



M STUDIO Software

AWRC
AUDIOMETRY & BINAURAL
REM/LSM IN ONE SYSTEM

MedRx

Studio Software AWRC Training Manual





0123

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

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Getting to Know Your MEDRX AWRC

The MEDRX AWRC (Audiometer and Wireless Real Ear Measurement combination) represents a new era of ultra-compact diagnostic audiometry and precision in-situ verification for your office. Compact yet rugged, this PC-Based system is USB powered and supports current ANSI and IEC audiometric and Real Ear tests. The software includes targets for DSL v5.0 and NAL-NL2. A unique feature of the Real Ear Measurement System is simultaneous, binaural Live Speech Mapping, MedRx's in-situ method for getting the fitting right the first time, every time. The device performs Real Ear Measurements where measurements are performed directly on the client's ear. These measurements can be done with or without a hearing instrument being in place. The reason to perform Real Ear Measurements for hearing instrument fittings is that shape and size of an ear canal significantly influence a hearing instrument's performance. Knowing the sound intensity outside and inside the ear enables the practitioner to determine the actual

amplification and output that the patient receives through the hearing aid and make the appropriate adjustments.

This unit is a Type 1 HFAE audiometer that meets the requirements of both ANSI S3.6 and IEC 60645-1 and IEC 60645-2. These standards specify the required precision that the MedRx AWRC does achieve. Measurement uncertainty is ± 1 dB. This device and transducers are intended for use at test frequencies between 125 Hz and 16000 Hz. This unit meets the requirements of both ANSI S3.46 and IEC 61669. These standards specify the required precision that the MedRx AWRC does achieve.

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

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

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 MEDRX AWRC packaging in PDF format. The scope of this manual is to get you "up and running" with your MedRx AWRC 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. Also refer to the Help files for test signal characteristics, analysis, equalization methods and the effects of analyzer settings on accuracy.

MedRx AWRC 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 lesions of the patient's auditory pathway and their ability to recall what is presented to them.

MedRx AWRC Audiometer Target Treated Population:

The target population for audiometry assessment includes all ages.

MedRx AWRC Audiometer 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.

MedRx AWRC REM Intended Use Statement:

The hearing aid analyzer is intended to be used for the purposes of correctly configuring and prescribing the audible sound levels from a hearing device/aid. It is intended to measure the internal effect of such device using small and thin probe microphones which can be placed in the patients' ear canal to allow the clinician to objectively quantify the benefit and effect the device has on the patients hearing. These measures are useful in the fitting and prescription of acoustic hearing aids in correspondence with the information acquired during the patient's hearing assessment.

MedRx AWRC REM Target Treated Population:

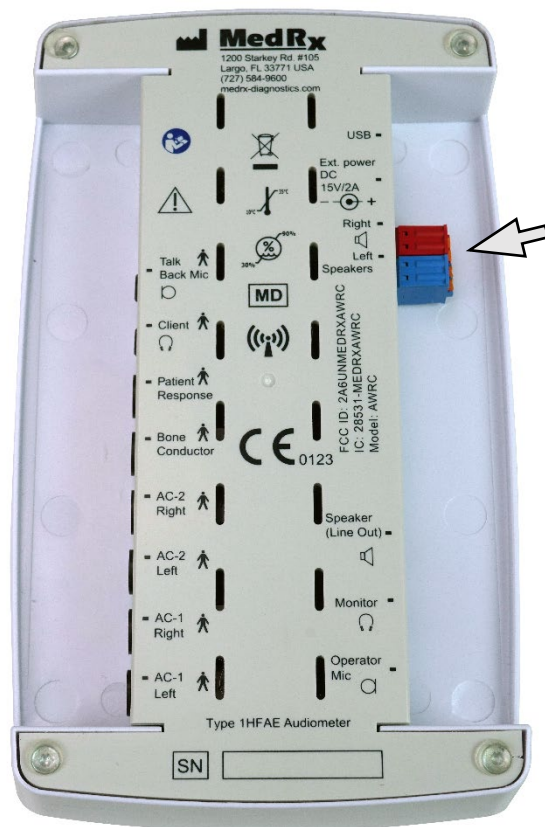
The target population for audiometry assessment includes all ages.

MedRx AWRC REM Indication for Use Statement:

The hearing aid analyzers are to be used by trained personnel only, such as audiologists, ENT surgeons, doctors, hearing healthcare professionals or personnel with a similar level of education. The device should not be used without the necessary knowledge and training to understand its use and how results should be interpreted.

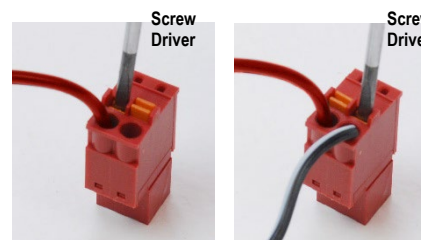
Alternate Speaker Option

MEDRX AWRC



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

To Install Free Field Speaker Wires:



Unplug both the Red & Blue connectors.

Place a small flat head screwdriver on the small orange tabs and push down while inserting a speaker wire into the opening then remove the screwdriver. Be sure the wire is secure.

Repeat until all the speaker wires are secured then plug both connectors into the device as indicated above.

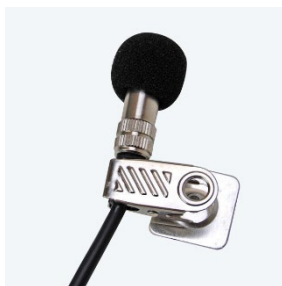
A 15V 2A DC Power supply provided by MedRx must be used when using passive Free Field speakers.

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 MEDRX AWRC. Use of unapproved accessories is not recommended.



IP30 insert Earphones



Talkback Microphone



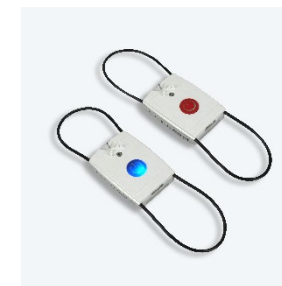
Patient Response Switch



USB A to C Cable



Power Supply



Probe Microphones



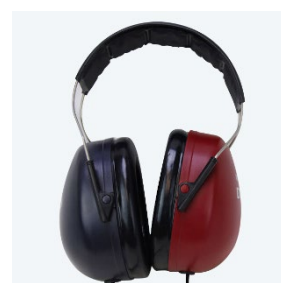
Supra-Aural
Headphones



Bone Conductor



Operator Mic & Monitor
(may vary)



DD450 High Frequency
Earphones



Probe Mic Hanger



Probe Mic Charger

NOTE: The MedRx Audiometer supports IP30 Insert earphones, DD45, DD65 and DD450 earphones extended high frequency earphones. The standard configuration includes either IP30 Insert Earphones or DD45 earphones.

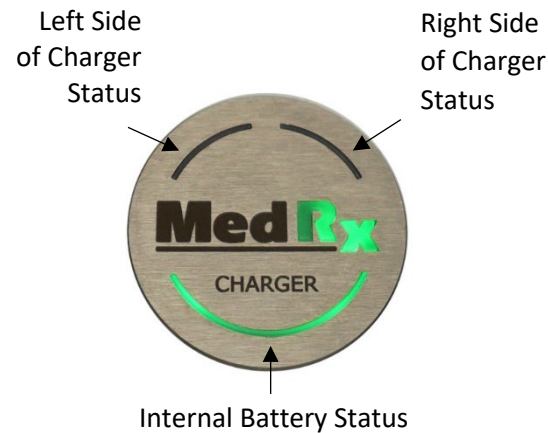
MedRx Charger and Probe Charging

The MedRx Charger is designed to charge the MedRx AWRC REM Probes through Qi charging. The MedRx Charger comes with a USB cable and wall adapter for power. The LED lights in the MedRx Charger are designed to display the charge level of the internal battery and the AWRC REM Probe batteries.

MedRx AWRC probes can be inserted into either side of the charger. It is important that the back (gray side) of the probe face toward the center of the MedRx Charger to prevent damage and ensure charging occurs.



MedRx Charger with AWRC Probes attached



MedRx Charger LEDs display status of Batteries

LED Color Indicators

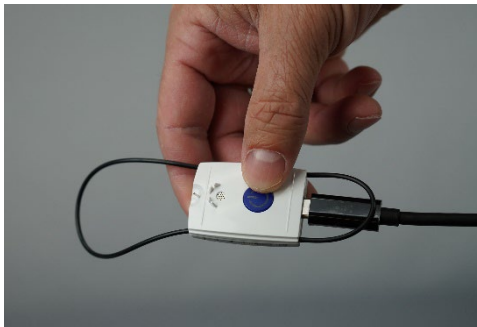
Blinking – Battery is charging

Green – Battery is $\geq 66\%$,

Yellow – battery is between 66% and 33% charged

Red – Battery is $\leq 33\%$ charged

NOTE: The MedRx Charger has an internal battery which can charge the REM probes during transit.



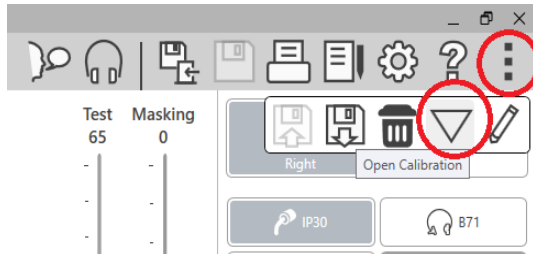
MedRx AWRC probes can also be charged with a USB-C cable.

Loading Calibration Files

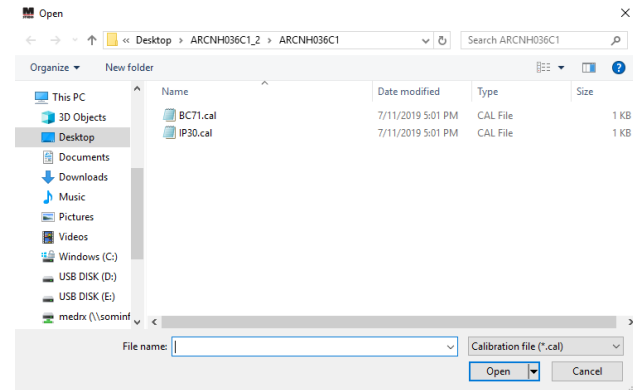


Each MedRx Audiometer is calibrated in compliance with the ANSI S3.6 standard. This calibration procedure results in a series of files that the Audiometer software reads to keep the hardware in calibration. These files are supplied on a USB Stick.

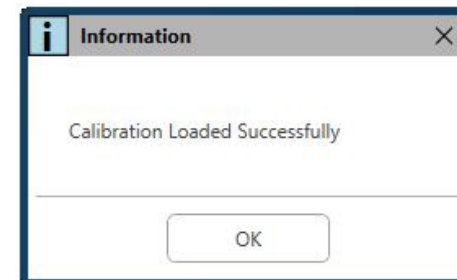
The final step before using your MedRx Audiometer to evaluate hearing is to load these device specific calibration files onto the computer used to operate the Audiometer device.



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).



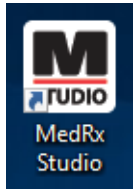
3. When the files are finished being loaded, this message will appear:
 - Click **OK** to complete loading the calibration.

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

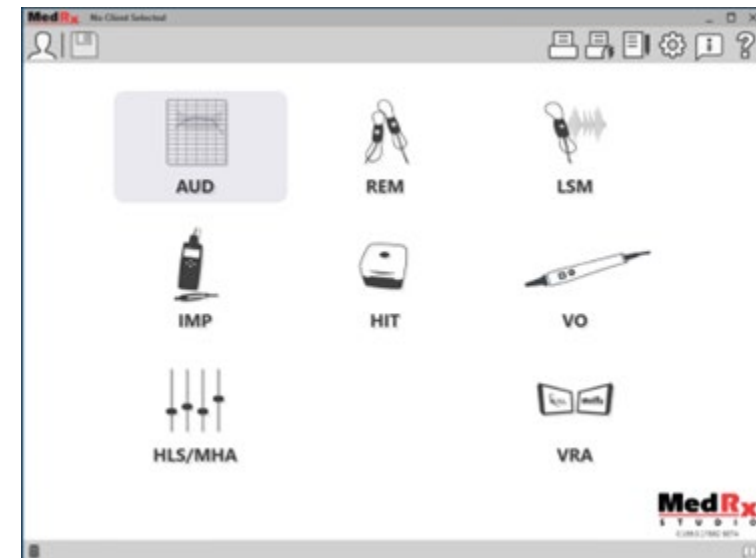
- Launch Noah.
- Select a patient
- Launch MedRx Studio module following Noah procedures.

Basic Software Options

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

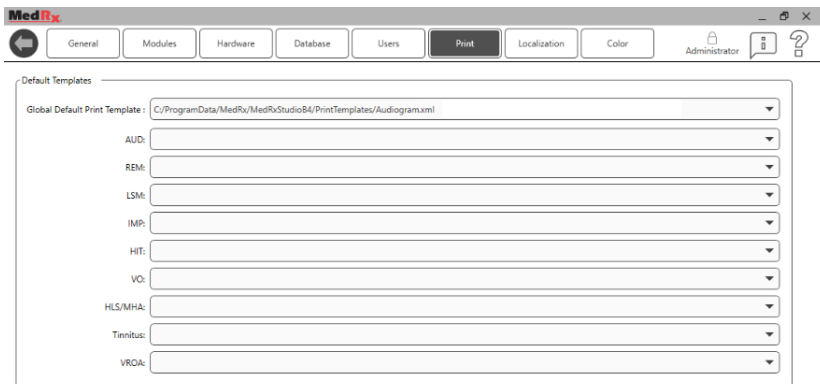


Access these options by clicking the settings wheel in the top right menu bar.

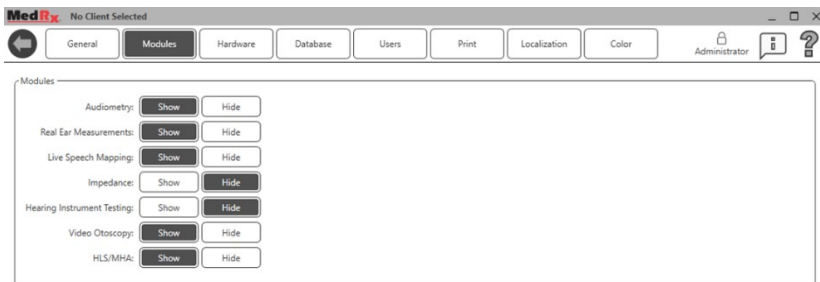


The MedRx Studio software main screen.

Icons are selectable depending on your equipment.



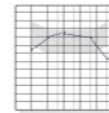
The Main Screen settings allows you to set the default modules, database, print templates and more.



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



AUD

Select AUD from the main menu.

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

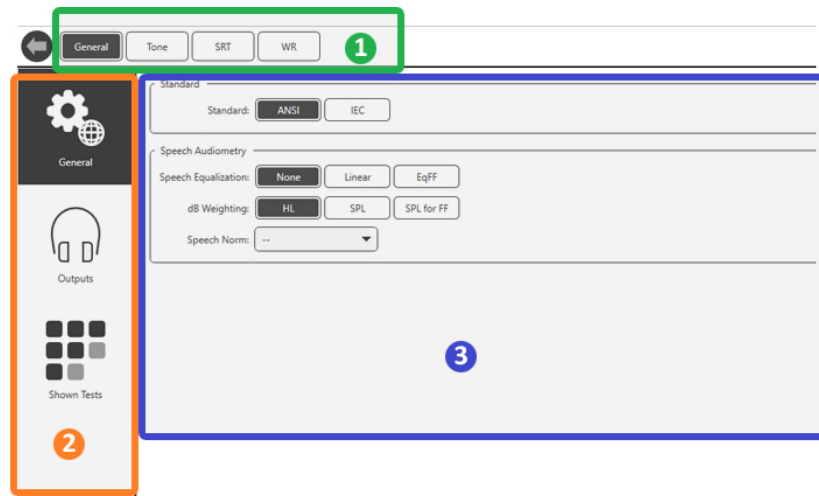


AUD

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



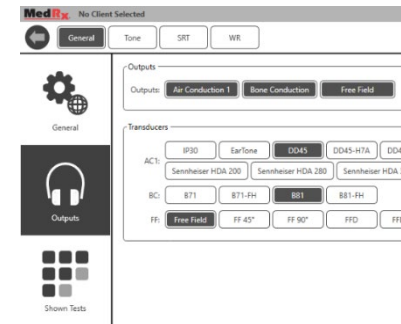
Enter the module and click the settings wheel to customize.



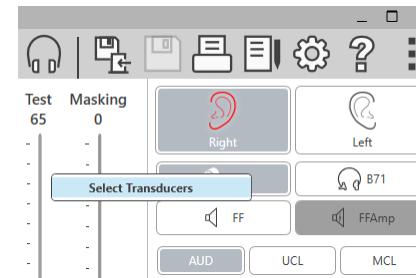
The Audiometry module has unique settings for the module. To navigate the settings you will:

- 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).

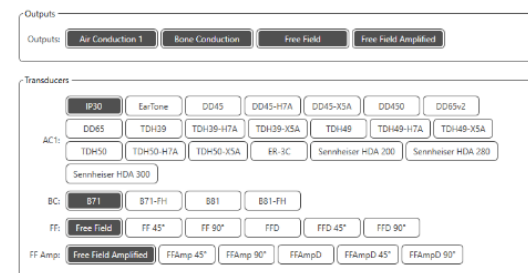
Assign Transducers



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 MedRx Audiometer. Typical acceptable transducers are shown on page 7. Operator headsets for use with the MedRx 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.

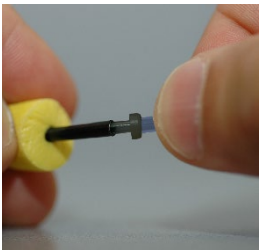
The Operator Headset with microphone is used by the device operator to communicate with the patient.

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

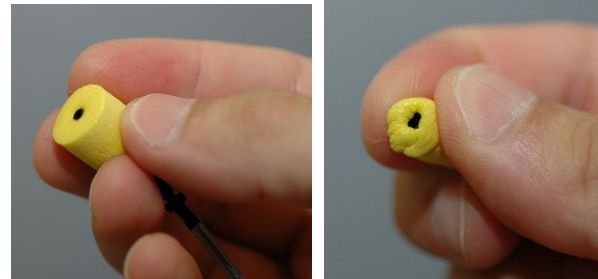
Placing the Earphones on the Patient

Insert Earphones

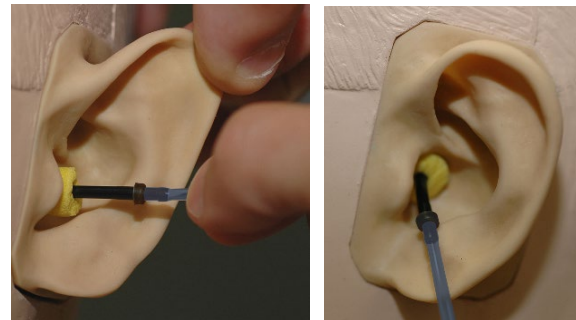
IMPORTANT: The foam tips used for the insert earphones are for SINGLE PATIENT USE ONLY. Do not attempt to wash and re-use them.



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 - AWRC (Optional)



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

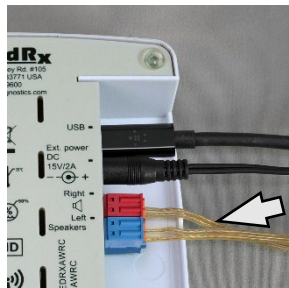


1. Locate the mastoid process behind the pinna. This is the bony shelf just behind where the ear meets the head.
2. Carefully place the bone conductor on the mastoid process and hold it in place.
3. Place the headband over the head to the opposite temple.
4. Carefully and slowly loosen your grip to check 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

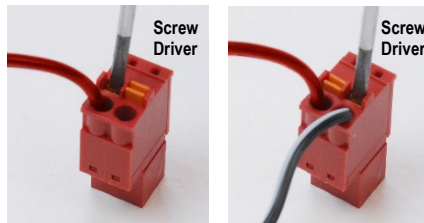
The Sound Field speakers (Free Field) should be connected using optional or user supplied amplifier and speakers. They should be calibrated annually as per ISO 8253-2, located at least 1 meter from the patient ear and at the same height.

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 AWRC audiometer.



Place a small flat head screwdriver 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 MedRx 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



Tone



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).

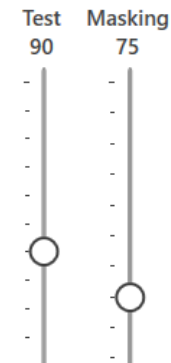
12. Repeat steps 5 through 8 for 4000 Hz, 8000 Hz, 500 Hz and 250 Hz.
13. Repeat steps 5 through 11 in the opposite ear.

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

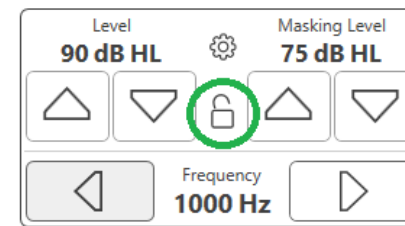
  IP30, AI: 33%, PTA: 40, HFA: 55

Pure Tone Audiometry via the Bone Conductor

1. Following the instructions on page 14, 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 17, 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.



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.

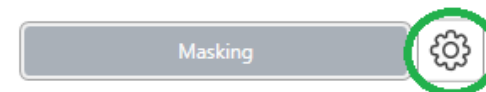
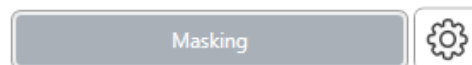


3. If you wish to maintain the balance of signal and masking (for example, masking always 30 dB above the signal), click the Lock button after setting the masking and signal levels.

Masking for Pure Tone Audiometry

To use the masking function on the MedRx 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.



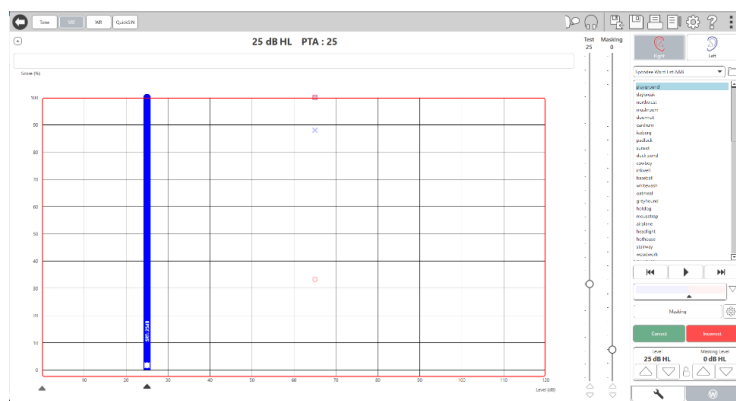
4. The default for pure tone audiometry is to deliver narrow band masking to the ear opposite the test ear. If you wish to use a different stimulus, or route the masking to the same or both ears, click on the settings wheel to the right of the Masking button.



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 Audiometry

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 following sections 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:



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.

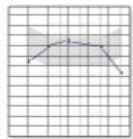
If the patient exceeds a 50% score at a given presentation level, stop the test and decrease the level by 10 dB and repeat the steps above.

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.

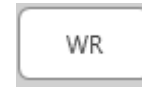
Speech MCL & Speech UCL

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

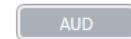


AUD

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



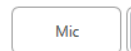
2. Click the WR button located on the toolbar on the top of the screen.



UCL

MCL

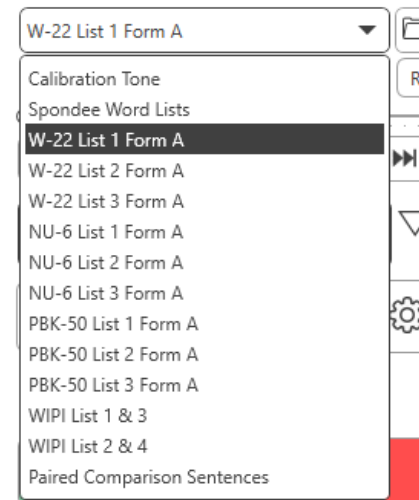
3. Click UCL or MCL.



File

CD

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.

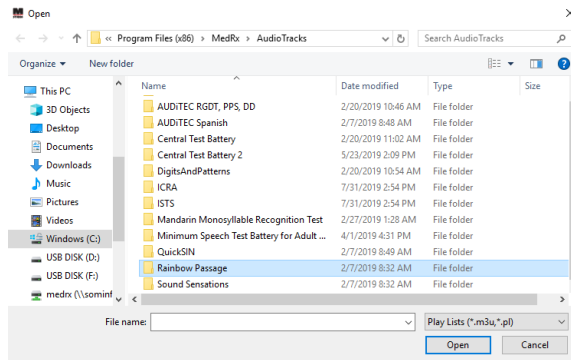
Adjust levels up or down with keyboard arrows or by clicking below the dB level at the bottom of the test slider or masking slider.

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

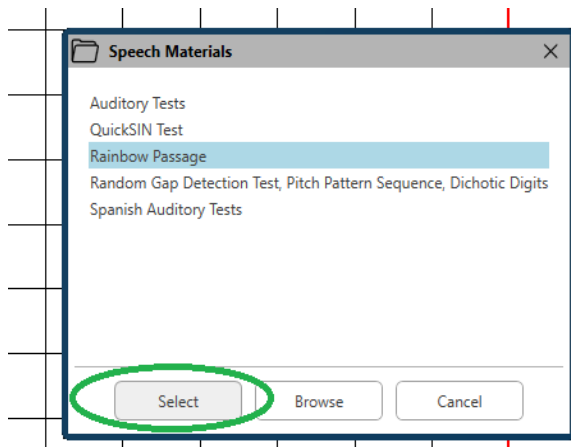
6. To Input & Calibrate the Rainbow Passage in WR for MCL:



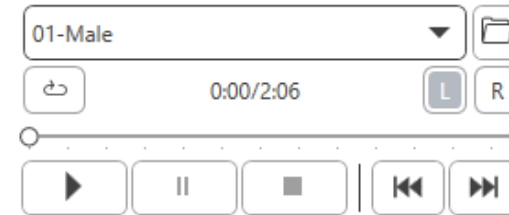
- a. Press the small file folder on the top right of media player. Then select “Browse” in the speech material.



- b. Select Rainbow Passage by double clicking twice.

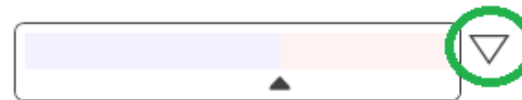


- c. The Rainbow Passage is now part of the MedRx Studio Audio Files for future use.



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

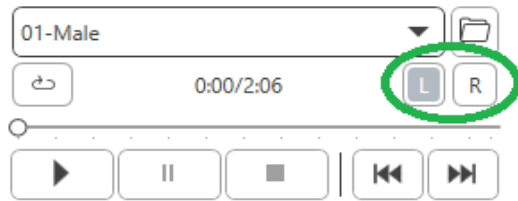
- e. Click play or start signal.



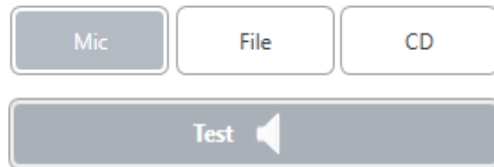
- f. Then click the calibration arrow next to the UV meter.



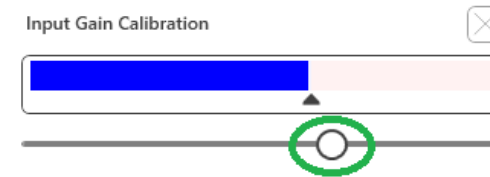
- g. On the VU meter pop-up, press the slider calibration icon just below the VU meter.
- h. Adjust with mouse or arrow keys so that the blue bar stops over the black arrow and there is no red.



- 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.

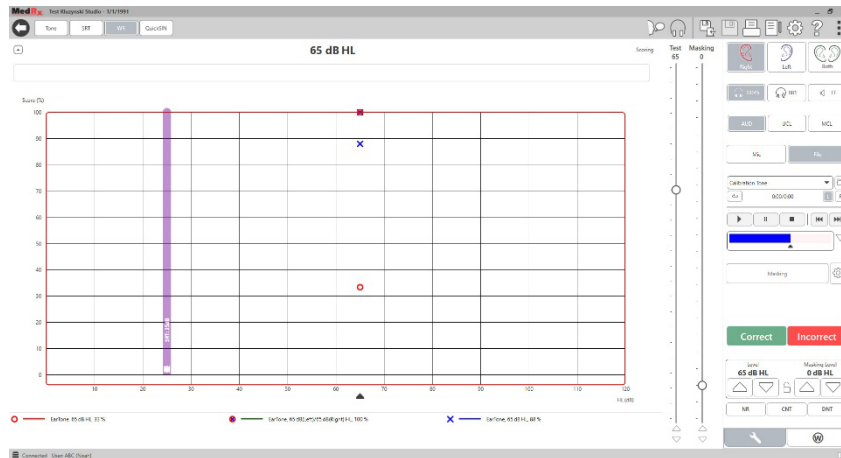


8. When using the Mic option adjust your input using the slider so that it is peaking at the black triangle under the VU meter.

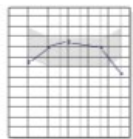
The VU meter is just below the Test button in MedRx Studio and will become active once you press Test.

Word Recognition (WR)

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.

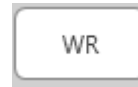


Before beginning the test, instruct the patient that they will hear a series of one-syllable words. They are to repeat the words the best they can. If they are not sure of a word, they should take a guess.



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.



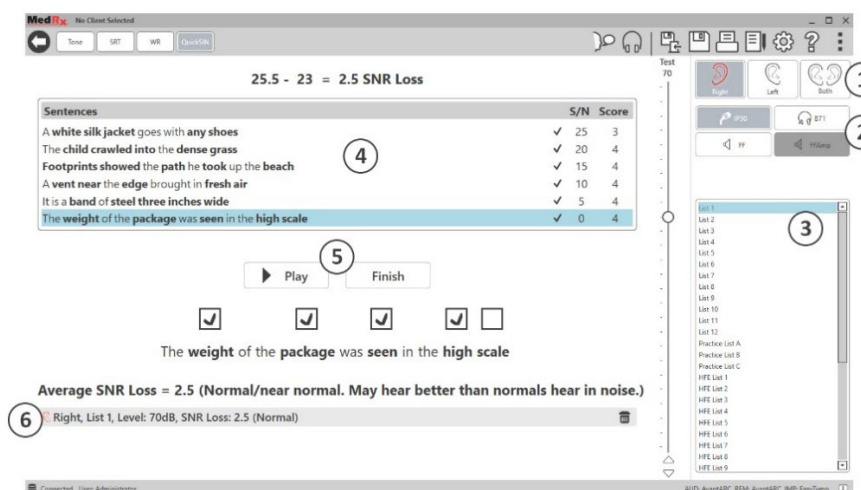
8. Click the Advance button >> or press the F10 key to present the next word. Score accordingly as described above.

QuickSIN

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

Performing the QuickSIN Test



AUD

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

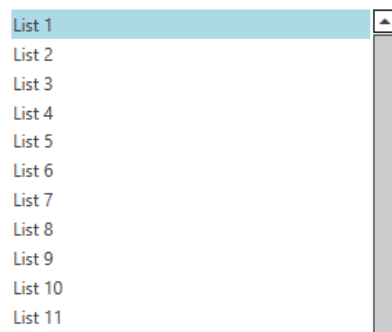


2. Click the QuickSIN button located on the toolbar on the top of the screen.

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

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.

▶ 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.)

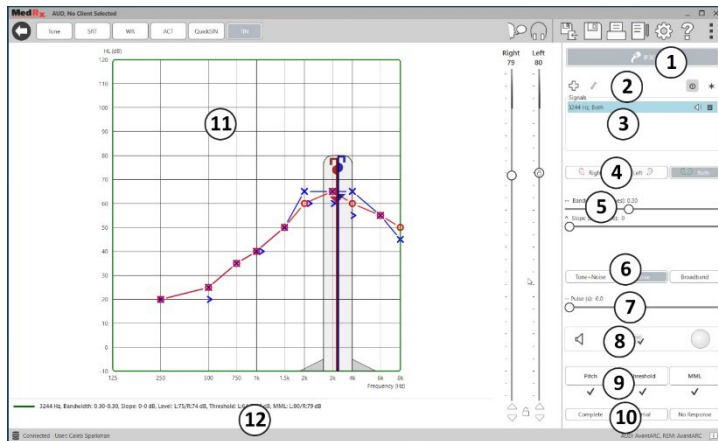
Right, List 1, Level: 70dB, SNR Loss: 2.5 (Normal)

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

- Average SNR Loss in dB.
- Recommendations.

Tinnitus

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.

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.



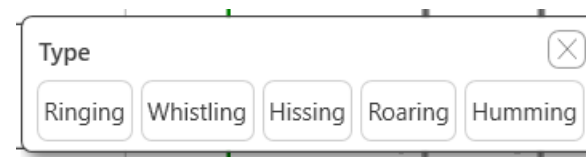
Step 1: Audiometry

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

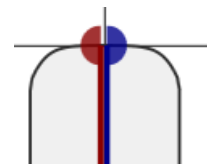
Now that the pitch has been matched to the listeners' tinnitus, the next step will be to match the loudness of the tinnitus. Continue to pulsate the stimulus being presented to make it easy for the listener to compare their tinnitus to the stimulus from the audiometer. Instruct the listener to try to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

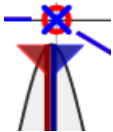
turn off the sound and lower below estimated threshold. Set the stimulus to a constant by moving pulse to 0 sec:



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.

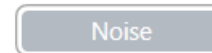
Step 6: Minimum Masking Levels

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 listeners tinnitus can indicate whether this could be viable.

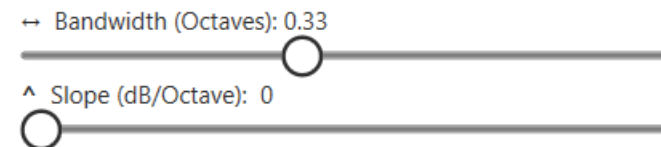
To complete minimum masking levels, you need to determine the type of stimulus you plan to use for masking. MedRx recommends using either

a narrowband noise centered at the listener's tinnitus pitch or a broadband noise.

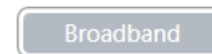
To make a narrowband noise, you must select the Noise from the sidebar.



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 MODULE (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:

Number Of Presentation Screens:

Primary:

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.

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.

The screenshot shows the 'Screen' configuration window for a two-screen setup. The 'Force Software Rendering' is set to 'Yes'. The 'Number Of Presentation Screens' is set to '2'. The 'Identify Screens' and 'Reset Screens' buttons are visible. The 'Primary' screen is set to 'Screen 1'. The 'Primary Screen Blackout' is set to 'Yes'. The 'Left' screen is set to 'Screen 1' and the 'Right' screen is set to '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.

The screenshot shows the 'Screen' configuration window for a three-screen setup. The 'Force Software Rendering' is set to 'Yes'. The 'Number Of Presentation Screens' is set to '3'. The 'Identify Screens' and 'Reset Screens' buttons are visible. The 'Primary' screen is set to 'Screen 1'. The 'Primary Screen Blackout' is set to 'Yes'. The 'Left' screen is set to 'Screen 1', the 'Right' screen is set to 'Screen 2', and the 'Center' screen is set to 'Screen 3'.

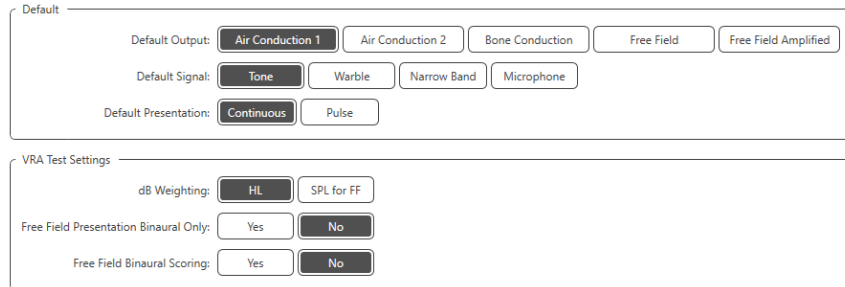
Click **Identify Screens** to determine which screen you would like as the left and right reward screen as well as the centering screen. These should be the screens that will be in the testing area where the child will be tested. Be sure that the left and right monitors are assigned in relation to the 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 buttons for 'Default Output' (Air Conduction 1, Air Conduction 2, Bone Conduction, Free Field, Free Field Amplified), 'Default Signal' (Tone, Warble, Narrow Band, Microphone), and 'Default Presentation' (Continuous, Pulse). The 'VRA Test Settings' section includes 'dB Weighting' (HL, SPL for FF), 'Free Field Presentation Binaural Only' (Yes, No), and 'Free Field Binaural Scoring' (Yes, No).

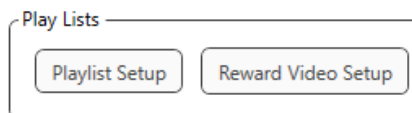
Default Output, Default Signal, Default Pulse Type, dB Weighting, can be selected in this section.

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.

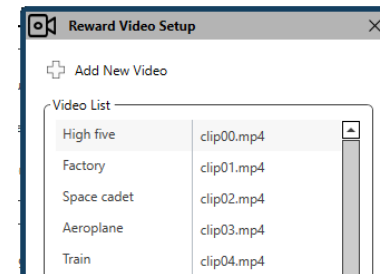
If **Free Field Presentation Binaural Only** is turned on, the thresholds will be scored binaurally. If it is turned off, the thresholds will be scored per ear.

Playlists Setup



The screenshot shows the 'Play Lists' section with two buttons: 'Playlist Setup' and 'Reward Video Setup'.

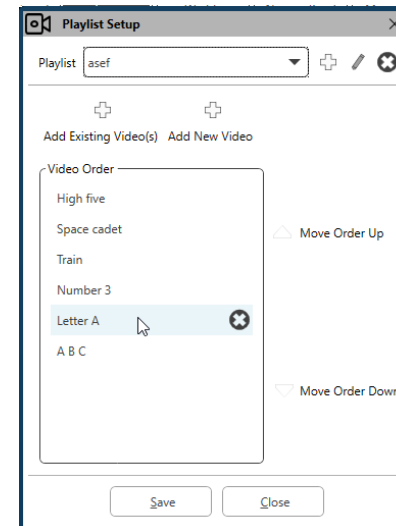
In the **Reward Video Setup**, custom videos can be added. In **Playlist Setup** the selection and order of video rewards can be edited.



The screenshot shows the 'Reward Video Setup' window. It has a title bar with a close button. Below the title bar is a section 'Add New Video' with a plus icon. Below that is a 'Video List' table with two columns: a description and a filename. The list contains: 'High five' (clip00.mp4), 'Factory' (clip01.mp4), 'Space cadet' (clip02.mp4), 'Aeroplane' (clip03.mp4), and 'Train' (clip04.mp4). There is a scrollbar on the right side of the list.

Description	Filename
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 for 'Playlist' with 'asef' selected. Below that are two buttons: 'Add Existing Video(s)' and 'Add New Video'. Below these is a 'Video Order' list with items: 'High five', 'Space cadet', 'Train', 'Number 3', 'Letter A', and 'A B C'. There are plus and minus icons next to 'Letter A'. To the right of the list are buttons for 'Move Order Up' and 'Move Order Down'. At the bottom are 'Save' and 'Close' buttons.

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

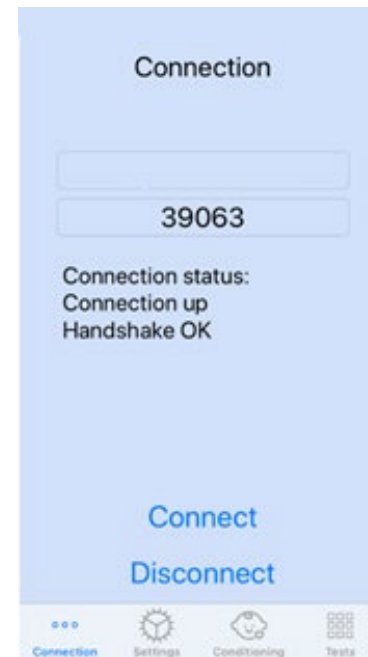
Port:

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.



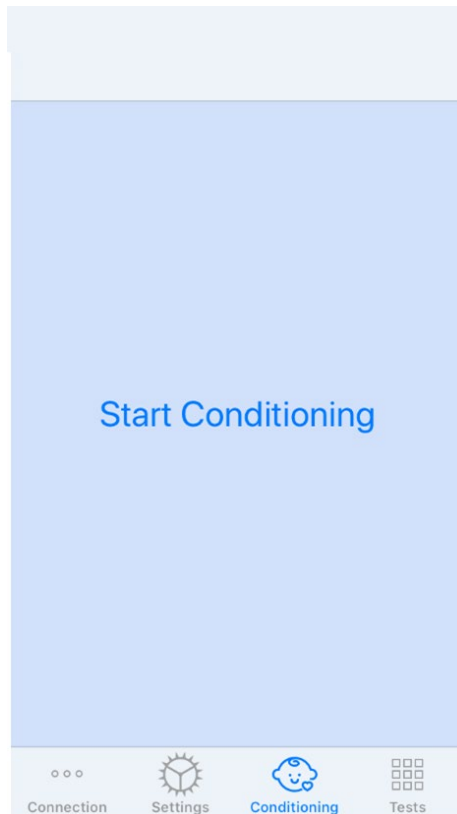
Settings Tab in the iVRA app

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

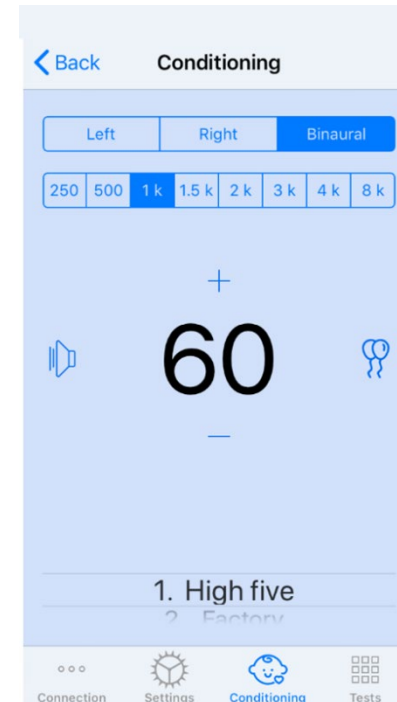
Reward Length (s)	Number of seconds to present the video reward
Rewards Randomized	Automatically randomizes video reward presentations during testing
Masking Signal for Clinician	Determines the masking type presented to the clinician through the iOS device headphones
Masking Past End of Stimulus(s)	How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

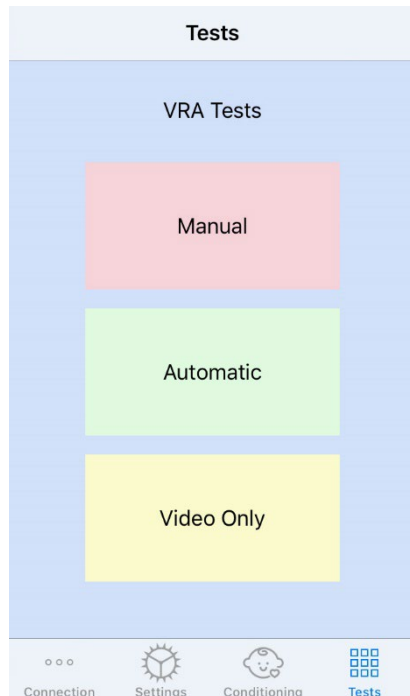
Change the presentation levels by **swiping up or down** on the presentation level that is displayed.

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.

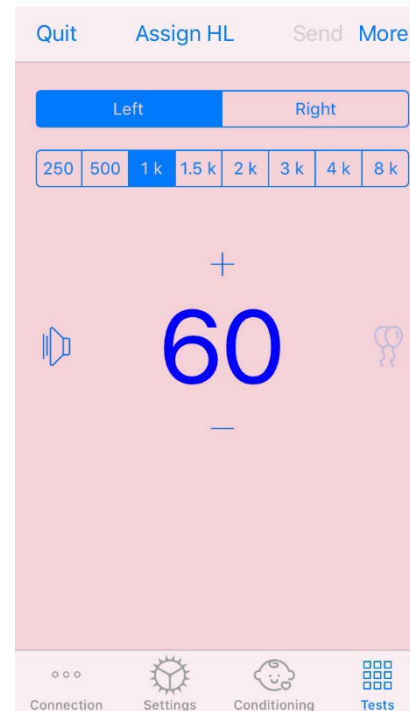
iVRA Manual Test Mode

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.

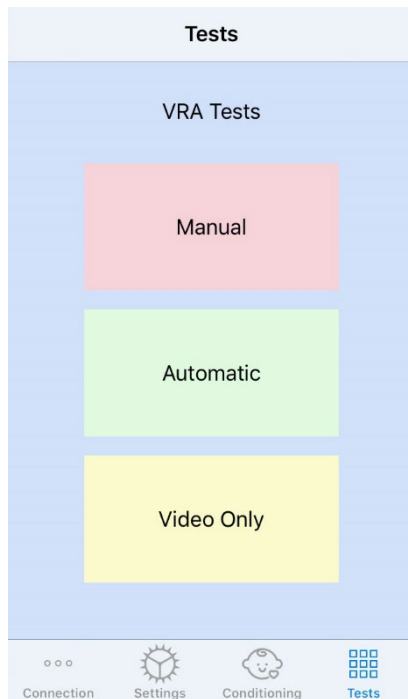
If there is a centering screen, **double tap** the presentation level to present a video reward on the center screen.

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.

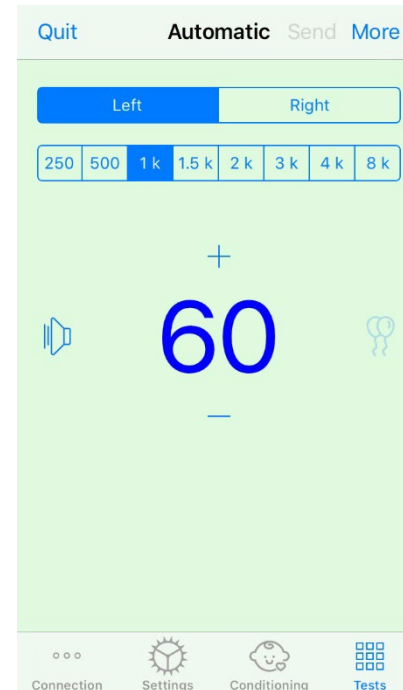
If you would like to exit the manual test mode from the PC, press the **Shift + ESC** key.

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.

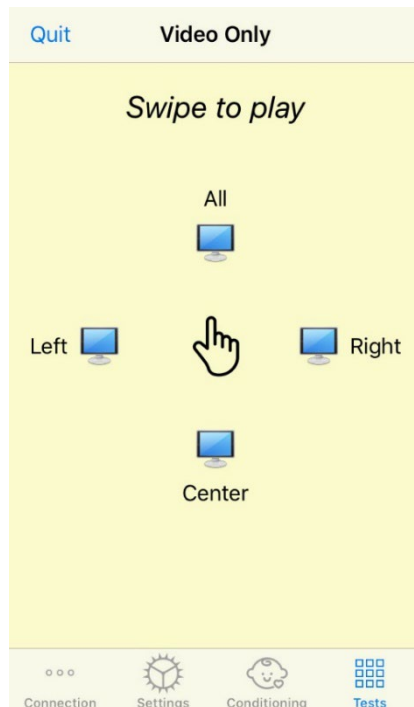
If there is a centering screen, **double tap** the presentation level to present a video reward on the center screen.

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.

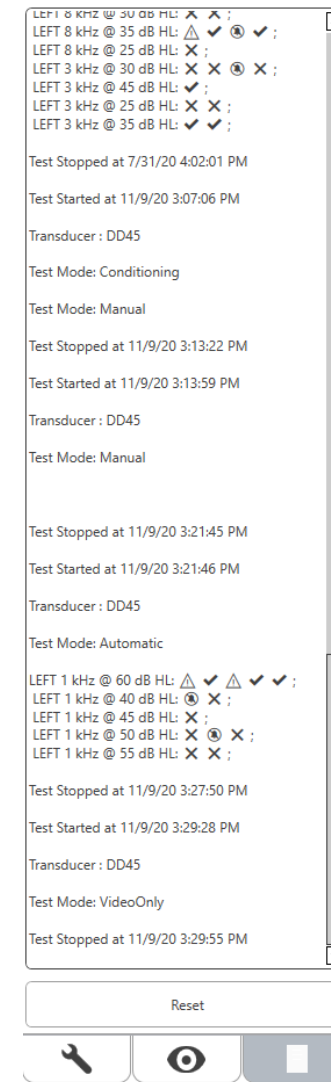
Swipe Right to display a video reward to the right screen.

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:

Air Conduction 1

Air Conduction 2

Bone Conduction

Free Field

Free Field Amplified

Default Signal:

Tone

Warble

Narrow Band

Microphone

Default Presentation:

Continuous

Pulse

VRA Test Settings

dB Weighting:

HL

SPL for FF

Free Field Presentation Binaural Only:

Yes

No

Free Field Binaural Scoring:

Yes

No

Reward Length (sec):

5

Reward Order:

None

Consecutive

Random

Auto Record Tone Points:

Yes

No

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

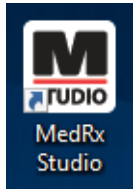
If **Auto Record Tone Points** is on, the threshold will record with every presentation made during audiometry testing.

REM / LSM MODULE

Studio Software Overview

The MedRx Studio software can run stand-alone, 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

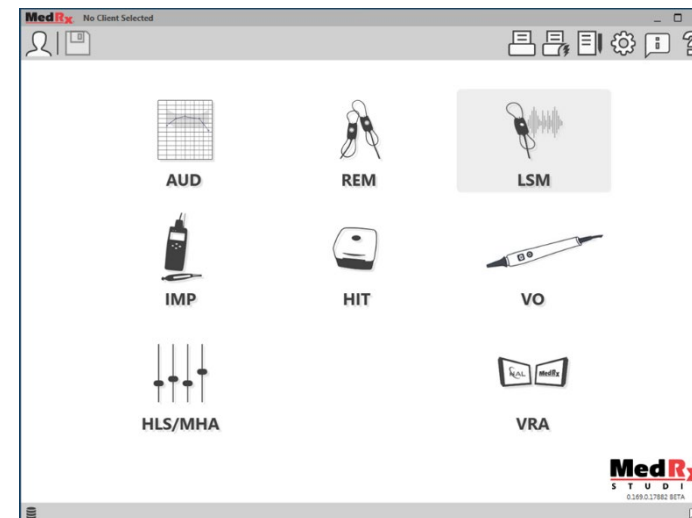
- Launch Noah.
- Select a patient.
- Launch MedRx Studio module following Noah procedures.

Basic Software Options

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

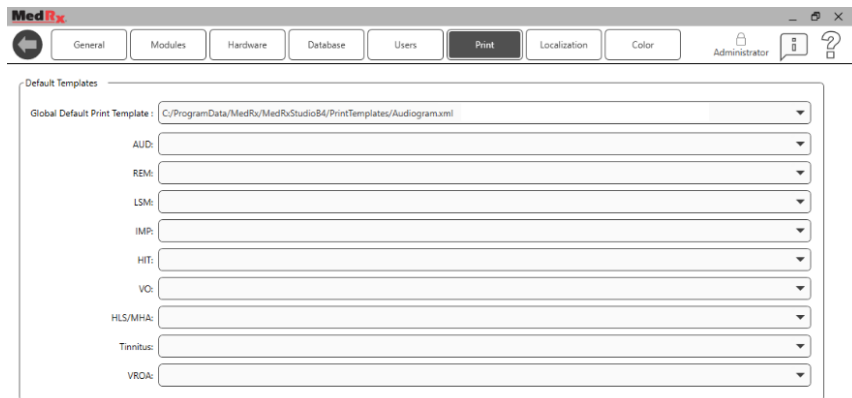


Access these options by clicking the settings wheel in the top right menu bar.



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.

Pairing AWRC REM Probes

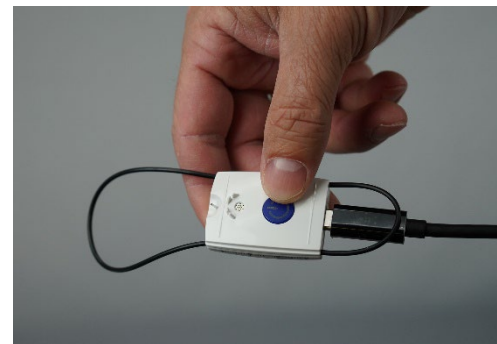
New AWRC devices will have the REM Probes pre-paired with the main unit. There will be no need to manually pair probes on new units. Pairing is for replacement probes or upgrades to an Audiometer only AWRC.

Pairing is only performed one time and is not needed for daily use.

Manually Pair Replacement AWRC Probes or upgraded systems

To pair replacement AWRC REM probes

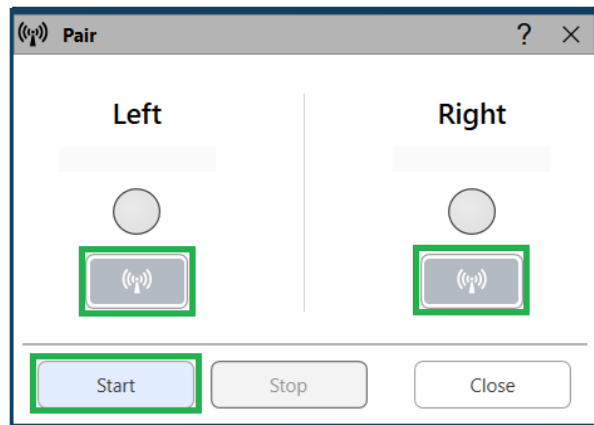
1. First you will need to prepare the probe for pairing. With the AWRC REM probe powered off, press and hold the power button while plugging in the new AWRC REM probe to USB power. Release the power button and now the probe light will begin flashing quickly.



2. Open Studio and Enter the REM or LSM module. Click the three dots in the top menu and select “Pair”



3. The pairing display will open with both probes selected to pair. Select only the probe you wish to pair. Click "Start" to place the AWRC in pairing mode.



4. The Studio software will lightly fill the status circle (blue or red depending on ear side) when a connection is established. The pairing is complete when the serial number is displayed in the pairing window. Confirm the serial number matches the probe you are trying to pair.



5. Click Stop
6. Pairing is complete. Repeat steps 1 to 5 if you need to pair another probe.
7. Once all probes are paired click "Close" to begin REM or LSM.

AWRC REM Probe Connections

NOTE: The AWRC REM Probe will only connect while MedRx Studio is in either the REM or LSM Module.

To connect AWRC REM probes to the baseboard

1. Open Studio and Enter the REM or LSM module



The Probe Indicator should show ? in the battery which indicates the software is searching for AWRC Probes

2. Power on the AWRC REM Probes. LED will blink green indicating probe is searching for connection.

3. The Studio software will lightly fill the status bar when a connection is being established



4. The AWRC is fully connected and ready for testing when the status bar has dark filled circles and battery status is available.



5. The AWRC REM Probe LED will turn a solid color upon successful connection.

Note: AWRC Probes will automatically turn off 30 seconds after powering on if MedRx Studio is not in either REM or LSM modules.

Live Speech Mapping



LSM

Select LSM from the main menu.

Top Tool Bar

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



1. On-Top Window
2. Tube Calibration
3. Speaker Calibration
4. Save Session and Exit
5. Save Session
6. Print
7. Show Journal
8. Show Settings
9. Show Help
10. 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. Probe Monitor
5. Microphone Calibration

Bottom Tool Bar

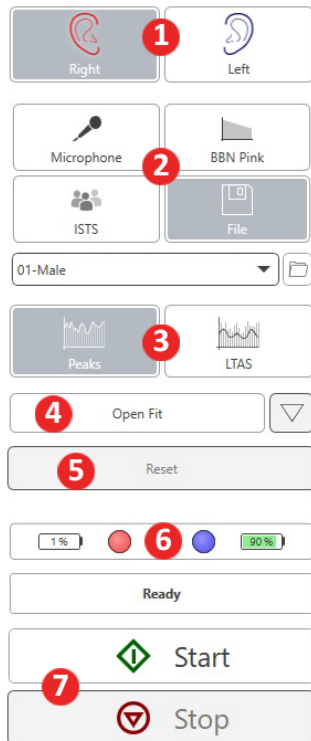


The **Bottom Tool Bar** icons have the following functions:

The **Wrench icon**

displays options for:

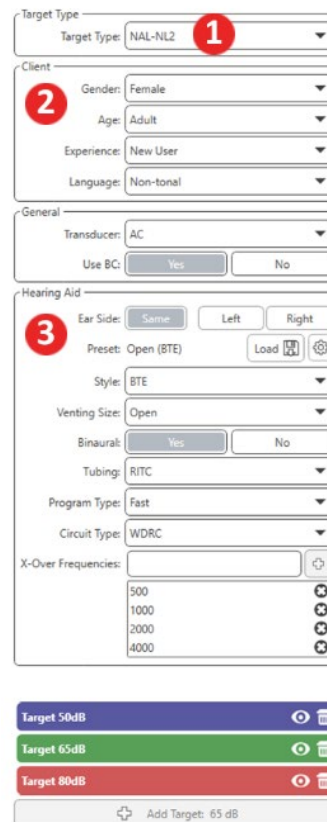
1. Ear Selection
2. Stimulus Selection
3. Viewing Mode
4. Open Fit Function
5. Reset Averages
6. Probe Connection
7. Start & Stop buttons



The **Target Selection icon**

sets up:

1. Target type
2. Client information
3. Hearing aid parameters



The **Display icon** sets up which target lines to display on the measurement screen.



NOTE: Probe connections: empty circle – not connected, light circle – connecting, dark circle – connected.

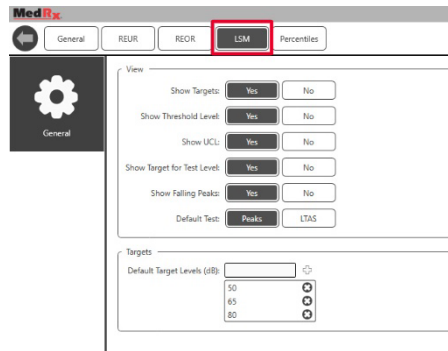


NOTE: Remember that more information is always available in the Interactive Help System by clicking the Help Icon or pressing the F1 key.

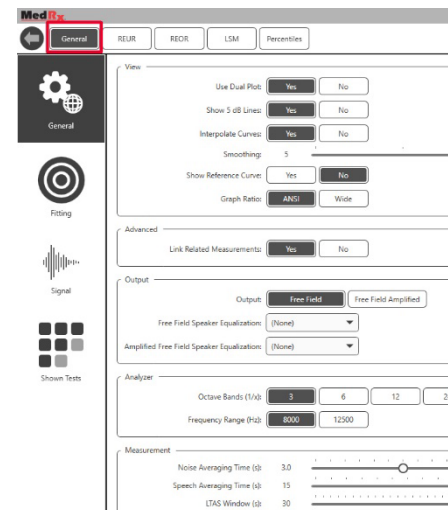
General LSM Options



Click the settings wheel in the top right menu bar.

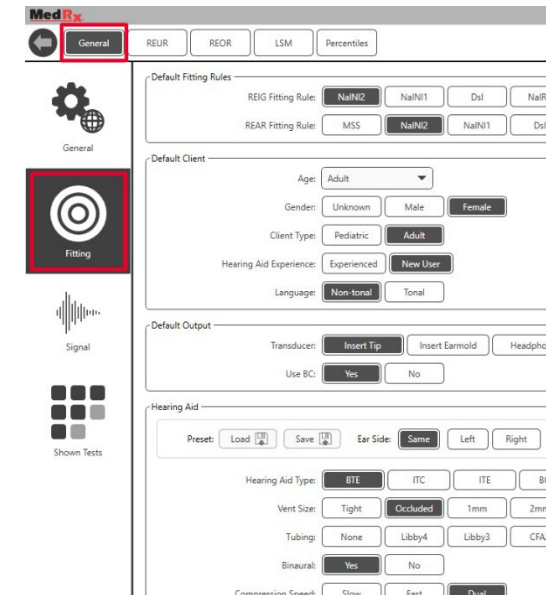


The **LSM tab** sets your default view and default target levels.

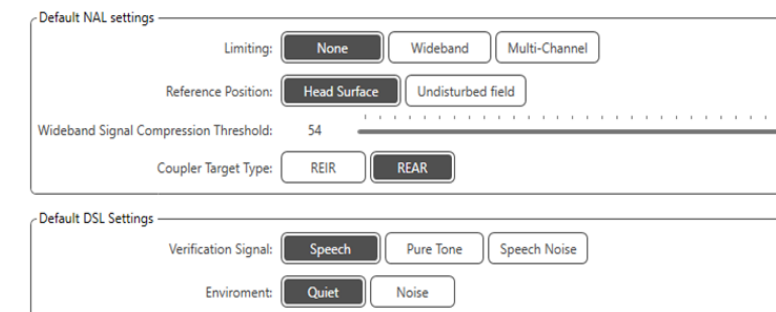


The **General tab** defines the default appearance of the Live Speech Mapping test environment.

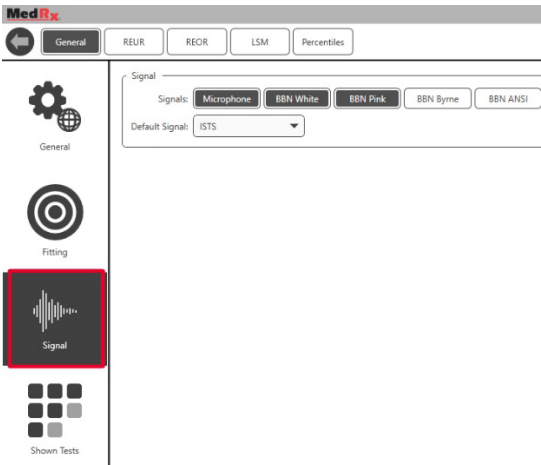
The **Fitting tab** sets the default fitting rule, client information, output and hearing aid parameters.



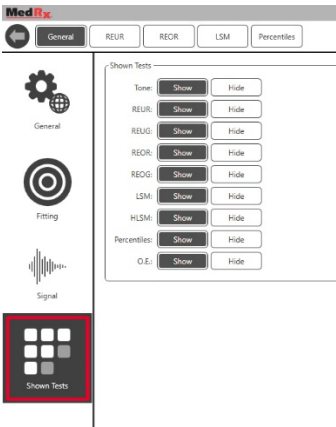
The **Fitting tab** also sets default NAL or DSL default settings.



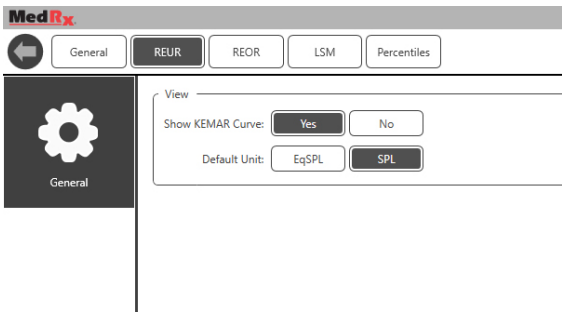
The **Signal** tab sets the signals displayed on the Live Speech Mapping Screen.



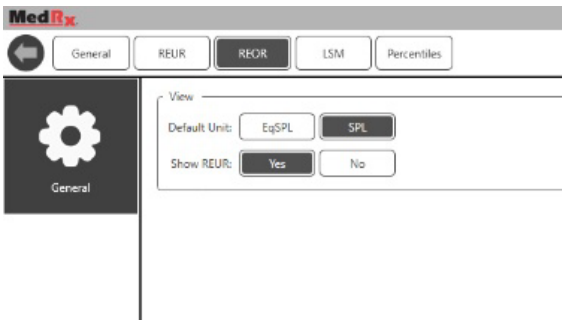
The **Shown Tests** tab sets the tests displayed in the Live Speech Mapping module.



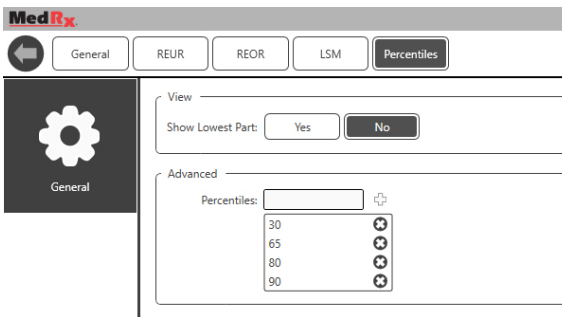
The **REUR** tab sets the view options.



The **REOR** tab sets the view options.

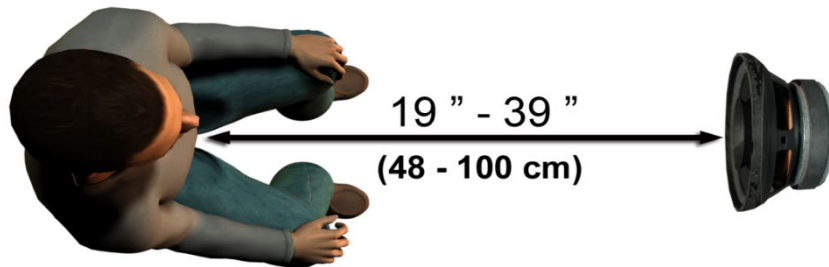


The **Percentiles** tab sets the view options.



Preparing for Testing

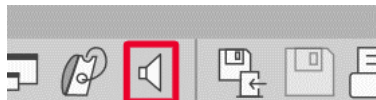
Positioning the Speakers



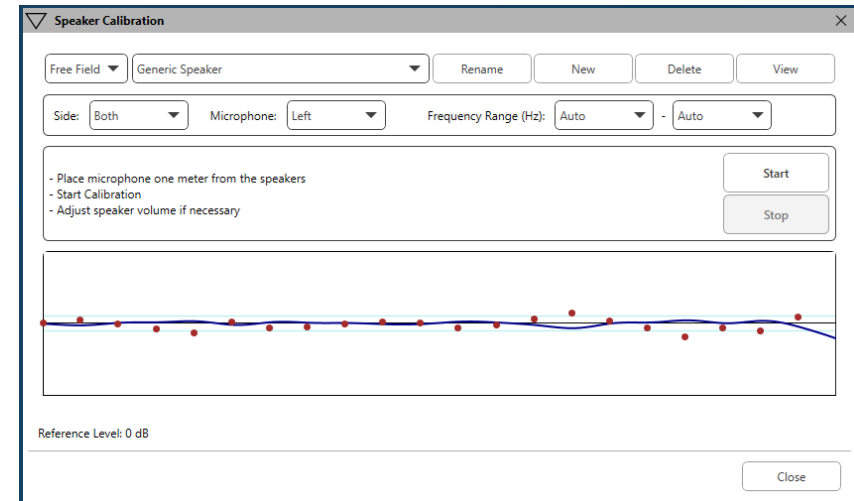
Proper positioning of the loudspeakers relative to the patient's hearing aids is critical for making accurate and repeatable measurements. Seat the patient so their ear is between 19 and 39 inches from the loudspeaker.

The speaker is designed to sit at desk height. When using Live Speech inputs, position the patient and loudspeaker as shown below.

Speaker Calibration



Open the Speaker Calibration screen by clicking the Speaker icon from the REM/LSM top menu bar.



The speaker should be positioned in such a way that nothing blocks the path of the emanated sound in front and on the sides of the speaker. For example, positioning a speaker behind a monitor is incorrect and can severely affect its response at the measurement location. The speaker diaphragm should be at about the same level as the patient's ear and the reference microphone.

Place the reference microphone on the patient about 1 meter from the speakers.

Click on Start to begin the calibration and wait until it ends. Observe the response curve to flatten itself out. The darker curve is showing the response used by the equalization algorithm, the lighter curve is showing the current microphone input. Use of the powered speaker supplied with this device is recommended.

Probe Tube Calibration

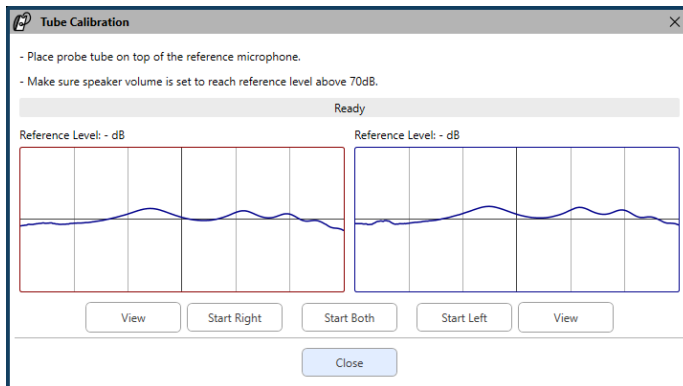


For reasons of infection control and reliability of results, MedRx recommends that a new probe tube be used with each patient. To ensure accurate measurements, it is necessary to calibrate the probe tube each time it is replaced.

1. Place a new probe tube on the probe microphone port as shown.
2. Place the probe tube between the calibration nibs as shown. Be sure that the opening of the probe tube is centered on the opening of the reference microphone.



In the MedRx Studio LSM software, click the Probe Tube Calibration icon.



Position probe microphone between 19 and 39 inches from the loudspeaker and click Start Both to run simultaneously. The signal must be at least 70 dB to complete a valid calibration. If the screen prompt indicates the signal is too low, increase the volume on the loudspeaker or move the patient closer and restart the calibration.

Repeat for the other probe if calibrated one at a time. Valid calibrations have the same approximate shape as the gray target curve. If the measured calibration curve differs greatly in shape or amplitude from the gray target curve, check or replace the probe tube and re-calibrate. If this does not correct the problem, contact MedRx technical support at (888) 392-1234.



- ▼ The calibration values are available under the Calibration top menu icon. Click the More Options icon (3 dots) then click the Calibration icon.

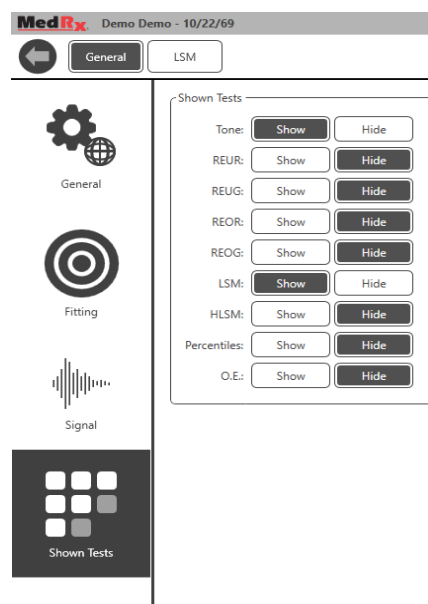
Return Probe Microphones to MedRx for annual re-calibration. Annual re-calibration of the MedRx REM Probe Microphones is recommended. There are no user repairable components on this device.

Step-by-Step Guide to Live Speech Mapping

Ensure that the Audiogram is entered

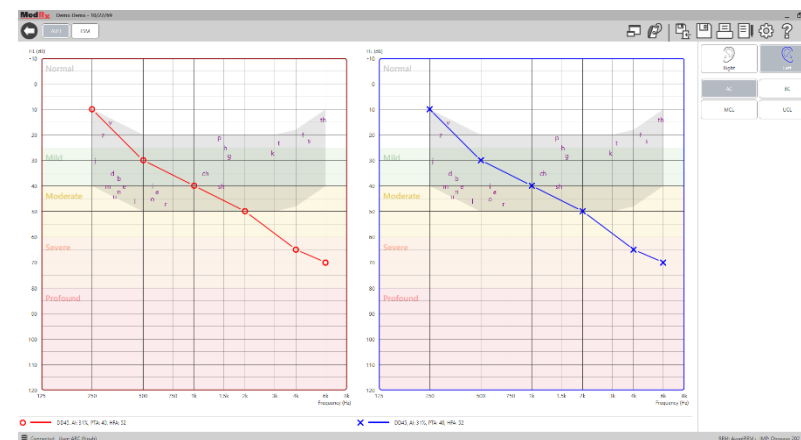
Before making Live Speech Mapping measurements, the patient's pure tone audiogram must be available to the software. This can occur several ways:

1. The audiogram was automatically entered by MedRx Studio software when testing.
2. The audiogram was manually entered into the Noah audiogram module or Noah 4 software and saved.
3. The audiogram was entered using another manufacturer's audiogram module.



If none of these have occurred, you may manually enter the audiometric data into the REM software as follows:

1. Under General, then Shown Tests, select show Tone.



AUD

2. Select AUD module located at the top left of the software.

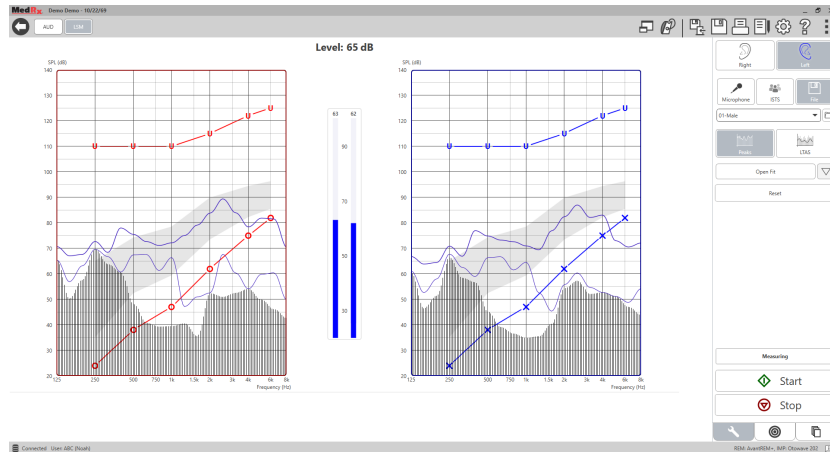
3. Using your mouse, select the test ear.
4. Select the test type AC.
5. Enter thresholds by clicking the intersection points with the mouse. (You may also enter the audiogram by selecting the audio tab in either the REM or HLS/MHA screens).
6. Repeat for UCL (Bone and MCL optional).
7. Repeat steps 3-5 for the other ear.

LSM

After the audiogram is entered, click the LSM button to return to the MedRx Studio LSM testing screen.

The Operator Headphone (optional) is used by the operator to monitor the signal being received by the probe microphone.

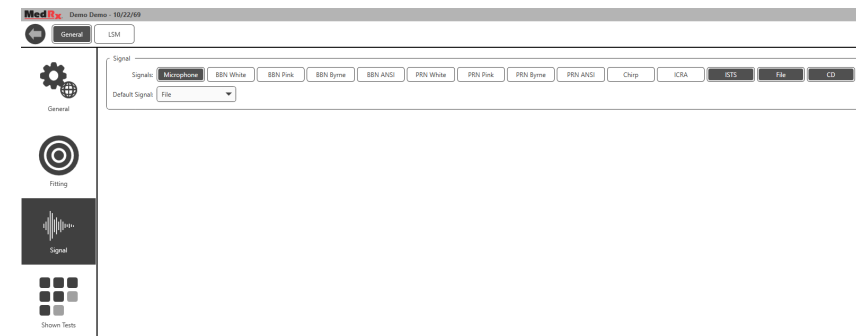
Speech Mapping with Recorded Inputs



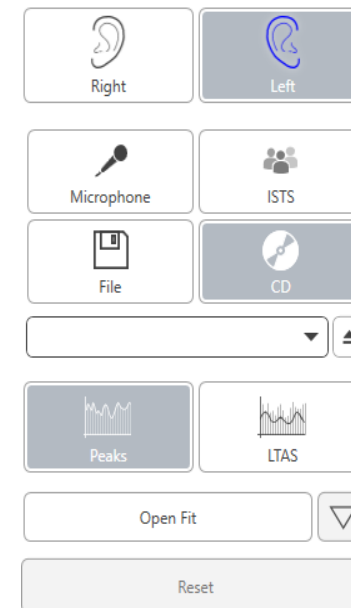
The Studio software provides several digital audio files to use as a repeatable stimulus for Speech Mapping. These are accessed by clicking the File button on the right and then selecting the desired track from the pull-down menu in the audio player. Peak measurements are recommended.

Once the desired pure tone or white noise track is selected, click the Start button to begin measuring. A pure tone or white noise will be presented and once it reaches the selected input level with the slide bar, the chosen track will play. When enough data is collected, click the Stop button to stop the recording and record the measurement.

It is also possible to use an audio CD, such as the patient's favorite music to perform Speech Mapping.

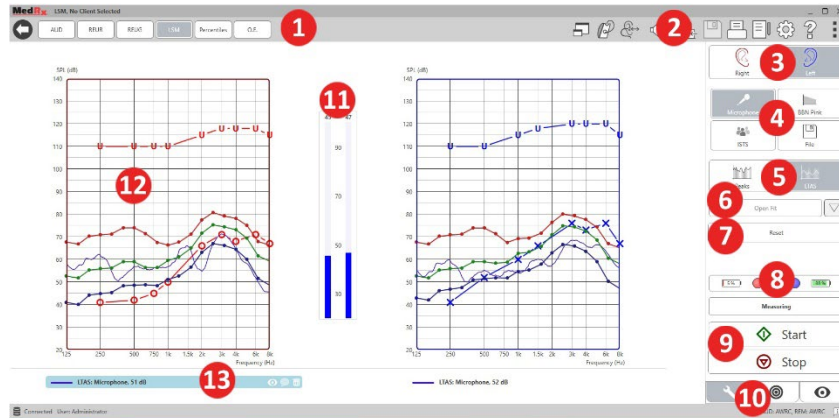


Select CD as an option under General and Signal.



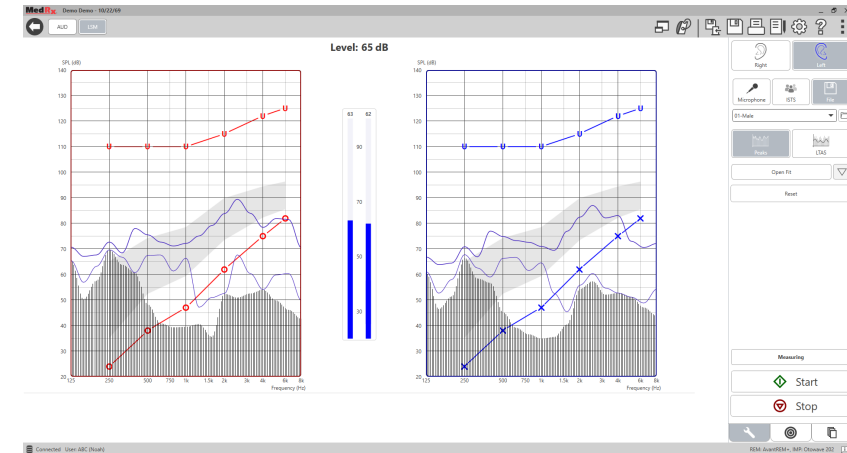
Select the CD button and then select a track. Use the sound level meter on screen to check the proper level. Adjust the output of the speaker to desired level using the sound level meter. (Remember conversational speech is 65 dB at 1 meter).

The screen shot below provides an overview of all the tools and controls on the Live Speech Mapping screen. For more information on these features, please consult the Interactive Help system by pressing the F1 key or clicking the Help icon.



1. Sound Level Meter
2. Settings Selection Bar
3. Ear Selection
4. Test Stimulus
5. Measurement Type
 - Peaks
 - LTAS
6. Open Fit Function
7. Reset Button
8. Probe Connection Status
9. Start and Stop Buttons
10. Tools Tab, Target Selection Tab, and Display Tab
11. VU Meter
12. Target Area – can be any of the following:
 - MedRx Modified Speech Spectrum
 - DSL IO
 - NAL-NL2
 - NAL-NL1
13. Legend

Speech Mapping with Live Voice Inputs



Using the microphone allows measurement of both the professional's voice and that of a third party e.g., the patient's significant other or family members.

To improve repeatability of measurements, it is recommended that the speaker read a standard passage such as the "Rainbow Passage" which is provided on page 65.

NOTE: The screen shot above shows the MedRx Modified Speech Spectrum (Canoe). It is also possible to use DSL IO or NAL-NL2 targets on this screen. Click the Setting wheel in the menu bar on the top right of the screen to select and configure these targets to meet the needs of your practice.

Running Speech Mapping “On-Top”

The MedRx Studio system is tightly integrated with Noah, the industry standard for audiometric and fitting data storage and retrieval. The On-Top mode of the LSM software allows you to effortlessly alternate between measurement and fitting adjustments.



From the MedRx Studio LSM main screen, click the On-Top Window.

The LSM window will reduce in size and “float” on top of your fitting software.

Use the text menus and green (start) and red (stop) buttons in the floating LSM window to perform Speech Mapping measurements.

Completing the On-Top Mode Process

Close the REM module by clicking the X button or the back arrow in the top left. Save the session as normally.

MedRx Live Speech Mapping Protocol

Unlike other products, the MEDRX AWRC system places full control over the measurement environment firmly in the hands of the hearing care professional. The system is powerful, yet extremely flexible, allowing each provider to use Live Speech Mapping in a way that complements their practice style rather than compromising it.

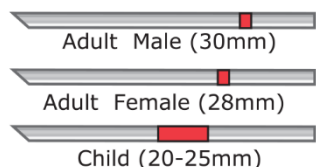
In order to get you “up and running” with the MEDRX AWRC system, MedRx has developed the following protocol. This simple procedure has been found to be effective with both audiologists and hearing instrument specialists. After mastering the basic operation of the system utilized in this protocol, you are encouraged to further expand your use of Live Speech Mapping in your practice. Feature-specific help is available by simply pressing the F1 key or clicking on the Help icon or text menu.

1. Complete a careful otoscopic examination as instructed by the manufacturer of your otoscope.
 - a. For MedRx Video Otoscopes, refer to the Help system within the software by pressing the F1 key or clicking the Help icon or text menu.



Probe Tube Insertion Guide for Live Speech Mapping and Conventional REM

(re: Pomford, J & Sinclair, S. Real-Ear Measurement:
Basic Terminology and Procedures. Audiology OnLine.com)



1. Perform Otoscopic Examination
2. Align end of Probe Tube with the left end of the appropriate guide
3. Align tube marker with the red marker above
4. Place Probe Tube in ear canal
5. Confirm placement with Otoscope
6. Perform Live Speech Mapping & REM

2. Basic Diagnostics.

- a. Using your audiometer, measure and record the following values:
- b. Pure Tone Air and Bone conduction thresholds.
- c. Narrow Band Noise or Pure Tone UCL at 500, 1000, 2000 and 4000 Hz.
- d. Other tests if needed in your practice or jurisdiction.

3. Position patient as described earlier in this manual on page 48.

4. Calibrate Probe Tube as described earlier in this manual on page 49.

5. Option 1: Measure and place the probe tube in the ear canal. (Use chart to the left).

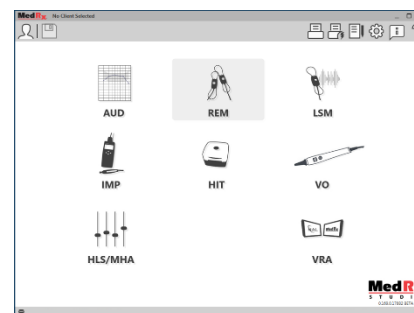
6. Option 2: Use the probe tube depth guide to accurately place the probe tube¹.

7. Complete a Live Speech Mapping measurement UNAIDED (RUER).

- a. ISTS or file input
- b. Peak Measures
- c. 1/3 Octave resolution

8. Carefully place the hearing instrument in the ear without disturbing the probe tube.
9. Complete a Live Speech Mapping measurement AIDED (LSM).
10. Using the On-Top mode, make any adjustments needed to the hearing instrument so that:
 - a. The LSM curve for Quiet Speech (50 dB) is at the bottom of the white modified speech spectrum (canoe).
 - b. The LSM curve for Conversational Speech (65 dB) should be within the white modified speech spectrum.
 - c. The LSM curve for loud sounds (80 dB) (very loud speech, clapping hands, etc.) is approximately 10 dB below the UCL curve.

Real Ear Measurements



In addition to Live Speech Mapping, the MedRx AWRC supports all conventional Real Ear Measurements (REM). All these tests are accessed from the main REM screen.

To begin, click the REM icon on the MedRx Studio main screen.

1. Probe placement indicator was developed and validated for adults with normal outer and middle ear function. Use with other patient populations is not advised.

Real Ear Measurement Settings

The screen shot below provides an overview of all the tools and controls on the REM screen. For more information on these features, please consult the Interactive Help system by pressing the F1 key or clicking the Help icon.



- | | |
|----------------------------|--|
| 1. REM Test Options | 10. Tools Tab, Target Selection Tab, and Display Tab |
| 2. Settings Selection Bar | 11. Target Area – can be any of the following: |
| 3. Ear Selection | a. DSL IO |
| 4. Test Stimulus | b. NAL-NL2 |
| 5. Open Fit Function | c. NAL-NL1 |
| 6. Probe Connection Status | 12. Legend |
| 7. Time Indicator | |
| 8. Start and Stop Buttons | |
| 9. MSC – Continuous Play | |

Descriptions of the various Stimulus options are presented in the Help files under the topic Signal Types. Access these by clicking on the Help tab at the top of the screen, and selection Help Topics. Select an item from the list in the Index tab, and click Display.

MedRx Real Ear Measures Protocol

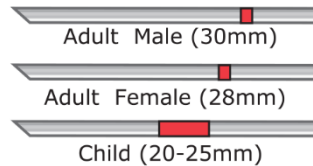
1. Complete a careful otoscopic examination as instructed by the manufacturer of your otoscope.
 - a. For MedRx Video Otoscopes, refer to the Help system within the software by pressing the F1 key or clicking the Help icon or text menu.



2. Basic Diagnostics.
 - a. Using your audiometer, measure and record the following values:
 - b. Pure Tone Air and Bone conduction thresholds.
 - c. Narrow Band Noise or Pure Tone UCL at 500, 1000, 2000 and 4000 Hz.
 - d. Other tests if needed in your practice or jurisdiction.
3. Position patient as described earlier in this manual on page 48.

Probe Tube Insertion Guide for Live Speech Mapping and Conventional REM

(re: Pomford, J & Sinclair, S. Real-Ear Measurement:
Basic Terminology and Procedures. Audiology OnLine.com)



1. Perform Otoscopic Examination
2. Align end of Probe Tube with the left end of the appropriate guide
3. Align tube marker with the red marker above
4. Place Probe Tube in ear canal
5. Confirm placement with Otoscope
6. Perform Live Speech Mapping & REM

4. Calibrate Probe Tube as described earlier in this manual on page 49.

5. Option 1: Measure and place the probe tube in the ear canal. (Use chart to the left).

6. Option 2: Use the probe tube depth guide to accurately place the probe tube¹.

7. Complete a Real Ear Measurements UNAIDED (RUER).

- a. ISTS or file input
- b. Peak Measures
- c. 1/3 Octave resolution

8. Complete a Real Ear Measurement AIDED (REAG)
9. Using the On-Top mode, make any adjustments needed to the hearing instrument so that:
 - a. The REM curve for Quiet Speech (50 dB) is within 3 to 5 dB of all of the points on the prescription curve.
 - b. The REM curve for Conversational Speech (65 dB) is within 3 to 5 dB of all of the points on the prescription curve.
 - c. The REM curve for Loud Speech or sounds (80 dB) is approximately 10 dB below the UCL curve.
10. If measuring for Insertion Gain (REIR), then it is suggested that REUR (no hearing aid seated in the canal) and REAG (hearing aid seated in the canal and functioning) be completed. After the REUR is run, a curve will be plotted by the software on the REUG screen as well. It is suggested because $REIR = REAG - REUG$. See the description of each measurement under REM tests in the manual, by clicking on F1

or by clicking on the question mark symbol at the top right of the window.

Stimulus Signal Types

Pure Tone: A pure sine wave. Crest Factor = 1.41 (3.0dB)

Broadband Noise (BBN): Uniform random noise with normal (Gaussian) amplitude distribution. Can be weighted to White, Pink, Speech ANSI, and Speech Byrne (see below.)

Pseudo Random Noise (PRN): A "synthetic" broadband random noise. It is less uniform than BBN, has lower spectral density and random volleys. Can be weighted to White, Pink, Speech ANSI, and Speech Byrne (see below.)

ICRA Noise: This stimulus was developed for measuring characteristics of non-linear instruments. The noise is weighted to Byrne LTASS.

ISTS: (International Speech Test Signal) Initiated by European Hearing Instrument Manufacturing Association (EHIMA.) This signal is based on natural recordings of 21 female speakers in six different languages - American English, Arabic, Chinese, French, German and Spanish. The signal is largely non-intelligible because of segmentation and remixing. The speech material was filtered to Byrne LTASS.

Crest Factor: 9.23 (19.3dB)

Rainbow Passage: Natural recordings of several voices reciting the rainbow passage. Shaped to Byrne LTASS.

Broadband Noise Weighting

White: This is essentially no weighting or filtering. The White Noise has flat power spectral density. Power at every frequency is equal. Because the density of frequencies (individual cycles) raises with frequency, there is more energy in high octaves.

1. Probe placement indicator was developed and validated for adults with normal outer and middle ear function. Use with other patient populations is not advised.

White-weighted noise can be used mostly for testing of equipment. It is not recommended to use it for hearing aid fitting, unless specified by the manufacturer.

Crest Factor: BBN = 1.73 (4.8dB), PRN = 7.86 (17.9dB)

Pink: The noise is filtered so its energy per frequency (power spectral density) is inversely proportional to the frequency. Each octave carries the same amount of energy. Comparing to White Noise, the Pink Noise energy drops approximately 3dB per octave.

Pink-weighted noise can be used mostly for testing of equipment. It is not recommended to use it for hearing aid fitting, unless specified by the manufacturer.

Crest Factor: BBN = 3.67 (11.3dB), PRN = 6.55 (16.3dB)

Speech – Byrne: The noise is approximately weighted to International Long Terms Average Speech Spectrum (ILTASS) as described in Byrne et. al., 1994.

The noise with this weighting is preferred for hearing aid fitting because its spectrum is the best approximation of the spectrum of real human speech.

Crest Factor: BBN = 4.22 (12.5dB), PRN = 3.47 (10.8dB)

Speech – ANSI: The noise is approximately weighted to ANSI S3.42 Speech Noise.

The noise with this weighting can be used for fitting hearing aids. The slope of ANSI-weighted noise is not as steep as Byrne-weighted, so there is more power in higher octaves. This will result in less gain required by the hearing aid to reach targets, but may result in under-fitting at high frequencies.

Crest Factor: BBN = 4.46 (13.0dB), PRN = 5.17 (14.3dB)

To activate specific REM tests, click the buttons as follows:

- | | |
|--|---|
|  | Opens the audiometry data entry screen. Use this if audiometry has not been previously measured and entered into Noah. |
|  | Real Ear Unaided Response - Measures the additive effect of the ear canal's resonance to a stimulus. Reported as dB SPL of output. |
|  | Real Ear Unaided Gain - Measures the additive effect of the ear canal's resonance to a stimulus. Reported as dB SPL of gain. If a real ear unaided response (REUR) curve has been measured, the corresponding real ear unaided gain curve is automatically plotted to the REUG screen. |
|  | The difference between the REUG and the REAG is called the Real Ear Insertion Gain (REIG). This Insertion Gain information is used to compare to the target gain curve selected for the client. |
|  | The Real Ear Aided Response (REAR) is the sound pressure level in the ear canal measured with the probe microphone close to the eardrum and the operating hearing instrument inserted in the ear and turned on. ANSI defines REAR as the SPL, as a function of frequency, at a specified measurement point in the ear canal for a specified sound field, with the hearing aid in place and turned on. |

REAG

The REAG is simply the REAR expressed as gain rather than SPL. Selecting REAG allows you to see the gain at each frequency for each of the REAR curves measured.

REOR

REOR measures the effect on the natural external ear effects resulting from inserting an ear mold or a hearing instrument, before it is turned on, into the ear canal. The REOR is also referred to as Insertion Loss. REOR is also useful for validating the effectiveness of venting or canal length changes to the mold.

REOG

The Real Ear Occluded Gain (REOG) is the difference in decibels, as a function of frequency, between SPL in the ear canal and SPL at the reference microphone at the entrance of the ear canal with the hearing aid in the ear and turned off. For each REOR measurement curve, the corresponding REOG curve is calculated and automatically plotted to the REOG screen. The REOG function is useful in determining the acoustic seal of a hearing aid, relative to a sound field outside the ear.

O.E.

Some clients report they seem like they are “speaking in a barrel” or “feel blocked up”. These are signs of a build-up of self-generated low frequency energy in the ear canal. This excessive occlusion can be measured objectively in the Occlusion Effect task.

RECD

The Real Ear to Coupler Difference (RECD) is used to simulate real ear measurements by coupler measurements and is useful when fitting children or “difficult” to fit patients. See the section on RECD later in this manual for more detail.

MPO

The Maximum Power Output test measures hearing aid response at high input levels. The software measures MPO with ISTS multitalker noise played at 55dB and then five

90dB tone bursts at the following frequencies: 500Hz, 1000Hz, 2000Hz, 4000Hz, 5000Hz.

Additional Tests & Features

Real Ear to Coupler Difference (RECD)

The Real Ear to Coupler Difference (RECD) is used to simulate real ear measurements by coupler measurements and is useful when fitting children or “difficult” to fit patients. RECD measurements can be conducted outside of a Hearing Instrument Test Box when using the optional MedRx RECD Coupler.



The RECD values are used as a correction to coupler measures for that client’s hearing instruments. By performing all subsequent measures in the coupler and applying the RECD corrections to the coupler measures,

the “real ear” factors are incorporated into the results. The resulting simulated measurements provide information to select and make adjustments to the hearing instrument and verify adjustments in the MedRx coupler rather than in the uncooperative client’s ear. This is particularly important in the case of children, whose small volume ear canals enhance high frequency amplification more so than in average adults. This is an essential consideration in determining the maximum output of the hearing instrument.

If RECD data is present, the software will display an option to choose between Ear or Coupler measurement on all Real Ear screens where measurements in a coupler are appropriate.

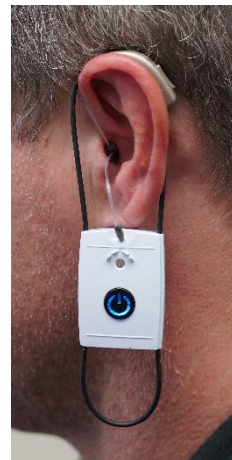
There are two ways to measure the REAR response with optional RECD coupler: using an insert headphone or a hearing instrument.

If a hearing instrument is used, its volume control setting and other parameters should remain the same for both REAR and coupler measurements. Set the volume control to moderate, and turn the compression and noise reduction circuits off.

Using open-fit hearing aids for RECD measurements may result in invalid low and mid-frequency measurements because of insufficient gain at those frequencies. Please contact your hearing aid manufacturer for recommendations.

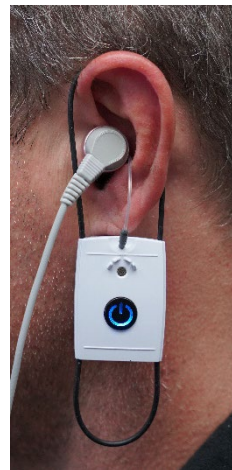
How to Perform the RECD Task

First, perform the REAR task to obtain a REAR curve. This can be measured with a hearing instrument or an insert earphone.



REAR with a hearing instrument

- Adjust volume of the hearing instrument to comfortable listening level. Turn the compression and noise reduction circuits off.
- Position the client less than one meter from the speaker and facing the speaker.
- Place the hearing instrument and the probe microphone tube as for all REM measurements.
- Select START to open the measurement type selection screen.
- Choose the REAR with a Hearing Aid option.
- Select OK to begin the test and wait until it concludes.



REAR with an insert headphone

- Place the probe microphone tube as for all REM measurements but use the insert headphone instead of a hearing instrument.
- Select START to open the measurement type selection screen.
- Choose the REAR with an Insert Headphone option.
- Select OK to begin the test and wait until it concludes.

Coupler Response

When the REAR measurement is complete, you are prompted to perform a coupler response.



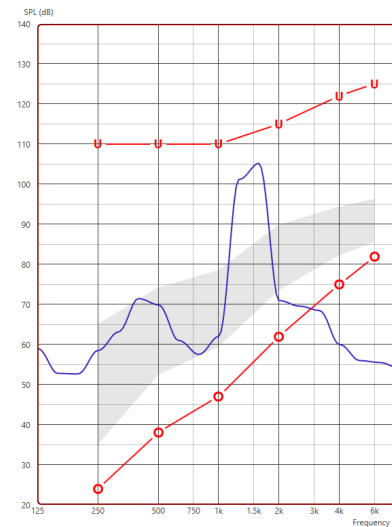
- Attach the hearing instrument or the insert headphone (must be the same as in the REAR test) to the appropriate coupler and place the probe tube inside the coupler.
- If a hearing instrument is used, be sure to perform this measurement at the same volume control setting as the first measurement.
- Select START to open the measurement type selection screen.
- Choose the Coupler Response option or Use Stored to skip the measurement (see note below.)
- Select OK and wait until the test completes.
- The calculated RECD curve is automatically displayed on the screen and is stored in memory for correction of subsequent coupler measurements made from the RECD function.

NOTE: If the REAR and the coupler response were measured with the insert headphone, the program saves the coupler response curve for later use. In this case to obtain another RECD, only REAR with insert headphone measurement is necessary. This is possible because the coupler response does not change provided that neither the coupler nor the insert earphone has changed.

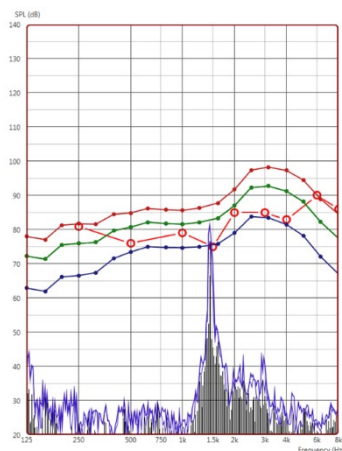
NOTE: After measuring RECD, it is possible to perform Live Speech Mapping in the coupler as well. Look for the “Measuring in” option on the LSM screen.

Measuring Acoustic Feedback

Feedback (whistling, howling) is one of the most common complaints of hearing instrument users. Even though many modern hearing instruments have sophisticated feedback management systems, knowing exactly where the feedback is occurring can greatly reduce the time required to resolve the problem. The MEDRX AWRC system does an excellent job measuring and displaying acoustic feedback.



1. Place the calibrated probe tube in the ear canal as instructed previously.
2. Place the hearing instrument in the ear without disturbing the probe tube.
3. Begin a Live Speech Mapping session as instructed previously.
4. When feedback is present, click the Start button.
5. Acoustic feedback appears as a large spike in the LSM response.



If a more specific frequency analysis of the feedback is desired, change the resolution of the system to 1/24 octave and adjust the smoothing in the General LSM or REM settings menu. This image shows the similar feedback as above at 1/24 octave, smoothing 1.

Using this information, make any necessary adjustments to the hearing instrument to reduce or remove the feedback.

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 use the Hearing Loss Simulator

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 each ear (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 player panel 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.



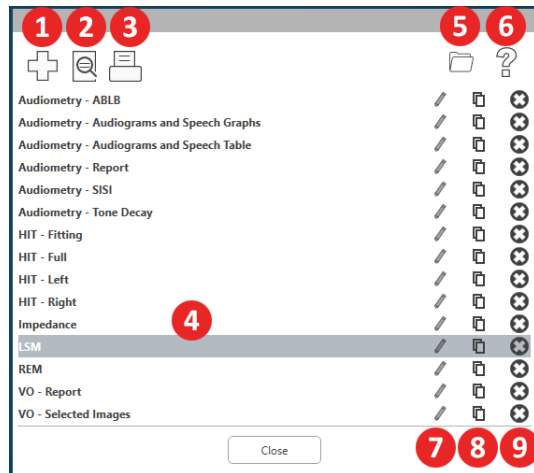
Hint: Use the track return icon on the player control panel to replay one track continuously.

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

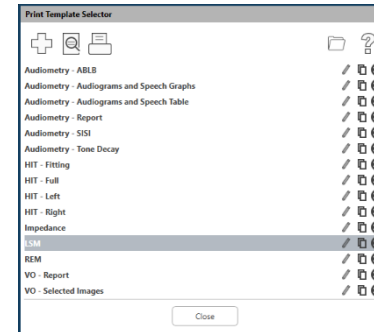


1. Create a new template.
2. Preview template icon.
3. Print template icon.
4. Select the template you would like to use.
5. Shortcut to templates folder on your desktop.
6. Studio Help icon.
7. Edit the template with the pencil icon. Editing a template will open the print editor and allow you to adjust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

To Use an Existing Print Template



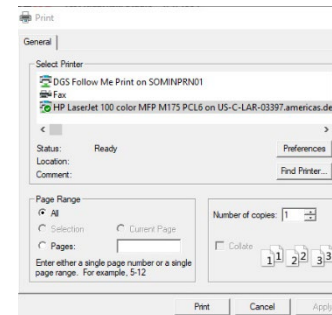
1. Click the print icon in the top tool bar or hold down the Ctrl key and click the P key on your keyboard.



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.



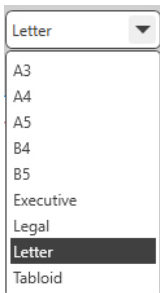
2. Select the + icon to create a new template.



3. Name the template you are creating.

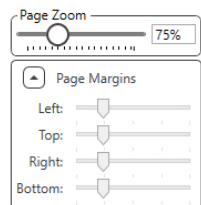


4. Choose page orientation.

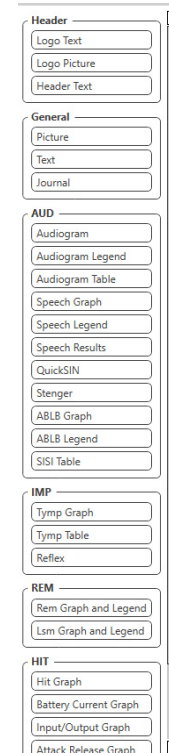


5. Use the drop-down menu to choose the size of paper you will be using.

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.



8. 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.



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



10. 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.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond his reach, his friends say he is looking for the pot of gold at the end of the rainbow.

EMC Precautions

MedRx AWRC should be operated only in a professional healthcare facility by trained professionals with education and/or training in the field of audiometry. Further the equipment can't be used in a residential environment.

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals. If it is used in a residential environment this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

BLE Uses 40 channels with a channel spacing of 2MHz in the 2.4GHz ISM band. This band ranges from 2402 MHz (Channel 0, logical channel 37) to 2480 MHz (Channel 39, logical channel 39). Logical Channels 37,38 and 39 are the advertising channels and channels 0 to 36 are the data channels. The three advertising channels are arranged in the frequency band so they cannot be disrupted by Wi-Fi channels.

As a basic safety features the device is designed in such a way that the output from the transducer never goes beyond 80db irrespective of the short-term disruptions that may occur.

The transmit power in BLE lies between -20dBm and 20dBm

The MedRx AWRC 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
Bone B-71	2 meters
All Headsets	2 meters
All Microphones	2 meters
REM Probe	2 meters
All Speakers	3 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 MedRx AWRC as replacement parts for internal components, may result in increased emissions or decreased immunity of the MedRx AWRC.
- The MedRx AWRC should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the MedRx AWRC should be observed to verify normal operation in the configuration in which it will be used.
- The MedRx AWRC may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.
- The MedRx AWRC does not have life supporting function.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the MedRx AWRC, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result

Guidance and manufacturer's declaration – electromagnetic emissions		
The MedRx AWRC is intended for use in electromagnetic environment specific below. The customer or the user of the MedRx AWRC should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The MedRx AWRC 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 MedRx AWRC 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 MedRx AWRC is intended for use in electromagnetic environment specific below. The customer or the user of the MedRx AWRC 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 MedRx AWRC is intended for use in electromagnetic environment specific below. The customer or the user of the MedRx AWRC 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 MedRx AWRC, 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 MedRx AWRC is used exceeds the applicable RF compliance level above, the MedRx AWRC should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MedRx AWRC. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.m.			

MedRx AWRC Baseboard and MedRx Wireless REM Probe ISED non-interference disclaimer

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following two conditions:

- (1) This device may not cause interference.
- (2) This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

- (1) L'appareil ne doit pas produire de brouillage;
- (2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

MedRx AWRC Baseboard ISED RF Exposure statement

This equipment complies with ISED RSS-102 radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20 cm (7.6 inches) between the radiator and any part of your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Pour se conformer aux exigences de conformité ISED RSS-102 RF exposition, une distance de séparation d'au moins 20 cm doit être maintenue entre l'antenne de cet appareil et toutes les personnes. Lanceurs ou ne peuvent pas coexister cette antenne ou capteurs avec d'autres.

MedRx Wireless REM Probe ISED SAR exemption statement

RF output power is 5 mW – which falls below the ISED SAR exemption limits for a device with a separation distance of 86 mm from the human body. These exemption limits are in accordance with ISED RSS-102, Section 2.5.1.

MedRx AWRC Baseboard and MedRx Wireless REM Probe FCC compliance statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) this device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation. Please note that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

MedRx AWRC Baseboard FCC RF Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter. In order to avoid the possibility of exceeding the FCC radio frequency exposure limits, this equipment should be installed and operated with minimum distance 20 cm (7.6 inches) between the antenna and your body during normal operation. Users must follow the specific operating instructions for satisfying RF exposure compliance.

MedRx Wireless REM Probe FCC SAR exemption statement

RF output power is 5 mW – which falls below the FCC SAR exemption limits for a device with a separation distance of 86 mm from the human body. These exemption limits are in accordance with FCC CFR 47 §2.1093.

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 ungrounded 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 MedRx AWRC.
- 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 probe tubes and new foam inserts are needed for each patient where applicable. Cleaning of the device and accessories should follow the procedure outlined below.
- The device is not intended to be operated in an environment with anesthetics, oxygen or NO. It is not an AP or APG device. This ME System is not intended for use with flammable anesthetics.
- This device uses Type B application parts temporarily placed on the patient during testing. They are nonconductive and can be immediately withdrawn from the patient at any time.
- The device is intended for continuous operation.
- The computer and the MedRx device or accessories may be located in the patient environment if required.
- The colored lights are as designated by ANSI S 3.6 and IEC 60645-1, conforming to the standard color designations for audiology. They signify that either the left (blue) channel is active or the right (red) channel is active, or no channel is active (green). The colors do not signify any dangerous or faulty condition.
- Contact the local MedRx distributor for safe and proper disposal of this equipment. Proper disposal may require that it be sent to collection facilities for recovery and recycling. 
- All repairs should be sent to MedRx for evaluation and / or repair. However, necessary diagrams and repair instruction will upon request be provided to authorized repair personnel.
- There are no known contraindications for the use of this equipment.
- The Instructions for Use (the Installation and Software Training manuals) are supplied as an electronic copy on a USB flash drive. Paper copies of the manuals may be also requested from the company, and will be sent within one business day of the request.
- Refer to the Training manual and Help files for test options and descriptions.

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)



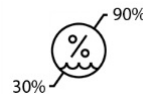
Authorized
Representative in
Europe



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)



Medical Device Label

Recommended Procedures for Cleaning and Disinfection

1. Foam ear tips and probe tubes are single use components, and should not be re-used by another patient.
2. It is recommended that 70% Isopropyl Alcohol should be applied to a soft clean cloth or tissue, not directly on the component to be cleaned. The cloth should never be wet, just damp. A mild soapy water solution is an alternative cleaning liquid.
3. To ensure that cross contamination does not occur, use clean cloth or sealed Alcohol swabs for each device to be cleaned.
4. Wipe the surfaces of the 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.

Permissions (Optional)

MedRx Studio uses the default windows user accounts to control access to the software. The default user settings are typically sufficient for regulatory bodies. These settings can be also adjusted if needed to comply with country requirements.

MedRx Studio software does not store private information. Data control is performed by the office management system or patient management system (i.e. Noah, Blueprint, Sycle).

The below Permissions information is for advanced users only needing to comply with specific country regulations.

Warning, changes to the settings below will change the overall Windows user accounts, settings and encryption.

Password Protection

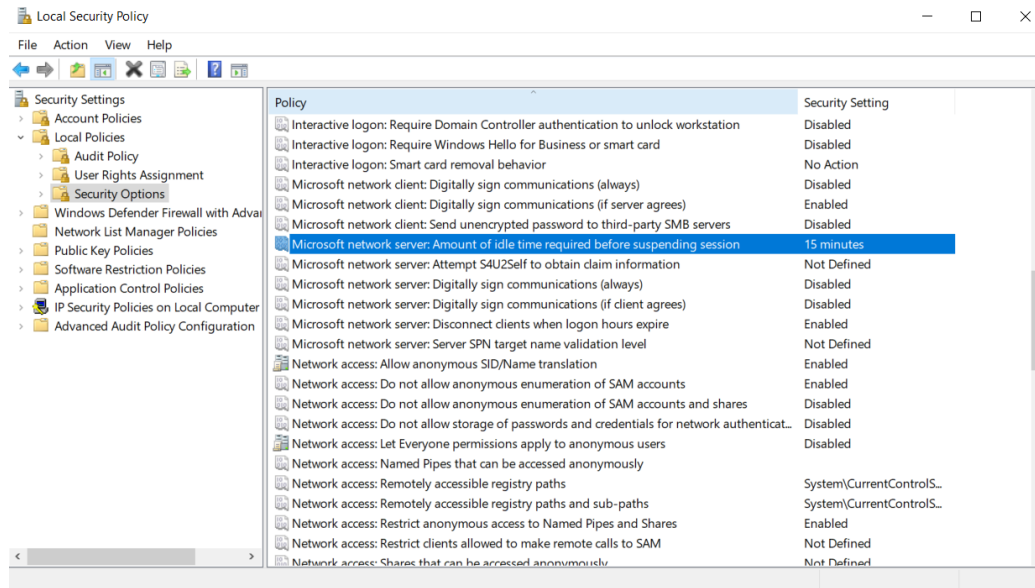
To access the Windows User settings, navigate to the Control Panel



Ensure that access to the computer is limited to those with permissions to health data. Add/Remove users as appropriate. Administrators will have access to add/remove programs, users and user settings.

Adjusting log out time period

Create user settings to lock the computer when not in use. Navigate to local security policy and adjust the Amount of idle time required before suspending session.



Adjusting this setting will prevent unintended access to the computer and health records.

Setting maximum password age

Local Security Policy will also identify the required password expiration timeframe. Be sure to set this to local standards.

Technical Information

The MedRx AWRC Audiometer/REM Combination 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
IEC 61669
ANSI S3.6: Type 1 HFAE
ANSI 3.46
ISO 15223-1
Medical Device Regulation

Test-Frequencies: 125 Hz – 20000 Hz

Level step: 5 dB or 1 dB level steps

Maximum Sound Pressure Level:

AC with earphone: - 10 dBHL to 120 dBHL
BC with bone conduction with B 71: - 10 dBHL to 80 dBHL
Sound field speaker: - 10 dBHL ... 90 dBHL

Test Signal: Pure tone, pulse tone, warble tone

Masking Signals: Narrow band noise: 5/12 Octave filter with the same center frequency resolution as pure Tone
White noise:
Speech Noise: falling 12 dB/octave above 1 kHz (+/- 5 dB)

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

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

Modulation:

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

Patient Response: Handheld response switch

Monitor: Build in monitor speaker, headset

Communication: Talk forward and talk back

Data Connection: USB

Mode of Operation: Continuous

Warm up Time: Less than 5 min after USB connection

Dimensions: Approx. 20 cm x 12 cm x 3 cm (L x W x H) Approx. 8" x 5" x 1.25" (L x W x H) (+/- 0.125")

Weight: < 1kg < 2lbs

Power Supply:

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

Power Consumption:

Less than 500 mA at 15 VDC / less than 500 mA at 5 VDC

Connection Sockets:	Specification
Power/Communication	USB: (5 VDC)
Power	15 VDC
Speaker left	ZA= 4Ω, UA= 8 Veff
Speaker right	ZA= 4 Ω, UA= 8 Veff
Pat patient response switch	RI= 500
Talk Back microphone	ZI= 1 k Ω, UI= 0.38 – 500 mVeff
Operator Microphone	ZI= 1 k Ω, UI= 0.38 – 500 mVeff
Operator Monitor headphone	ZA= 32Ω , UA= 3 Veff
Left Probe microphone (X2)	ZI= 1 k Ω, UI= 0.38 – 500 mVeff
Right Probe microphone (X2)	ZI= 1 k Ω, UI= 0.38 – 500 mVeff
Bone (bone conductor)	ZA= 10Ω, UA= 8 Veff
AC phone left	ZA=10 Ω, UA=1 Veff
AC phone right	ZA=10 Ω, UA=1 Veff
Patient (Client) headphone	ZA= 32Ω , UA= 3 Veff
Line Level Stereo Speaker Output	ZA= 32Ω , UA= 3 Veff

Calibration values and Max Levels:	Calibration values and Max Levels:	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 DD450 IEC 318-1 acoustic coupler Force 9N, ANSI and IEC RETSPL dB re 20µPa 125=30.5 250=18.0 500=11.0 750=6.0 1000=5.5 1500=5.5 2000=4.5 3000=2.5 4000=9.5 6000=17.0 8000=17.5 9000=19.0 10000=22.0 11200=23.0 12500=27.5 14000=35.0 16000=56.0 18000=83.0 20000=105 Speech=19.0	Headphone DD65v2 IEC 318-1 acoustic coupler Force 9N, ANSI and IEC RETSPL dB re 20µPa 125=30.5 250=17.0 500=8.0 750=5.5 1000=4.5 1500=2.5 2000=2.5 3000=2.0 4000=9.5 6000=21.0 8000=21.0 ANSI S3.6 Speech=17.0 IEC 60645-1 Speech=20.0	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 +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.