

Audiometry & Binaural REM/LSM in One System



Contents

EMC Precautions	Getting to Know Your AVANT ARC	3
Probe Mic Hanger Installation7Software Installation9Connecting the Device15Loading Calibration Files18EMC Precautions19Safety22Cleaning23Technical Information24	Computer Requirements	4
Software Installation9Connecting the Device15Loading Calibration Files18EMC Precautions19Safety22Cleaning23Technical Information24	Transducers & Accessories	6
Connecting the Device.15Loading Calibration Files.18EMC Precautions.19Safety .22Cleaning .23Technical Information .24	Probe Mic Hanger Installation	7
Loading Calibration Files.18EMC Precautions.19Safety	Software Installation	9
EMC Precautions	Connecting the Device	15
Safety22Cleaning23Technical Information24	Loading Calibration Files	18
Cleaning	EMC Precautions	19
Technical Information 24	Safety	22
	Cleaning	23
Limited Warranty 27	Technical Information	24
	Limited Warranty	27



TÜV SUD Certificate Body Ridlerstraße 65 ° 80339 Munich ° Germany



www.medrx-usa.com



1200 Starkey Rd., #105, Largo, FL 33771 U.S.A. Toll Free: (888) 392-1234 • (727) 584-9600 Fax: (727) 584-9602 • Email: medrx@medrx-usa.com



MedRx's Authorized Representative in Europe DGS Diagnostic A/S Audiometer Alle 1 ° 5500 Middelfart ° Denmark

Getting to Know Your AVANT ARC

Intended Use Statement:

The MedRx AVANT ARC is an electronic instrument containing an audiometer 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. The device also contains a REM (Real Ear Measurement) function intended to measure sound levels directly in patient 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 MedRx Avant ARC is an audiometer and a REM (Real Ear Measurement) device combined into one system. It is for use by professionals with education and/or training in the field of audiometry to conduct diagnostic hearing evaluations, evaluate basic hearing function, aid in the diagnosis of otologic disorders, as well as to evaluate the fitting of hearing aids and for hearing loss simulation in adults and children.

The software includes targets for DSL v5.0 and NAL-NL2. A unique feature of the Real Ear Measurement System is simultaneous, binaural Live Speech Mapping, MedRx's in-situ method for getting the fitting right the first time, every time. The device performs Real Ear Measurements where measurements are performed directly on the patient's ear. These measurements can be done with or without a hearing instrument being in place. The reason to perform Real Ear Measurements for hearing instrument fittings is that shape and size of an ear canal significantly influence a hearing instrument's performance. Knowing the sound intensity outside and inside the ear enables the practitioner to determine the actual amplification and output that the patient receives through the hearing aid and make the appropriate adjustments.

This unit is a Type 2 AE audiometer that meets the requirements of both ANSI S3.6 and IEC 60645-1 and IEC 60645-2. These standards specify the required precision that the AVANT ARC does achieve. Measurement uncertainty is +/- 1 dB. This device and transducers are intended for use at test frequencies between 125 Hz and 8000 Hz. This unit meets the requirements of both ANSI S3.46-1997 and IEC 61669:2001. These standards specify the required precision that the AVANT ARC the Avant ARC does achieve.

The AVANT ARC is an electronic instrument intended for the testing of human hearing using both tone and speech audiometry. This device meets the specifications and tolerances for audiometers and standard reference threshold levels for audiometric transducers such as supra-aural, circumaural, and insert earphones, bone vibrators, and loudspeakers as defined in ANSI S-3.6 and IEC 60645.

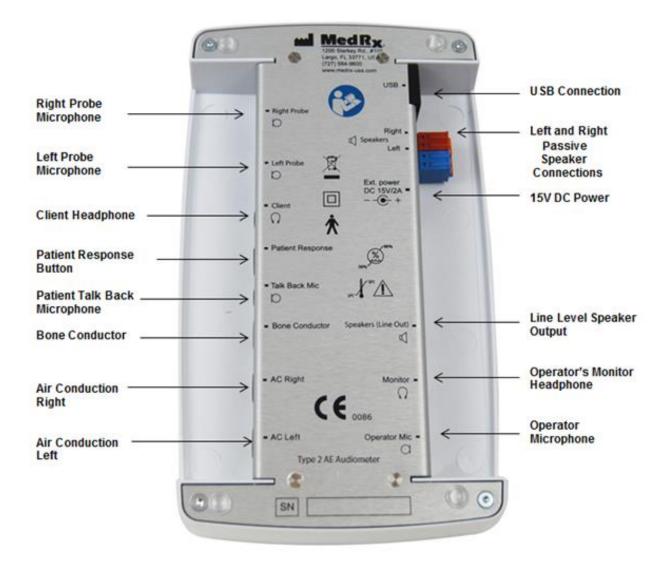
The AVANT ARC conforms to the RoHS directive 2011/65/EU when used with the supplied accessories.

Computer Requirements

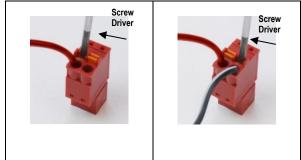
MedRx Minimum Computer Specs:
Windows [®] -PC compatible computer
Intel™ i5 Dual Core, 2.0 GHz or better
4 GB RAM
20 GB free hard drive space
Available 2.0 USB port
Windows 7, 8 or 10 Professional (32 or 64-bit)
MedRx Recommended Computer Specs:
Windows [®] -PC Computer
Intel™ i5 Dual Core, 3.2 GHz or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



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.

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.

Use passive speakers with 4 ohm impedance when using the internal speaker amplifier.

Transducers and Accessories

Use the accessories provided with your Avant ARC. Use of unapproved accessories is not recommended



IP30 Insert Earphones (Standard)



Supra-Aural Headphones Optional



Bone Conductor



Patient Response Switch



Operator Mic & Monitor (may vary)



Probe Microphones



USB Cable



Talkback Microphone



Probe Mic Hanger & Clip



Speaker Optional



Client Headset





3A Insert Earphones (Optional)



Headphones

DC Power Supply

NOTE: The Avant Audiometer supports IP30 Insert earphones,

3A Insert earphones, TDH-39 or DD450 earphones and HDA 300 extended high frequency earphones. The standard configuration includes either IP30 Insert Earphones or TDH-39 or DD450 earphones.

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



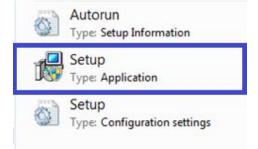
Larger view of clip with wires inserted



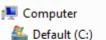
Probe Mic Hanger installation assembly complete.

Software Installation





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



- 🚗 Removable Disk (E:)
- (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.

Installing Audiometer Software



Install Avant Audiometer

Install Avant REM

Instruction Manuals



Exit

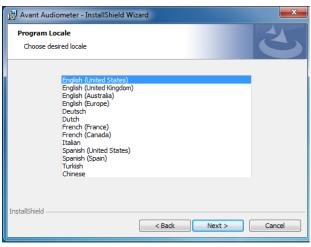
3. On the Setup screen, choose *Install AVANT Audiometer.*

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

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

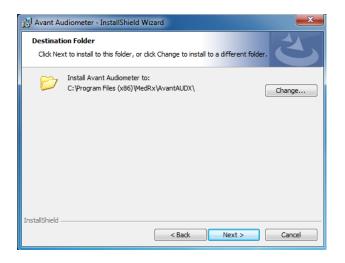






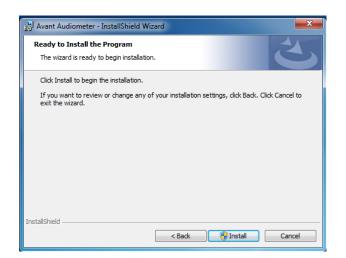
- 4. This is the Welcome screen.
 - To continue, click **Next.**

- 5. Read the Software License Agreement. This important document defines the acceptable usage of the ARC Audiometer software.
 - Select Accept.
 - Click Next.
- 6. This screen sets the language and location choice. Make a selection.
 - 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.**

NOTE: 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. Wait while the InstallShield Wizard Installs the AVANT Audiometer.
 - Click Next.



10. When the installation is complete. Click *Finish.*

Installing REM Software



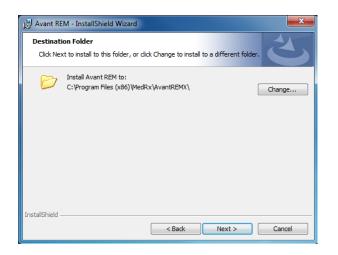


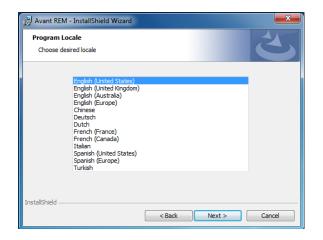
1. On the Setup screen, choose **Install** Avant REM.

- 2. Wait for the program to setup the InstallShield Wizard.
- 3. This is the Welcome screen.
 - To continue, Click Next.



- 4. Read the Software License Agreement. This important document defines the acceptable usage of the Avant REM Software.
 - Click I accept.
 - Click Next.

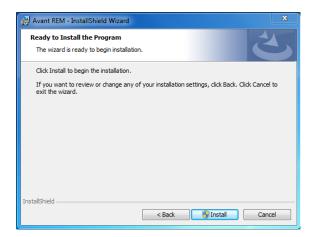




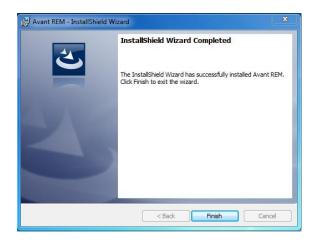
- This screen indicates the location of the program files. The default location is recommended for most users. If necessary, this location can be changed.
 - To continue with the default settings, Click **Next.**

Note: To change the location of the files (advanced users or system administrators only), click **Change.**

- 6. This screen sets the language and location choice. Make selection.
 - Click Next.







- 7. Installation of Program is ready to start.
 - To continue, Click *Install.*
 - To make changes, Click **Back.**

- 8. Wait while the InstallShield Wizard installs the Avant REM program.
 - Click Next.

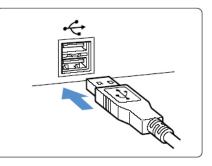
- 9. When the installation is complete,
 - Click Finish.

Connecting Device

Your AVANT ARC is USB powered.

Connect the USB cable from the AVANT ARC to your computer as shown below.



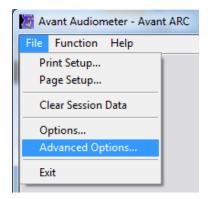


Wait for the system to copy and install <u>default</u> Windows drivers.

Driver Software Installation		×
Your device is ready to use		
USB Composite Device USB Audio Device USB Input Device	Ready to use Ready to use Ready to use	
		Close

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.



- 1. Launch the AVANT Audiometer Software.
- 2. Open the *Advanced Options* from File menu as shown.

Advanced Options
General Audio Video Tympanometry
Output Device: Speakers (5- USB Audio Device)
Input Device: Line (5- USB Audio Device)
Output Mixer: 5- USB Audio Device
Input Mixer: 5- USB Audio Device
Microphone Gain (dB): 6 💌 Set Defaults Audio Properties
OK Cancel Help

💮 Sound	Sound X						
Playback Re	cording	Sounds	Communications				
Select a pla	yback de	vice belo	ow to modify its s	ettings:			
	Speakers 4- USB Audio Device Ready						
3	Speake 5- USB Ready	rs Audio D	evice				
0,	Speaker/HP Realtek High Definition Audio Default Device						
Realtek HD Audio 2nd output Realtek High Definition Audio Not plugged in							
Configure Set Default V Properties							
OK Cancel Apply							

AVANT REM

Avant REM - Avant ARC				
File Function Help				
Clear Session Data				
Print Setup				
Page Setup				
Options				
Advanced Options				
Exit				

3. 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.

- 4. Click Audio Properties.
- In the Windows Sound control panel, make sure the MedRx Audio Device is not set as default. If its the default, change this by clicking on your system audio device (non-MedRx) 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.

- 5. Click *OK*.
- 1. Launch the **REM Software**.
- 2. Open the *Advanced Options* from File menu as shown.

Advanced Options	x
General Audio - A	Audio - B Video Tympanometry
Output Device:	Speakers (3- USB Audio Device) - REM+(A)
Input Device:	Line (3- USB Audio Device) - REM+(A)
Output Mixer:	3- USB Audio Device
Input Mixer:	3- USB Audio Device
Input Line:	<default line=""></default>
	Set Defaults Audio Properties
	OK Cancel Help

Advanced Options
General Audio - A Audio - B Video Tympanometry
Output Device: Speakers (4- USB Audio Device) - REM+(B)
Input Device: Line (4- USB Audio Device) - REM+(B)
Output Mixer: 4- USB Audio Device
Input Mixer: 4- USB Audio Device
Input Line: <a>Cefault Line>
Set Defaults Audio Properties
OK Cancel Help

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.

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. Click **OK.**

Loading Calibration Files



W Avant Audiometer - Avant ARC						
	File	Function Help			_	
		Audiometry HLS/MHA Tympanometry Screening Audiometry				
		Calibrate 🔸		۲	Load Calibration	
					Calibration Information	

Load Calibration							
This will load calibration files for the system.							
Insert the Calibration Disk into drive and click Load.							
Load Cancel							
Avant Audi	ometer			23			
This will load calibration files for the system. E:\AvantAUD.set							
	Continue?						
		Yes	N	。			

Each AVANT ARC audiometer is calibrated in compliance with the ANSI S3.6 standard. This calibration procedure results in a series of files that the AVANT ARC software reads to keep the hardware in calibration. These files are supplied on a USB Flash Drive the same serial number as your AVANT ARC device.

The final step before using your AVANT ARC to evaluate hearing is to load these device specific calibration files onto the computer used to operate the AVANT ARC device.

- 1. With the MedRx USB Flash Drive connected, open the AVANT ARC 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 ARC 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	3,0 meters
Insert Earphones	2,0 meters
Bone B-71	2,0 meters
All Headsets	2,0 meters
All Microphones	2,0 meters
REM Probe	2,0 meters
All Speakers	3,0 meters



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

Guidance and manufacturer's declaration – electromagnetic emissions					
The Avant ARC is intended for use in electromagnetic environment specific below. The customer or the user of the Avant ARC should assure that it is used in such an environment.					
Emission test	Compliance	Electromagnetic environment - guidance			
RF emissions CISPR 11	Group 1	The Avant ARC 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 ARC is suitable for use in all establishments, including domestic establishments			
Harmonic emissions IEC 61000-3-2	Non applicable	 and those directly connected to the public low - voltage power supply network that supplies buildings used for domestic purposes. 			
Voltage fluctuations / flicker emissions IEC 61000-3-3	Non applicable				

Guidance and manufacturer's declaration – electromagnetic immunity					
The Avant ARC is intended for use in electromagnetic environment specific below. The customer or the user of the Avant ARC should assure that it is used in such an environment.					
Immunity test IEC 60601 test level Compliance level Electromagnetic environmen 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 at least 30%.		
Electrical fast transient / burst IEC 61000-4-4	+/- 2 kV for power supply lines	+/- 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.		

	+/- 1 kV for input / output lines	+/- 1 kV for input / output lines	
Power frequency (50/60 Hz) Magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical
IEC 61000-4-8			commercial or hospital environment.

	nded for use in electromagne at it is used in such an enviror		ow. The customer or the user of the Avant
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 ARC, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF			
IEC 61000-4-6	3 V _{eff}	3 V _{eff}	d = 1,17 $\times \sqrt{P}$
Radiated RF			
IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	d = 1,17 $ imes \sqrt{P}$ 80 to 800 MHz
			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 ^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 freq	Liency ranges applies	
	, 6 1	, , , ,	opagation is affected by absorption and
-	rom structures, objects and pe		· · ·
radios, amateur r To assess the ele considered. If the compliance level	adio, AM and FM radio broad ectromagnetic environment du measured field strength in th above, the Avant ARC should	cast and TV broadcast can te to fixed RF transmitters, e location in which the Ava I be observed to verify norm	Ilular/cordless) telephones and land mobile not be predicted theoretically with accuracy. an electromagnetic site survey should be nt ARC is used exceeds the applicable RF nal operation. If abnormal performance is relocating the Avant ARC.

Recommended separation distances between

Portable and mobile RF communications equipment and the Avant ARC

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

Rated maximum output power of	Separation distance according to frequency of transmitter meters			
transmitter W	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

90%

%



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 500mA at the standard USB voltage.
- Power is supplied by the USB cable connected to a computer.
- 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 ARC, CUI ETMA150200UD-P5P-IC.

- 350

- 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}, humidity within 30% to 90% ^{30%} and an atmospheric pressure range from 80 kPa to 104 kPa.
- Storage temperature range -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 and new foam inserts are needed for each patient where applicable. 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.
- There are no known contraindications for the use of this equipment.
- 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.
- Refer to the Training manual and Help files for test options and descriptions.

Symbols that may be used:





Indicates that the device

serial number will follow

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



Special Disposal Required



Class II equipment





Loudspeaker (Speaker)



Headphones



Microphone

Manufacturer

(MedRx)

Caution, General

warning sign

Stop (of action)



Recordina

Calibration

CAUTION For Single Patient Use Only

Cleaning - Recommended Procedures for Cleaning & Disinfection

- 1. Foam ear tips and probe tubes are single use components and should not be re-used on another patient.
- It is recommended that 70% Isopropyl Alcohol should be applied to a soft clean cloth or tissue, not directly 2. on the component to be cleaned. The cloth should never be wet, just damp. A mild soapy water solution is an alternative cleaning liquid.
- 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. 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.
- 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 wav.
- 7. 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.
- 8. Let all components that have been cleaned, thoroughly dry before use.
- 9. Cleaning of the computer should be performed using the methods suggested in the computer's manual.



Non-ionizing

electromagnetic radiation

Read the instruction

manuals for safe usage of the device (operating instructions)



Type B applied part. (Type B



equipment)





Start (of action)





Authorized Representative in Europe

Temperature

limitation

Percentile Setup

100

35C

Technical Information

The Avant ARC Audiometer/REM Combination 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 IEC 60645-1 -2 ANSI S3.6-2010 : Type 2 AE Medical Device Directive 93/42/EEC

Test-Frequencies: 125 Hz – 8000 Hz

Level step: 5 dB or 1 dB level steps

Maximum Sound Pressure Level:

AC with earphone: - 10 dBHL to 120 dBHL BC with bone conduction with B 71: - 10 dBHL to 80 dBHL

Sound field speaker: - 10 dBHL ... 90 dBHL

Test Signal: Pure tone, pulse tone, warble tone

Masking Signals: Narrow band noise: 5/12 Octave filter with the same center frequency resolution as pure Tone White noise:

Speech Noise: falling 12 dB/octave above 1 kHz (+/-5 dB)

Masking Signals: Tone Audiometry: Narrow Band Noise (Default), Speech Weighted Noise, White Noise. Speech Audiometry: Speech Weighted Noise (Default), White Noise, External Recorded (Opposite Channel).

Speech Signals: External input is through the computer (CD, memory card, Wave file) Operator Microphone

Modulation:

Pulse tone: 0.25/0.5 s on time Warble tone: 5% sinus frequency modulation, repetition rate 5 Hz

Patient Response: Handheld response switch

Monitor: Build in monitor speaker, headset

Communication: Talk forward and talk back

Data Connection: USB

Mode of Operation: Continuous

Warm up Time: Less than 5 min after USB connection

Dimensions: W x D x H: Approx. 7.75" x 5" x 1.25" (+/- 0.125")

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
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
Left Probe microphone (X2)	ZI= 1 k Ω, UI= 0.38 – 500 mVeff
Right Probe microphone (X2)	ZI= 1 k Ω, UI= 0.38 – 500 mVeff
Bone (bone conductor)	ZA= 10Ω, UA= 8 Veff
AC phone left	ZA=10 Ω, UA=1 Veff
AC phone right	ZA=10 Ω, UA=1 Veff
Patient (Client) headphone	ZA= 32Ω , UA= 3 Veff
Line Level Stereo Speaker Output	ZA= 32Ω , UA= 3 Veff

Calibration values and Max Levels:	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	Headphone TDH39 NBS-9A acoustic coupler Force 4-5 N, ANSI and IEC RETSPL dB re 20µPa
	125=45.0
125=47.5	250=25.5
250=27.0	500=11.5
500=13.0	750=8.0
750=6.5	1000=7.0
1000=6.0	1500=6.5
1500=8.0	2000=9.0
2000=8.0	3000=10.0
3000=8.0	4000=9.5
4000=9.0	6000=15.5
6000=20.5	8000=13.0
8000=12.0	9000=13.0
Speech=18.5	10000=13.0
	11200=13.0
	12500=13.0
	Speech=19.5
	opeedi-18.0

Calibration values:		Calibration	Calibration values:	
Insert phone Eartone 3A HA-2 acoustic coupler RETSPL dB re 20µPa		HA-2 acoustic	Insert phone IP30 HA-2 acoustic coupler RETSPL dB re 20µPa	
S	ound Attenuation	So	und Attenuation	
125=26.0	32.5	125=26.0	32.5	
250=14.0	36	250=14.0	36	
500=5.5	37.5	500=5.5	37.5	
750=20	-	750=2.0	-	
1000=0	36.5	1000=0	36.5	
1500=2.0	-	1500=2.0	-	
2000=3.0	33	2000=3.0	33	
3000=3.5	-	3000=3.5	-	
4000=5.5	39.5	4000=5.5	39.5	
6000=2.0	-	6000=2.0	-	
8000=0	42.5	8000=0	42.5	
Speech=12.5		Speech=12.5		
-				

Calibration values:		Calibration values:	
Bone conductor Radioear B71 Force Mastoid placement – RETFL dB re1 N 125=82.5 250=67.0 500=58.0 750=48.5 1000=42.5 1500=36.5 2000=31.0 3000=30.0 4000=35.5 - 6000=40.0 8000=40.0 Speech=55.0	ANSI S3.13 coupler Air Radiation mean /maximum - - - - - 4/18 10.5/31 -	Sound field (0 degree incidence) Reference equivalent threshold sound pressure level RETSPL dB 125=22.1 250=11.4 500=4.4 750=2.4 1000=2.4 1500=2.4 2000=-1.3 3000=-5.8 4000=-5.4 6000=4.3 8000=12.6 Speech=14.5	

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.

Check that audiometer output is approximately correct on both air and bone conduction by sweeping through at a hearing level of, for example, 10 dB or 15 dB and listening for "just audible" tones. This test shall be performed at all appropriate frequencies and for both earphones as well as the bone vibrator.

Check at high level (e.g. hearing levels of 60 dB on air conduction and 40 dB on bone conduction) on all appropriate functions (and on both earphones) at all frequencies used; listen for proper functioning, absence of distortion, freedom from interrupter clicks, etc.

Listen at low levels for any sign of noise or hum, for unwanted sounds (break-through arising when a signal is introduced in another channel) or for any change in tone quality as masking is introduced. Keep a record the results.

Congratulations

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

Limited Warranty

MedRx, Inc warrants this product to be free from defects in material and workmanship for one year from the time of purchase. If this system fails to perform as specified during this period, the purchaser is responsible for calling MedRx at (888) 392-1234 or (727) 584-9600. The company's representative will advise the owner to either return specific components or the entire system to:

MedRx, Inc.

1200 Starkey Road #105

Largo, FL 33771 USA

MedRx will repair or replace any defective devices, fully test the system and/or components and ship the system promptly back to the owner. There is no cost for the repair or return shipping, provided the system is one year old or less and has not been misused, abused or damaged. Such damage includes, but is not limited to, dropping, exposure to excessive heat greater than 100°F and water/liquid damage.

Repair or replacement of the system as provided under this warranty is the sole and exclusive remedy of the purchaser. MedRx shall not be liable for any consequential or incidental damages or for breach of any express or implied warranty. Except to the extent of applicable law, any implied warranty, merchantability or fitness of this product is limited to the duration of this warranty.

MedRx will, at its discretion, service and repair out of warranty products at the purchaser's request, charging for parts and labor as necessary.

The limited warranty is deemed void if software or hardware is installed on this product which is not pre-approved by MedRx, Inc. Approved software includes NOAH[™] and HIMSA approved hearing aid manufacturer programming modules for fitting hearing aids.

MedRx, Inc is not responsible for problems resulting from installation of unapproved software or hardware. In the event of unapproved software or hardware installed on the system causing a conflict, MedRx will service the product for a fee to be determined at the time of service.

Any extension of this warranty past the initial one-year warranty is subject to the following (where applicable).

- 1. A \$300 deductible per repair.
- 2. Extended warranty does not include cables, connectors or peripherals.
- 3. Extended warranty of the Video Otoscope covers optics only.