometer USB Flash Drive into USB port:
   - ❖ Launch ***My Computer***
   - ❖ Locate USB Drive



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



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

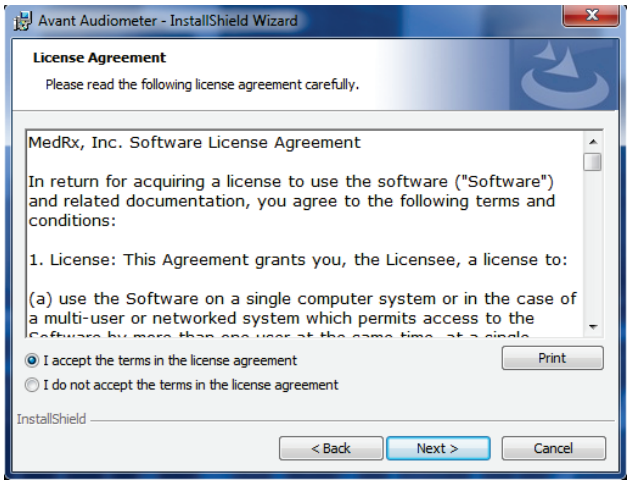


3. On the Setup screen, choose ***Install AVANT Audiometer***.

   NOTE: No MedRx driver installation is required with the AVANT Audiometers.

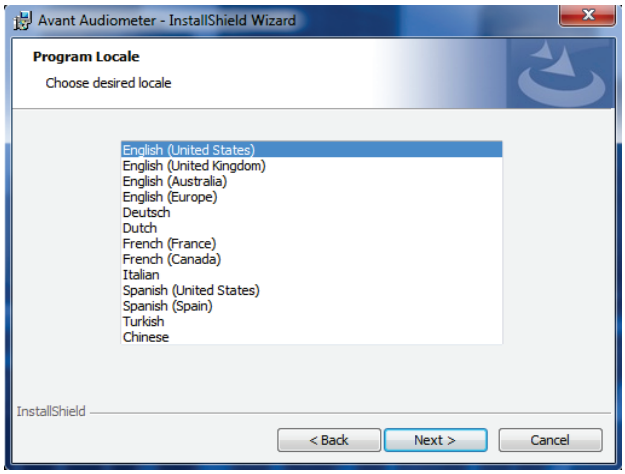
   Also, the Electronic Copy of this Manual is located under ***Manual.***

4. This is the Welcome screen.
   - ❖ To continue, Click ***Next.***

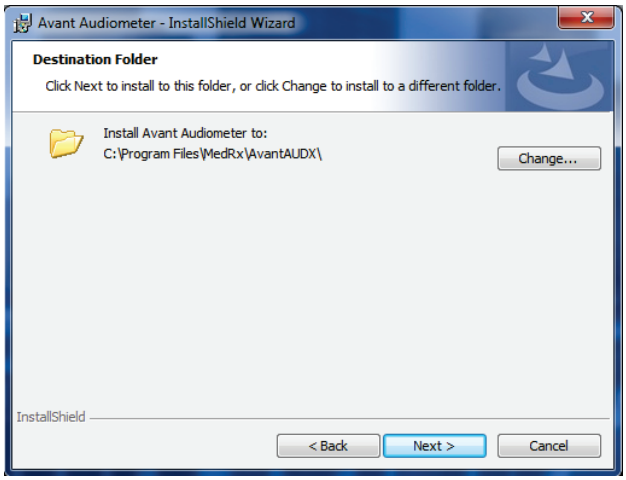


5. Read the Software License Agreement. This important document defines the acceptable usage of the Audiometer software.

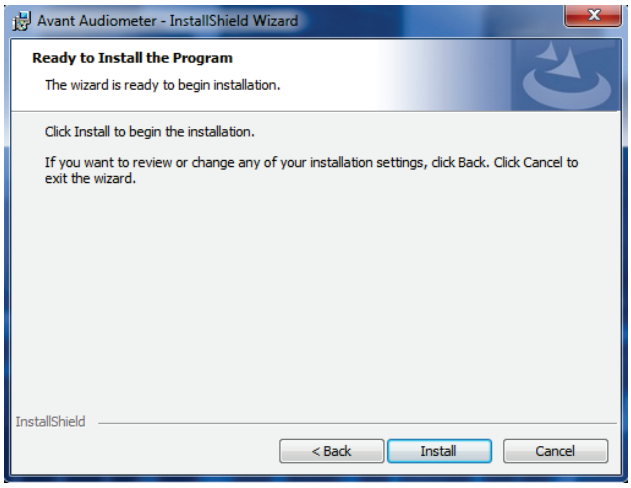
   - After reading the Agreement,
   - select "I accept …"
   - click ***Next.***



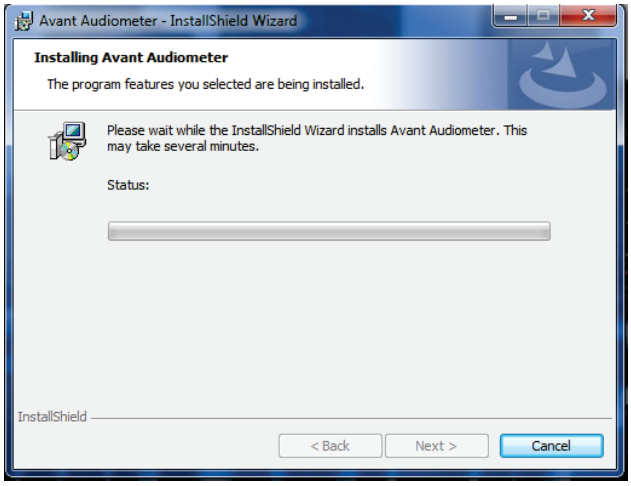
6. This screen sets the language and location choice. Make a selection and click ***Next.***



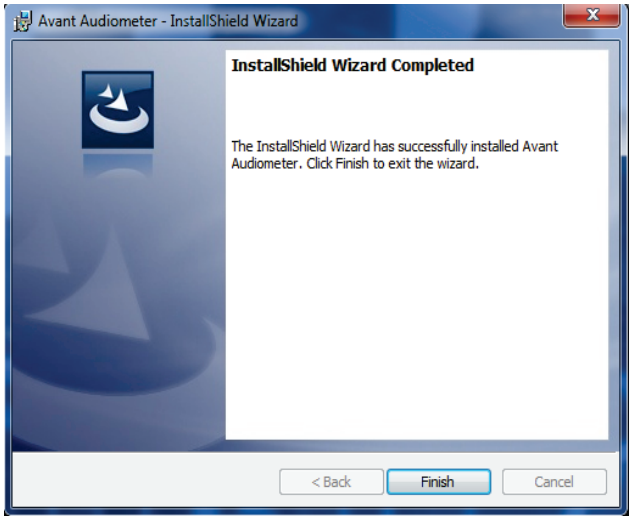
7. This screen indicates the location of the program files. The default location is recommended for most users. If necessary, this location can be changed.
   - To continue with the default settings, click ***Next.***
   - To change the location of the files (advanced users or system administrators only,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



8. Installation of Program is ready to start.
   - ❖ To continue, click ***Install.***
   - ❖ To make changes, click ***Back.***



9. Installation is in process.

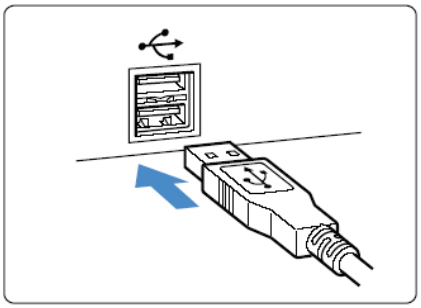


10. When the installation is complete, click ***Finish.***

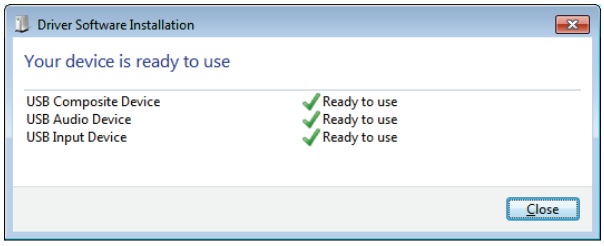
Connecting Device

Your MedRx Tinnometer is USB powered.

Connect the USB cable from the MedRx Tinnometer to your computer as shown below.

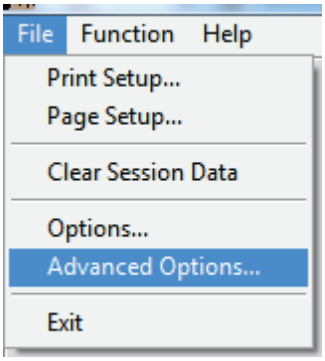


Wait for the system to copy and install default Windows drivers.



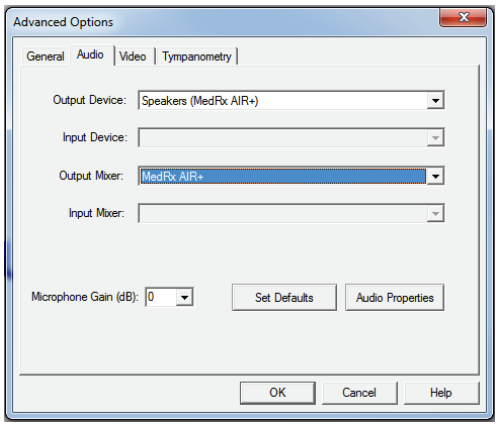
When this screen appears and all devices are "Ready to use", click ***Close.***

Next you need to confirm or 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.



Launch the ***AVANT Audiometer*** software.

Open the ***Advanced Options*** from File menu as shown.

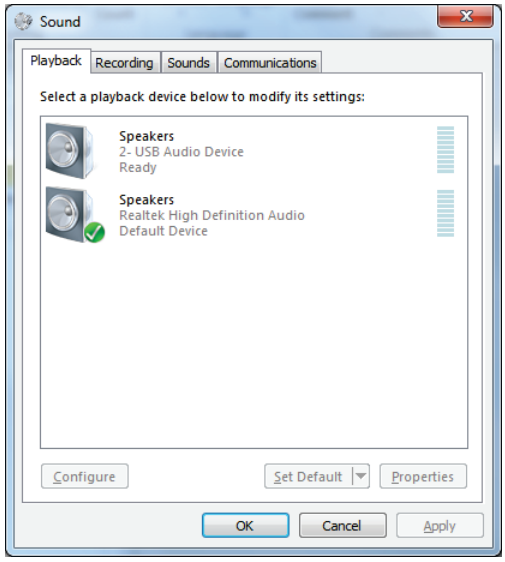


Open **Audio tab**.

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.

NOTE: Your specific Avant Audiometer will appear in both Output and Input Device Tab.

Click ***Audio Properties***.

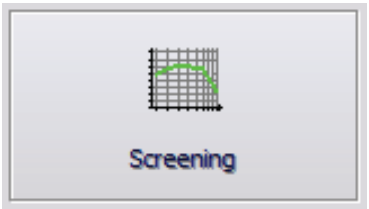


In Windows Sound control panel, make sure the MedRx Audio Device is not set as default. If it is default, change this by clicking on your system (non-MedRx) audio device and then choose ***Set Default***.

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.

Click ***OK***.

Screening Module



- Once the Audiometer is connected to the PC (Connecting Device on pg 9). The Screening Icon will appear on the main screen.

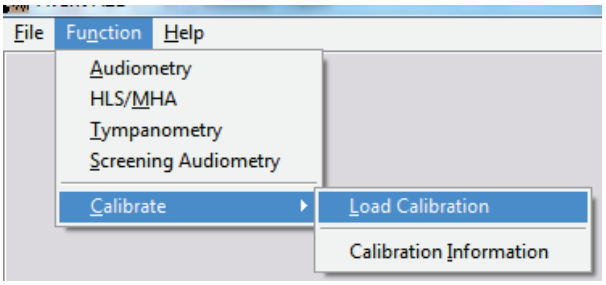
Tinnometer Module

- Once the Tinnometer is connected to the PC (Connecting Device on pg 9). The Tinnometer Icon will appear on the main screen.

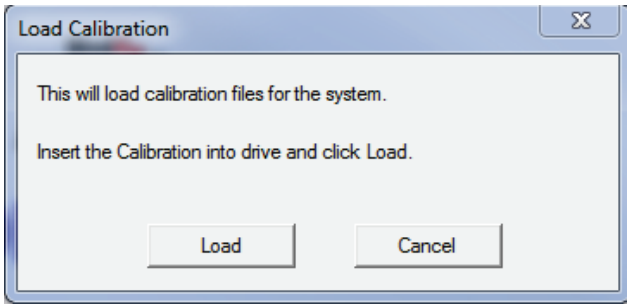
Loading Calibration Files

Each MedRx Tinnometer is calibrated in compliance with the ANSI S3.6 standard. This calibration procedure results in a series of files that the Audiometer software reads to keep the hardware in calibration. These files are supplied on a USB Stick.

The final step before using your MedRx Tinnometer to evaluate hearing is to load these device-specific calibration files onto the computer used to operate the Audiometer device.

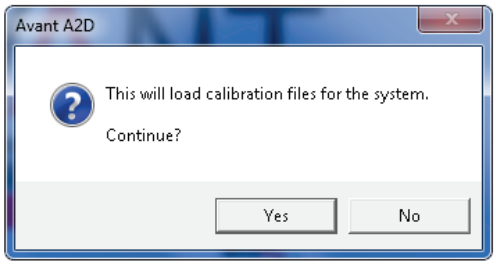


1. With the AVANT Audiometer USB Flash Drive in the USB port, open the AVANT Audiometer software and click:
   - ***Function.***
   - ***Calibrate.***
   - ***Load Calibration.***



2. After a few seconds, this message will appear.

   - Click **Load.**



3. When the files are finished being loaded, this message will appear:

   - Click **YES** to complete loading the calibration.

EMC Precautions

The Avant 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, transducers and accessories:

Transducer / Accessories	Maximum Cable length
USB Cable	3 meters
Insert Earphones	2 meters
All Headsets	2 meters
All Microphones	2 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 Audiometer as replacement parts for internal components, may result in increased emissions or decreased immunity of the Avant Audiometer.
- The Avant Audiometer should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the Avant Audiometer should be observed to verify normal operation in the configuration in which it will be used.
- The Avant Audiometer may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.
- The Avant Audiometer does not have life supporting function
- Portable and mobile RF communications equipment can affect the Avant Audiometer.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Avant Audiometer is intended for use in electromagnetic environment specific below. The customer or the user of the Avant Audiometer should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Avant 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 A	The Avant Audiometer is suitable for use in all establishments other than domestic 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 Audiometer is intended for use in electromagnetic environment specific below. The customer or the user of the Avant Audiometer 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 discharge +/- 2, 4, 8 &15kV air discharge	+/- 8 kV contact discharge +/- 2, 4, 8 &15kV air discharge	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	NA	NA	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 Audiometer is intended for use in electromagnetic environment specific below. The customer or the user of the Avant 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 Audiometer, 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	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM Band 1 kHz AC Mains	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM Band 1 kHz AC Mains	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 Audiometer is used exceeds the applicable RF compliance level above, the Avant 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 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 Audiometer

The Avant Audiometer is intended to use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Avant Audiometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Avant Audiometer 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 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 water protection level is **IP21.**
- Power is supplied by the USB cable connected to a computer.
- A USB Optical Isolator, with a minimum of 1000 DC volt isolation, should be placed in-line between the computer's USB connection and the MedRx device. The Optical Isolator should be powered by a power supply that conforms to IEC 60601-1. The computer, Optical Isolator's power supply and the speaker's power supply should be connected to the Medical Grade isolation transformer that conforms to IEC 60601-1. Follow the manufacturer's instructions for installation and use.
- The computer used with this device should conform to the requirements of IEC 60950-1 and IEC 60601-1-4.
- A MULTIPLE PORTABLE SOCKET-OUTLET or extension cord shall not be connected to the system.
- The device warm-up time is less than 2 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 0°C to 50°C
- 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. No Sterilization is required for components of this device. However, new foam inserts are needed for each patient where applicable and cleaning of the device and accessories should follow the procedure outlined below.
- 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.
- The colored lights are as designated by ANSI S 3.6 and IEC 60645-1. They signify that either the left (blue) channel is active or the right (red) channel is active, or no channel is active (green). The colors do not signify any dangerous or faulty condition.

- 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.

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.

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

Temperature limitation

Type B applied part. (Type B equipment)

Class II equipment

Manufacturer (MedRx)

Microphone

Start (of action)

Stop (of action)

Non-ionizing electromagnetic radiation

Authorized Representative in Europe

Special Disposal Required.

Percentile Setup

Humidity Limitation

Calibration

Loudspeaker (Speaker)

Caution, General warning sign

Headphones

Handheld microphone (Talkback Microphone)

Recording

Recommended Procedures for Cleaning and Disinfection

1. Foam ear tips are single use components, and should not be re-used by another patient.
2. It is recommended that 70% Isopropyl Alcohol should be applied to a soft clean cloth or tissue, not directly on the component to be cleaned. The cloth should never be wet, just damp. A mild soapy water solution is an alternative cleaning liquid.
3. To ensure that cross contamination does not occur, use clean cloth or sealed Alcohol swabs for each device to be cleaned.
4. Wipe the surfaces of the Operator headset and headphone pads with the 70% Isopropyl Alcohol. Clean other transducers in the same way. Do not let 70% Isopropyl Alcohol or water enter the microphone sound inlet.
5. The white device housing may also be wiped with 70% Isopropyl Alcohol. The speaker controls, headphone ear pads, head band and other components may be cleaned in a similar way.
6. Let all components that have been cleaned, thoroughly dry before use.
7. Cleaning of the computer should be performed using the methods suggested in the computer's manual.

Technical Information

The Avant Tinnometer is an active, diagnostic Class IIa Medical Device according to the EU medical directive 93/42/EEC.

Standards: Screening Audiometer as per ANSI S3.6-2010, IEC 60645-1:2012, Type 4; Tone Audiometry, Tinnitus Assessment

Outputs: Insert Earphones, DD45 Or DD450

Tinnometer Frequency Range: Air: 125 Hz – 8 kHz

Max Output: Air Conduction: 100 dB HL For Mid-Range
Frequencies

Attenuation: 1 dB Step Or 5 dB Step, User Selectable

Optional Accessories: DD45 Headphones & Insert Earphones

Compatible with: NOAH™, TIMS® and SycleNet™

Power Requirements: USB-powered

Dimensions: Approx. Approx. 12cm x 12cm x 3cm (L x W x H)

Weight: < 500 g

Standard Accessories: DD450,Patient Response Switch, Talkback Microphone, Operator Mic, Monitor Headset, Software & Manuals, Carrying Case

Connection Sockets:	***Specification***
• Power/Communication	USB: (5 VDC)
• Pat patient response switch	RI= 500
• Talk Back microphone	ZI= 1 k Ω, UI= 0.38 – 500 mVeff
• Operator Microphone	ZI= 1 k Ω, UI= 0.38 – 500 mVeff
• Operator Monitor headphone	ZA= 32Ω , UA= 3 Veff
• AC phone left	ZA=10 Ω, UA=1 Veff
• AC phone right	ZA=10 Ω, UA=1 Veff

Calibration values and Max Levels:

Headphone DD45
NBS-9A acoustic coupler
Force 4-5 N, ANSI and IEC
DD45 RETSPL Values
RETSPL dB re
20µPa

125=47.5
250=27.0
500=13.0
750=6.5
1000=6.0
1500=8.0
2000=8.0
3000=8.0
4000=9.0
6000=20.5
8000=12.0
Speech=18.5

Maximum Sound Levels:

Frequency	Inserts	Supra-aural	Sound Field	Bone Conduction
125	75	80	65	
250	100	100	80	45
500	110	110	90	60
750	110	110	90	60
1000	115	120	90	70
1500	115	120	90	70
2000	115	120	90	70
3000	115	120	90	70
4000	115	120	90	60
6000	100	105	90	50
8000	90	100	80	45

Routine checking and subjective tests

The user of the instrument should perform a subjective instrument check once a week. The purpose of routine checking is to ensure, as far as possible, that the equipment is working properly, that its calibration has not noticeably altered and that its attachments, leads and accessories are free from any defect that might adversely affect the test result.

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-int.com in our Download Section.

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 +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

MAICO 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.

MAICO 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.

MAICO 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.