



M 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



www.medrx-diagnostics.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-diagnostics.com

www.medrx-diagnostics.com



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

Distributor: MedRx International
DGS Diagnostics Sp. z o.o.
Rosówek 43
72-001 Kołbaskowo, Poland
Tel.: +48 91 835 63 00
Email: orders@medrx-diagnostics.com
www.medrx-diagnostics.com



MedRx's Archived manuals are available at www.medrx-diagnostics.com/support/manuals-studio-software/archive

Contents

Getting to Know Your AVANT Audiometer	4
Avant A2D+ Audiometer	5
Avant AIR+	5
Transducers and Accessories	6
Loading Calibration Files	7
AUDIOMETER MODULE Studio Software Overview	8
Audiometry	9
Top Tool Bar	9
Assign Transducers	10
Preparing for Testing	11
Placing the Earphones on the Patient	11
Sound Field Testing	13
Performing Audiometric Testing	14
Pure Tone Audiometry	15
Speech Audiometry ¹	17

Word Recognition (WR) ¹	21
QuickSIN ¹	22
Tinnitus ¹	24
VRA MODULE ¹ (Optional)	29
Hearing Loss Simulator	39
Master Hearing Aid	39
Printing	41
EMC Precautions	43
Safety	47
Complaints/Safety Reporting	48
Symbols that may be used	49
Recommended Procedures for Cleaning and Disinfection	50
Technical Information	51
Limited Warranty	54



Getting to Know Your AVANT Audiometer

Intended Use Statement:

The MedRx Audiometer is intended to be used for the purposes of determining patient hearing sensitivity. It is intended to quantify the patient's level of hearing by presenting pure tone stimuli through specific transducers at different frequencies and at different sound pressure levels. In addition to tonal stimuli, the devices can also present language-specific stimuli in order to identify further legions of the patient's auditory pathway and their ability to recall what is presented to them.

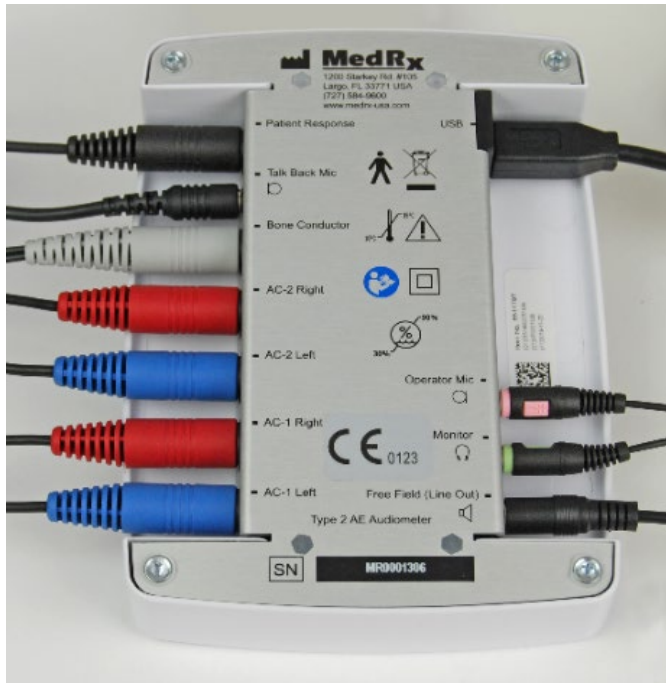
Indication For Use Statement:

The MedRx Audiometer is intended to be used for the identification and etiology of hearing loss in patients of any age. It is intended to be used by an audiologist, ENT, hearing healthcare professional, or trained technician in a hospital, clinic, healthcare facility or other suitable quiet environment as defined in ANSI S3.1 or equivalent.

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.

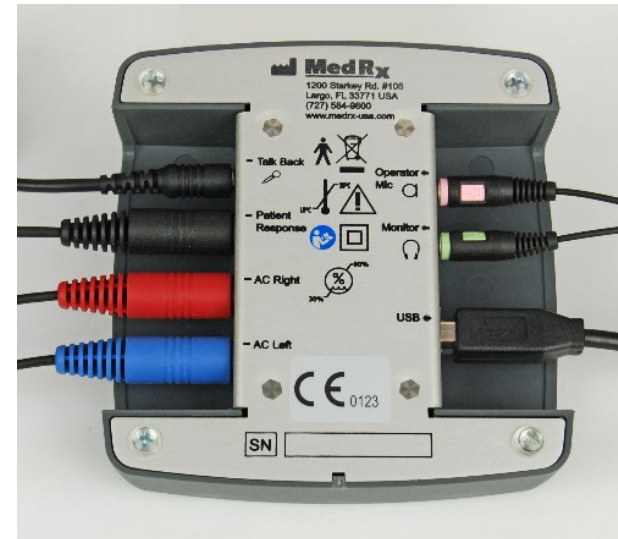
This manual assumes that the system hardware, software and drivers are installed and working properly. Please refer to the Studio Software Installation Manual for assistance. The Installation Manual is included in the original AVANT Audiometer packaging in PDF format.

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 AIR+

The AVANT AIR+ 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.

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



Supra-Aural Headphones



Bone Conductor



Operator Mic & Monitor (may vary)



3A Inserts (Optional)

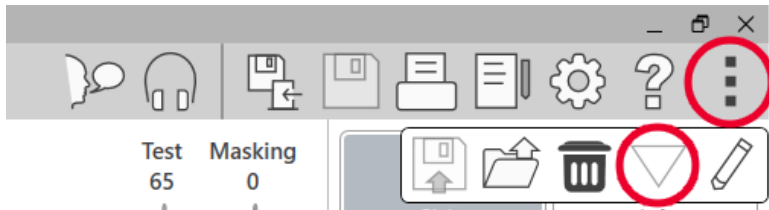
NOTE: The Avant Audiometer supports IP30 Insert earphones, 3A Insert earphones, TDH-39, DD450, DD45, and DD65v2. The standard configuration includes either IP30 Insert Earphones or DD45 or DD450 earphones.

Loading Calibration Files

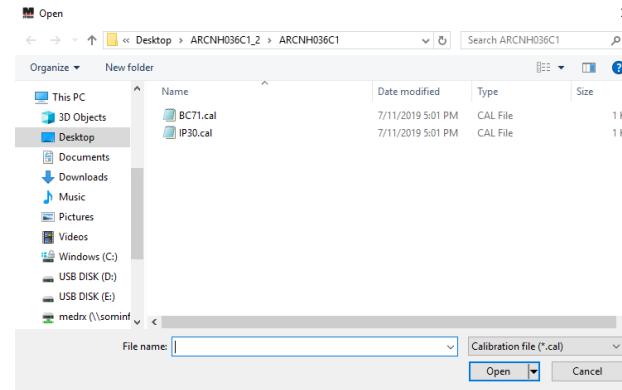


Each AVANT Audiometer is calibrated in compliance with the ANSI S3.6 standard. This calibration procedure results in a series of files that the Audiometer software reads to keep the hardware in calibration. These files are supplied on a USB Stick.

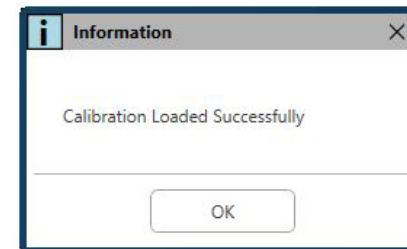
The final step before using your AVANT Audiometer to evaluate hearing is to load these device specific calibration files onto the computer used to operate the Audiometer device.



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).



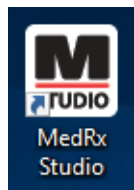
3. When the files are finished being loaded, this message will appear:
 - Click **OK** to complete loading the calibration.

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

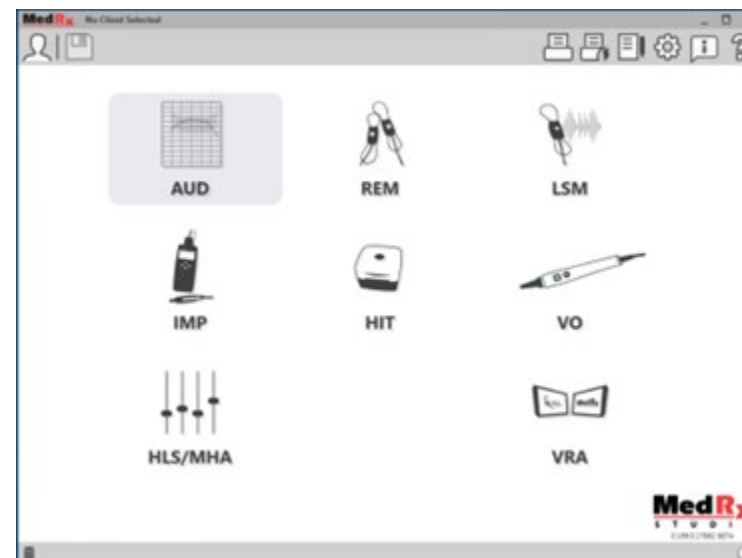
- Launch Noah.
- Select a patient
- Launch MedRx Studio module following Noah procedures.

Basic Software Options

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

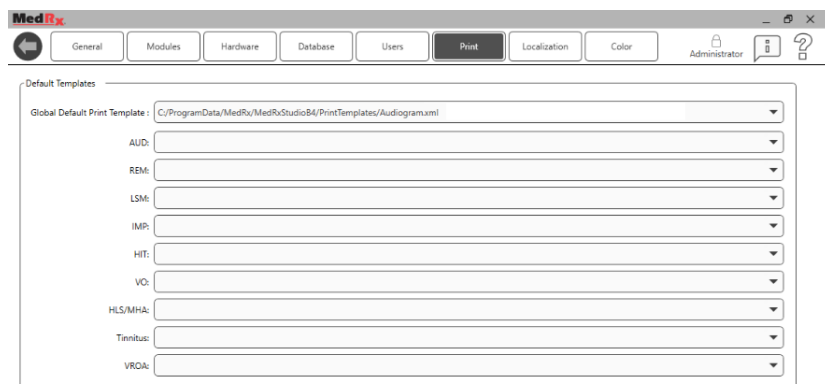


Access these options by clicking the settings wheel in the top right menu bar.

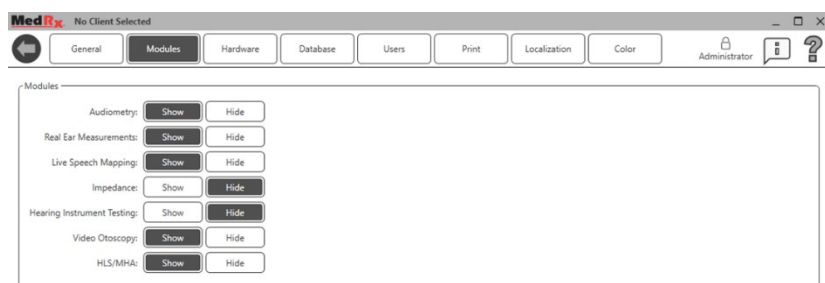


The MedRx Studio software main screen.

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

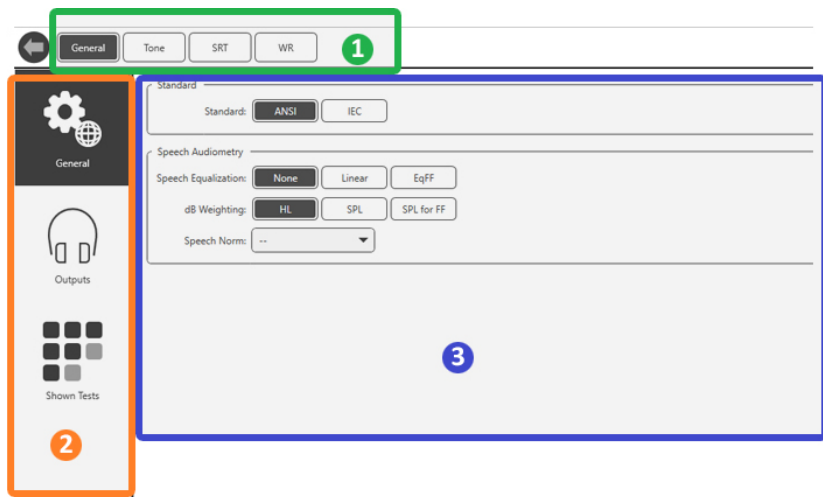


AUD

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



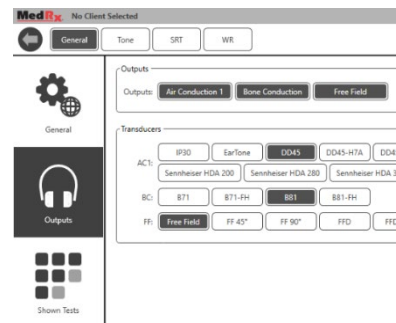
Enter the module and click the settings wheel to customize.



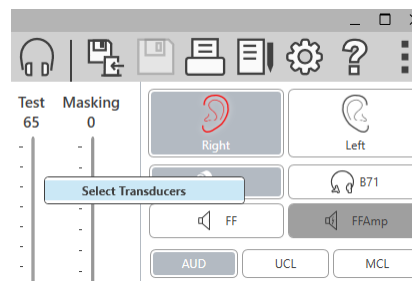
The Audiometry module has unique settings for the module. To navigate the settings you will:

- 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).

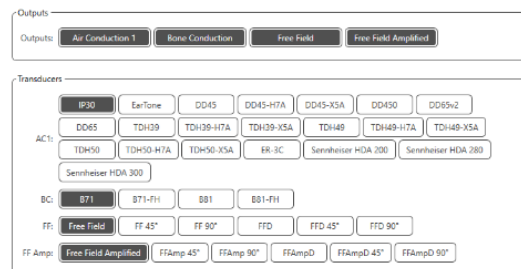
Assign Transducers



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.

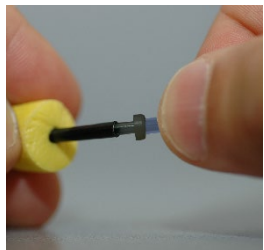
The Operator Headset with microphone is used by the device operator to communicate with the patient.

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

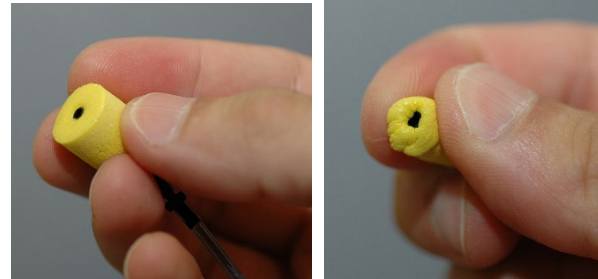
Placing the Earphones on the Patient

Insert Earphones

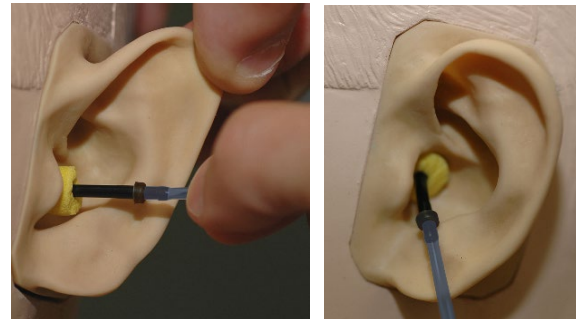
IMPORTANT: The foam tips used for the insert earphones are for SINGLE PATIENT USE ONLY. Do not attempt to wash and re-use them.



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.

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.

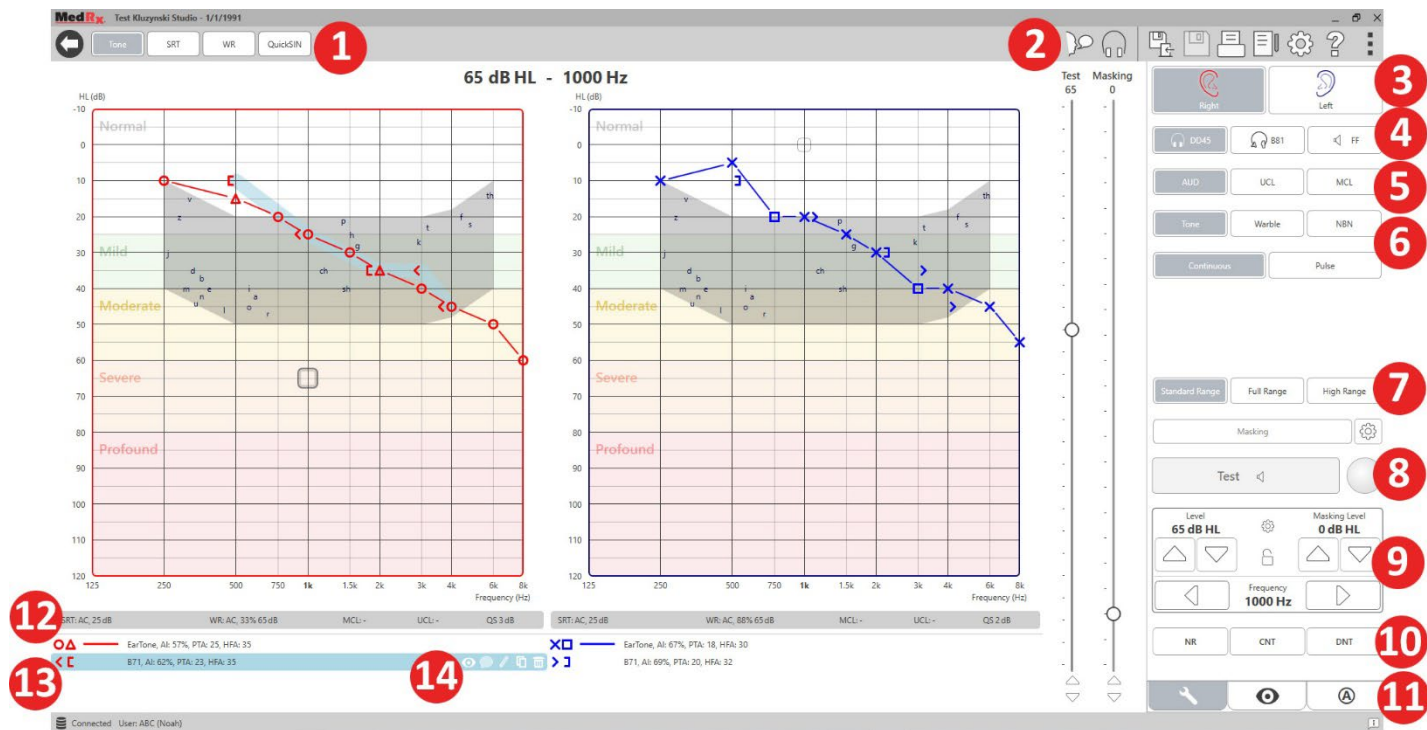
Device Maintenance

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. Display Options (Frequency)
8. Test and Masking Interrupter, Routing Selector
9. Output Level Potentiometers
10. Response Options
11. Screen Option Tabs
12. Test Results
13. Legend
14. 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.
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: 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).

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.

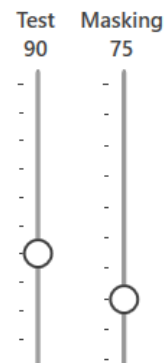
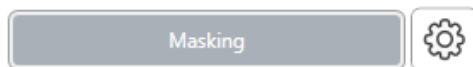


2. Establish bone conduction thresholds as described above (see page 15, steps 5-8) for 1000 Hz, 2000 Hz, 4000 Hz, 500 Hz and 250 Hz.
3. If the Bone Conduction (BC) threshold at a given frequency is less (better) than the Air Conduction (AC) threshold by 15 dB or more, you must confirm the threshold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

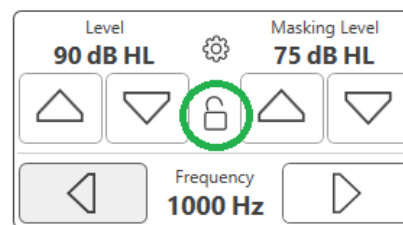
Masking for Pure Tone Audiometry

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

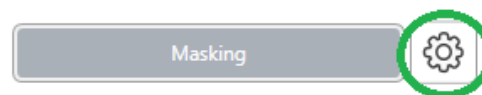
1. Click the Masking button or press the “m” key. The button will appear grey (as shown) indicating that the masking is on.



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+

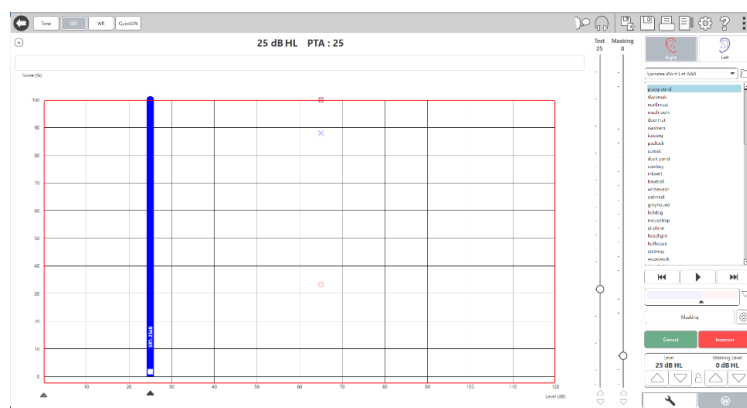


5. Use your mouse to select the new masking type and routing for your specific application.

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

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.



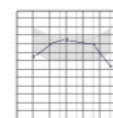
The sections below detail how to perform these tests in MedRx Studio.

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.”

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.

¹ Not Available in AIR+



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.

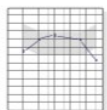
If the patient exceeds a 50% score at a given presentation level, stop the test and decrease the level by 10 dB and repeat the steps above.

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

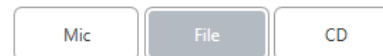
1. From the MedRx Studio main screen, Click the AUD button.



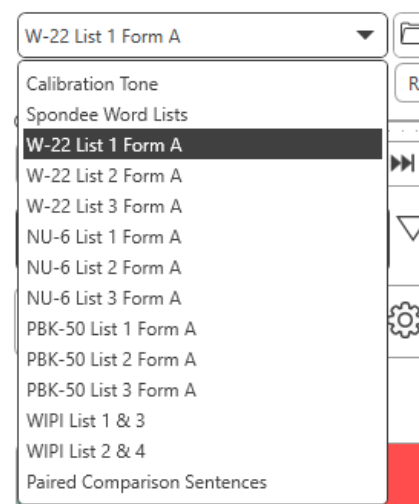
2. Click the WR button located on the toolbar on the top of the screen.



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.

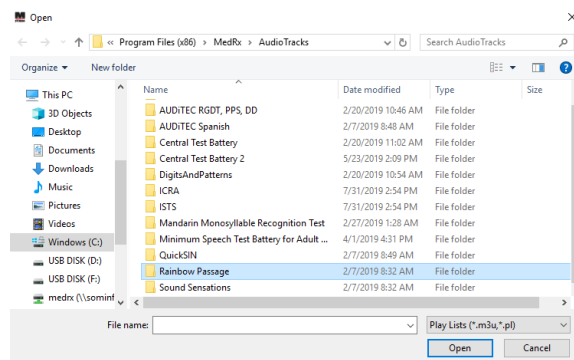
Adjust levels up or down with keyboard arrows or by clicking below the dB level at the bottom of the test slider or masking slider.

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

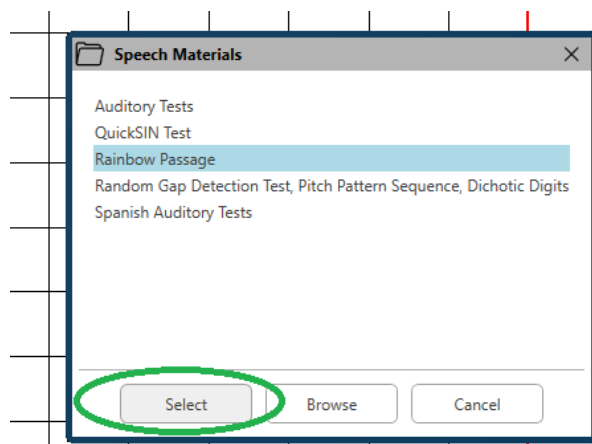
6. **To Input & Calibrate the Rainbow Passage** in WR for MCL:



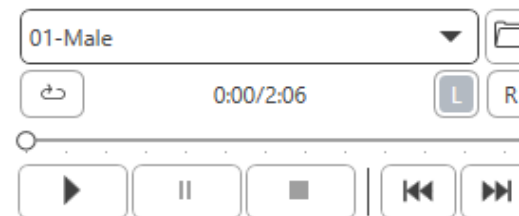
a. Press the small file folder on the top right of media player. Then select "Browse" in the speech material.



b. Select Rainbow Passage by double clicking twice.

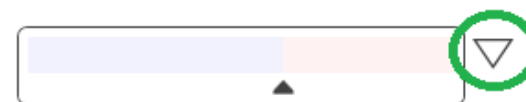


c. The Rainbow Passage is now part of the MedRx Studio Audio Files for future use.



d. Use the drop down in the media player and select track 10 – Calibration (1000Hz).

e. Click play or start signal.

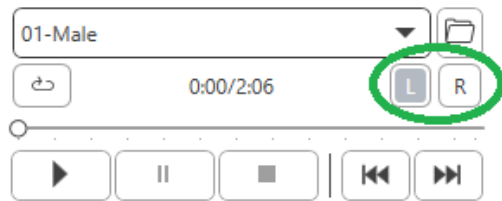


f. Then click the calibration arrow next to the UV meter.

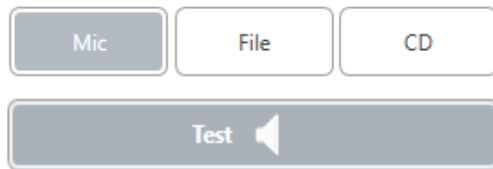


g. On the VU meter pop-up, press the slider calibration icon just below the VU meter.

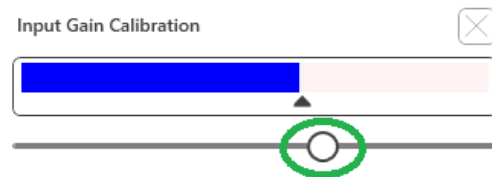
h. Adjust with mouse or arrow keys so that the blue bar stops over the black arrow and there is no red.



- 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.

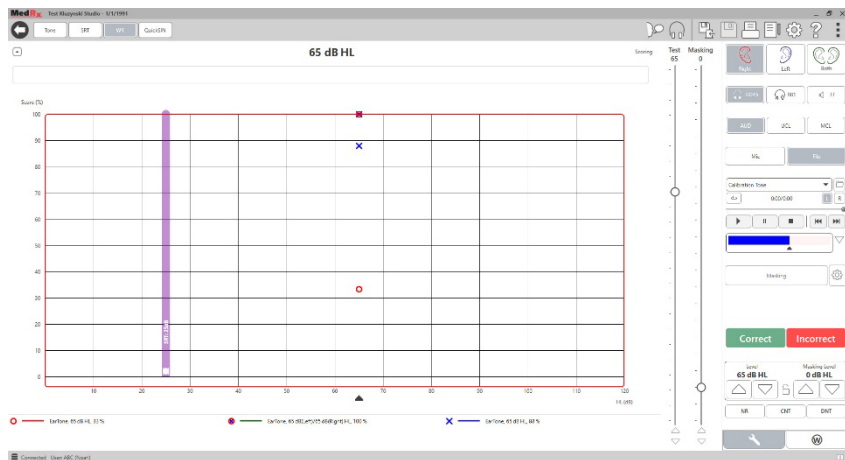


8. When using the Mic option adjust your input using the slider so that it is peaking at the black triangle under the VU meter.

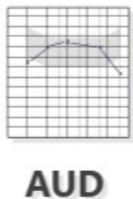
The VU meter is just below the Test button in MedRx Studio and will become active once you press Test.

Word Recognition (WR)¹

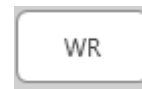
Word Recognition (WR) is a discrimination, or recognition type test using speech as the stimulus. WR testing measures the percentage of mono-syllable words repeated correctly from a phonetically balanced list. Unlike the SRT test, the WR test is performed at a fixed intensity (dB) level. Typical patients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



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.

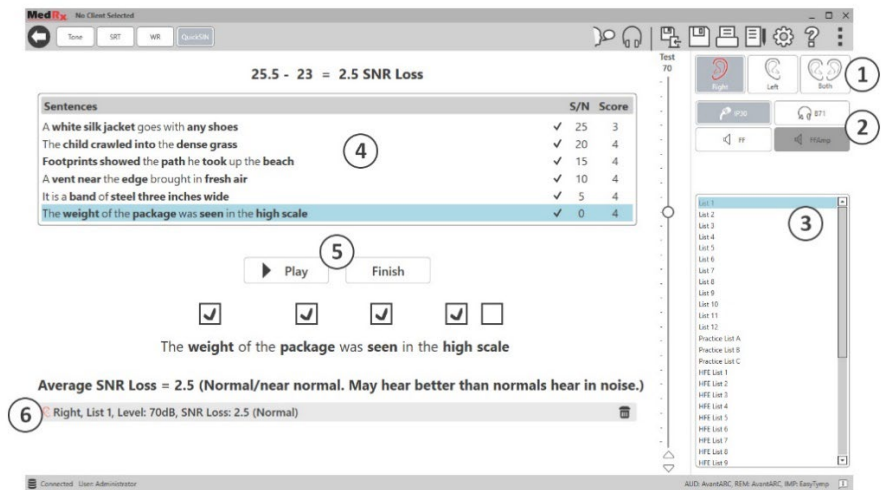
¹ Not Available in AIR+

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.

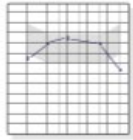


The screenshot above shows the key features of the QuickSIN test.

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

¹ Not Available in AIR+

Performing the QuickSIN Test



AUD

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

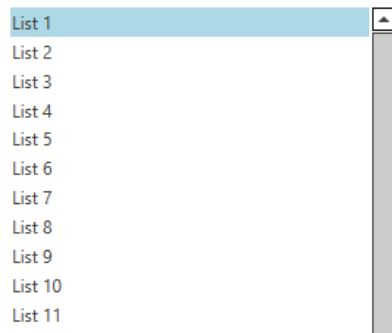


2. Click the QuickSIN button located on the toolbar on the top of the screen.

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

▶ Play

▶▶ Next



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.

▶ Play

▶▶ Next

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.)

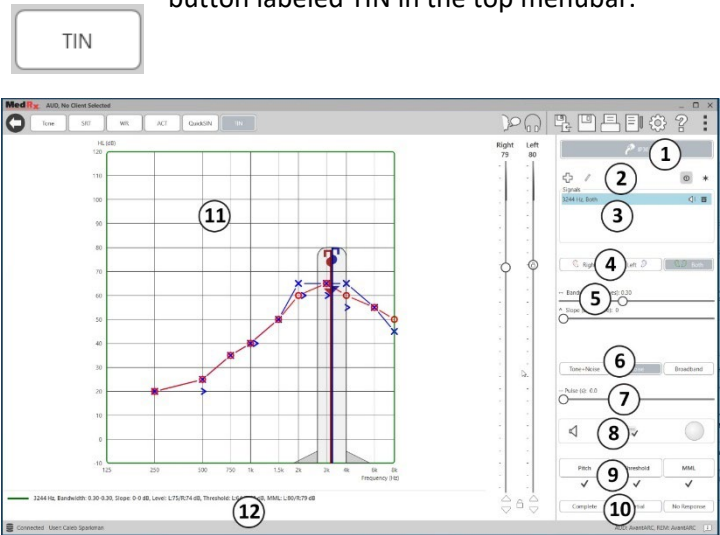
Right, List 1, Level: 70dB, SNR Loss: 2.5 (Normal)

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

- Average SNR Loss in dB.
- Recommendations.

Tinnitus¹

Tinnitus is the perception of ringing or other noises in one or both ears without an external sound source. The MedRx tinnitus test is designed to create customized stimulus designed to match a person’s perceived tinnitus. The tinnitus test is available within the AUD module and found by clicking the button labeled TIN in the top menubar.



The above screenshot shows the key features of the Tinnitus test marked numerically.

- | | |
|------------------------------|--------------------|
| 1. Input Transducers | 2. Signal Options |
| 3. Signals | 4. Earside |
| 5. Bandwidth & Slope | 6. Stimulus signal |
| 7. Pulse | 8. Controls |
| 9. Tinnitus Measurements | 10. Result |
| 11. Graphical Representation | 12. Legend |

The following explain the elements of the key features:

Input transducer	Inserts, Circum Aural, or Free Field.
Signals Options	➕ Add new signal. ✎ Select predefined shape for selected signal. ① Play only one signal. Individual signals can still be re-selected. ★ Play all signals. Individual signals can still be de-selected.
Signals	Number of signals available to present to a patient.
Earside	Right, Left, Both
Bandwidth	Adjust the width of the signal presented.
Slope	Adjust the signal filter by dB/Octave.
Stimulus signal	Tone+Noise - Signal with noise and a pure tone signal embedded at the center frequency designed to replicate tinnitus sounds. Noise - Signal with noise within the bandwidth and slope desired. This is designed for replicating noise based tinnitus and achieving Minimum Masking Levels. Broadband - Broadband signal designed to perform Minimum Masking Levels (MML).
Pulse	Adjustment of the duration between signal and quiet. Designed to allow the patient to listen to the signal presented and compare to perceived tinnitus during quiet periods.

¹ Not Available in AIR+

Controls	 Starts/stops signals activated in the signals box.  Link/Unlink the high and low frequency portions of bandwidth and slope.  Follow/Unfollow the tinnitus signal levels presented in each ear to the audiogram thresholds plus desired sensation level set in settings.  Patient response indicator.
Tinnitus Measurements	Pitch - will save signal information for the pitch and level match of the patient's tinnitus. Once the pitch is selected, frequency changes are unavailable for threshold and MML. Threshold - will save signal information for the threshold match of the replicated signal for the patient's tinnitus. MML - Minimum Masking Level (MML) - will save signal information for the MML. It is recommended to move to Noise or Broadband to achieve masking. If Noise is selected, it is possible to change bandwidth/slope of the noise for MML. To set the filters to the scored values, click the ✓ (check) symbol. To delete the score, click the check symbol with the Right mouse button.

Result	Complete - complete masking was achieved. Patial - partial masking was achieved. No response - no masking was achieved.
Graphical Representation	A view of the stimulus being played and the shape of the signal being presented to the listener
Legend	Descriptions of the items found in the graphical representation

Tinnitus Test Procedure

There are many different procedures that can be used to match a listener's tinnitus. The following will be one way that a clinician can measure a listener's tinnitus, but not the only way.

In Tinnitus testing we recommend setting the Threshold Offset to 5-10 dB which will allow the signal to follow the audiogram levels at your chosen 5 or 10 dB above threshold. Also, be sure you choose Follow Audiogram in the test screen.



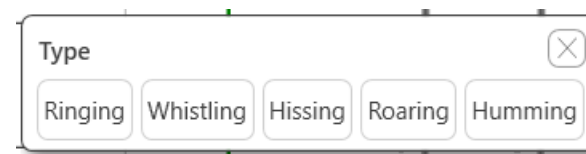
Step 1: Audiometry

Complete audiometric testing

Step 2: Stimulus Setup

Ask the listener what their tinnitus sounds like to them.

In **Signal Options** add new signal, choose the closest pre-tuned signal that best matches their answer.



Be sure that you have the appropriate earside chosen when adding new stimulus. We recommend presenting all signals binaurally whenever a patient describes their tinnitus as similar in both ears.

Step 3: Pitch Matching

To present the stimulus to a listener and allow the listener to compare it to their tinnitus, we recommend pulsating the sound by 1 to 3 seconds. Use the Pulse slider to adjust the pulsation to your desired tempo.



 Begin the presentation of the sound to the listener by clicking the speaker icon. Ask them to compare it to their tinnitus. Ask the listener if the sound quality is like the tinnitus they hear. Adjust the bandwidth and slope of the stimulus until the patient says the sound quality is similar. Ask the listener if the pitch being played is higher or lower than their tinnitus pitch.

Let the listener know you will adjust the pitch of the stimulus (in the direction indicated) and instruct the listener to push the button when the sound presented is close to their tinnitus in pitch. Move frequencies slowly as the sound pulsates every few seconds. Stop at the button push and ask the listener to compare the new sound to their tinnitus. Repeat this process until you have matched the patient's tinnitus pitch.

Step 4: Loudness Matching

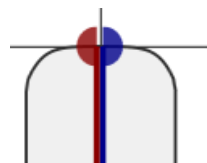
Now that the pitch has been matched to the listeners' tinnitus, the next step will be to match the loudness of the tinnitus. Continue to pulsate the stimulus being presented to make it easy for the listener to compare their tinnitus to the stimulus from the audiometer. Instruct the listener to try to match the

loudness of their tinnitus with the sound being played. Determine whether to increase or decrease the stimulus then have the listener push the button when the stimulus is blending with their tinnitus. Use the level slider or arrow keys to adjust the level from the audiometer. Once complete, confirm that the tinnitus level and pitch are a fair representation of the listeners tinnitus.

Press the Pitch button to lock in the pitch and loudness of the listeners tinnitus.



You will see the check mark filled in under the button and marks appear on the tinnitus graph.



This indicates that you have successfully matched both pitch and loudness for the listener. The frequency adjustments will be locked for this stimulus from this point forward in the testing.

Note: If you need to remove your recording, right click the check mark under the button.

Step 5: Threshold

As you are presenting a novel stimulus to the listener it is important to determine the threshold of the new stimulus. To complete this, turn off the

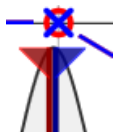
sound and lower below estimated threshold. Set the stimulus to a constant by moving pulse to 0 sec:



instruct the patient to listen and push the button as soon as they hear the stimulus being presented. Complete this task until a repeatable threshold is found. Click the threshold button to mark the threshold.



You will see the check mark filled in under the button and marks appear on the tinnitus graph.



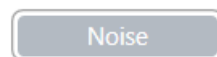
This indicates that you have successfully matched both pitch and loudness for the listener. The frequency adjustments will be locked for this stimulus from this point forward in the testing.

Step 6: Minimum Masking Levels

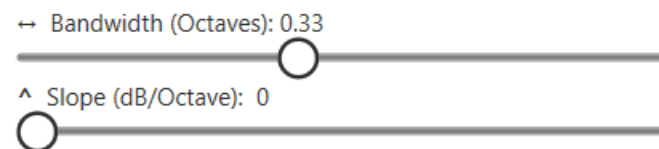
At this point in the testing, pitch, loudness and threshold of the tinnitus has been determined. It is important to next determine if the listener is a good candidate for sound therapies like hearing aid maskers. Determining the minimum masking levels for the listener's tinnitus can indicate whether this could be viable.

To complete minimum masking levels, you need to determine the type of stimulus you plan to use for masking. MedRx recommends using either a narrowband noise centered at the listener's tinnitus pitch or a broadband noise.

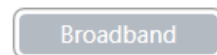
To make a narrowband noise, you must select the Noise from the sidebar.



This removes the tonal component meant to mimic a tinnitus sound. It is also recommended to set a slope close to 0 and open the bandwidth to at least 1/3 (0.33) of an octave.



To make a broadband noise, you must select broadband from the sidebar.



This will change the signal to a broadband noise where slope and bandwidth will no longer affect the noise.

After determining the type of noise you would like to present to the listener, you will need to instruct the listener of the task. Instruct the listener to listen to the stimulus being played and their tinnitus. Have the listener push the button when the stimulus being played is the only sound that can be heard or the tinnitus is less noticeable than the tinnitus sound in the listener's head. Begin to increase the volume of the masking noise gradually until the listener pushes the button. Continue to play the sound for up to 60 seconds. Ask the

listener if their tinnitus was less noticeable but still perceptible (partial masking) or completely covered (complete masking) while you were playing the stimulus. If the listener states that neither partial or complete masking occurs then this would be considered a not maskable (no response). Click the MML button and mark the appropriate masking type.

Pitch	Threshold	MML
✓	✓	✓
Complete	Partial	No Response

If the initial level does not produce masking, then it is acceptable to increase the level above initial and try again.

Listeners that experience complete and partial masking are considered candidates where sound therapies may be viable.

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 monitors 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.

Screen

Force Software Rendering:

Yes

No

Number Of Presentation Screens:

1

2

3

Identify Screens

Reset Screens

Primary:

Screen 1

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.

¹ Not Available in AIR+

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

Reset Screens will discard the selected screen set up.

Two Screen Setup

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

Screen

Force Software Rendering:

Yes

No

Number Of Presentation Screens:

1

2

3

Identify Screens

Reset 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. These should be the screens that will be in the testing area where the child will be tested. If there are two monitors in the testing area the left and right monitors should be assigned in relation 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.

Reset Screens will discard the selected screen set up.

Three Screen Setup

Select 3 for **Number of Presentation Screens**. This will allow for three monitors to be used with the VRA Studio module.

Screen

Force Software Rendering:

Yes

No

Number Of Presentation Screens:

1

2

3

Identify Screens

Reset Screens

Primary:

Screen 1

Primary Screen Blackout:

Yes

No

Left:

Screen 1

Right:

Screen 2

Center:

Screen 3

Click **Identify Screens** to determine which screen you would like as the left and right reward screen as well as the centering screen. These should be the screens that will be in the testing area where the child will be tested. Be sure that the left and right monitors are assigned in relation 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.

Reset Screens will discard the selected screen set up.

VRA General Test Settings

The screenshot shows the 'VRA General Test Settings' window. It is divided into two main sections: 'Default' and 'VRA Test Settings'. The 'Default' section includes three rows of settings: 'Default Output' with buttons for 'Air Conduction 1', 'Air Conduction 2', 'Bone Conduction', 'Free Field', and 'Free Field Amplified'; 'Default Signal' with buttons for 'Tone', 'Warble', 'Narrow Band', and 'Microphone'; and 'Default Presentation' with buttons for 'Continuous' and 'Pulse'. The 'VRA Test Settings' section includes 'dB Weighting' with buttons for 'HL' and 'SPL for FF', 'Free Field Presentation Binaural Only' with 'Yes' and 'No' buttons, and 'Free Field Binaural Scoring' with 'Yes' and 'No' buttons.

Default Output, Default Signal, Default Pulse Type, dB Weighting, can be selected in this section.

dB Weighting determines whether the presentation is in HL or SPL during Free Field testing.

If **Free Field Presentation Binaural Only** is turned on, all presented sounds will be presented through both speakers. If it is turned off, the speakers will present independently.

If **Free Field Presentation Binaural Only** is turned on, the thresholds will be scored binaurally. If it is turned off, the thresholds will be scored per ear.

Playlists Setup

The screenshot shows the 'Play Lists' section of the software interface. It contains two buttons: 'Playlist Setup' and 'Reward Video Setup'.

In the **Reward Video Setup**, custom videos can be added. In **Playlist Setup** the selection and order of video rewards can be edited.

The screenshot shows the 'Reward Video Setup' window. It has a title bar with a close button. Below the title bar is a section labeled 'Add New Video' with a plus icon. Below that is a 'Video List' table. The table has two columns: the first column lists video names and the second column lists their file paths. The videos listed are 'High five', 'Factory', 'Space cadet', 'Aeroplane', and 'Train'. Their corresponding file paths are 'clip00.mp4', 'clip01.mp4', 'clip02.mp4', 'clip03.mp4', and 'clip04.mp4'. There is a vertical scrollbar on the right side of the table.

Video Name	File Path
High five	clip00.mp4
Factory	clip01.mp4
Space cadet	clip02.mp4
Aeroplane	clip03.mp4
Train	clip04.mp4

Click **Reward video setup** to access available reward videos, upload custom videos, and remove unwanted videos.

The screenshot shows the 'Playlist Setup' window. It has a title bar with a close button. Below the title bar is a dropdown menu labeled 'Playlist' with the value 'asef'. To the right of the dropdown are three icons: a plus icon, an edit icon, and a delete icon. Below the dropdown is a section labeled 'Add Existing Video(s)' and 'Add New Video' with plus icons. Below that is a 'Video Order' list. The list contains the following items: 'High five', 'Space cadet', 'Train', 'Number 3', 'Letter A', and 'A B C'. To the right of the list are two buttons: 'Move Order Up' and 'Move Order Down'. There is a plus icon next to 'Letter A' and a minus icon next to 'A B C'. At the bottom of the window are two buttons: 'Save' and 'Close'.

Playlist Setup allows users to create custom playlists of reward videos. The Playlist section will add, edit and delete playlists. Use the dropdown to select the playlist you want to edit. Under Playlists, you have the videos included in the playlist. Use the + icons to add more videos and the order icons to reorder videos. Hover over a video and click the x to remove the video from the playlist.

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:

Communication

Monitor Video Device: (None) Refresh List of Devices

Computer Name: US-C-MIS-03460

Identify IP Address

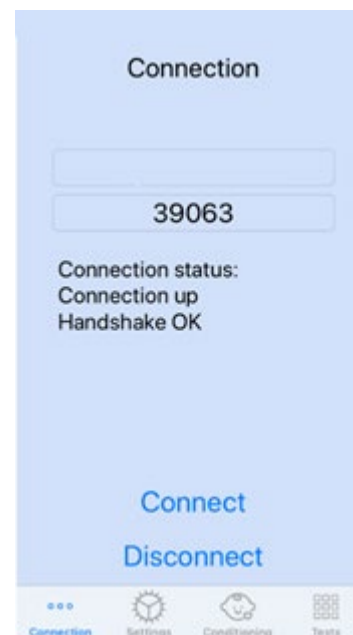
Port:

Studio will then list all available network connections. The VRA will need to be located on the same wireless network or Wi-Fi. On the iOS app, you can enter the computer name or Wi-Fi IP Address into the Server IP Address location

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.

Monitor Video Device will allow you to connect a webcam to your testing PC. The webcam is designed to be placed in the testing booth to monitor the testing. This webcam video feed can be activated during testing to view patient responses and determine when the child is ready for testing.



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

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.

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

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

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.



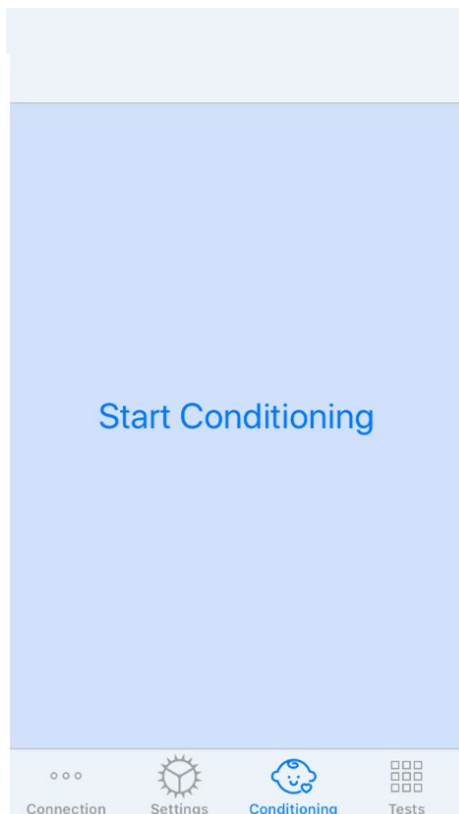
Settings Tab in the iVRA app

Check Ambient Noise	Opens a 1/3 octave band noise monitor to test the sound levels at 1kHz and 4kHz
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

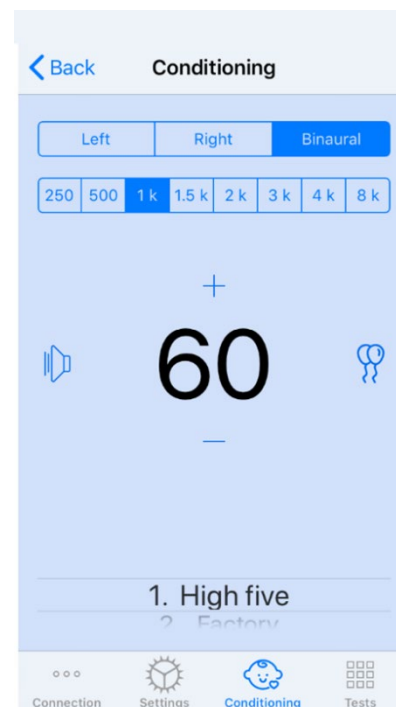
Non-stim rate	How often are catch trials inserted
Reward Length (s)	Number of seconds to present the video reward
Rewards Randomized	Automatically randomizes video reward presentations during testing
Masking Signal for Clinician	Determines the masking type presented to the clinician through the iOS device 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 though 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
Calibrate iPod Microphone	This is designed to calibrate the iPhone microphone to an SLM meter. This is required for Ambient noise checks and Calibrate FF Setup
Calibrate Free Field Setup	An SPL meter built into iVRA app to calibrate FF speakers quickly
Double Tap (Grab Atten)	Present video reward to center monitor

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.



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



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

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

Note: You have the option in the Studio settings to fix presentation ear 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.

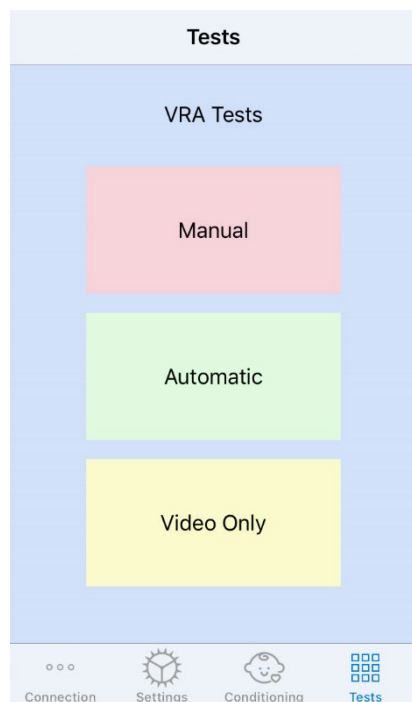
If there is a centering screen, **double tap** the presentation level to present a video reward on the center screen.

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

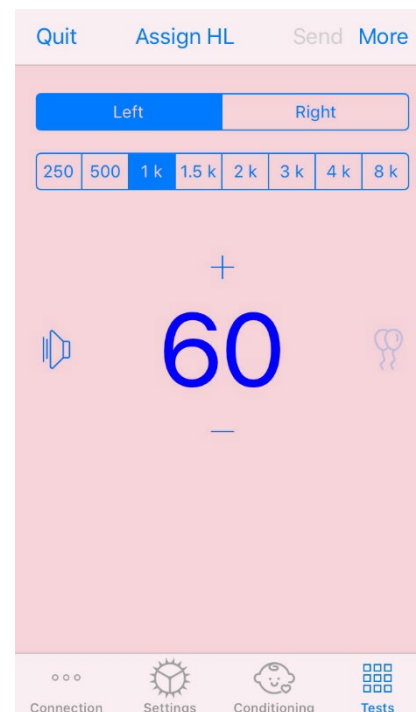
The iVRA manual test mode is initiated through the iOS app. The iOS app and MedRx Studio must be connected for the testing to begin.

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: You have the option in the Studio settings to fix presentation ear 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, **click Assign HL** on the top of the screen.

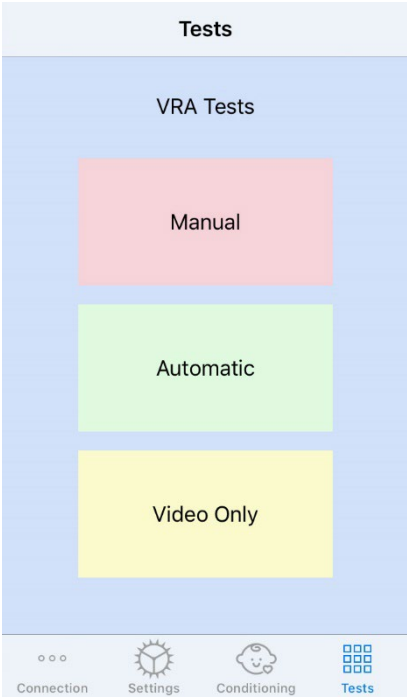
If there is a centering screen, **double tap** the presentation level to present a video reward on the center screen.

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

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.

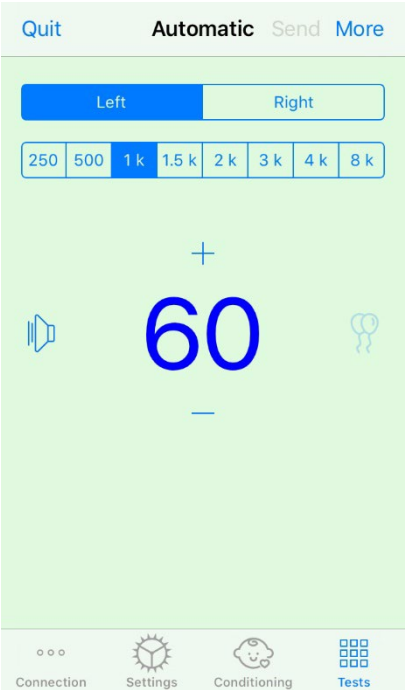
If you would like to exit the manual test mode from the PC, press the **Shift + ESC** key.

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: You have the option in the Studio settings to fix presentation ear 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.

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.

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.

Thresholds are recorded automatically in this test mode.

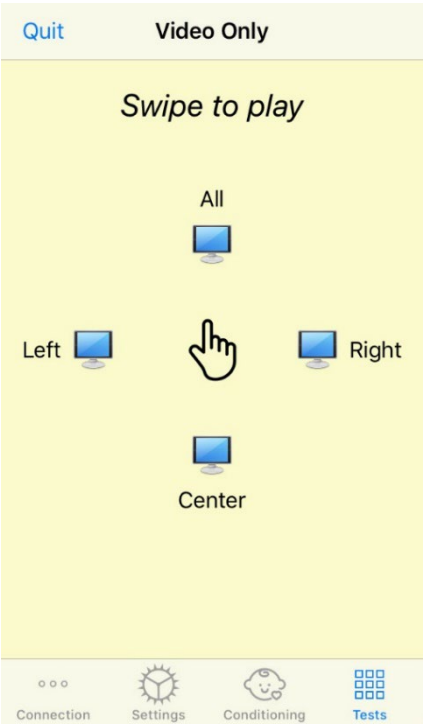
If there is a centering screen, **double tap** the presentation level to present a video reward on the center screen.

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

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 Automatic Test Mode from the PC, press the **Shift + ESC** key.

Video Only Mode



Video Only Mode, is designed for use with a separate audiometer. Video Only Mode will control the screens only. No stimulus is being presented and no thresholds are being recorded during this type of testing.

Swipe Left to display a video reward to the left screen.

Swipe Right to display a video reward to the right screen.

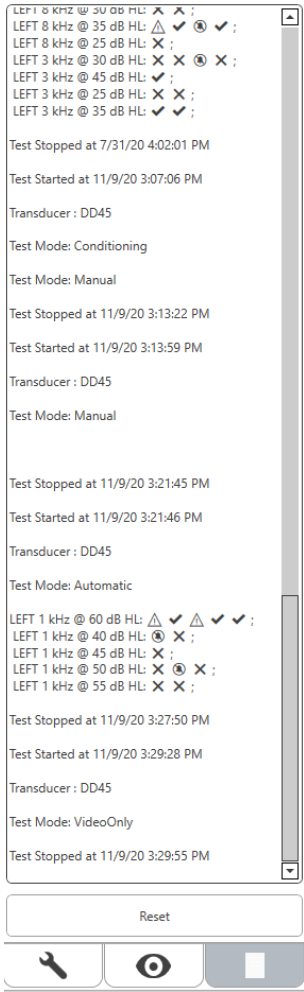
Swipe Up to display a video reward to all screens.

Swipe Down to display a video reward to a center screen.

To exit the automatic test mode you can hit **Quit** in the iOS app.

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.



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.

Traditional VRA Settings

Default

Default Output:

Default Signal:

Default Presentation:

VRA Test Settings

dB Weighting:

Free Field Presentation Binaural Only:

Free Field Binaural Scoring:

Reward Length (sec): 5

Reward Order:

Auto Record Tone Points:

Traditional VRA adds a few specific test options for Traditional VRA.

Default Output, Default Signal, Default Pulse Type, dB Weighting, can be selected in this section.

dB Weighting determines whether the presentation is in HL or SPL during Free Field testing.

If **Free Field Presentation Binaural Only** is turned on, all presented sounds will be presented through both speakers. If it is turned off, the speakers will present independently.

If **Free Field Presentation Binaural Only** is turned on, the thresholds will be scored binaurally. If it is turned off, the thresholds will be scored per ear.

Reward Length will determine how many seconds the rewards will play in traditional VRA

Reward Order will determines the order rewards will play in traditional VRA

If **Auto Record Tone Points** is on, the threshold will record with every presentation made during audiometry testing.

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.



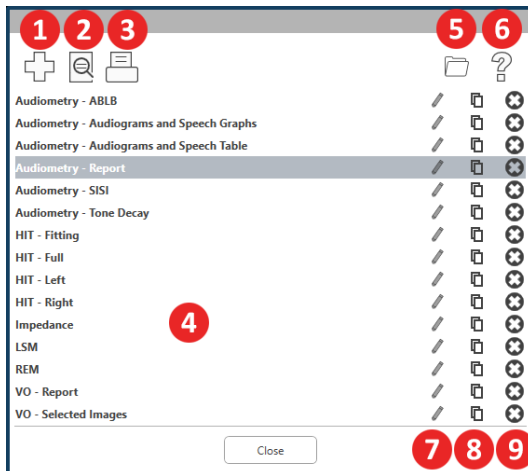
Hint: Use the track return icon on the player control panel to replay one track continuously.

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

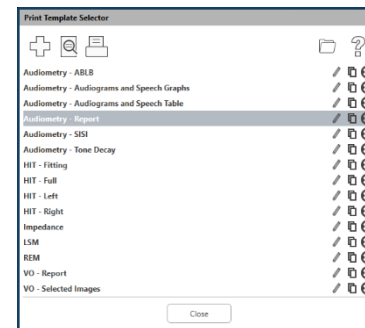


1. Create a new template.
2. Preview template icon.
3. Print template icon.
4. Select the template you would like to use.
5. Shortcut to templates folder on your desktop.
6. Studio Help icon.
7. Edit the template with the pencil icon. Editing a template will open the print editor and allow you to adjust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

To Use an Existing Print Template

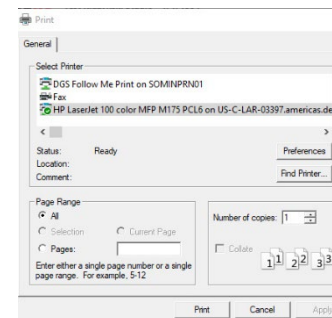


1. Click the print icon in the top tool bar or hold down the Ctrl key and click the P key on your keyboard.



4. Click the print icon.

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.



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.

New Template

3. Name the template you are creating.



4. Choose page orientation.

Letter ▼

A3
A4
A5
B4
B5
Executive
Legal
Letter
Tabloid

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.

Page Zoom
75%

Page Margins

Left:
Top:
Right:
Bottom:

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.

Picture

Text

Journal

AUD

Audiogram
Audiogram Legend
Audiogram Table
Speech Graph
Speech Legend
Speech Results
QuickSIN
Stenger
ABLB

IMP

Tym Graph
Tym Table
Reflex

REM

Rem Graph
Lsm Graph

HIT

Hit Graph
Battery Current Graph
Input/Output Graph
Attack Release Graph

VO

VO Image
All Selected VO Images

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.

D-0126017-F 2025/03 42

EMC Precautions

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

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

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



Warnings!

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

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

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

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

Recommended separation distances between Portable and mobile RF communications equipment and the Avant Audiometer			
The Avant Audiometer is intended to use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Avant Audiometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Avant Audiometer as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter meters		
	150 kHz to 80 MHz $d = 1,17 \times \sqrt{P}$	80 MHz to 800 MHz $d = 1,17 \times \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,33 \times \sqrt{P}$
0,01	0,12	0,12	0,233
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,7	3,7	7,40
100	11,7	11,7	23,3
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Safety

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

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

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

- This device is not protected from ingress of water. 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.
- 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.

Complaints/Safety Reporting

Please contact your local distributor in case of any incidents related to product defects (hardware defects or software bugs) or adverse events (which does not necessarily have a causal association to the product). It is recommended for a user to report all the known facts about the incident. Upon receipt of any serious incident with serious health impact for the patient or user (serious adverse events), local distributor shall report to MedRx through its appropriate vigilance system. MedRx shall ensure that the regulatory authority in patient's home country is informed according to the vigilance requirements. MedRx shall handle all the product complaints and adverse events as per the internal procedure.

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)



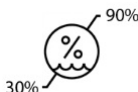
Authorized
Representative in
Europe



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 Device Regulation.

Standards:

IEC 60601-1: Class II
IEC 60601-1-2 Class A
IEC 60645-1
ANSI S3.6: Type 2 AE (A2D+)
Medical Device Regulation

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: Approx. 19 cm x 12 cm x 3 cm (L x W x H)
Approx. 7.75" x 5" x 1.25" (L x W x H) (+/- 0.125")
AIR+: Approx. 12 cm x 12 cm x 3 cm (L x W x H) Approx. 5" x 5" x 1.25" (L x W x H)

Weight: < 1 kg < 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)
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= 32 Ω , 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= 10 Ω , 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= 32 Ω , UA= 3 Veff
Line Level Stereo Speaker Output	ZA= 32 Ω , UA= 3 Veff

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 +48 91 835 63 00. The company's representative will advise the owner to either return specific components or the entire system to:

MedRx International
DGS Diagnostics Sp. z o.o.
Rosówek 43
72-001 Kołbaskowo
Poland

MedRx International 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.

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

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

MedRx international 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.