INSTALLATION MANUAL

AVANT™
A²D⁺ Audiometer

MedRx.

Contents

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#0086

MedRx®

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Getting to Know Your AVANT A2D+ Audiometer

The AVANT A2D+ represents a new era of ultra compact diagnostic 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 A2D+ system.

Unit Powered On – No Ear Selected   Rear View

A unique feature of the AVANT A2D+ Audiometer is the light panel which indicates which ear is selected in the software. When the unit is powered up and no ear is selected, the light shines green as shown above. During testing, the light shines blue when the left ear is selected and red when the right is selected as shown below.

Left Side View   Right Side View

Left Ear Selected   Right Ear Selected
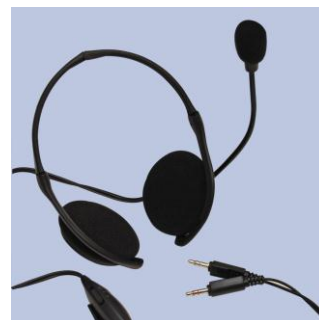
Transducers and Accessories

Insert Earphones

Headset Optional

Bone Conductor

Talkback Microphone

Patient Response Switch

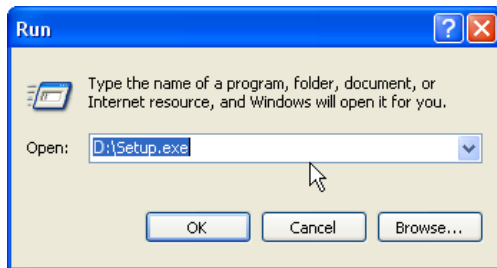**Operator Mic and Monitor (may vary)**

Use the accessories provided with your Avant A2D+. Use of un-approved accessories is not recommended.
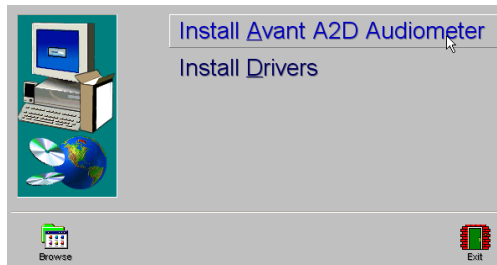

**USB Cable**

Software Installation

Do Not Plug in the AVANT A2D+ USB Cable yet!

1. Insert the AVANT A2D+ CD-ROM into the CD drive. Wait until the Setup program starts.
   - If the Setup program does not automatically start:
     - Press the "**Win – R"** keys on the keyboard**.**
     - Type **D:\Setup.exe** in the window where 'D' is the drive letter assigned to the CD ROM drive on your computer.
     - Press **OK** to start the Setup.

2. On the Setup screen, choose **Install AVANT A2D Audiometer**.
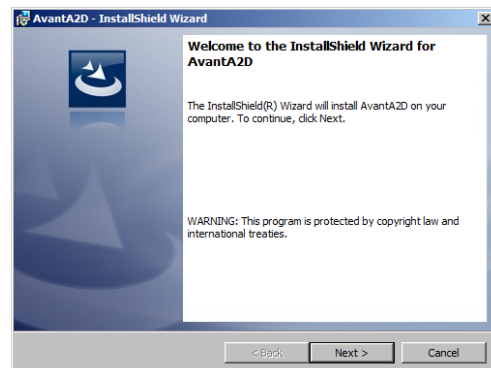
3. This is the Welcome screen.
   - To continue, Click **Next.**

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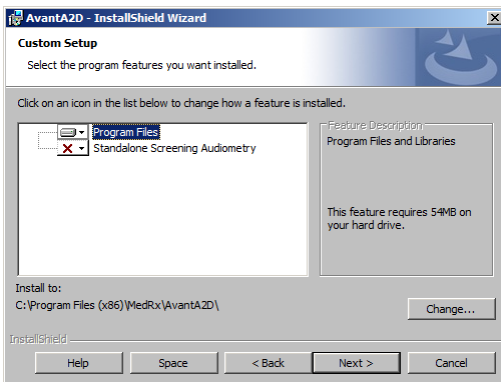Effective Date: 04-07-2014
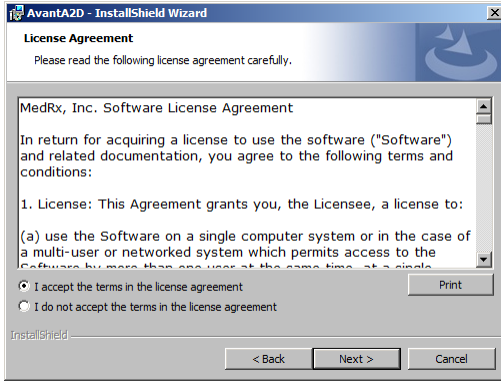
4. Read the Software License Agreement. This important document defines the acceptable usage of the A2D+ Audiometer software.

- After reading the Agreement,
- select "I accept …"
- click **Next.**
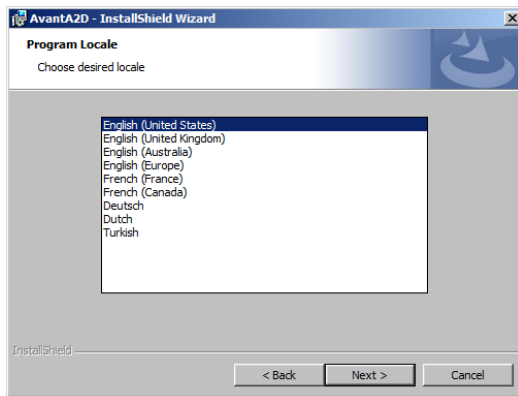
5. This screen sets the language and location choice. Make a selection and click **Next.**

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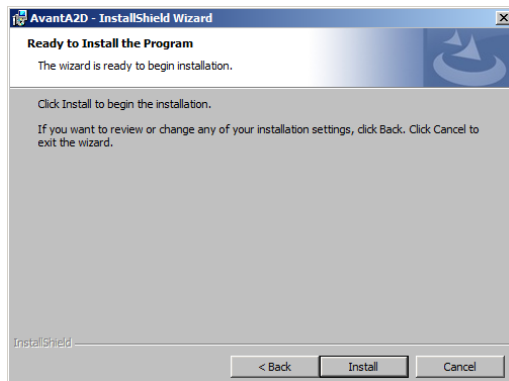
7. Installation of Program is ready to start.
   - To continue, click **Install.**
   - To make changes, click **Back.**

6
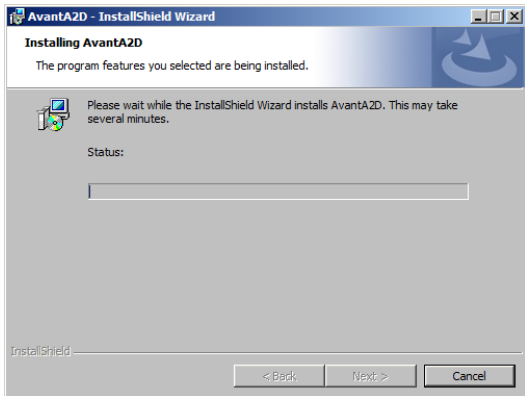
8. Installation is in process.
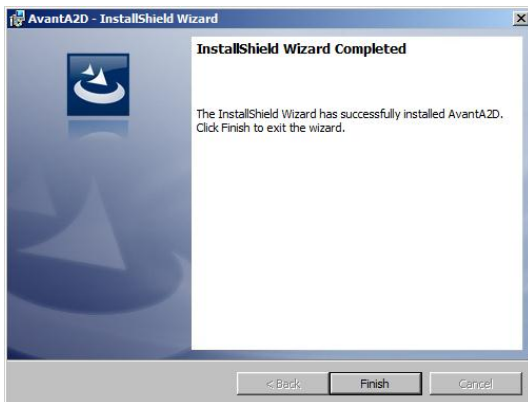
9. When the installation is complete, click **Finish.**

Driver Installation - <u>Windows 7</u>
(see page 9 for Windows XP Driver Installation)

Your AVANT A2D+ is USB powered.

1. **Connect the USB cable from the AVANT A2D+ ™ to your computer as shown on page 9.**

2. **Wait for the system to copy and install <u>default</u> drivers. During this process, you will see the following screen.**
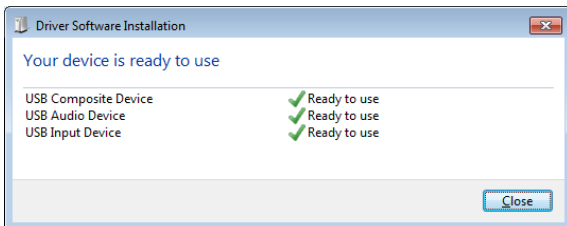
3. When this screen appears and all devices are "Ready to use", click **Close.**

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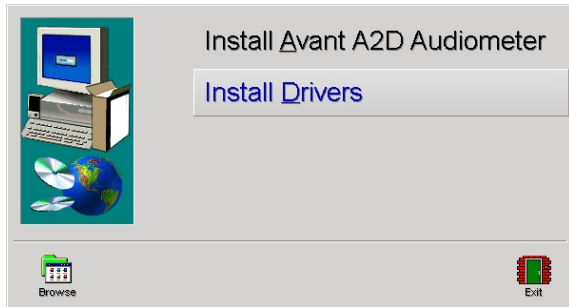
4. On the Avant A2D Setup screen, click **Install Drivers.**
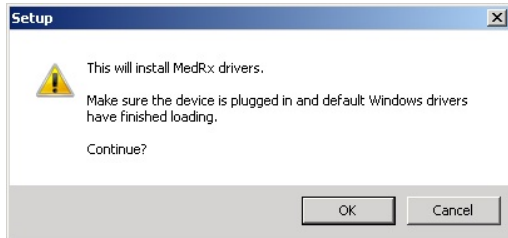
5. When this screen appears, click **Ok.**
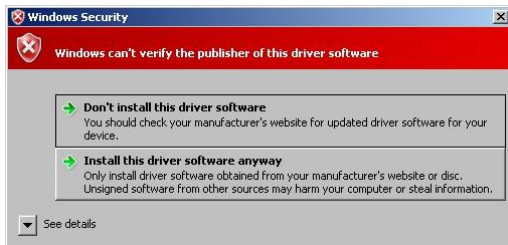
6. If a warning screen appears, click **Install this driver software anyway.**
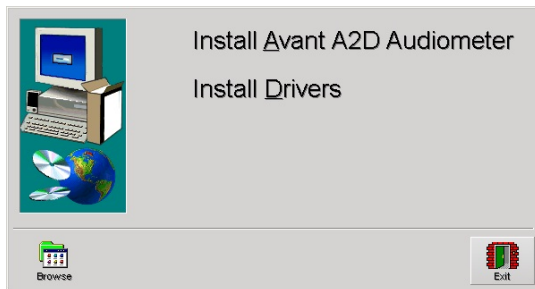
7. On Setup Window click **Exit.**

Next you need to confirm or set the Default Windows sound card settings. This will route all non-AVANT^{TM} 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.
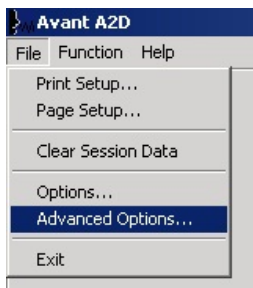
1. Launch the **AVANT A2D** software.

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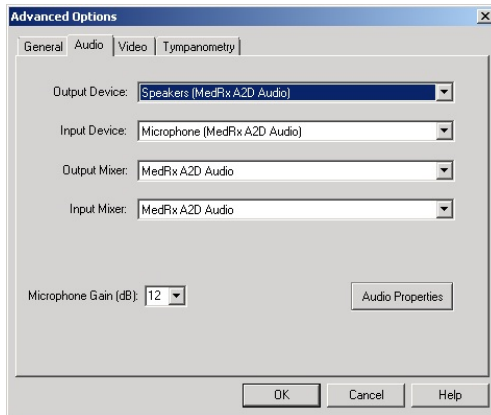
3. Open **Audio tab**.

4. When the audio properties are configured properly, during driver installation, the Audio Tab will appear like the image on the left. If not, use the pull-down lists to adjust the settings to match the image.

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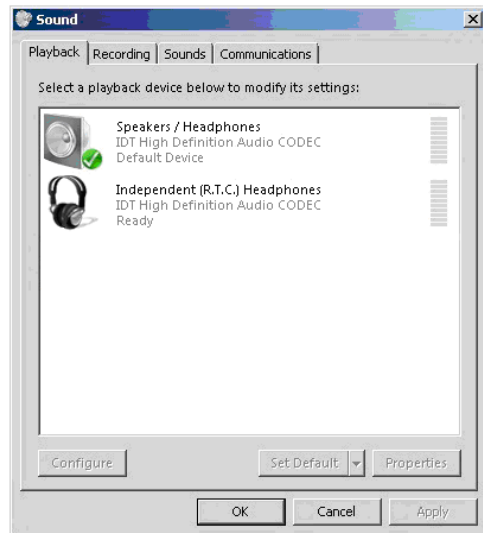
6. In Windows Sound control panel, make sure the MedRx Audio Device is not set as default. If it is default, change this by clicking on your system (non-MedRx) audio device and then choose **Set Default**.

   NOTE: The internal sound card on your computer will likely <u>not</u> have the same name as this screen shot. Consult your computer's documentation for the name of the internal sound card and set this control accordingly.

7. Click **OK**.

Driver Installation – Windows XP

Connect the USB cable from the AVANT A2D+ to your computer as shown below.
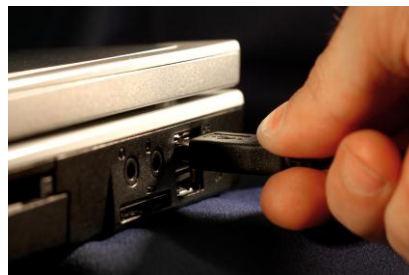
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Wait for the system to copy and install default drivers. During this process, you will see the following prompts in your system tray (lower right corner of the screen).
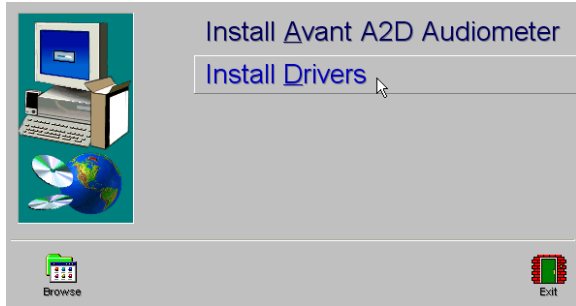
1. After the Windows hardware has been installed, click **Install Drivers.**
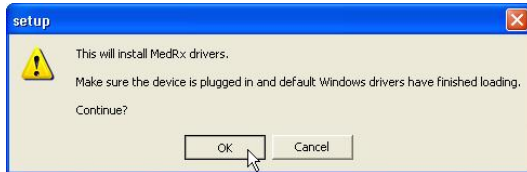
2. When this screen appears, click **OK.**

3. When the driver signature check screen appears, click **Continue Anyway.**

4. When this window appears,
   - Select "No, not at this time".
   - Click **Next.**

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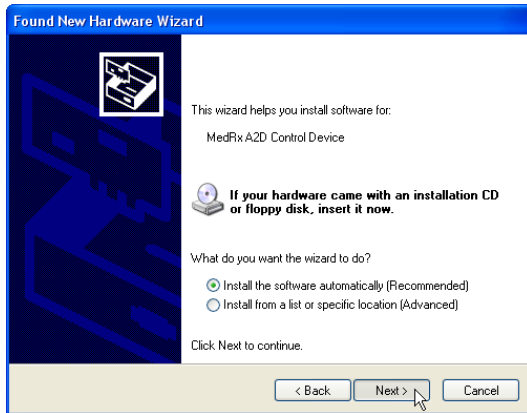
5. When this screen appears,
- Select "Install the software automatically (recommended)".
- Click **Next.**
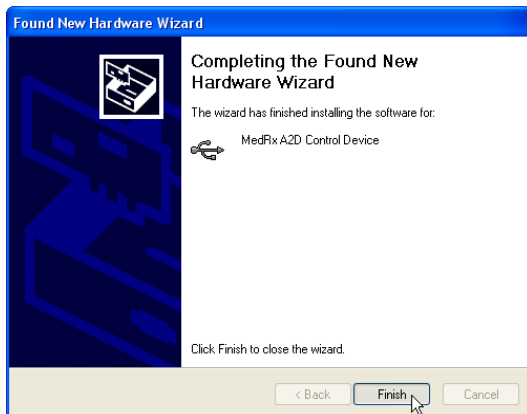
6. When the driver installation is complete, this screen will appear.
- Click **Finish.**

7. **Exit the Setup screen** when the driver installation is finished.

Continue with: Page 12
"Loading Calibration Files"

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Loading Calibration Files
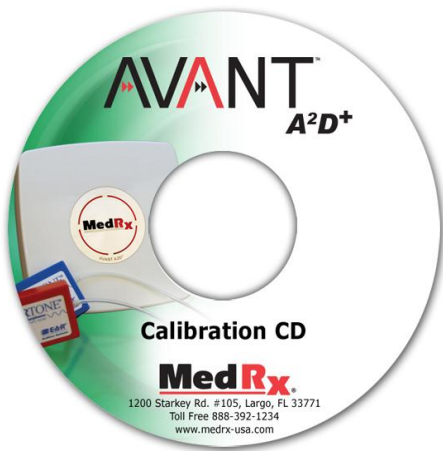
Each AVANT A2D+ audiometer is calibrated in compliance with the ANSI S3.6 standard. This calibration procedure results in a series of files that the A2D+ software reads to keep the hardware in calibration. These files are supplied on a CD bearing the same serial number as your A2D+ device.

The final step before using your AVANT A2D+ to evaluate hearing is to load these device-specific calibration files onto the computer used to operate the A2D+ device.
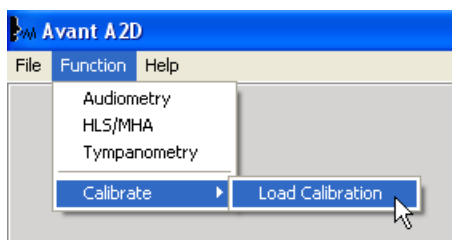
1. With the Calibration CD in the drive, open the AVANT A2D software and click:
   - **Function.**
   - **Calibrate.**
   - **Load Calibration.**
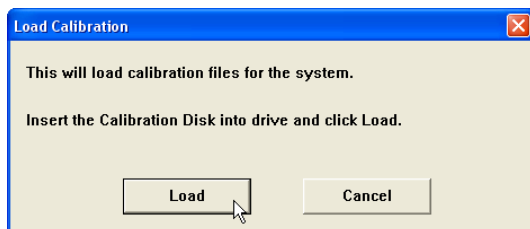
2. After a few seconds, the CD will "spin up" and this message will appear.

   - Click **Load.**
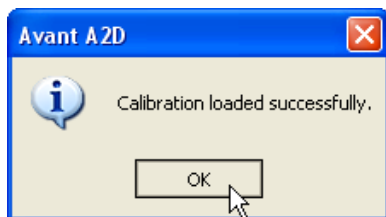
3. When the files are finished being loaded, this message will appear:

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

EMC Precautions

The Avant A2D+ 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	2,9 meters
Insert Earphones	2,9 meters
All Headsets	2,9 meters
All Speakers	2,9 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 A2D+ as replacement parts for internal components, may result in increased emissions or decreased immunity of the Avant A2D+.
- The Avant A2D+ should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the Avant A2D+ should be observed to verify normal operation in the configuration in which it will be used.
- The Avant A2D+ may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.
- The Avant A2D+ does not have life supporting function
- Portable and mobile RF communications equipment can affect the Avant A2D+.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Avant A2D+ is intended for use in electromagnetic environment specific below. The customer or the user of the Avant A2D+ should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Avant A2D+ 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 A2D+ is suitable for use in all establishments, including domestic establishments and those directly connected to the public low - voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions 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 A2D+ is intended for use in electromagnetic environment specific below. The customer or the user of the Avant A2D+ should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input / output lines	+/- 2 kV for power supply lines +/- 1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity

The Avant A2D+ is intended for use in electromagnetic environment specific below. The customer or the user of the Avant A2D+ 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 A2D+, 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	$d = 1{,}17 \times \sqrt{P}$ 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 A2D+ is used exceeds the applicable RF compliance level above, the Avant A2D+ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Avant A2D+. |
| 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 A2D+

The Avant A2D+ is intended to use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Avant A2D+ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Avant A2D+ 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.
- 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.

 Type B applied part. (Type B equipment)

 Manufacturer (MedRx)

  Authorized Representative in Europe

 Non-ionizing electromagnetic radiation

 Special Disposal Required.
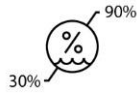
Humidity Limitation

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

Handheld microphone (Talkback Microphone)

Recording

Microphone

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.

Congratulations

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

Limited Warranty

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

MedRx, Inc.

1200 Starkey Road #105

Largo, FL 33771 USA

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