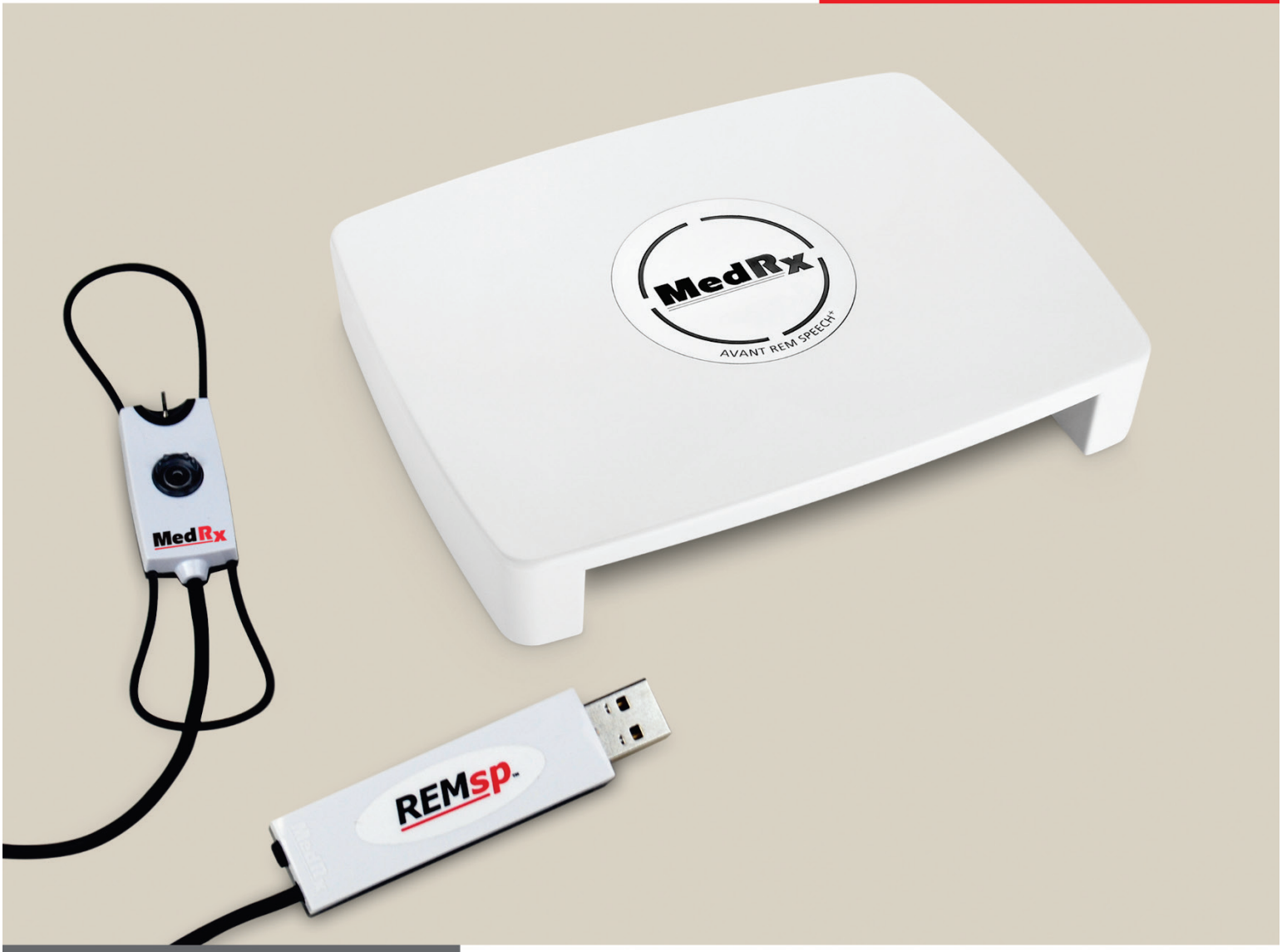
MedRx

INSTALLATION MANUAL



Real Ear Measurements & Live Speech Mapping

AVANT™ REM

www.medrx-usa.com

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EC REP

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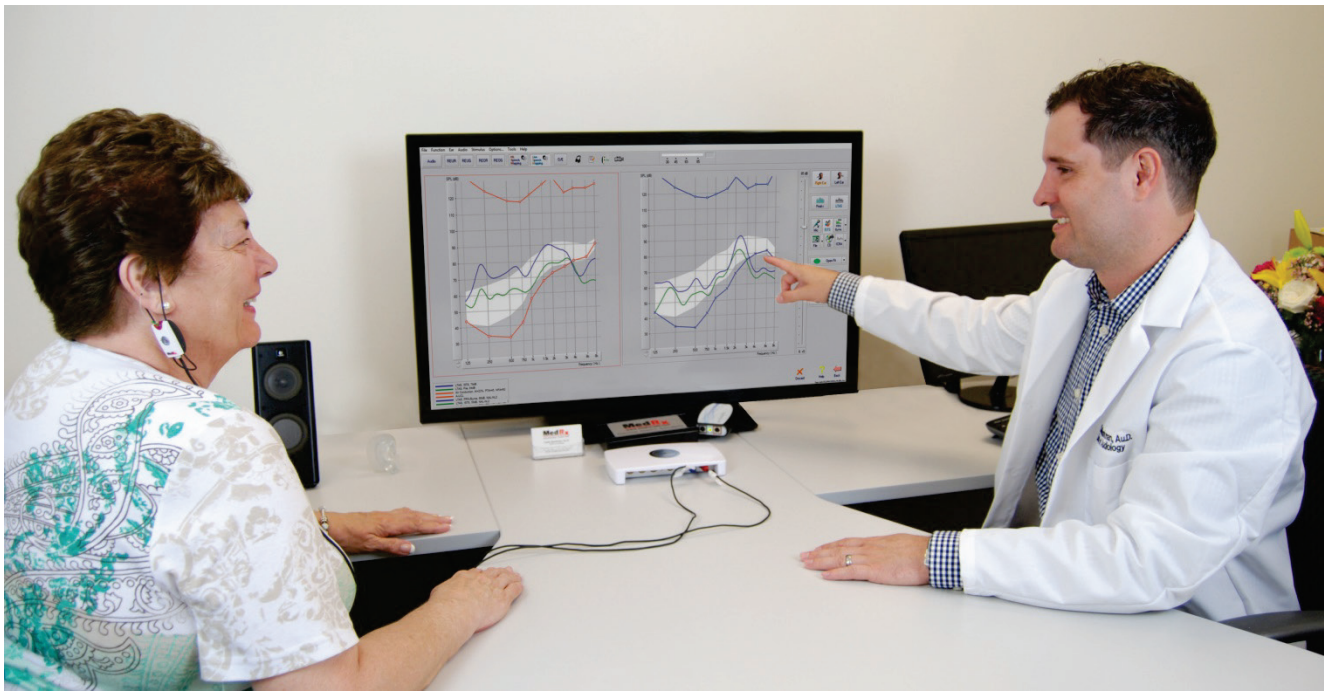
Getting to Know Your AVANT REM+

Intended Use Statement:
The AVANT series of REM (Real Ear Measurement) devices measure sound levels directly in patient's ears. They are used in the measurement and fitting of hearing aids for adults and children. These measurements can be done with or without the hearing instrument being worn. They are also used for hearing loss simulation. The REM can perform Live Speech Mapping (MedRx's in-situ method for getting the fitting right the first time). These devices should be operated by trained professionals with education and/or training in the field of audiometry.

Indication for Use Statement:
The AVANT REM (Real Ear Measurement) devices are for use by professionals with education and/or training in the field of audiometry to evaluate the fitting of hearing aids and are used for hearing loss simulation in adults and children.

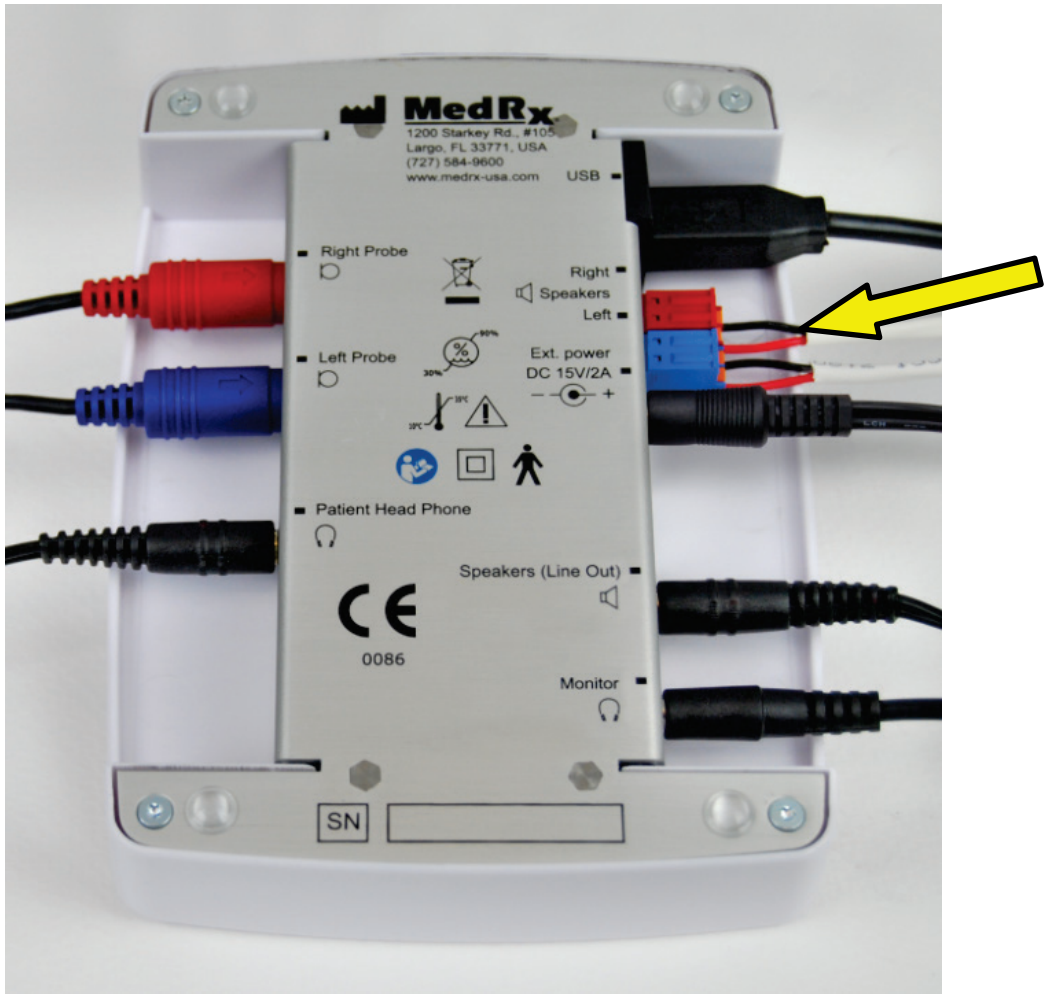
The AVANT REM+ represents a new era of precision in-situ verification for your office. Compact yet rugged, this PC-Based system is USB powered and supports ANSI and IEC Real Ear tests. The software includes targets for ***DSL I/O 5.0*** and ***NAL-NL-2***.



Computer Requirements

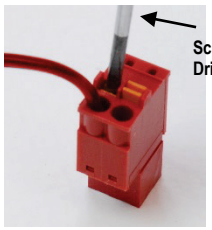
MedRx Minimum Computer Specs:
Windows®-PC compatible computer
Intel™ i5 Dual Core, 2.0 GHz or better
4 GB RAM
20 GB free hard drive space
Available 2.0 USB port
Windows 7, 8 or 10 Professional (32 or 64-bit)
MedRx Recommended Computer Specs:
Windows®-PC Computer
Intel™ i5 Dual Core, 3.2 GHz or better
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

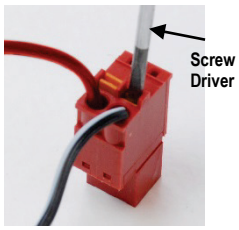
Avant REM+



The AVANT REM+ is a device that is used in measuring the real-ear acoustical characteristics of hearing instruments. The device performs measurements of real-ear acoustical characteristics of a hearing instrument on a given human ear, and does comply with the International Standards ANSI S-3.46 and IEC 61669.

⚠**Notice!** The Red & Blue adapters are included and must be removed to attach 18 gage (1.0mm) Free Field speaker wires and then reinstalled. DC Power supply must be used when using passive Free Field speakers.





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 speaker 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.

Avant REMsp

All of the features of the advanced dual probe AVANT REM+ are also offered in the AVANT REMsp. (See the AVANT REM+ for features) The REMsp is a single probe comprehensive REAL EAR Measurement and Live Speech Mapping system that is remarkably small. Measuring only about 3.25 inches long, this device plugs into the USB port of the computer.

⚠ *We strongly recommend utilizing the supplied 6 inch or 6 foot USB extension cable with your REMsp. Plug the USB extension cable into your computer as shown below.*

Transducers and Accessories

Use the accessories provided with your REM device. Use of unapproved accessories is not recommended.

Probe Microphones
REM+ Only

Probe Mic Hanger & Clip *REM+ Only*

Headphones

DC Power Supply
REM+ Only

Bluetooth *"Active"* **Speaker**

Desktop *"Active"* **Speakers**

USB Extension Cable - 6 foot
REMsp Optional

USB Extension Cable - 6 inch
REMsp Only

Bluetooth Speaker Power Supply

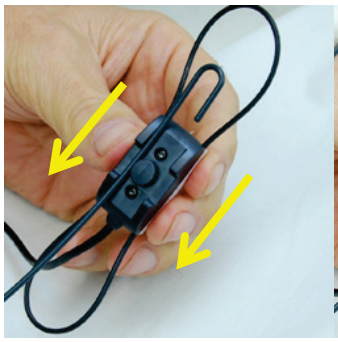
Bluetooth Audio Cable

Probe Mic Case
(REMsp Box)

USB Cable

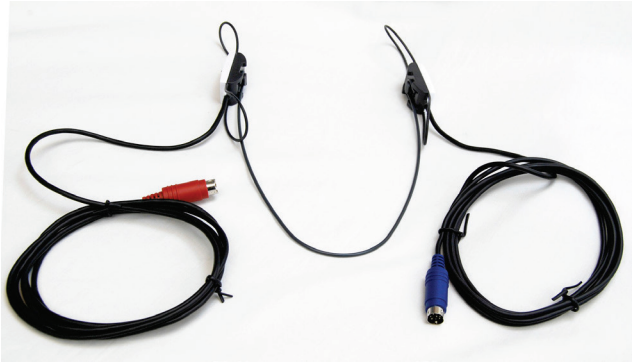
Probe Mic Hanger Installation

You will need the two Probe Mics, the Probe Mic Hanger and the Clip



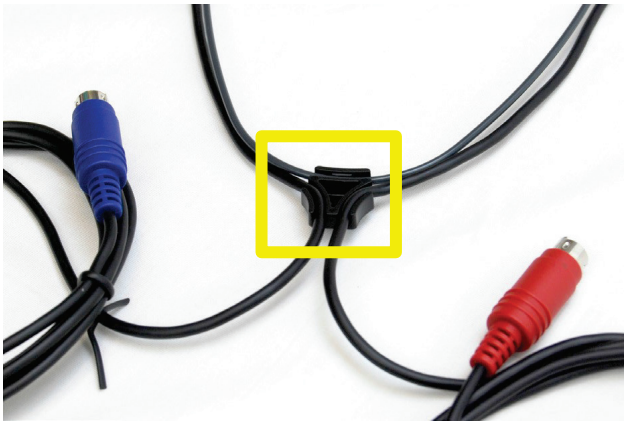
Install the hook on the back side of probe mic

Pull hook down to seat on post

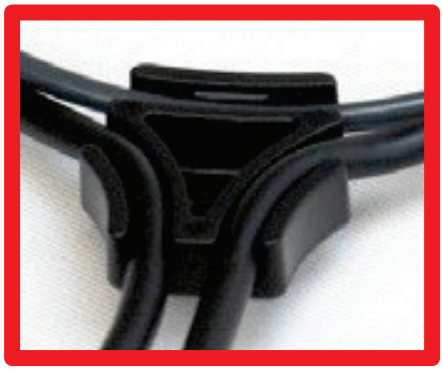


Once Installed the large O-ring should be adjustable for fitting.

Gently press clip into place.



Turn clip over place probe mic wires into clip



Larger view of clip with wires inserted

Probe Mic Hanger installation assembly complete.

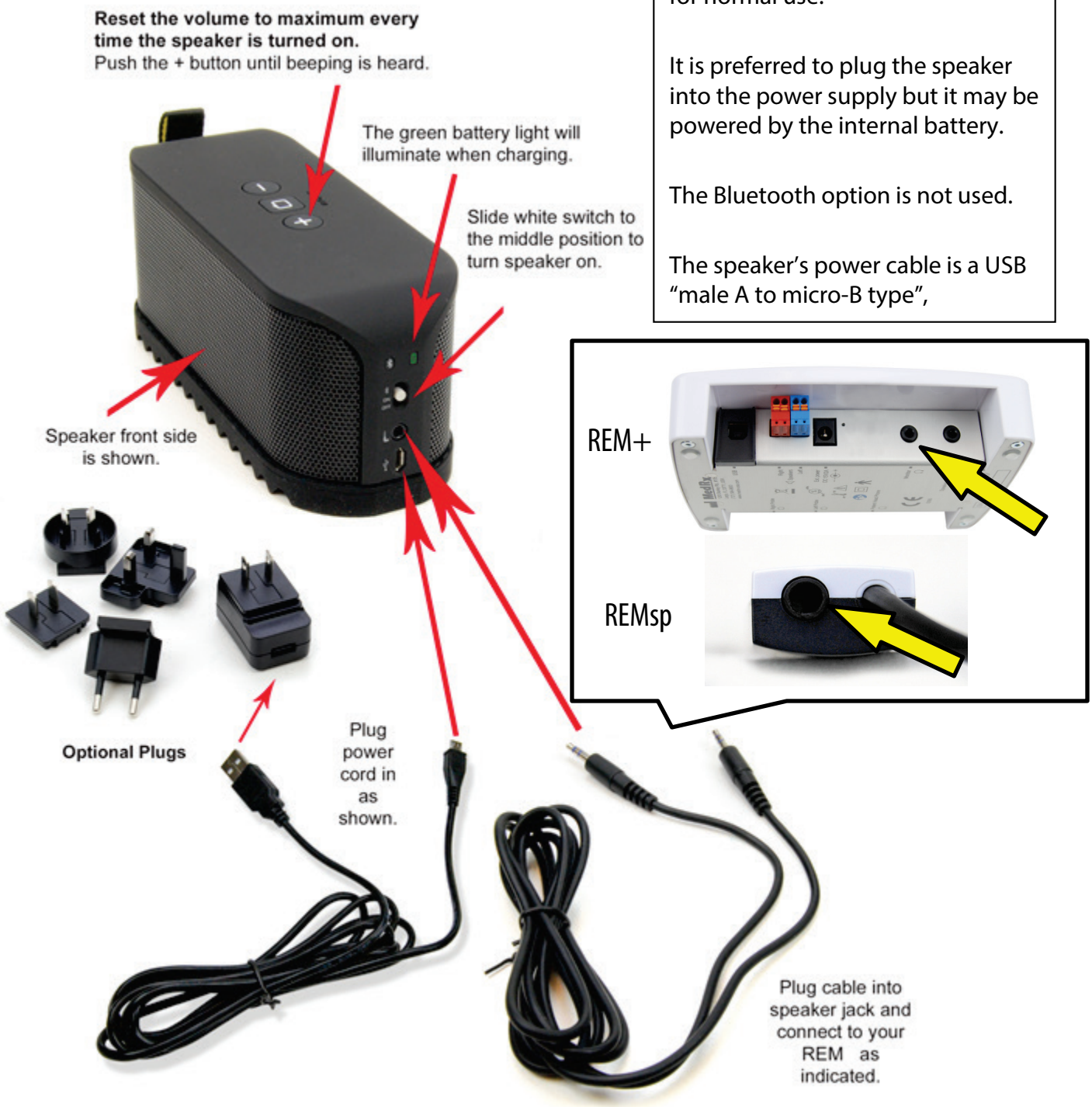
Connecting the Speaker

The front side of the speaker is placed at a distance of about 1 meter (19”-39”) from the patient, for normal use.

It is preferred to plug the speaker into the power supply but it may be powered by the internal battery.

The Bluetooth option is not used.

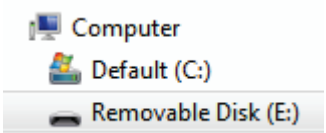
The speaker’s power cable is a USB “male A to micro-B type”,



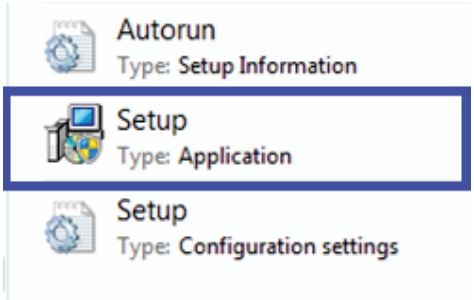
Software Installation

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

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

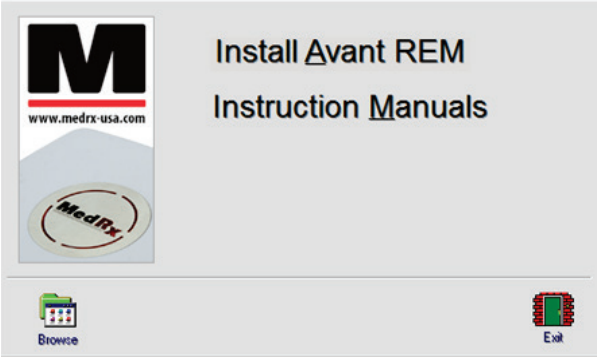


(E:) may vary depending on the USB port selected. Consult your computer's documentation.

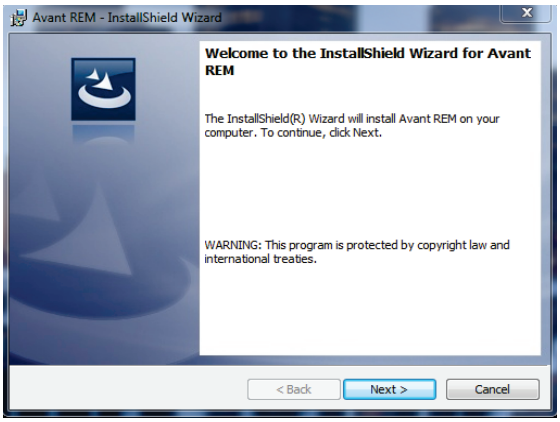


2. Double Click on ***Setup*** to launch:

If requested, Accept Permission to Install Software.

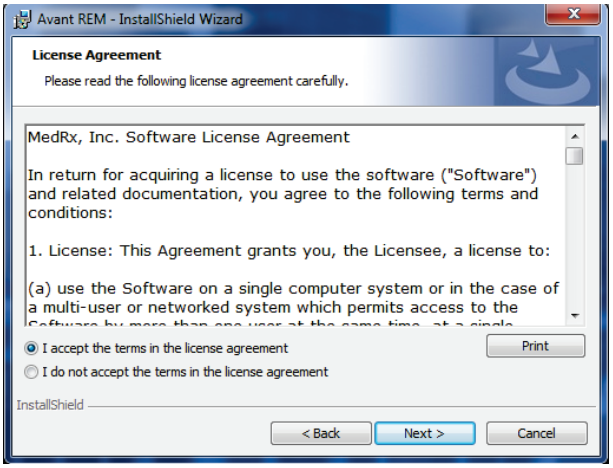


3. On the Setup screen, choose ***Install Avant REM.***



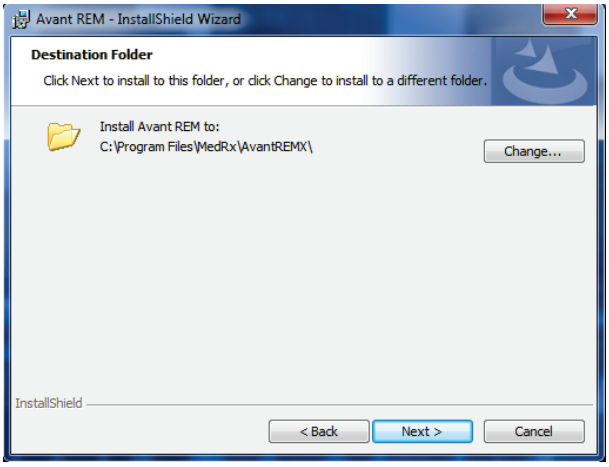
4. This is the Welcome screen.

- To continue, click ***Next.***



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

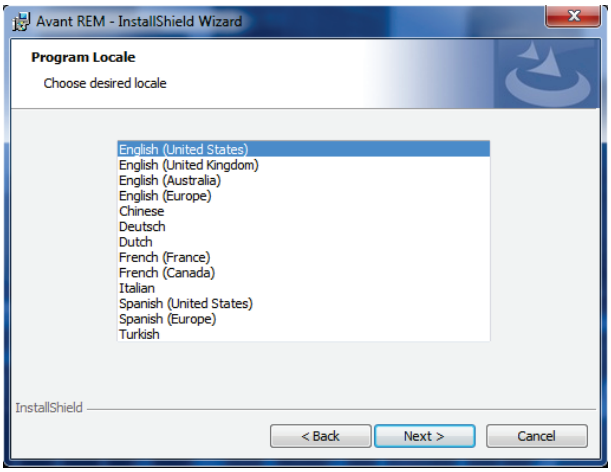
    - After reading the Agreement, click ***I accept.***
    - Click ***Next.***



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

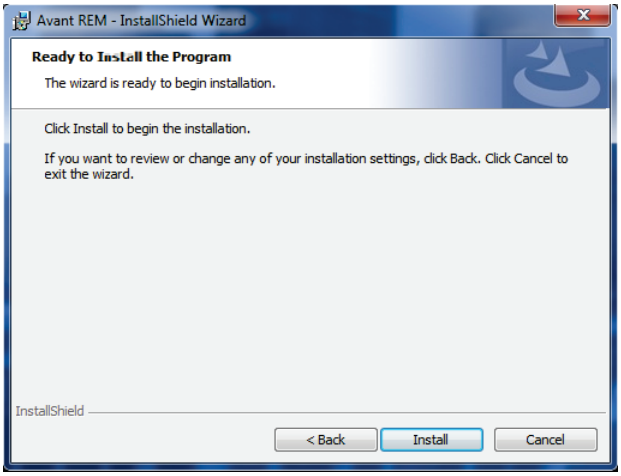
    - Click ***Next.***

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



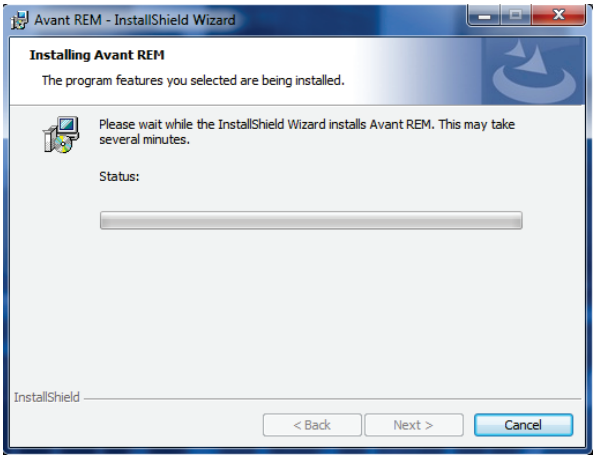
7. Choose desired language and locale

    - Click ***Next.***

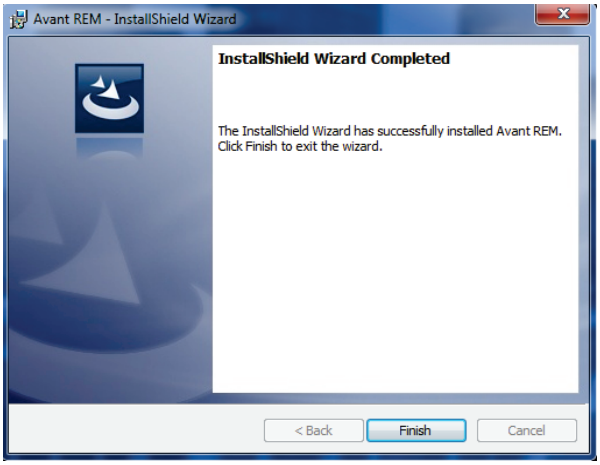


8. Ready to Install Program.

    - Click ***Install***.



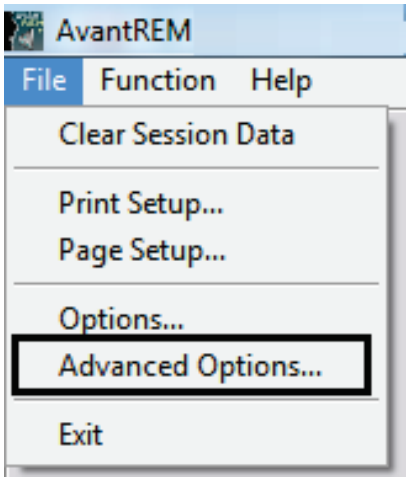
9. Wait while the InstallShield Wizard installs the Avant REM program.



10. When the installation is complete,

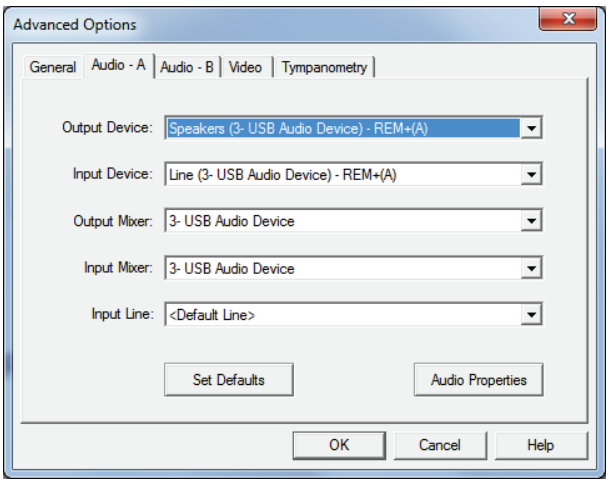
    - Click ***Finish.***

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.



1. Launch the ***REM*** software.

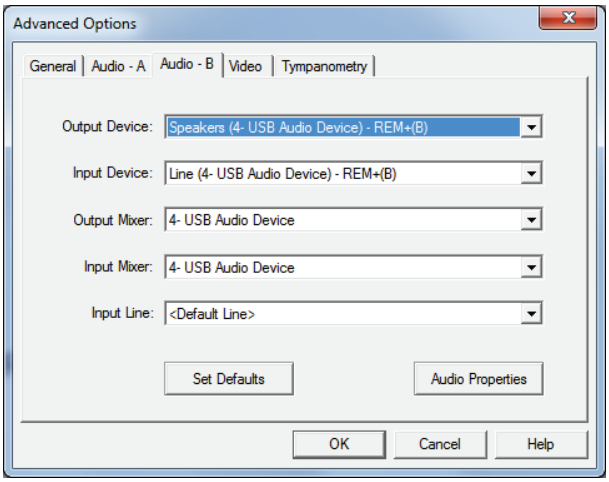
2. Open the ***Advanced Options*** from File menu as shown.



3. Open ***Audio–A 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.

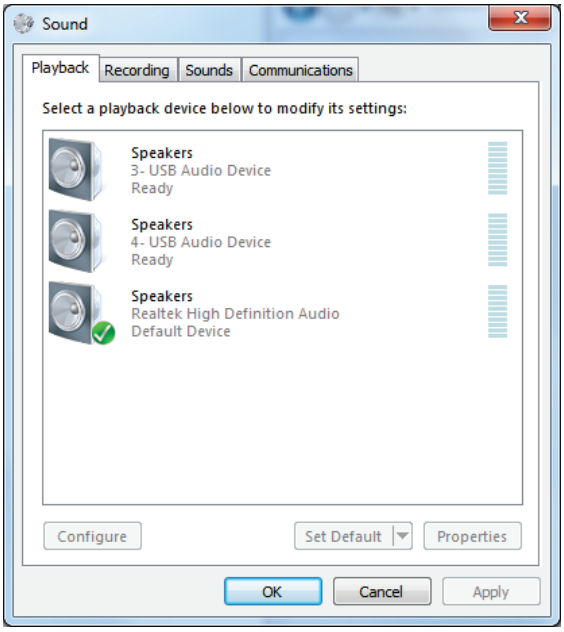
NOTE: Your specific Avant REM will appear in both Output and Input Device Tab.



5. Open ***Audio–B tab***.

6. 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.

7. Click ***Audio Properties.***



8. 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 computer's (non-MedRx) audio device and then choose Set Default.

When complete, click ***OK.***

⚠ **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.

EMC Precautions

The Avant REM 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	2,0 meters
REM Probe	2,0 meters
All Headsets	2,0 meters
All Speakers	2,0 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 REM as replacement parts for internal components, may result in increased emissions or decreased immunity of the Avant REM.
- The Avant REM should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the Avant REM should be observed to verify normal operation in the configuration in which it will be used.
- The Avant REM may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.
- The Avant REM does not have life supporting function
- Portable and mobile RF communications equipment can affect the Avant REM.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Avant REM is intended for use in electromagnetic environment specific below. The customer or the user of the Avant REM should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Avant REM 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 REM 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 REM is intended for use in electromagnetic environment specific below. The customer or the user of the Avant REM 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 REM is intended for use in electromagnetic environment specific below. The customer or the user of the Avant REM 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 REM, 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 REM is used exceeds the applicable RF compliance level above, the Avant REM should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Avant REM.

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 REM			
The Avant REM is intended to use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Avant REM can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Avant REM 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.			

A medical grade computer is recommended, conforming to the requirements of IEC 60950-1 and IEC 60601-1-4.

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.
- Power is supplied by an un-grounded mains power cable to a medical grade power supply and also supplied by the USB cable connected to a computer. The USB computer power must be able to supply at least 400mA at the standard USB voltage.
- A USB Optical Isolator, with a minimum of 1500V AC isolation and 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. All connected equipment provides 2 MOPP per IEC 60601-1.
- This device is to be operated on non-conductive surfaces only.
- The computer used with this device should conform to the requirements of IEC 60601-1.
- A MULTIPLE PORTABLE SOCKET-OUTLET or extension cord shall not be connected to the system.
- The device warm-up time is less than 5 minutes.
- Use only the 15 VDC, 2A medical power supply supplied with your Avant REM, CUI ETMA 150200UD-P5P-IC.
- The power supply cable should always be accessible in order to disconnect it from the supply mains.
- Do not connect items that are not specified as part of the system.
- The use environment should be between 10°C and 35°C 10C 35C, humidity within 30% to 90% 30% 90% and an atmospheric pressure range from 80 kPa to 104 kPa.
- Storage temperature range at least from -20°C to 50°C and humidity level from 10% to 90%.
- 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 probe tubes 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, conforming to the standard color designations for audiology. 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.
- 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.
- 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)

Indicates that the device serial number will follow

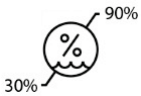
Type B applied part. (Type B equipment)

Manufacturer (MedRx)

Authorized Representative in Europe

Non-ionizing electromagnetic radiation

Special Disposal Required



Humidity Limitation

Caution, General warning sign

Temperature limitation

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

Class II equipment

Start (of action)

Stop (of action)

Percentile Setup

Calibration

Loudspeaker (Speaker)

Headphones

Microphone

Recording

CAUTION
For Single Patient Use Only

Recommended Procedures for Cleaning and Disinfection

1. Probe Tubes 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 probe microphone, black ear loop 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 probe microphone cords and 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 REM is an active, diagnostic Class IIa Medical Device according to the EU medical directive 93/42/EEC.

Standards:
IEC 60601-1 class II, protection class B

REM Speech+ Standards: ANSI S3.46-1997, IEC 61669:2001, EN 61669:2001

Dimensions: Approx. 6.5″ x 5″ x 1.25″ (L x W x H). Approx. 16.5 cm x 12.7 cm x 3.2 cm (L x W x H)

Weight: < 1 lb < 500 g

System Modality: Real Ear Measurement; Binaural Live Speech Mapping; Hearing Loss Simulator; Hearing Instrument Simulator.

Probe Microphones (L/R): Dual Electret Microphone Elements (2 Probe Microphones)

Probe Microphone Tube: Silicone 1.0 mm Nominal Diameter

Measurement Frequency Range: 125 – 8000 Hz

Test Stimuli: Broadband Noise and Synthesized Random Noise – Pink, White, Byrne LTASS and ANSI weighted; ICRA; ISTS; Microphone, File, CD-ROM for Live Speech Mapping , Chirp

Test Stimulus Levels at 1m: 45 – 90 dB SPL in 1 dB Steps – 200 Hz thru 8K Hz (depending on speaker wattage & efficiency)

Test Stimulus Accuracy: ± 3 dB SPL

Analysis Mode: User Selectable 1/3, 1/6, 1/12, 1/24, 1/48 Octave Bands

ANSI S3.46-1997 Test Available IEC/EN 61669:2001: Real Ear Unaided Response, Real Ear Unaided Gain; Real Ear Insertion Gain; Real Ear Occluded Response; Real Ear Occluded Gain; Real Ear Aided Response; Real Ear Aided Gain

Other Test Available: Live Speech Mapping with Peaks and LTASS analysis; Real Ear to Coupler Difference, Occlusion Effect, Percentile Analysis

Prescription Methods: NAL-RP; 1/3 Gain; 1/2 Gain; Berger; Pogo 1; Pogo 2; FIG6; DSL m[I/O] NAL-NL1; NAL-NL2

External Connections: Power Connection USB 2.0 Input 5.0 Volt Bus; Line-Output Jack (Speakers) 3.5 mm Stereo Jack; Speaker Output (Internal Amplifier) (2) 3.81mm Pluggable Spring Clamp; Probe Microphones Inputs (2) 8 Pin Mini-DIN; Operator Headset Jack 3.5 mm Stereo Jack; Patient Headset Jack 3.5 mm Stereo Jack; Power Jack 2.1 mm X 5.5 mm.

Communication: Talk forward and talk back

Data Connection: USB

Mode of Operation: Continuous

Warm up Time: Less than 5 min after USB connection

Weight: Less than 2 lbs.

Power Supply:
100 - 240 V~ 50/60 Hz ±10 %
producing 15 VDC
USB: 5 VDC

Power Consumption:
Less than 500 mA at 15 VDC / less than 500 mA at 5 VDC

Connection Sockets:	***Specification***
• Power/Communication	USB: (5 VDC)
• Power	15 VDC
• Speaker left	ZA= 4Ω, UA= 8 Veff
• Speaker right	ZA= 4 Ω, UA= 8 Veff
• Operator Monitor headphone	ZA= 32Ω , UA= 3 Veff
• Left Probe	ZI= 1 k Ω, UI= 0.38 – 500 mVeff
• Right Probe	ZI= 1 k Ω, UI= 0.38 – 500 mVeff
• Patient (Client) headphone	ZA= 32Ω , UA= 3 Veff
• Line Level Stereo Speaker Output	ZA= 32Ω , UA= 3 Veff

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 100ºF 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.