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STUDIO

Software

AVANT AUDIOMETERS
AIR, BONE, SPEECH &
MASKING AUDIOMETRY

MedRx

Studio Software Audiometer Training Manual





0123

TÜV SÜD Product Services GmbH
Ridlerstraße 65 • 80339 Munich • Germany

MedRx

www.medrx-int.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
www.medrx-usa.com

EC REP

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

Distributor: MedRx International
c/o MAICO Diagnostics GmbH
Sickingenstr. 70-71, 10553 Berlin, Germany
Tel.: +49 30/70 71 46-50
Fax: +49 30/70 71 46-99
E-mail: medrx-sales@maico.biz
Web: www.medrx-int.com

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Getting to Know Your AVANT Audiometer

Intended Use Statement:

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

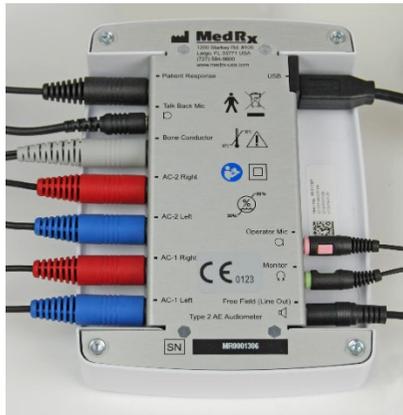
Indication For Use Statement:

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

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

This manual assumes that the system hardware, software and drivers are installed and working properly. Please refer to the Studio Software Installation Manual for assistance. The Installation Manual is included in the original AVANT Audiometer packaging in PDF format.

The scope of this manual is to get you “up and running” with your AVANT Audiometer System. Please consult the interactive Help System within the software for more detailed information of features and functionality. To access this tool, press the F1 key at any time, or click the Help icon or text menu with your mouse. Access these by clicking on the “?” icon at the top of the screen. Select an item from the list in the Contents tab.



Avant A2D+ Audiometer

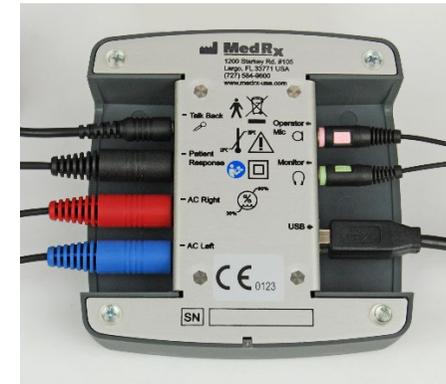
AVANT™ A2D+ is truly plug and play. The new design also provides dual air conduction ports, allowing two separate transducers to be plugged in simultaneously. No more inconvenient plugging and unplugging of transducers.



Avant Stealth Audiometer

AVANT Stealth+ has two sets of air conduction transducer connections and two Operator Microphone connections. High frequency transducers, such as DD450, can be plugged into either AC 1 or AC 2 output.

Either amplified or non-amplified speakers can be used. Amplified speakers are connected to the Free Field (Line Out) output. Non-amplified speakers are connected to the Free Field Loudspeaker outputs.



Avant AIR+/Tinnometer

The MedRx Tinnometer represents a new era of ultra-compact screening audiometry for your office. Compact yet rugged, this PC-Based system is USB powered and supports current ANSI and IEC audiometric tests. This manual assumes that the system hardware, software and drivers are installed and working properly.

Transducers and Accessories

Make sure that the correct transducers are set in the software by right clicking any transducer button on the audiometry screen and left-clicking to change the transducer. Use the accessories provided with your Audiometer. Use of unapproved accessories is not recommended.



IP30 Insert Earphones



Talkback Microphone



Patient Response Switch



USB Cable



DD450 High Frequency Earphones*



Free Field Speakers



Supra-Aural Headphones



Bone Conductor



Operator Mic & Monitor (may vary)



3A Inserts (Optional)



Stealth Power Supply



Amplifier (Optional for extra cost)

NOTE: The Avant Audiometer supports IP30 Insert earphones, 3A Insert earphones, TDH-39, DD450, DD45 and HDA 300 extended high frequency earphones. The standard configuration includes either IP30 Insert Earphones or DD45 or DD450 earphones.

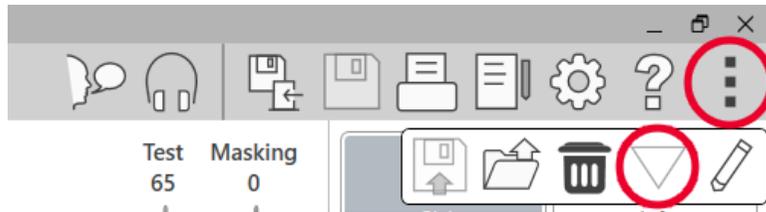
* DD450 earphones must be ordered with the Stealth High Frequency Option Upgrade.

Loading Calibration Files



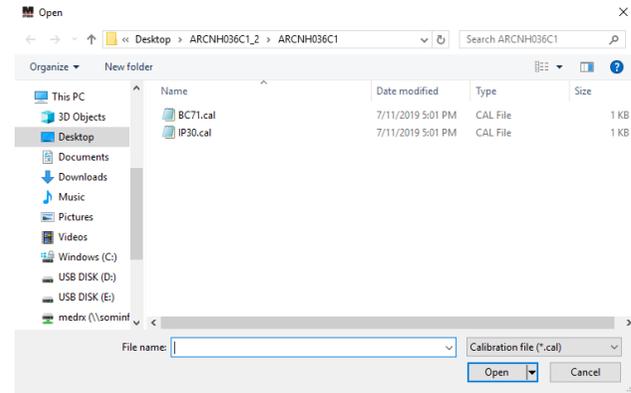
Each AVANT Audiometer is calibrated in compliance with the ANSI S3.6 standard. This calibration procedure results in a series of files that the Audiometer software reads to keep the hardware in calibration. These files are supplied on a USB Stick.

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

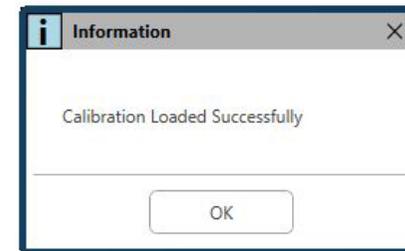


1. With the MedRx USB Flash Drive connected, open the MedRx Studio software, enter the module you will be loading calibration files into and click:
 - More Icon (three vertical dots).
 - Triangle Icon.

- Load Calibration (in pop-up).



2. After a few seconds, a navigation box will appear. Navigate to the files you would like to load.
 - Click Load (choose *.set or *.cal files).



3. When the files are finished being loaded, this message will appear:
 - Click **OK** to complete loading the calibration.

AUDIOMETER MODULE

Studio Software Overview

The MedRx Studio software can run stand-alone or from NOAH™ System or the TIMS® NOAH-Compatible Office System.

Launching the MedRx Studio Software



Stand Alone

- Double click the MedRx Studio shortcut on your Windows Desktop.



NOAH

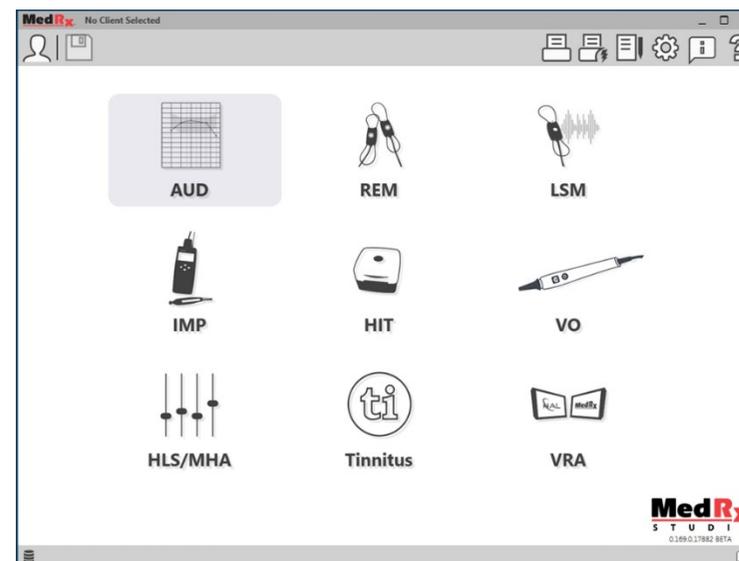
- Launch NOAH.
- Select a patient
- Launch MedRx Studio module following NOAH procedures.

Basic Software Options

Several options are available which allow the user to customize the MedRx Studio Software to meet their needs.

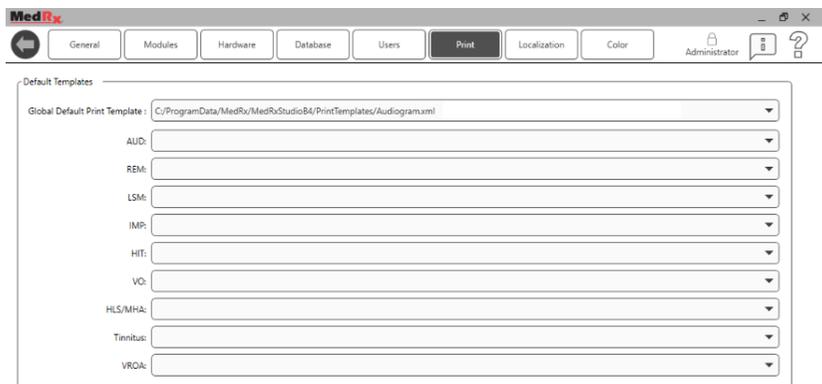


Access these options by clicking the settings wheel in the top right menu bar.

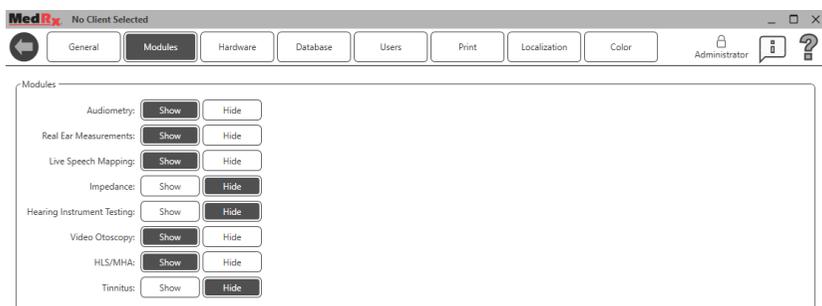


The MedRx Studio software main screen.

Icons are selectable depending on your equipment.



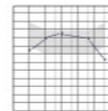
The Main Screen settings allows you to set the default modules, database, print templates and more.



If you have more than one MedRx product you can show/hide modules in the Main Screen settings.

NOTE: Remember, more information is always available in the Interactive Help System by clicking the “?” icon in the top right corner of the software or pressing the F1 key.

Audiometry

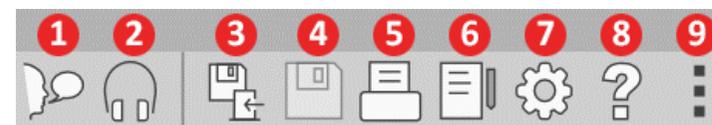


Select AUD from the main menu.

AUD

Top Tool Bar

The **Tool Bar** icons have the following functions:



1. Start Talk Forward
2. Show Monitor
3. Save Session and Exit
4. Save Session
5. Print
6. Show Journal
7. Show Settings
8. Show Help
9. More Options

The **More Options** icons have the following functions:



1. Save the Current Session to a File
2. Open session from a file
3. Clear Data from Current Test
4. Open Calibration
5. Data Editor

Configuring the AUD Software

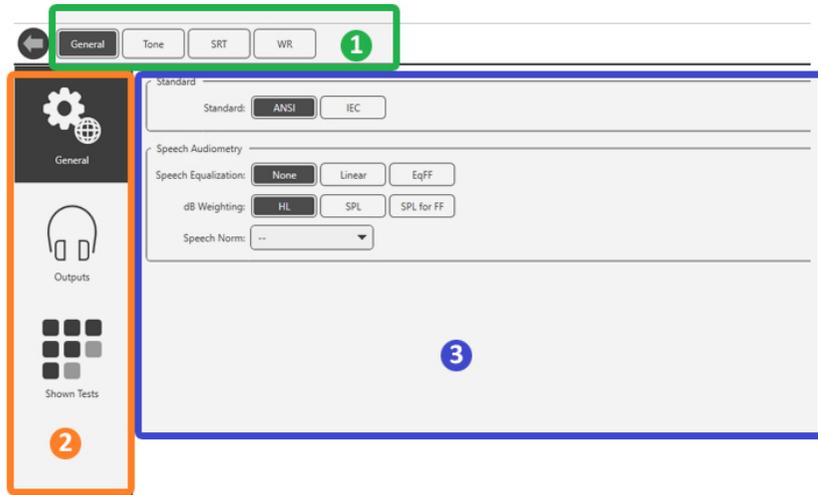


AUD

It is important to note that each module will have different settings available for customization.



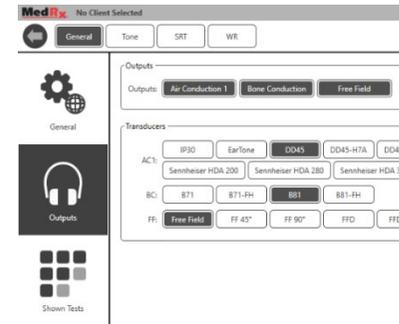
Enter the module and click the settings wheel to customize.



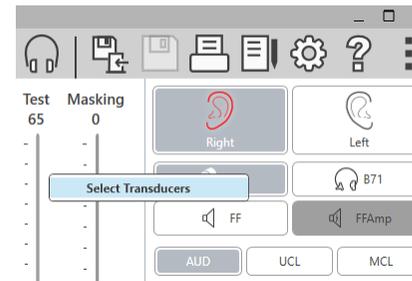
The Audiometry module has unique settings for the module. To navigate the settings you will:

- Select the group of settings from the header (1).
- Then choose the setting options from the left sidebar (2).
- The customization options will change based on the group and settings chosen in the main body (3).

Assign Transducers



Option 1: On the General Options screen click Outputs to assign specific transducers to the audiometer outputs.



Option 2: You can change transducers by Right-Clicking on any transducer icon on the Audiometry screen.



The main body of the settings will have options for outputs shown and default transducer by output.

Select the appropriate transducer for each output.

To add or remove outputs, click the desired outputs to enable or disable transducer buttons on the audiometry screen.

Preparing for Testing

Use the accessories provided with your Avant Audiometer. Typical acceptable transducers are shown on page 6. Operator headsets for use with the Avant Audiometer should have 32 ohms impedance and the speaker power should be at least 50 watts. Air conduction transducers for use with this device should have an impedance of 10 ohms. The speaker voltage should match the local mains voltage where the device is used.

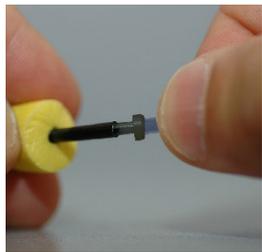
The Operator Headset with microphone is used by the device operator to communicate with the patient.

The patient talks to the operator using the Talk-Back microphone. 

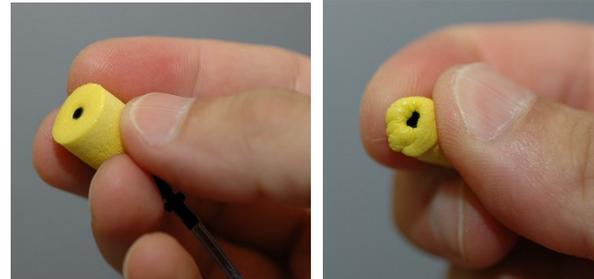
Placing the Earphones on the Patient

Insert Earphones

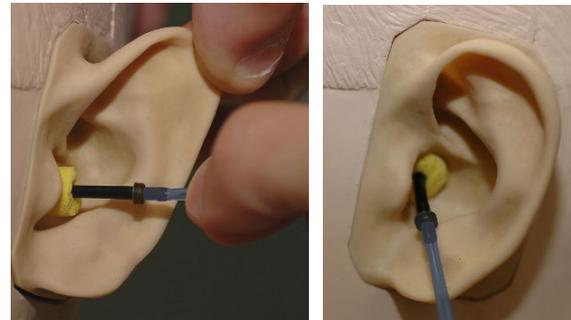
IMPORTANT: The foam tips used for the insert earphones are for SINGLE PATIENT USE ONLY. Do not attempt to wash and re-use them.



1. Place a new set of foam tips on the earphone tubes as shown. These tips are designed for single patient use and should not be washed and reused. **NOTE:** When removing foam tips after use, be sure the clear or black plastic tubing nipple remains attached to the long earphone tube.



2. Carefully compress the tip between your fingers to allow it to fit into the patient's ear canal as shown. Do not roll the tip between your fingers.



3. Pull up and back on the patient's pinna to straighten the ear canal.
4. Place the compressed foam tip deep within the ear canal.
5. When properly placed, the outer surface of the insert tip will be flush with the opening of the ear canal as shown.

Supra-Aural Headphones



1. Place the headphones on the patient's head so the center of the headphone is directly over the opening of the ear canal.
2. Adjust the headband so the headphones remain in place, but be careful not to make it so tight as to cause patient discomfort.

High Frequency Earphones - Stealth & Tinnometer



NOTE: The DD450 Earphones comes standard with the Tinnometer and are part of an upgrade option for the AVANT Stealth Audiometer. If you need to test frequencies beyond 8000 Hz, you must notify MedRx. This option carries a price differential which will be detailed at the time of order.

1. Place the earphones on the patient's head so the center of the earphone is directly over the opening of the ear canal.

Adjust the headband so the earphones remain in place, but be careful not to make it so tight as to cause patient discomfort.

Placing the Bone Conductor

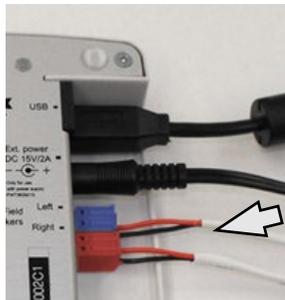


1. Locate the mastoid process behind the pinna. This is the bony shelf just behind where the ear meets the head.
2. Carefully place the bone conductor on the mastoid process and hold it in place.
3. Place the headband over the head to the opposite temple.
4. Carefully and slowly loosen your grip to check if the bone vibrator and headband will stay in place.
5. If either moves, reposition until both the headband and bone vibrator are secure.

Sound Field Testing

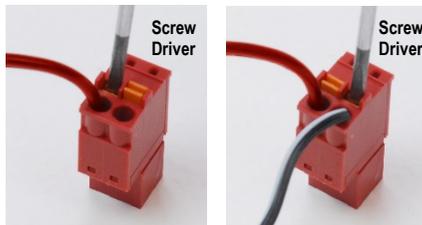
The Sound Field speakers (Free Field) should be connected using optional or user supplied amplifier and speakers. They should be calibrated annually as per ISO 8253-2, located at least 1 meter from the patient ear and at the same height.

To Install Free Field Speaker Wires:



⚠ Notice! The Red & Blue adapters are included and must be removed to attach 18 gage (1.0mm) Free Field speaker wires and then reinstalled.

Unplug both the Red & Blue connectors on the Stealth audiometer.



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.

DC Power supply must be used when using passive Free Field speakers or performing High Frequency.

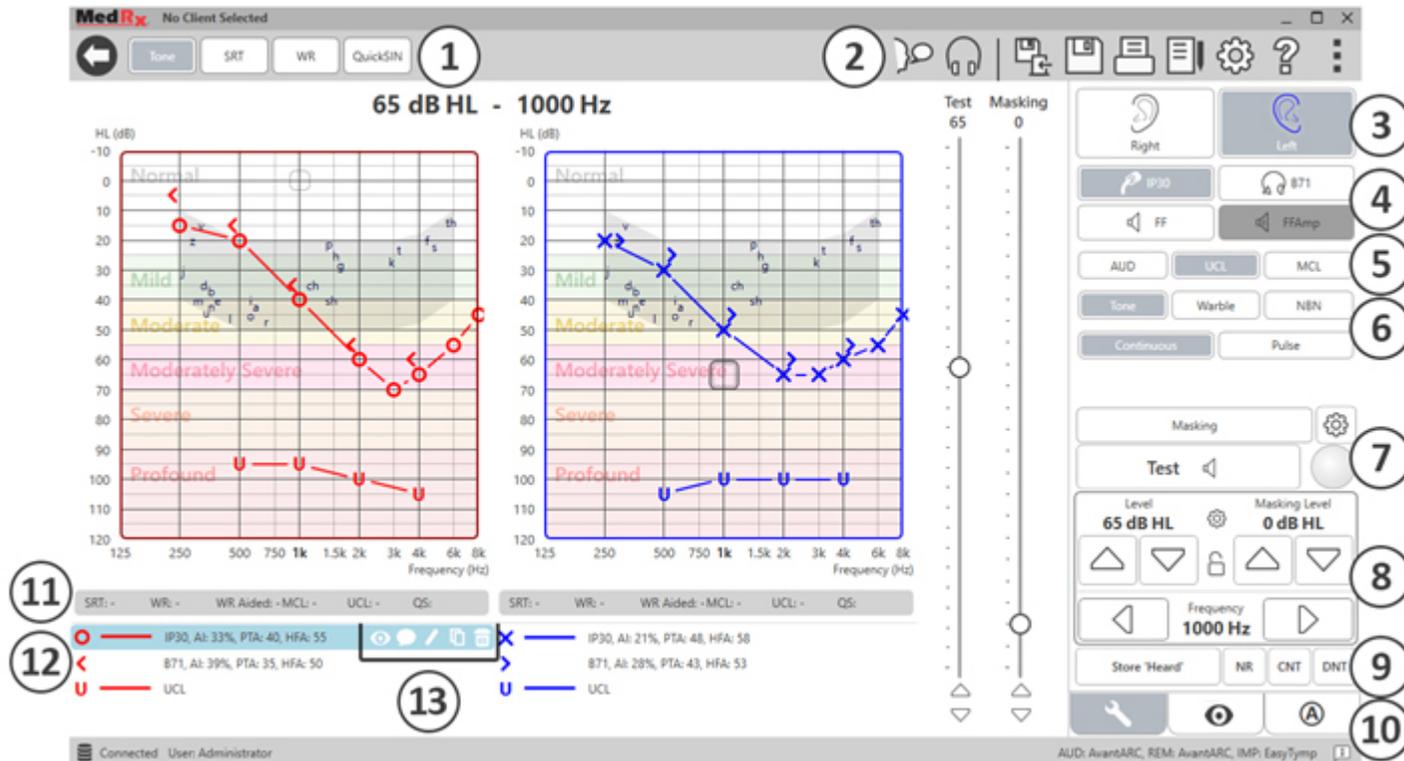
Device Maintenance

Annual re-calibration of the transducers used with the Avant Audiometer is recommended. There are no user repairable components of this device. Refer to the recommended procedures for cleaning and disinfection in this manual.

Performing Audiometric Testing

The screen shot below shows the controls which are available from the Audiometer main window. The sections of the manual that follow explain how to use these tools to perform hearing evaluations using your Audiometer.

1. Test Selection Tool Bar
2. Settings Selection Bar
3. Ear Selection
4. Output Selector
5. Test Type Selector
6. Tone Type Selectors
7. Test and Masking Interrupter, Routing Selector
8. Output Level Potentiometers
9. Response Options
10. Screen Option Tabs
11. Test Results
12. Legend
13. Discard, Edit, Copy and other options



Pure Tone Audiometry

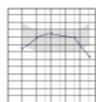
Pure Tone Audiometry measures the patient's peripheral hearing sensitivity, or the softest levels they can hear pure tones at a variety of frequencies. These thresholds are plotted on a standard graph called an audiogram. The MedRx Studio software controls the hardware, stores the data (if running within NOAH or TIMS) and prints a standard or custom audiogram report. Pure tone Audiometry can be performed via earphones or a Bone Conductor (Bone Conduction).

Prerequisites:

Before performing audiometry, careful inspection of the ear canal should be performed. This is best done with Video Otoscopy. After ensuring the ear canal is clear, place the appropriate transducer on the patient.

Pure Tone Audiometry via Earphones

IP30 Insert Earphones, Eartone 3A Inserts or Supra-Aural Headphones



AUD



1. From the main Window, Click the AUD button.
2. By default, the Tone button will be selected once you enter the main Audiometry Screen. Other default settings (based on typical clinical practice and procedures) are:
 - a. Right Ear
 - b. AC (Air Conduction)
 - c. Tone Stimulus
 - d. Continuous Tone
3. All defaults can be set in each module by clicking on the settings wheel.

4. Instruct the patient that they will hear several very quiet (soft) tones (beeps) and that they should signal (raise their hand, press the patient response button, etc.) as soon as they hear it. It is helpful to also say "even if it seems very far away".
5. Begin at 1000 Hz in the Right ear (unless the patient reports better hearing in the left ear).
6. Present a tone at 60 dB by pressing the space bar or clicking the "Test" button.
7. If the patient does not hear the tone (does not signal), raise the level 5 dB using the up arrow on your keyboard and present again.
8. Repeat step 6 until the patient signals that they hear the tone.
9. When the patient signals they hear the tone, decrease the level by 10 dB and present the tone again.
10. Repeat steps 6 through 8 until the patient responds to a tone at the same level 2 times with the level ascending.
11. Using the right arrow key, change the test frequency to 2000 Hz and repeat steps 5 through 8 to establish the threshold at 2000 Hz.

NOTE: If the threshold at 2000 Hz is more than 20 dB different (less than or greater than) the threshold at 1000 Hz, repeat steps 5 through 8 at 1500 Hz (the "half octave" between 1000 Hz and 2000 Hz).

12. Repeat steps 5 through 8 for 4000 Hz, 8000 Hz, 500 Hz and 250 Hz.
13. Repeat steps 5 through 11 in the opposite ear.

NOTE: The software automatically calculates the 3-frequency Pure Tone Average (PTA) which is displayed above and inside the legend as follows:

  IP30, AI: 33%, PTA: 40, HFA: 55

Pure Tone Audiometry via the Bone Conductor¹

1. Following the instructions on page 12, place the Bone Conductor on the mastoid process behind the ear with better air conduction thresholds as measured above. If the thresholds are equal, place the Bone Conductor on the mastoid process behind the right ear.



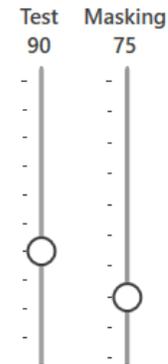
2. Establish bone conduction thresholds as described above (see page 15, steps 5-8) for 1000 Hz, 2000 Hz, 4000 Hz, 500 Hz and 250 Hz.
3. If the Bone Conduction (BC) threshold at a given frequency is less (better) than the Air Conduction (AC) threshold by 15 dB or more, you must confirm the threshold by performing masking.

Masking for Pure Tone Audiometry

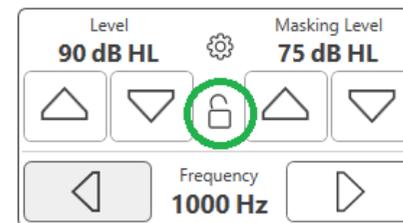
To use the masking function on the AVANT Audiometer, follow the steps below:



1. Click the Masking button or press the “m” key. The button will appear grey (as shown) indicating that the masking is on.



2. Use your mouse or hold control and use the up and down arrow keys to adjust the Masking Level Slider to the appropriate level based on your preferred method of masking.



3. If you wish to maintain the balance of signal and masking (for example, masking always 30 dB above the signal), click the Lock button after setting the masking and signal levels.



4. The default for pure tone audiometry is to deliver narrow band masking to the ear opposite the test ear. If you wish to use a different stimulus, or route the masking to the same or both ears, click on the settings wheel to the right of the Masking button.

¹ Not Available in AIR+/Tinnometer



5. Use your mouse to select the new masking type and routing for your specific application.

6. When you are finished making changes to the Masking, click X.

High Frequency Audiometry

(Optional)

The AVANT Stealth Audiometer is available with the option to perform extended range high frequency pure tone audiometry. This is used clinically to evaluate noise induced hearing loss, ototoxicity and tinnitus. High frequency testing uses the same procedure as described on page 15 for pure tone audiometry.



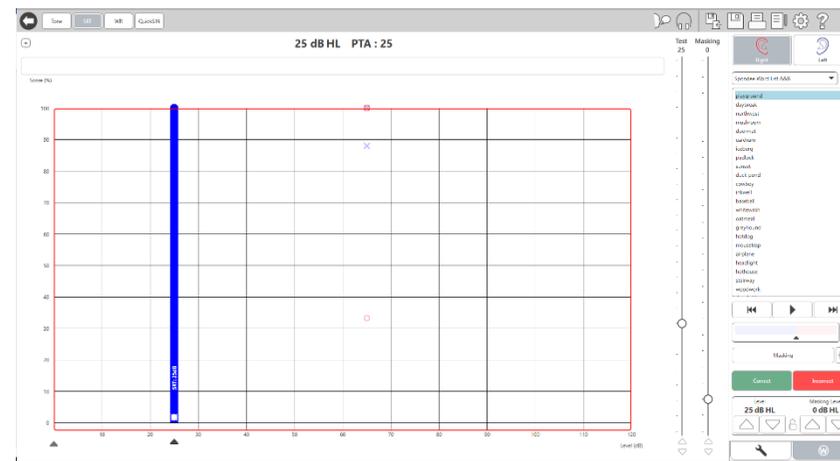
To start High Frequency audiometry, plug Stealth into DC power, select a transducer that supports high frequencies, such as the DD450.

The High Frequency control will appear on the right panel and will allow choosing frequency ranges to be shown on the plot. The power supply must be connected to activate the high frequency control or when using the free field amplifier.

NOTE: Extended High Frequency Audiometry is an upgrade option for the AVANT Stealth Audiometer only. If the high frequency control selectors do not appear on the right panel and if you need to test frequencies beyond 8000 Hz, you must notify MedRx. This option carries a price differential which will be detailed at the time of order.

Speech Audiometry¹

Speech audiometry evaluates how well the patient can hear and understand speech. The typical test battery includes tests of speech threshold and tests of speech discrimination.



The sections below detail how to perform these tests in MedRx Studio.

Speech Reception Threshold (SRT)

The Speech Reception Threshold (SRT) is defined as the lowest level at which the patient can repeat Spondee words with 50% accuracy. Spondee words are two syllable words with equal vocal emphasis on each syllable such as “baseball” or “hotdog.”

¹ Not Available in AIR+/Tinnometer

Instruct the patient that they will hear a series of two-syllable words that will get quieter as the test progresses. They are to repeat the words as best they can, even if they sound very far away. If they are not sure of a word, they should take a guess.

SRT is typically started 10-20 dB more than the patient's Pure Tone Average, which is displayed on the top of the screen. Set the level of the test signal to 10dB above the PTA and follow the steps as follows:



AUD

1. From the MedRx Studio main screen, click the AUD button.



2. Click the SRT button located on the toolbar on the top left of the screen.



3. Click the W tab on the bottom right.



4. Use the folder icon and drop-down list to select Spondee Word Lists A&B or Child Spondee from the list.



5. Click the Play button or press the F9 key to present a word. The word will play through the chosen transducer as well as display on the screen.

6. If the patient correctly repeats the word, click the Correct button or press F7.

7. If the patient incorrectly repeats the word, click the Incorrect button or press F8.

NOTE: F7 and F8 auto advance the playlist to the next word but will not play the next word. F9 plays the highlighted word. F10 advances to the next word and plays it.

The score is calculated and displayed automatically.

If the patient exceeds a 50% score at a given presentation level, stop the test and decrease the level by 10 dB and repeat the steps above.

If the patient fails to achieve a 50% score after 6 words at a given level, stop the test, raise the level 5 dB and repeat the steps above.

When the patient scores 50% at a given level, the test is complete. The software automatically plots the score on the SRT graph.

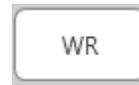
Speech MCL & Speech UCL

The patient's most Comfortable Level and Uncomfortable Level for speech can be obtained while you are in Word Recognition (WR).



AUD

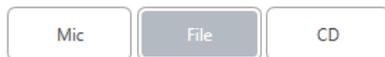
1. From the MedRx Studio main screen, Click the AUD button.



2. Click the WR button located on the toolbar on the top of the screen.

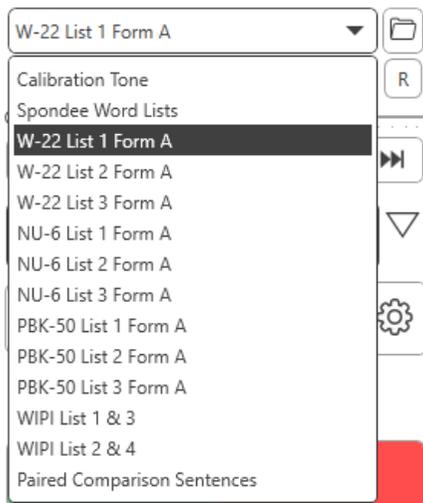


3. Click UCL or MCL.



4. Choose an input option.

5. If you selected File or CD*, select the track you would like to play for the test in the media player at the bottom of the screen.



When you have selected your track in the media player, click play on media player or hit the spacebar to start.

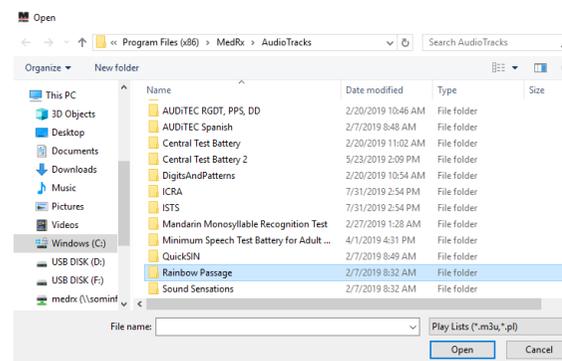
Adjust levels up or down with keyboard arrows or by clicking below the dB level at the bottom of the test slider or masking slider.

NOTE: *CD function will only be displayed if you have a disc drive

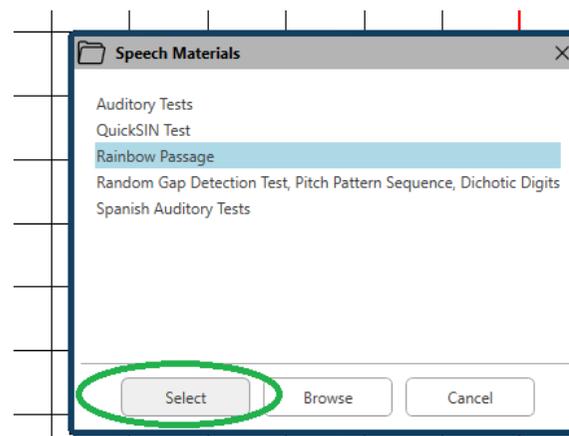
6. To Input & Calibrate the Rainbow Passage in WR for MCL:



a. Press the small file folder on the top right of media player. Then select "Browse" in the speech material.



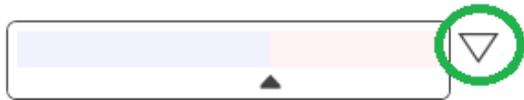
b. Select Rainbow Passage by double clicking twice.



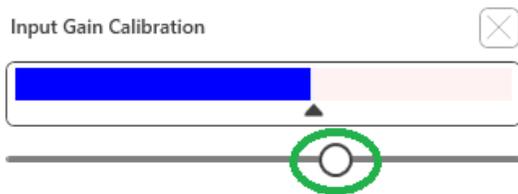
c. The Rainbow Passage is now part of the MedRx Studio Audio Files for future use.



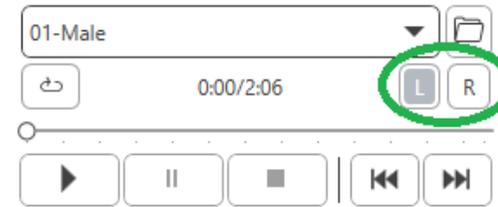
- d. Use the drop down in the media player and select track 10 – Calibration (1000Hz).
- e. Click play or start signal.



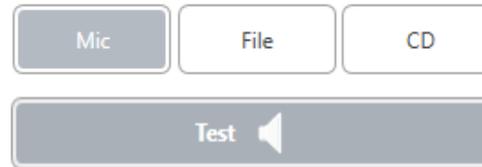
- f. Then click the calibration arrow next to the UV meter.



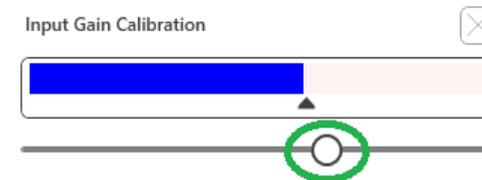
- g. On the VU meter pop-up, press the slider calibration icon just below the VU meter.
- h. Adjust with mouse or arrow keys so that the blue bar stops over the black arrow and there is no red.



- i. Click on the channel icon just below and to the right of the VU to switch channels.
- j. Repeat steps d - f for the remaining channel.
Note: This calibration also needs to be done with any custom word list.



- 7. When using the Mic or live voice option make sure you press the Test or space bar to begin.

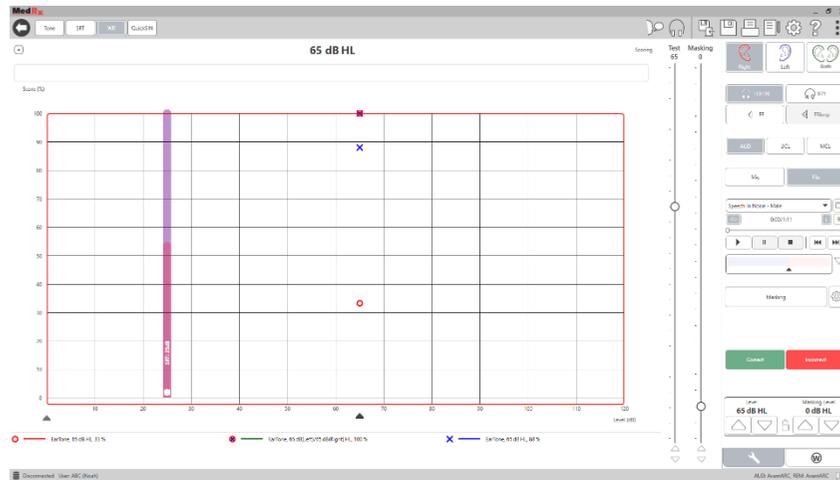


- 8. When using the Mic option adjust your input using the slider so that it is peaking at the black triangle under the VU meter.

The VU meter is just below the Test button in MedRx Studio and will become active once you press Test.

Word Recognition (WR)¹

Word Recognition (WR) is a discrimination, or recognition type test using speech as the stimulus. WR testing measures the percentage of mono-syllable words repeated correctly from a phonetically balanced list. Unlike the SRT test, the WR test is performed at a fixed intensity (dB) level. Typical patients will score their best on WR testing at a level between 35 and 40 dB above their SRT.

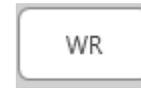


Before beginning the test, instruct the patient that they will hear a series of one-syllable words. They are to repeat the words the best they can. If they are not sure of a word, they should take a guess.



AUD

1. From the MedRx Studio main screen, click the AUD button.



2. Click the WR button located on the toolbar on the top of the screen.



3. Click the W tab on the bottom right.



4. Use the folder and drop-down list to select the desired Word List. The W-22 or NU-6 lists are good choices for typical adult patients. When testing children, the PBK lists are commonly used. More lists are available by calling MedRx Tech Support at 727-584-9600.



5. Click the Play button or press the F9 key to present a word. The word will play through the chosen transducer as well as display on the screen.



6. If the patient correctly repeats the word, click the Correct button or press F7.

7. If the patient incorrectly repeats the word, click the Incorrect button or press F8.

NOTE: that the score is calculated and displayed automatically. The test is complete when all words in the list have been presented. The software automatically plots the score on the WR graph.



8. Click the Advance button >> or press the F10 key to present the next word. Score accordingly as described above.

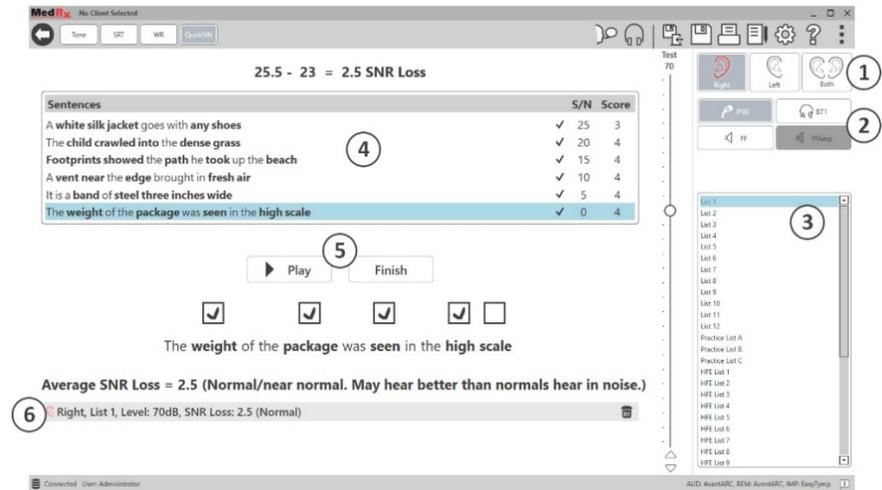
¹ Not Available in AIR+/Tinnometer

QuickSIN¹

The primary complaint of hearing-impaired persons is difficulty hearing in background noise. The measurement of SNR loss (signal-to-noise ratio loss) is important because speech understanding in noise cannot be reliably predicted from the pure tone audiogram (Killion & Niquette, 2000).

The QuickSIN test was developed to:

1. Provide a one-minute estimate of SNR loss.
2. Provide a quick way for clinicians to quantify a patient's ability to hear in noise.
3. Determine if extended high frequency emphasis improves or degrades understanding of speech in noise.
4. Assist professionals in choosing appropriate amplification and other assistive technologies.
5. Demonstrate that hearing aids with directional microphones improve speech intelligibility in noise.
6. Provide a large number of equivalent test lists for use in clinical and research work.
7. Provide information useful in counseling patients regarding realistic expectations.



The screenshot above shows the key features of the QuickSIN test.

1. Ear Selector
2. Output Selector
3. List Selector
4. Track Display
5. Track Control
6. Legend

¹ Not Available in AIR+/Tinnometer

Performing the QuickSIN Test



1. From the MedRx Studio main screen, Click the AUD button.

AUD

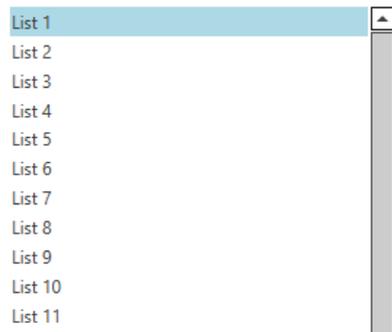


2. Click the QuickSIN button located on the toolbar on the top of the screen.

Present the test with earphones or in a sound field. The attenuator dial is set to 70 dB HL. For subjects with PTA hearing losses greater than 45 dB HL, the attenuator dial is set to a level that is “loud but OK.”, this is done by the program automatically. A warning legend at the bottom of the window is shown if PTA is not available.

Instruct the patient to repeat the sentences spoken by the target (female) speaker.

When testing in a sound field, have the patient hold the talkback microphone close enough so that responses are clearly audible to the tester.



1. Select a list from the List Selection Window one of the following two ways:

- Click the list, then click Select.
- Or Double-Click the list number.

Sentences	S/N	Score
Pitch the straw through the door of the stable	25	0
The sink is the thing in which we pile dishes	20	0
Post no bills on this office wall	15	0
Dimes showered down from all sides	10	0
Pick a card and slip it under the pack	5	0
The store was jammed before the sale could start	0	0



2. Play the first sentence in the list by clicking the Play button. Ask the patient to repeat the sentence.



Pitch the **straw** through the door of the stable

3. To score the patient's response: Click the check-box of each correct key word with your mouse. This will record the total number of correct key words in the score pull-down.



4. Click the next sentence and then click Play or click Next. This will advance & play.

5. Repeat steps 2-4 until all 6 sentences in the list have been played and scored.

Average SNR Loss = 2.5 (Normal/near normal. May hear better than normals hear in noise.)

Right, List 1, Level: 70dB, SNR Loss: 2.5 (Normal)

After all six sentences are scored, the following results are displayed:

- Average SNR Loss in dB.
- Recommendations.

¹ Not Available in AIR+/Tinnometer

VRA MODULE¹ (Optional)

The VRA module is a Visual Reinforced Audiometry (VRA) module available in the MedRx Studio software. This is an optional module which must be licensed to activate. Contact your MedRx representative if you have questions regarding activation.

Visual Reinforced Audiometry is a test designed for pediatrics when the child is too young for normal pure tone testing. This test is typically performed with children 6 months to 2-3 years of age. The VRA system utilizes cartoon videos reward system to help determine responses from the child.

VRA Requirements

The VRA system will require a PC that meets the MedRx recommended specifications:

- Windows® PC computer
- Intel™ i5 Quad Core or better
- 8 GB RAM or more
- Available USB 2.0, Compatible with 3.0 USB
- Graphics Adapter with 2GB Dedicated Video Memory
- 50 GB or more free hard drive space
- High Speed Internet Connection
- Windows 10 Professional 64-bit
- A PC that can handle from 1 to 4 depending on configuration

Download the iVRA app. The icon will look like this:



1. Go to the App Store app on your iPod or iPad.
2. Search for MedRx iVRA then tap the app.
3. Tap install.

Consult with your local MedRx representative for assistance with installation.



VRA



VRA Setup

The VRA system will require initial setup in order to begin performing hearing tests.

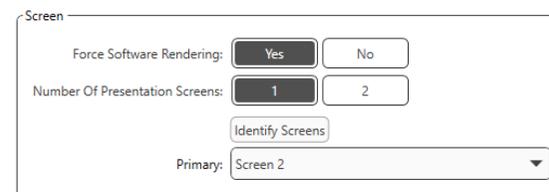
1. Open the VRA module
2. Navigate to settings

The VRA Test settings are determined inside of the iOS VRA application and cannot be adjusted in the MedRx Studio module.

Screen setup will need to be determined prior to beginning a test.

One screen setup

Select 1 for **Number of Presentation Screens**. This will allow the rewards to be presented to only one screen.

A screenshot of the VRA settings screen. It shows a 'Screen' section with the following options: 'Force Software Rendering' with 'Yes' and 'No' buttons; 'Number Of Presentation Screens' with '1' and '2' buttons; an 'Identify Screens' button; and a 'Primary:' dropdown menu currently set to 'Screen 2'.

Click **Identify Screens** to determine which screen you would like as the reward screen. This should be the screen that will be in the testing area that the child will be present in.

Force Software Rendering should always be set to **Yes** to prevent delays in video presentation.

Two or more screen setup

Select 2 for **Number of Presentation Screens**. This will allow for multiple monitors to be used with the VRA Studio module.

¹ Not Available in AIR+/Tinnometer

Screen

Force Software Rendering: Yes No

Number Of Presentation Screens:

Primary: Screen 1

Primary Screen Blackout: Yes No

Left: Screen 1

Right: Screen 2

Click **Identify Screens** to determine which screen you would like as the left and right reward screen. This should be the screen that will be in the testing area where the child will be tested. If you are using one monitor in the testing area these should be set to the same screen. If there are two monitors in the testing area the left and right monitors should be assigned in relationship to the child's left and right ear.

If the primary screen is not being used for reward presentation this screen may keep the MedRx Studio software present or it may be hidden with **Primary Screen Blackout**.

Force Software Rendering should always be set to **Yes** to prevent delays in video presentation.

Connecting MedRx Studio and iVRA App

To connect MedRx Studio and the iVRA app you will need to connect to the **same wireless network**. This can be a local network or a network with

internet access. Once you have connected the devices to the same network, you will need to determine the IP address of the PC. To do so:

In Studio VRA Settings, Click Identify IP Address:

Information

Studio will then list all available network connections. The VRA will need to be located on the same wireless network or Wi-Fi. Be sure that you use the Wi-Fi IP address.

Information

Network Name : Ethernet
IP Address :

Network Name : Local Area Connection* 2
IP Address :

Network Name : Local Area Connection* 3
IP Address :

**Network Name : Wi-Fi
IP Address :**

Network Name : Loopback Pseudo-Interface 1
IP Address :

NOTE: You cannot be connected to a VPN and use the iVRA. You must disconnect from the VPN to allow VRA connections.

NOTE: You may use a local Wi-Fi network without internet access for the VRA connection.



The Port number entered will always be the same as shown in the screenshot: **39063**.

Click Connect in the iVRA app.

After you click connect, you should see the **Connection up, Handshake OK** displayed in the iVRA app.

Enter the IP Address found in the Studio settings. The IP address will remain the same unless you change wireless networks or change PCs.

You will need to click **Connect** at the beginning of every iVRA session.

VRA Settings

The transducer selection is performed in MedRx Studio software prior to beginning the VRA test. All transducers are inherited through the AUD module. If you do not see a transducer you would like to use then you will need change the preferences in the AUD module. The MedRx Studio transducer selection will appear as below:



Type of tone (i.e. warble, pure tone, narrowband, continuous, pulsed) is also set up in MedRx Studio software prior to beginning the VRA testing.

The settings for the VRA system are found in the iOS app. You can find these in the Settings tab of the app.



Settings Tab in the iVRA app

The MedRx Studio software will indicate that you have successfully connected when the iOS Icon in the VRA side bar changes from Red to Green.



Disconnected



Connected

Stim Length (s)

How long the tones are presented in seconds

Response Window (s)

How many seconds post stimulus in which to record a response

Non-stim rate

How often are catch trials inserted

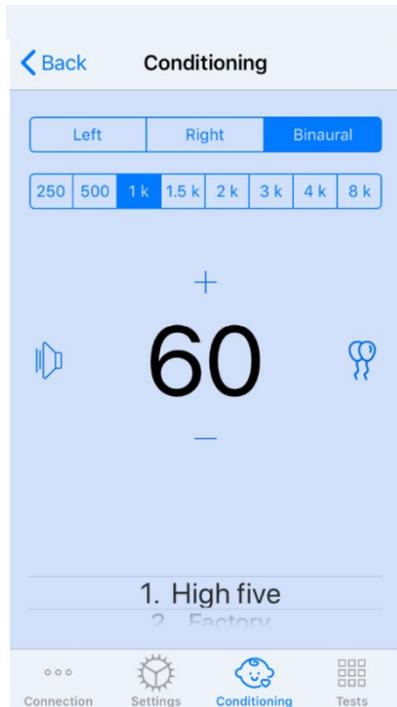
Reward Length (s)	Number of seconds to present the video reward
Rewards Randomized	Automatically randomizes video reward presentations during testing
Masking Signal for Clinician	Determines the masking type presented to the clinician through the iOS device headphones
Masking Past End of Stimulus(s)	How long after stimulus end will the clinician be under masking
Audio Feedback	Toggle feedback to be played through headphones during automatic testing (i.e. Threshold determination, levels, etc.)
Audio Feedback Volume	Level to which the clinician will hear feedback through the iOS device



The reward screens will turn black when the **Start Conditioning** button is clicked.

iVRA Conditioning Mode

The iVRA conditioning is initiated through the iOS app. The iOS app and MedRx Studio must be connected for the testing to begin. Once the iOS app and MedRx Studio are connected, navigate to the conditioning tab.



Once the conditioning has begun, the iOS app will look like the left image.

You may select presentation ear, frequency, level, video reward, and video to display.

Note: Presentation ear is fixed to binaural during free field testing

To present a stimulus you will **swipe left** on the presentation level in the center of the screen.

To record a response **swipe right**, this will also display a reward. Rewards will always be displayed in conditioning mode.

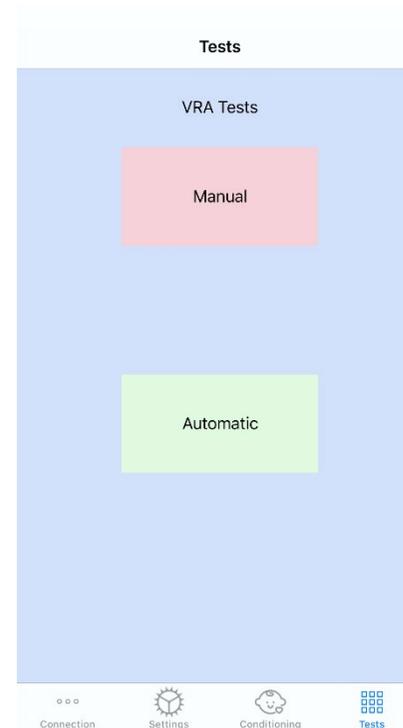
Change the presentation levels by **swiping up or down** on the presentation

level that is displayed.

To **exit** the conditioning mode, you can hit back in the iOS app and immediately begin Manual and Automatic testing. If you would like to exit the conditioning mode from the PC, press the **Shift + ESC** key.

iVRA Manual Test Mode

The iVRA manual test mode is initiated through the iOS app. The iOS app and MedRx Studio must be connected for the testing to begin. Once the iOS app and MedRx Studio are connected, navigate to the Tests tab.



To begin manual testing, click the Manual button in the Test tab.

When you click the Manual button, the reward screens will go to black and the testing will be ready.



Once the manual test mode has begun, the iOS app will look like the left image.

You may select presentation ear, frequency, level, and video reward.

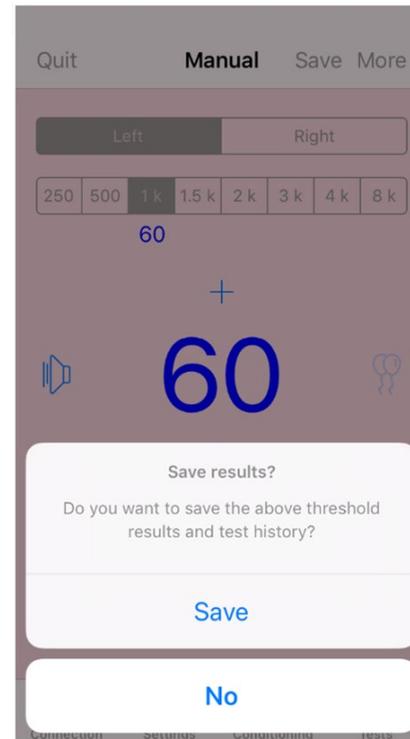
Note: Presentation ear is fixed to binaural during free field testing

To present a stimulus you will **swipe left** on the presentation level in the center of the screen.

To record a response **swipe right**, this will also display a reward. Rewards will only be shown if a stimulus was presented. Rewards are not displayed during catch trials.

Change the presentation levels by **swiping up or down** on the presentation level that is displayed.

To record a threshold, **double tap** the number in the center of the screen.



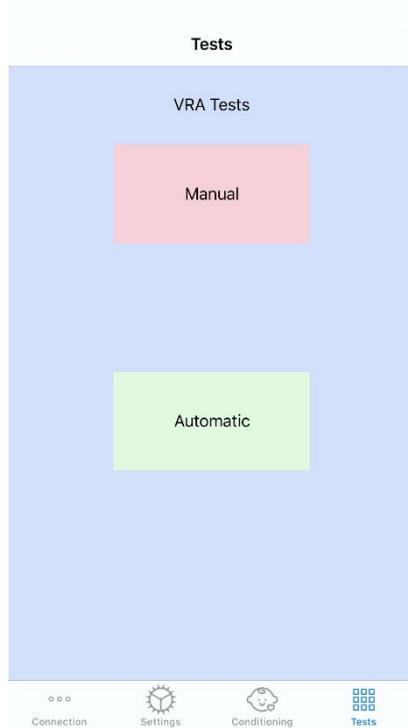
Be sure to click **Save** in the top right of the iOS app when testing is complete.

A confirmation box will appear upon clicking **Save**. Saving the information transfers the test results from the iOS app into MedRx Studio software.

To **exit** the manual test mode, you can hit **Quit** in the iOS app. Be sure that your test results are saved prior to exiting.

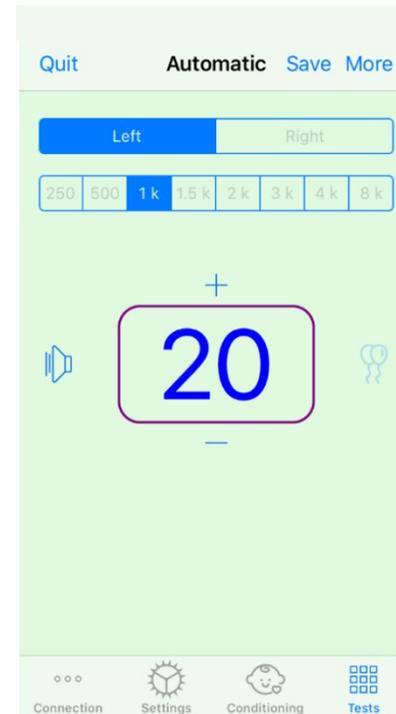
If you would like to exit the manual test mode from the PC, press the **Shift + ESC** key.

iVRA Automatic Test Mode



To begin automatic testing, click the Automatic button in the Test tab.

When you click the Automatic button, the reward screens will go to black and the testing will be ready.



Once the automatic test mode has begun, the iOS app will look like the left image.

You may select presentation ear, frequency, starting level, and video reward.

Note: Presentation ear is fixed to binaural during free field testing.

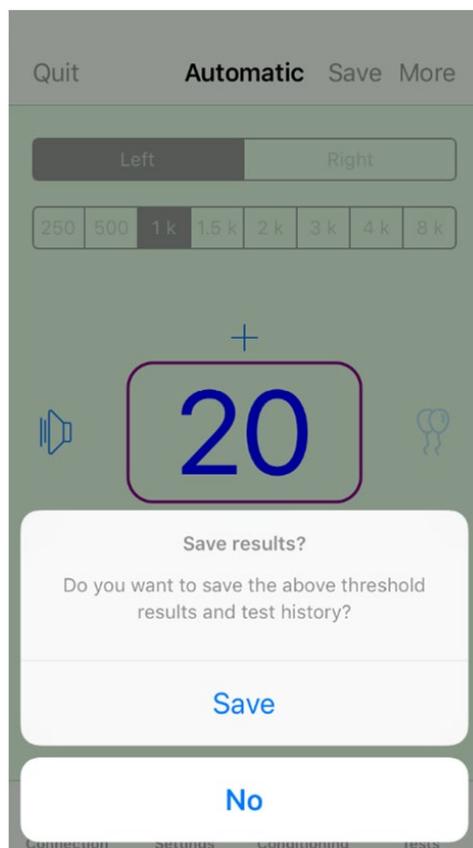
Note: Presentation level is automatically adjusted during the automatic test mode until threshold is determined. Only the starting level can be adjusted.

To present a stimulus you will **swipe left** on the presentation level in the center of the screen.

To record a response **swipe right**, this will also display a reward. Rewards will only be shown if a stimulus was presented. Rewards are not displayed during catch trials.

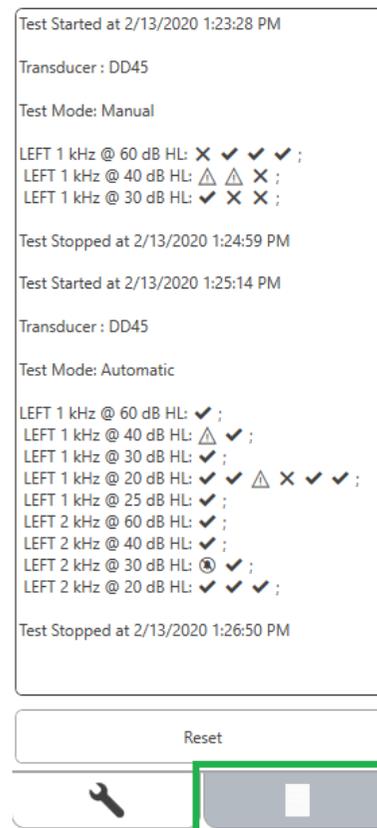
Starting presentation levels can be changed by **swiping up or down** on the presentation level that is displayed. Once automatic testing has begun for a frequency, the levels can no longer be adjusted. These will adjust automatically based on recorded responses until a threshold is found.

Thresholds are recorded automatically in this test mode.



Be sure to click **Save** in the top right of the iOS app when testing is complete.

A confirmation box will appear upon clicking **Save**. Saving the information transfers the test results from the iOS app into MedRx Studio software.



Testing information for both manual test mode and automatic test mode will be stored here. The following are what each log symbol means:

- ✓ Correct Response
- ✗ No Response
- △ False Positive
- 🕒 Catch Trial Success

All log information will be stored in the session data. To recall the log information, open the session which contains the VRA results.

To **exit** the automatic test mode you can hit **Quit** in the iOS app. Be sure that your test results are saved prior to exiting.

If you would like to exit the Manual Test Mode from the PC, press the **Shift + ESC** key.

VRA MedRx Studio Logging

Logging of test sessions are available through MedRx Studio. To access the logs, click the Log tab in the MedRx Studio VRA sidebar.

Tinnometer MODULE (Optional)

Purpose of the Tinnometer

Tinnitus is experienced by millions of people worldwide. The Tinnometer is designed to mimic the sounds of tinnitus in order to provide an accurate and flexible tinnitus assessment. Tinnitus assessment increases patient rapport with the clinician when an equivalent tinnitus sound can be created. The Tinnometer can accurately create tinnitus sounds for fast and reliable tinnitus assessment. All test results should be used to help counsel the patient on their specific tinnitus and what the assessment has found.

The Tinnometer test was developed to:

- Break away from the traditional limitation of tinnitus assessment with an audiometer.
- Produce accurate and flexible sounds that mimic patient tinnitus.
- Provide extended frequency ranges to more accurately match tinnitus sounds.
- Decrease the time needed to complete a tinnitus assessment
- Standardize reporting needed when completing tinnitus assessment.
- Allow clinicians to save and recall prior tinnitus assessments.
- Provide general guidelines for implementing results into tinnitus sound therapies provided by leading hearing aid manufacturers.

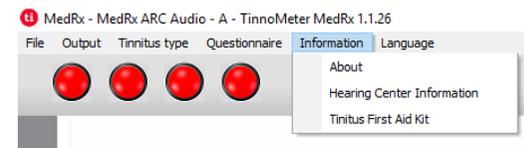
Performing the Tinnometer Testing



Tinnitus

1. From the MedRx Studio main screen, Click the Tinnometer button.

2. Add Clinic Information to Templates. Go up to Information in the top tool bar.



3. Enter Information into the pop-up form.

Office form

MedRx
HEARING CENTER

Hearing Center Name: MedRx Hearing Center

Address: 1200 Starkey Street

Zip: FL

City: LARGO

State: USA

Gender: Mr

Last Name: CARROU

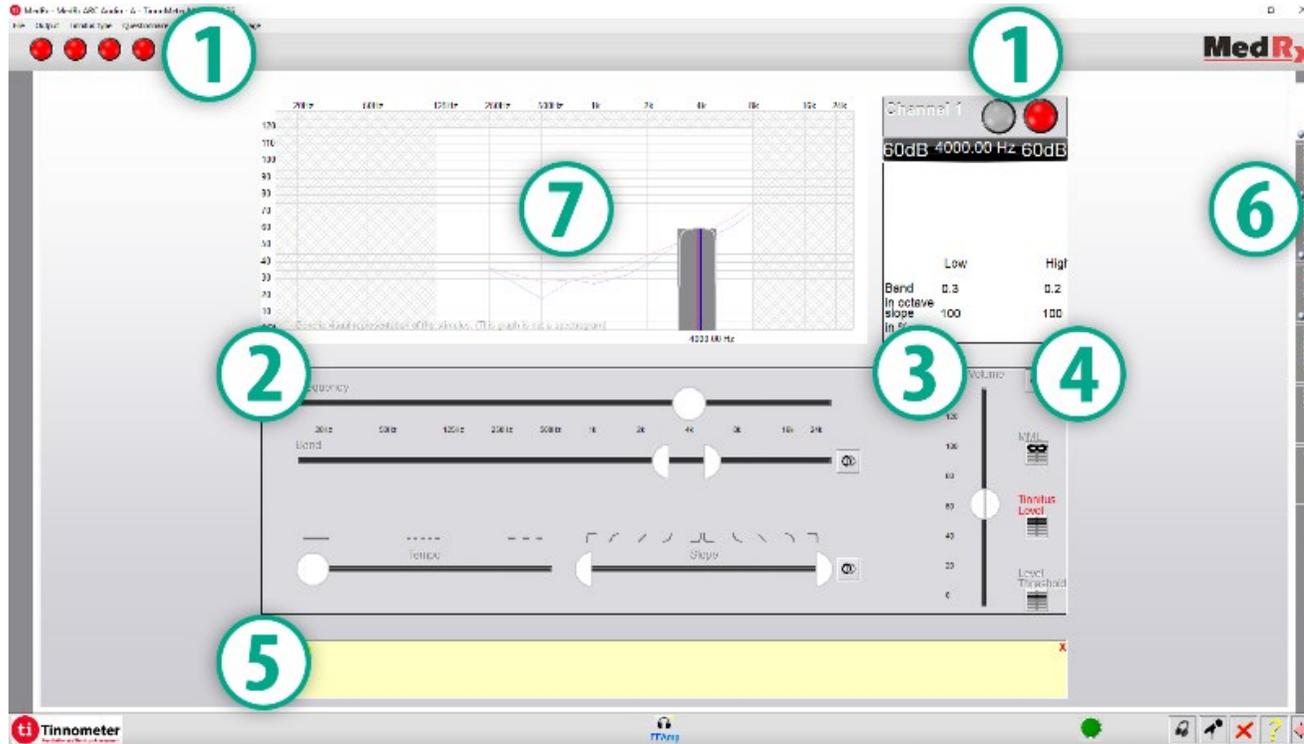
First Name: Xavier

Phone:

Email Address: medrx@medrx-usa.com

UnitLabel1: OK No

Key features of the Tinnometer Main Screen:



1. Toggle Switch to Start/Stop stimulus
2. Sliders to control frequency, bandwidth, slope and tempo of the stimulus
3. Slider to control the intensity of the stimulus
4. Buttons used in determining tinnitus match, threshold and minimum masking level
5. Area where description of items will be displayed
6. Channels designed to present multiple types of tinnitus sound
7. A graphical display of the sounds being played for the patient. Stimulus and Audiogram are display in dB SPL section

Interactions with the Patient are Controlled as Follows:

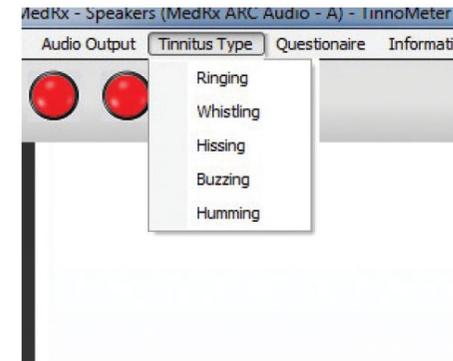


1. Patient Response Switch Indicator
2. Patient Monitor Microphone
3. Talk Forward
4. Undo
5. Toggle Help Section
6. Return to Studio

There are 3 Steps Needed for Tinnitus Assessment with the Tinnometer

1. Identify patient's tinnitus by frequency, bandwidth, slope and tempo.
2. Lower the identified tinnitus until patient threshold is reached.
3. Raise the tinnitus level above the identified tinnitus intensity (widen bandwidth if needed) until the patient states they no longer hear the tinnitus. Play stimulus for 60 seconds to ensure masking is achieved.

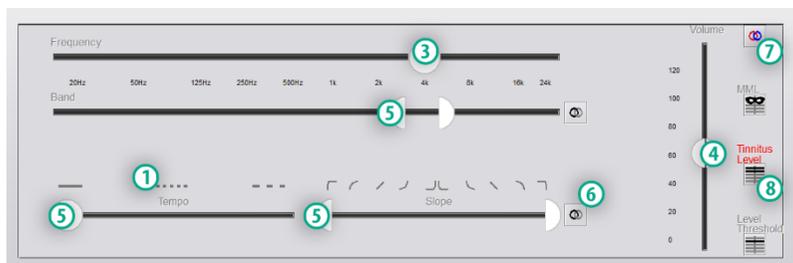
Step 1: Identify Patient's Tinnitus



1. Start by selecting the tinnitus type that has been described by the patient. This is an approximation of the tinnitus sound your patient hears. Tinnitus type will provide a starting frequency, bandwidth and slope to help speed up testing time.



2. Use the stimulus start/stop toggle to present the selected signal to the patient.



3. Use frequency slider to match the pitch of the patient's perceived tinnitus.
4. Use volume slider to match patient's perceived intensity of tinnitus.
5. Adjust bandwidth, slope and tempo (for pulsating tinnitus or prevention of adaptation) as needed.
6. Buttons to allow greater flexibility in bandwidth and slope of tinnitus. Allows the addition of high/low frequency sounds independently.
7. Allows for independent right/left volume control.
8. Press Tinnitus Level button once the patient's tinnitus is matched.

Step 2: Find Identified Tinnitus Threshold



1. Use down arrow on your keyboard to lower stimulus until patient states they are no longer able to hear the tinnitus.
2. Click Threshold Level button.

Step 3: Masking Tinnitus for 60 Seconds



1. Use volume slider to increase intensity of the stimulus until the patient states they are no longer able to hear their tinnitus.

NOTE: Lower levels of masking may be achieved by increasing bandwidth of the masking stimulus. Pulsating the masking noise can prevent tinnitus adaptation.



2. Press the MML button and continue presenting stimulus until 60 second countdown ends.

If patient begins to hear their tinnitus within the 60 seconds, raise intensity until masking is achieved and repeat number 2.

Tinnometer Modulation Tab

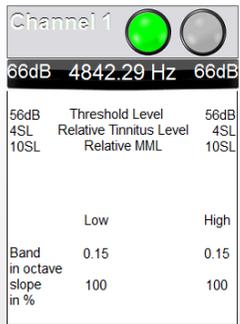
The Tinnometer modulation tab is designed to simulate sound generators when hearing aid demonstrations cannot be performed.

The following are controls used in Modulation.

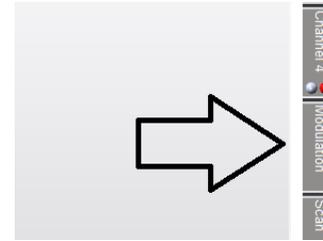


1. Type of Modulation Sound
2. Speed of Modulation
3. Frequency of Modulation
4. Modulation Volume Range

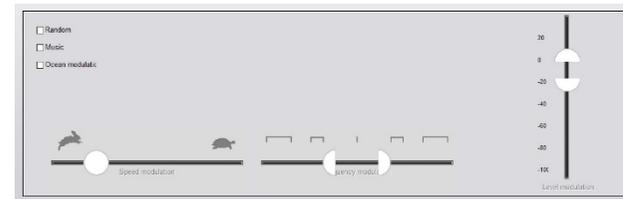
To use the Modulation features within Tinnometer, you must first complete the three steps involved with tinnitus assessment. Once tinnitus assessment is complete, you can use modulation by:



1. Activating the channel in which the tinnitus assessment was performed.

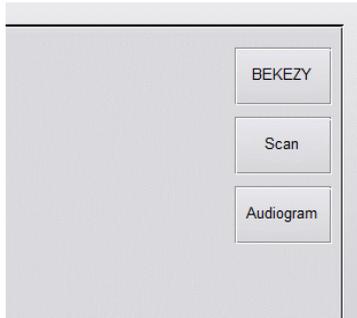


2. Enter the modulation tab on the right side of Tinnometer software.



3. Adjust the modulation stimulus with sliders as a counseling tool for the patient.

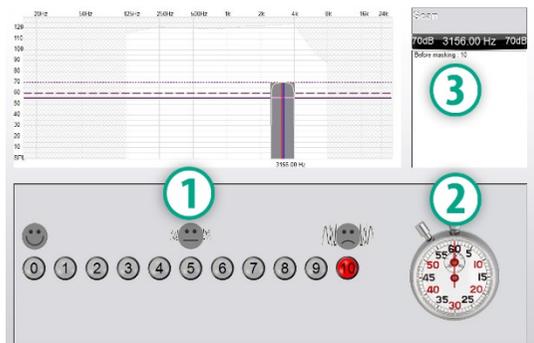
Tinnometer Audiometry Scan



The Tinnometer Scan tab is designed for various forms of air conduction audiometry. There are three types of audiometry that can be performed with Tinnometer. You can access the forms of audiometry with the buttons located in the image to the left.

Tinnometer Residual Inhibition (RI)

The Tinnometer RI tab is designed for Residual Inhibition (RI) testing for a patient's tinnitus. The controls in the RI tab are as follows:

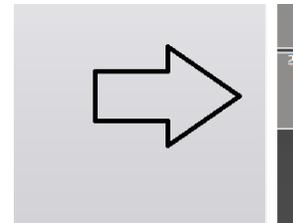


1. Scale from 0-10 of tinnitus bothersome level.
2. Stop watch to begin stimulus.
3. Tracking of patient's tinnitus bothersome level as a function of time.

A complete tinnitus assessment must be performed prior to performing testing in the RI tab. Once tinnitus assessment testing is completed, optional residual inhibition testing can be performed with the following steps:



1. Activating the channel in which the tinnitus assessment was performed.



2. Select the RI tab on the right side of the Tinnometer software.



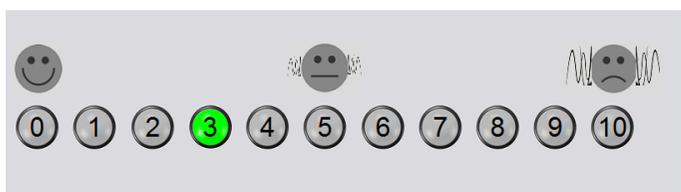
3. Ask the patient the bothersome level of their tinnitus from 1 to 10 and mark their response.



- Click the stop watch to begin the masking stimulus (stimulus to play for 60 seconds).

You will hear a masking noise for 1 minute
Then the noise will suddenly stop
The patient will have to redefine his discomfort about every 30 seconds.

- Stimulus will play for 60 seconds and automatically stop at the 60 second point.



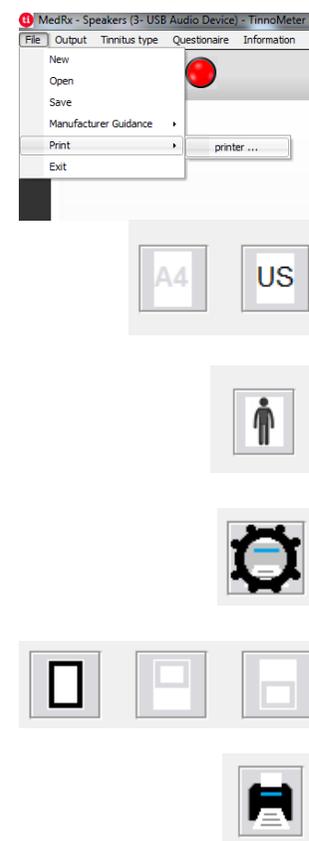
- When the stimulus stops the patient must redefine their tinnitus bothersome level every 30 seconds. The bothersome level will increase with time.
- The test continues until the bothersome level returns to pre-test level.

Tinnometer Report Printing

The Tinnometer has four reports available for printing:

- Tinnitus Assessment Report.
- Manufacturer Guidance Report.
- Questionnaire Report.
- Channel Report.

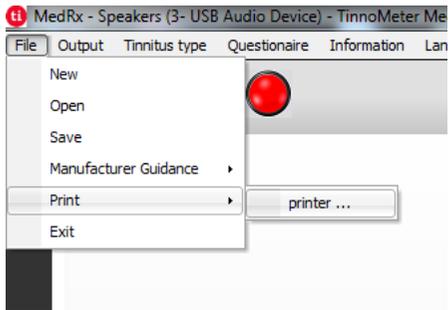
The following are common features found across reports:



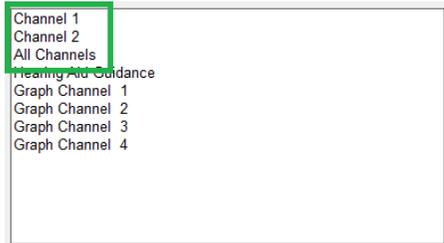
- To generate your report, select "printer ..." from the File menu.
- Select the paper style you are printing.
- Confirm all patient information is correct.
- Choose your print preferences.
- Change the zoom of your print preview.
- Print your Report.

Tinnitus Assessment Report

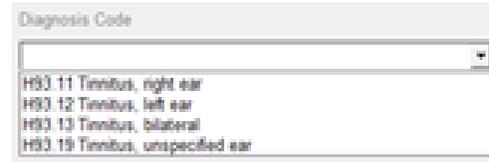
Tinnitus assessment reports are able to be generated after completing the three steps to tinnitus assessment. Once all steps are complete you are able to print a report



1. To generate your tinnitus assessment report, select “printer ...” from the File menu.



2. The “Channel” reports are the tinnitus assessment reports. Select the channel used for testing or All Channels when multi-channel testing is completed.



3. Use the drop down box to select a diagnosis for the patient.



4. Comments can be entered in 4 separate lines with a maximum of 60 characters.

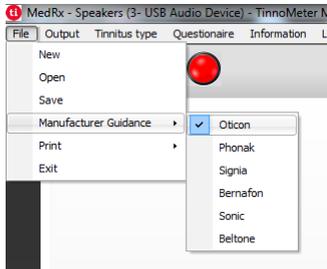


5. Print the Report.

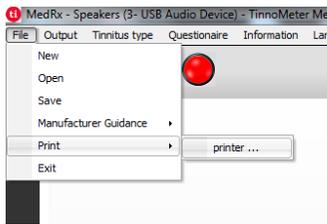
Manufacturer Guidance Report

Manufacturer guidance reports are designed to provide hearing aid sound therapy guidance to a clinician based on tinnitus assessment results. Sound therapy is an option to tinnitus treatment. We encourage all clinics to develop a tinnitus treatment protocol that is in line with their tinnitus treatment goals. Manufacturer guidance generated by the Tinnometer is designed to be a starting point in sound therapy and each patient may differ in preferred sound.

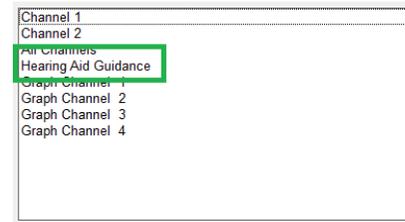
Manufacturer guidance reports are able to be generated after completing the three steps to tinnitus assessment. Once all three tinnitus assessment steps are complete you are able to print a report.



1. Select the manufacturer that you would like to have printed in your report.



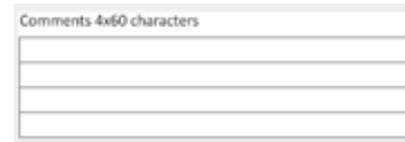
2. To generate your tinnitus assessment report, select “printer ...” from the File menu.



3. Select “Hearing Aid Guidance” from the list of reports



4. Use the drop down box to select a diagnosis for the patient.



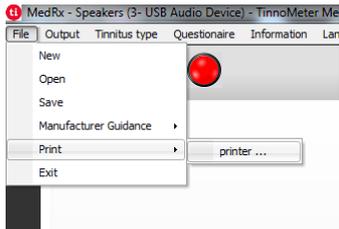
5. Comments can be entered in 4 separate lines with a maximum of 60 characters.



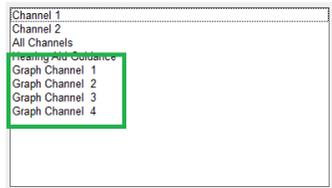
6. Print the report.

Graph Channel Report

Graph channel reports will print a patient report which displays an image of the patient's tinnitus with QR codes for YouTube videos that play a wind modulation noise nearest to their tinnitus. To generate the report you must:



1. To generate your tinnitus assessment report, select "printer ..." from the File menu.



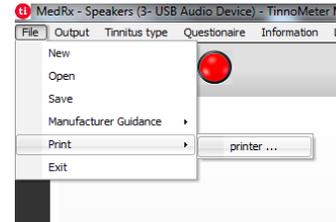
2. Select "Graph Channel" from the list of reports. Select the channel number which you used to match your patient's tinnitus sound.



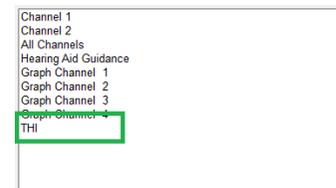
3. Print the report.

Questionnaire Report

Questionnaire reports will only show as an option once the questionnaire has been completed. Once a questionnaire has been completed and you are ready to print a report you must:



1. To generate your tinnitus assessment report, select "printer ..." from the File menu.



2. Select the name of the questionnaire you want to print from the list of reports.



3. Print the report.

Hearing Loss Simulator

The Hearing Loss Simulator demonstrates the effect of the client's hearing loss for the significant third party. The program attenuates an input signal to simulate the audiogram. The third party listens to the free field speakers.

The Hearing Loss Simulator requires the client's audiogram data. This data can be manually entered in the Audio screen of this or any other task.

How to perform the Hearing Loss Simulator task

1. Select the Hearing Loss Simulator tab on the toolbar.
2. Enter the audiogram values manually if the data is not automatically imported to this screen.
3. Select the input signal type: File or CD. Select the track and the Play button on the control panel. The HLS output is directed to the free field loudspeakers.
4. Select Simulate to turn on the simulation of the client's hearing loss. Deselect simulate to present the stimulus as a normal hearing person would perceive the sound. Toggle between these selections as necessary.
5. The Reset option restores the audiogram to the original state. Use this option if you have modified the audiogram while in the simulate mode but want to undo the changes. The changes to the audiogram that are made on the HLS screen are temporary and will not affect the client's original audiometry record.
6. A volume control adjustment bar allows modifying the audio for manual adjustment of the output level of the free field speakers. This allows the practitioner to demonstrate improvements to hearing loss with amplification or what happens when further hearing loss occurs.

7. To stop the playback, select the Stop button on the player.

Note: It is recommended you use a variety of tracks from the list to demonstrate the hearing loss.

Master Hearing Aid

Master Hearing Aid is an alternative to using a stock hearing aid to demonstrate the benefits of amplification to an inexperienced user. The system applies the fitting rules by default to the patient's audiogram and simulates a hearing aid. The patient listens to this signal through the headphones. Options for editing the gain applied to the audiogram are provided.

About the Master Hearing Aid Display

The Master Hearing Aid screen displays a graph with dB gain on the vertical axis and frequency in Hz on the horizontal axis. The plot on the graph represents the gain applied to the patient's audiogram. The NAL-RP is applied by default. A new rule can be selected from the list on the right side of the display. A volume adjustment bar allows for manual adjustment of the output level. The control panel on the right of the display provides options for input signal source and the task icons for normal and simulate.

The Master Hearing Aid applies gain separately for each ear. If audiogram values are entered for the left and right ear, the selected fitting rules will be applied to each ear separately. Different rules may be entered for different ears (i.e. NAL-RP for left ear and BERGER for right ear). If an audiogram is entered only for one ear, the gain will not be adjusted for the opposite ear and the sound for that ear will be normal.

If binaural mode is selected, the sound will be heard from both channels (left and right). If monaural mode is selected, the sound will be heard only from the channel corresponding to the active ear when the channel for the opposite ear will be muted.

Input signal

File allows the user to play sound files. The program supports MP3 and WAV files and comes with a preset MedRx Sounds Sensations set of files. After the option is activated, use the media player to control the playback.

CD allows the user to play music CDs. After the option is activated, use the player panel to control the playback.

How to use the Master Hearing Aid:

1. Select the Master Hearing Aid (MHA) icon from the main screen.
2. Enter the audiogram values manually if the data is not automatically imported to this screen.
3. Select the input signal type: File or CD.
4. Select Monaural or Binaural.
5. Select the Simulate icon to modify the input signal according to the selected rule. This selection allows the patient to hear the benefits of amplification. Deselect the Simulate icon which will send the input signal through to the inserts without modification. The patient is listening to the signal without any amplification benefit. Toggle between these two selections as necessary.
6. If the simulated frequency response needs to be adjusted, based on feedback from the patient, manually edit the response by clicking on the gain curve at the desired frequency and new gain level. The gain curve of the selected test ear on the control panel can be edited. To

edit the other ear, click the appropriate test ear icon on the control panel first.



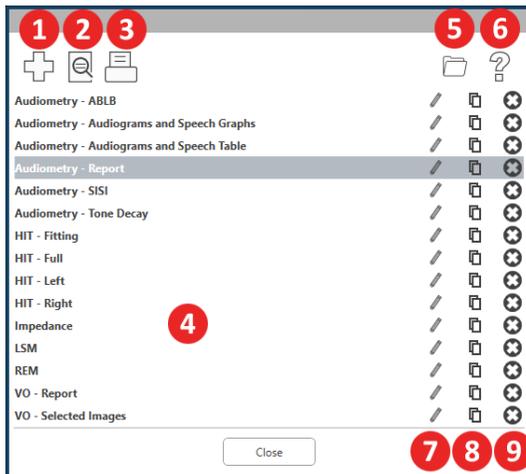
Hint: Use the track return icon on the player control panel to replay one track continuously.

The Reset option restores the rule to the original state. Use this option if you have modified the rule but want to undo the changes.

Printing

Printing within the MedRx Studio software. You can use the templates provided at installation or create your own templates to suit your needs.

Icons in the Print Window

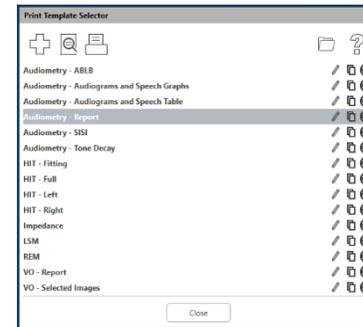


1. Create a new template.
2. Preview template icon.
3. Print template icon.
4. Select the template you would like to use.
5. Shortcut to templates folder on your desktop.
6. Studio Help icon.
7. Edit the template with the pencil icon. Editing a template will open the print editor and allow you to adjust print elements.
8. Duplicate existing templates icon.
9. Delete template icon.

To Use an Existing Print Template



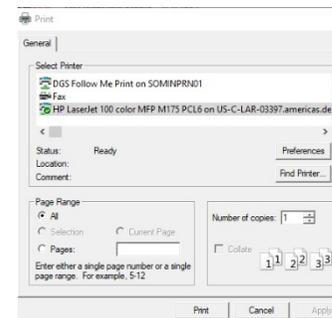
1. Click the print icon in the top tool bar or hold down the Ctrl key and click the P key on your keyboard.



2. Select the template you would like to use.
3. Click the print preview icon to see the patient's data & images on the template before printing.



4. Click the print icon.



5. The printer options box will pop-up.
6. Click print.
7. Or click Ctrl+Shift+P to print the modules default template.

Create New Print Templates



1. Select the printer icon.



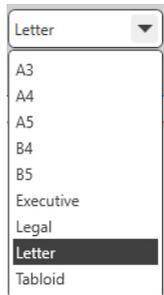
2. Select the + icon to create a new template.



3. Name the template you are creating.

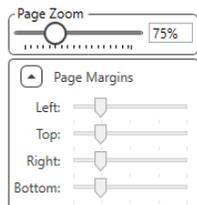


4. Choose page orientation.

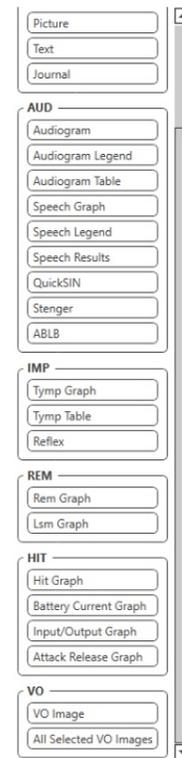


5. Use the drop-down menu to choose the size of paper you will be using.

6. In the bottom left, Page Zoom will allow you to zoom in/out of the template for easier editing.



7. In the bottom left, the Page Margin is set by default to the ideal level. Adjusting this will determine how far items will print from the edges.



1. Drag and drop elements onto the page to create your template.

- a. You can combine data from multiple modules into a single template.
- b. Elements may overlap and will stack/cover previously added elements.
- c. Certain elements will have settings that can be adjusted after dropping onto the page.
- d. You can resize all elements. The contents of each element will resize within the box depending on the amount of data in the element.



2. Use the + button to add additional pages if needed.



3. After template completion, use the Save, Save As, Preview and Print Icons for your template.

- a. Saved templates will be available for future sessions.
- b. Print a template to ensure that all elements print as expected.

EMC Precautions

The Avant Audiometer needs special precautions regarding EMC and needs to be installed and put into service according to the following EMC information.

List of all cables and maximum lengths of cables, transducers and accessories:

Transducer / Accessories	Maximum Cable length
USB Cable	3 meters
Insert Earphones	2 meters
All Headsets	2 meters
All Microphones	2 meters



Warnings!

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

Guidance and manufacturer's declaration – electromagnetic emissions		
The Avant Audiometer is intended for use in electromagnetic environment specific below. The customer or the user of the Avant Audiometer should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Avant Audiometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Avant Audiometer is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Non applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Non applicable	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Avant Audiometer is intended for use in electromagnetic environment specific below. The customer or the user of the Avant Audiometer should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact discharge +/- 2, 4, 8 & 15kV air discharge	+/- 8 kV contact discharge +/- 2, 4, 8 & 15kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input / output lines	+/- 2 kV for power supply lines +/- 1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	NA	NA	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Avant Audiometer is intended for use in electromagnetic environment specific below. The customer or the user of the Avant Audiometer should assure that it is used in such an environment.			
Immunity test	IEC 60601- test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Avant Audiometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM Band 1 kHz AC Mains	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM Band 1 kHz AC Mains	$d = 1,17 \times \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,17 \times \sqrt{P}$ 80 to 800 MHz $d = 2,33 \times \sqrt{P}$ 800 MHz to 2,5 GHz
			<p>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).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>
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.			
<p>a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Avant Audiometer is used exceeds the applicable RF compliance level above, the Avant Audiometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Avant Audiometer.</p> <p>b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

**Recommended separation distances between
Portable and mobile RF communications equipment and the Avant Audiometer**

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter meters		
	150 kHz to 80 MHz $d = 1,17 \times \sqrt{P}$	80 MHz to 800 MHz $d = 1,17 \times \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,33 \times \sqrt{P}$
0,01	0,12	0,12	0,233
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,7	3,7	7,40
100	11,7	11,7	23,3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Safety

- Regarding electrical safety, this device is designed to be used only by professionals in the hearing healthcare industry.

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

device provides Type B protection  (Type B equipment, Type B applied part)

- This device is not protected from ingress of water. 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 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 Audiometer, CUI ETMA150200UD-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  , humidity within 30% to

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 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, 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



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)



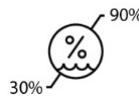
Authorized Representative in Europe



Non-ionizing electromagnetic radiation



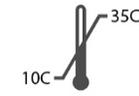
Special Disposal Required



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



Handheld microphone
(Talkback 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.

Technical Information

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

Standards:

IEC 60601-1: 2012 Class II
 IEC 60601-1-2 Class A
 IEC 60645-1: 2012
 ANSI S3.6-2010 : Type 2 AE (A2D+)
 ANSI S3.6-2010 : Type 1 AE (Stealth)
 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: 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") Tinnometer/AIR+: Approx. 5" x 5" x 1.25"

Weight: Less than 2 lbs.

Power Supply: 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)
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:	Calibration values:	Calibration values:	Calibration values:	Calibration values:
Headphone DD45 NBS-9A acoustic coupler Force 4-5 N, ANSI and IEC DD45 RETSPL Values RETSPL dB re 20µPa 125=47.5 250=27.0 500=13.0 750=6.5 1000=6.0 1500=8.0 2000=8.0 3000=8.0 4000=9.0 6000=20.5 8000=12.0 Speech=18.5	Headphone TDH39 NBS-9A acoustic coupler Force 4-5 N, ANSI and IEC RETSPL dB re 20µPa 125=45.0 250=25.5 500=11.5 750=8.0 1000=7.0 1500=6.5 2000=9.0 3000=10.0 4000=9.5 6000=15.5 8000=13.0 9000=13.0 10000=13.0 11200=13.0 12500=13.0 Speech=19.5	Insert phone Eartone 3A HA-2 acoustic coupler RETSPL dB re 20µPa Sound Attenuation 125=26.0 32.5 250=14.0 36 500=5.5 37.5 750=20 - 1000=0 36.5 1500=2.0 - 2000=3.0 33 3000=3.5 - 4000=5.5 39.5 6000=2.0 - 8000=0 42.5 Speech=12.5	Insert phone IP30 HA-2 acoustic coupler RETSPL dB re 20µPa Sound Attenuation 125=26.0 32.5 250=14.0 36 500=5.5 37.5 750=2.0 - 1000=0 36.5 1500=2.0 - 2000=3.0 33 3000=3.5 - 4000=5.5 39.5 6000=2.0 - 8000=0 42.5 Speech=12.5	Bone conductor Radioear B71 Force: 4.9 ... 5.9 N Mastoid placement – ANSI S3.13 coupler Air Radiation mean /maximum 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 4/18 4000=35.5 - 6000=40.0 10.5/31 8000=40.0 - Speech=55.0	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.

Limited Warranty

MedRx warrants this product to be free from defects in material and workmanship for two years from the time of purchase. If this system fails to perform as specified during this period, the purchaser is responsible for calling MedRx at +49 30 70 71 46 43. The company's representative will advise the owner to either return specific components or the entire system to:

MedRx International
c/o MAICO Diagnostics GmbH
Sickingenstr. 70-71 10553 Berlin
Germany

MAICO will repair or replace any defective devices, fully test the system and/or components and ship the system promptly back to the owner. There is no cost for the repair or return shipping, provided the system is two years old or less and has not been misused, abused or damaged. Such damage includes, but is not limited to, dropping, exposure to excessive heat greater than 37,78° C and water/liquid damage.

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

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

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

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