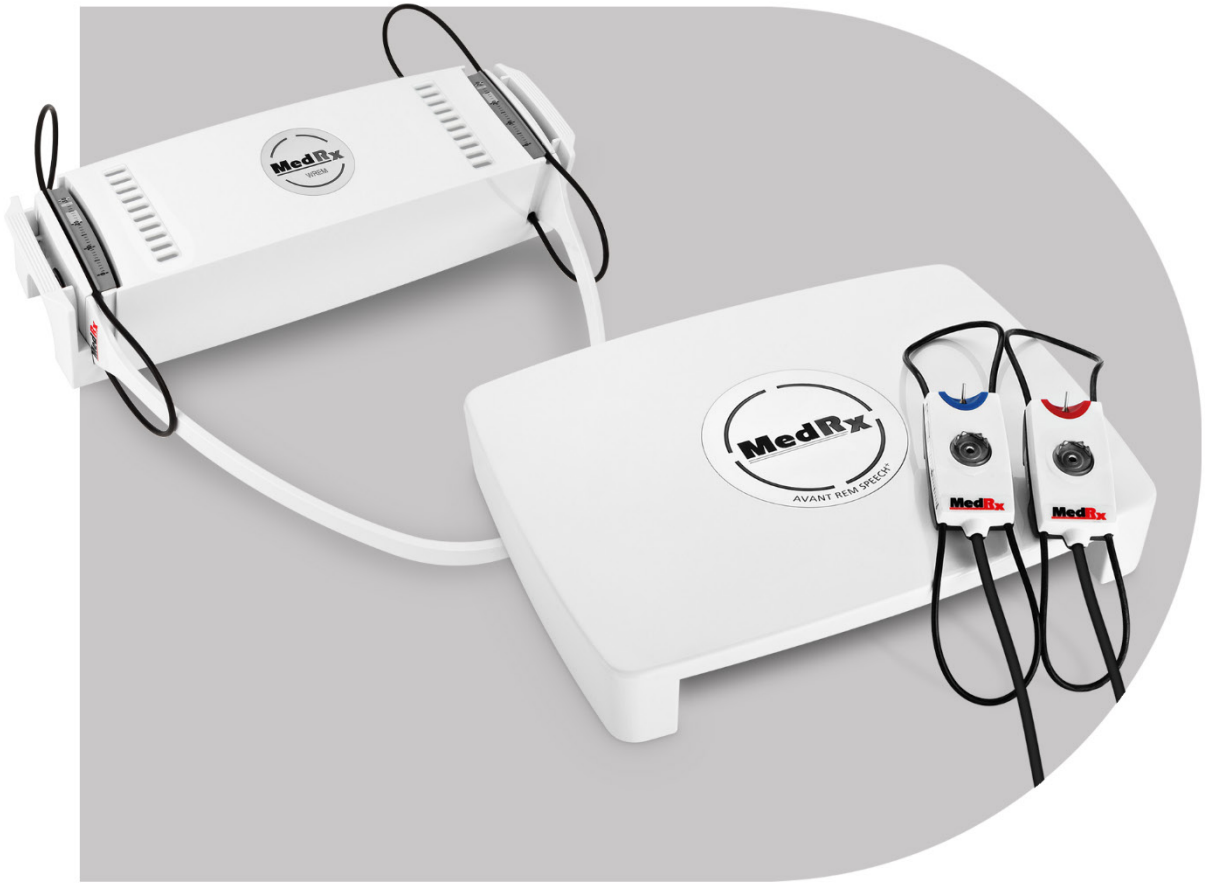


STUDIO Software

REAL EAR MEASUREMENTS
& LIVE SPEECH MAPPING

MedRx

Studio Software REM/LSM Training Manual

CE

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

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The AVANT REM+ and MedRx WREM are devices that are used in measuring the real ear acoustical characteristics of hearing instruments in-situ. The device performs measurements of real ear acoustical characteristics of a hearing instrument on a given human ear, and does comply with the International Standards ANSI S-3.46 and IEC 61669.

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

The scope of this manual is to get you “up and running” with your AVANT REM and MedRx WREM (Real Ear Measurement) 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 “Help” tab at the top of the screen, and select “Help Topics”. Select an item from the list in the Index tab and click “Display”. Measurement uncertainty is +/- 1 dB.

Getting to Know Your Real Ear Measurement

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.

Target Treated Population:

The target population for real ear measurement assessment includes all ages.

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.

Transducers and Accessories

Avant REM+

Use the accessories provided with your REM+ device. Use of unapproved accessories is not recommended.



Probe Microphones



Headphones (Optional)



Bluetooth *Active* Speaker



USB Cable A-B



Bluetooth Speaker Power Supply



Probe Mic Hanger



DC Power Supply (Optional)



Bluetooth Speaker Audio Cable



Desktop *Active* Speakers

MedRx WREM

Use the accessories provided with your WREM device. Use of unapproved accessories is not recommended.



Probe Microphones



Headphones (Optional)



USB Cable A-C



Bluetooth *Active* Speaker



Bluetooth Speaker Power Supply



Probe Mic Hanger



DC Power Supply (Optional)



Bluetooth Speaker Audio Cable



Desktop *Active* Speakers

Alternate Speaker Option

AVANT REM Speech+



⚠ 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.

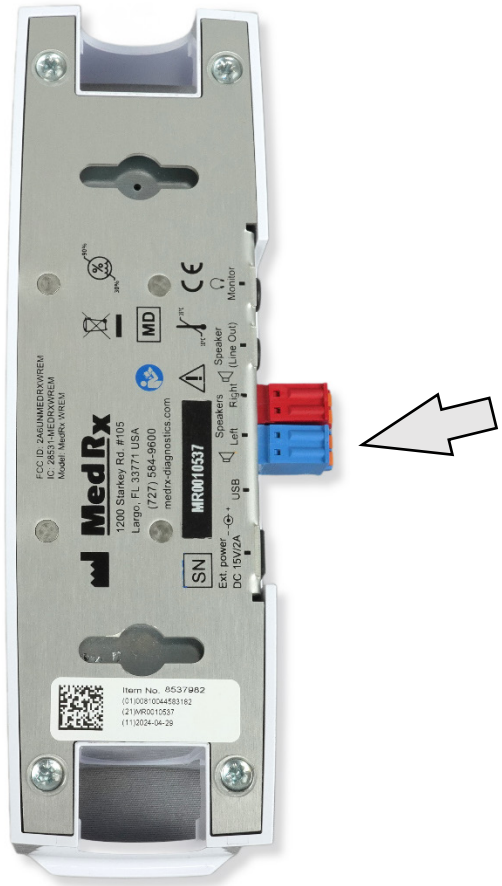
Place a small flat head screwdriver on the small orange tabs and push down while inserting a speaker wire into the opening then remove the screw driver. Be sure the wire is secure.

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

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

Alternate Speaker Option

MedRx WREM



⚠ 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 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.

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

Probe Mic Hanger Installation

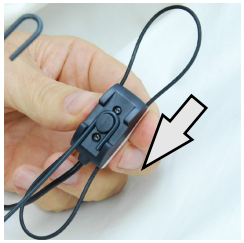
Avant REM+



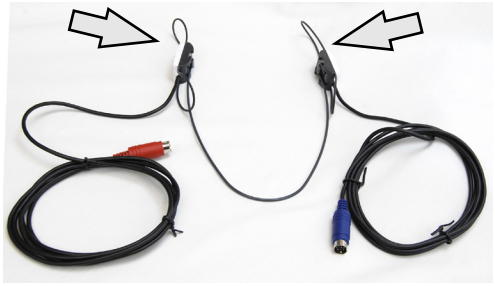


1. You will need the two Probe Mics, the Probe Mic Hanger and the clip.





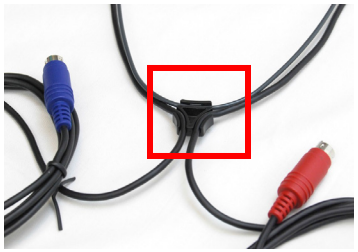
2. Install the hook on the back side of the probe mic. Pull hook down to seat on the post.



3. Once installed the large O-rings should be adjustable for fitting.



4. Gently press clip into place.



5. Turn clip over, place probe mic wires into clip.



6. Larger view of clip with wires inserted.



7. Probe Mic Hanger installation assembly complete.

Connecting the Speaker

The red battery light will illuminate when charging.

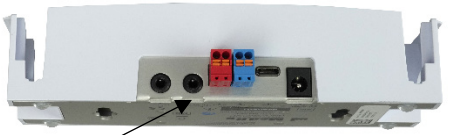
To turn the speaker on push and hold the first symbol for 1 second.

Reset the volume to maximum every time the speaker is turned on. Push the + button until beeping is heard.



Front Side of Speaker.







Optional Plugs.

Plug power cord in as shown.



Plug cable into speaker jack and connect to your REM+ as shown.



The front side of the speaker is placed at a distance of about 1 meter (19”-39”) from the patient, for normal use.

It is preferred to plug the speaker into the power supply but it may be powered by the internal battery. The Bluetooth option is not used.

The speaker’s power cable is a USB “male A to micro-B type”.

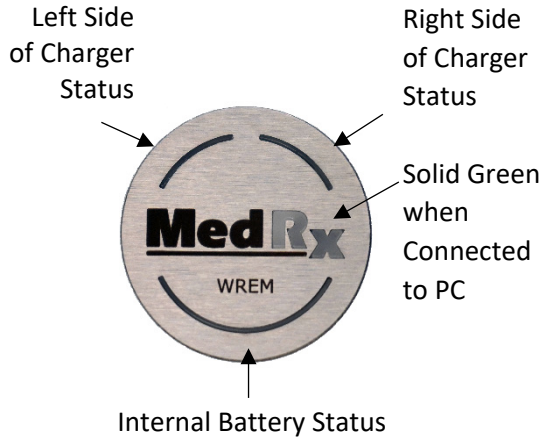
MedRx Charger and Probe Charging

The MedRx WREM is designed to charge the wireless REM Probes though Qi charging. The MedRx WREM 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 charging status of wireless REM Probes.

MedRx wireless 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 WREM to prevent damage and ensure charging occurs. Batteries are not changeable by the user.



MedRx WREM with Probes attached



MedRx WREM LEDs display status of Batteries

Internal Battery LED Color Indicators

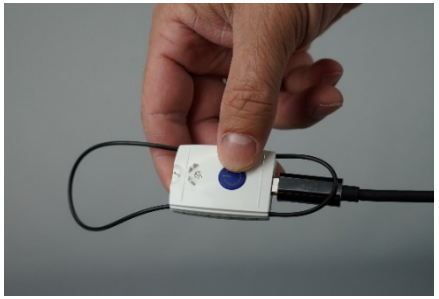
Blinking – Battery is charging

Green – Battery is ≥ 66%,

Yellow – battery is between 66% and 33% charged

Red – Battery is ≤ 33% charged

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



To prevent charging of the REM probes when not necessary in the MedRx Charger, inserting the probes into the device and then turning off the device.
To turn off the device, unplug the PSU and/or USB-C cable. Place the Probes in the MedRx Charger.
Touch the medallion until the LED(s) turn on and as soon as the LED(s) turn off, touch and hold the medallion until the RX light flashes on and off. Touch the medallion to verify the LED(s) remains off. There are 3 options to power back on the device; re-insert a probe, apply USB power, or apply 15VDC power.

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

Pairing Wireless Probes

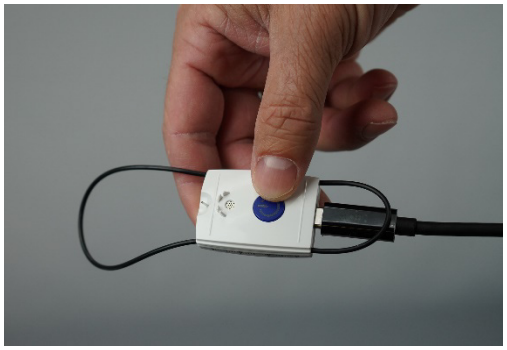
New WREM devices will have the REM Probes pre-paired with the main unit. There will be no need to manually pair probes on new units. Pairing is for replacement probes for the WREM.

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

Manually Pair Replacement wireless Probes

To pair replacement wireless REM probes

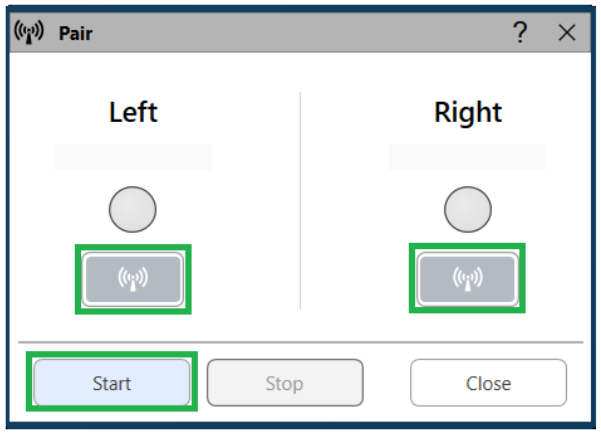
1. First you will need to prepare the probe for pairing. With the Wireless REM probe powered off, press and hold the power button while plugging in the new Wireless REM probe to USB power. Release the power button and now the probe light will begin flashing quickly.



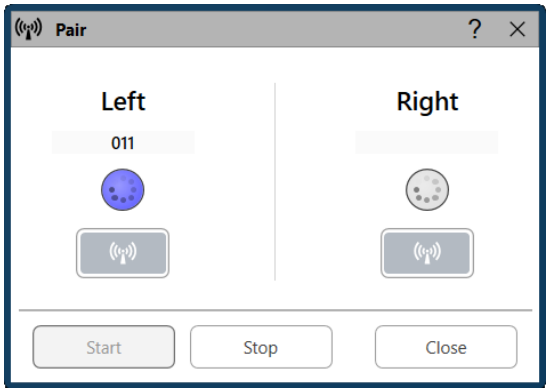
2. Open Studio and Enter the REM or LSM module. Click the three dots in the top menu and select “Pair”



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 WREM in pairing mode.



4. The Studio software will lightly fill the status circle (blue or red depending on earside) 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.

Wireless REM Probe Connections

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

To connect wireless 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 wireless Probes

2. Power on the wireless 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 WREM is fully connected and ready for testing when the status bar has dark filled circles and battery status is available.



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

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

The MedRx 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

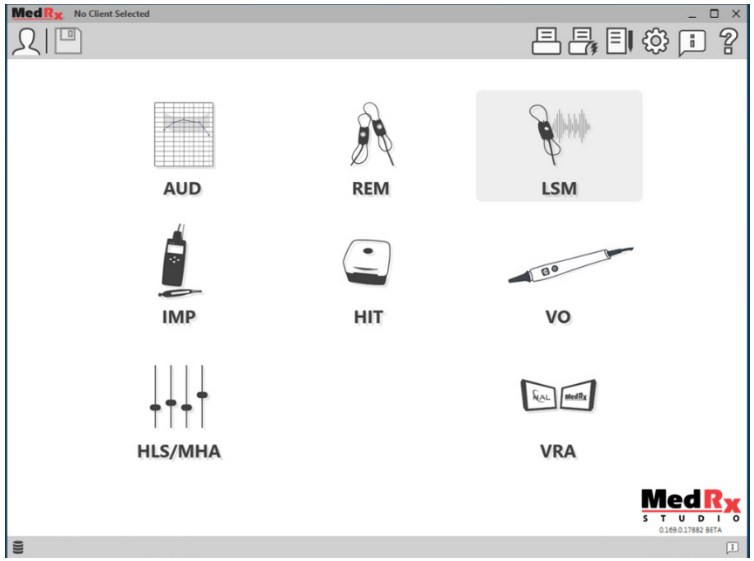
- Launch Noah.
- Select a patient.
- Launch MedRx Studio module following Noah procedures.

Basic Software Options

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

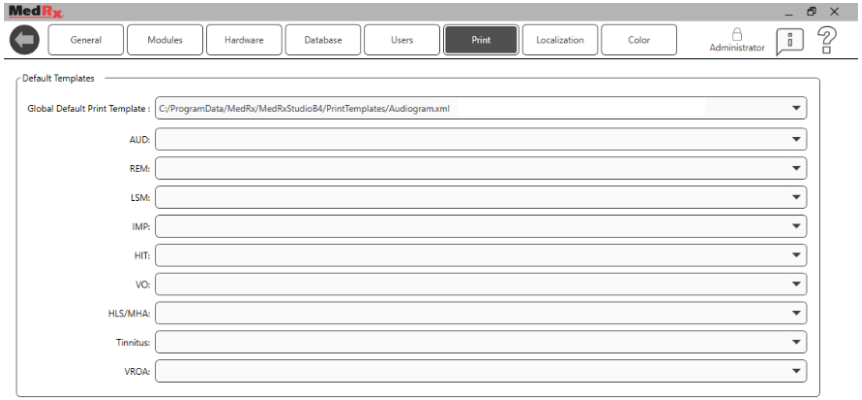


Access these options by clicking the settings wheel in the top right menu bar.



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.

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

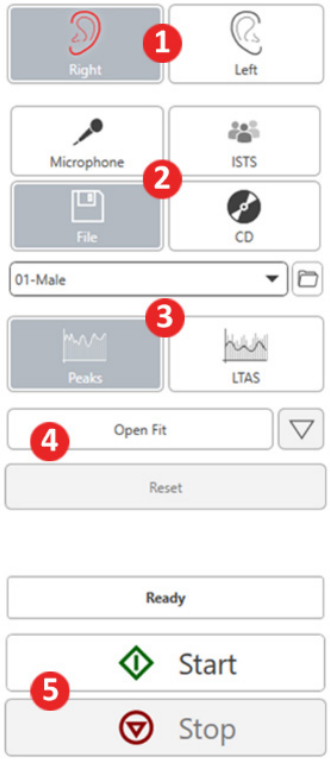


The **Bottom Tool Bar** icons have the following functions: _____

The **Wrench icon** displays options for:



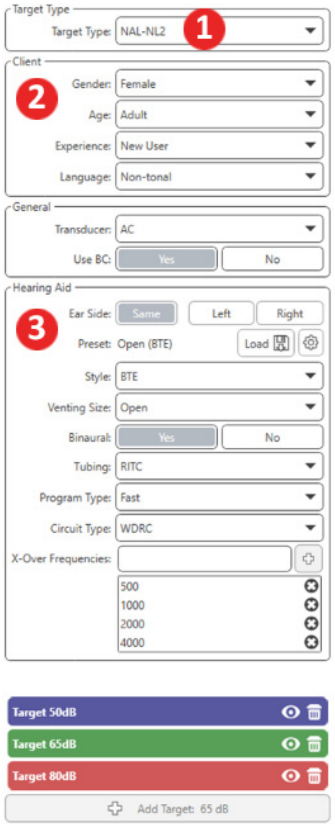
1. Ear Selection
2. Stimulus Selection
3. Viewing Mode
4. Open Fit Function
5. Start & Stop Buttons



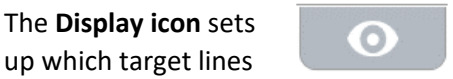
The **Target Selection icon** sets up:

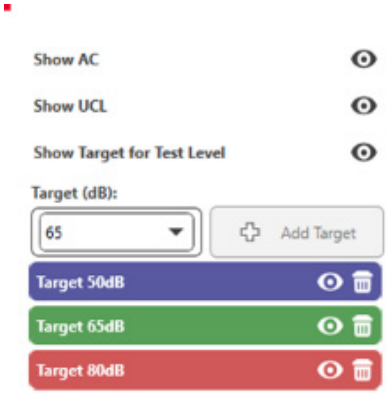


1. Target type
2. Client information
3. Hearing aid parameters



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



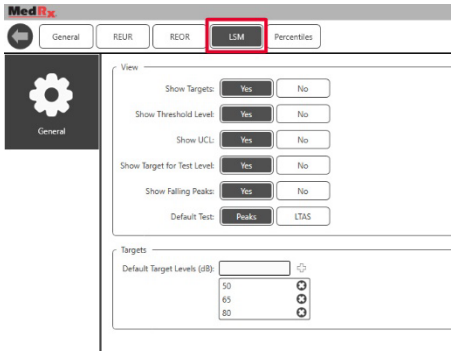


⚠ NOTE: Remember that more information is always available in the Interactive Help System by clicking the Help Icon or pressing the F1 key.

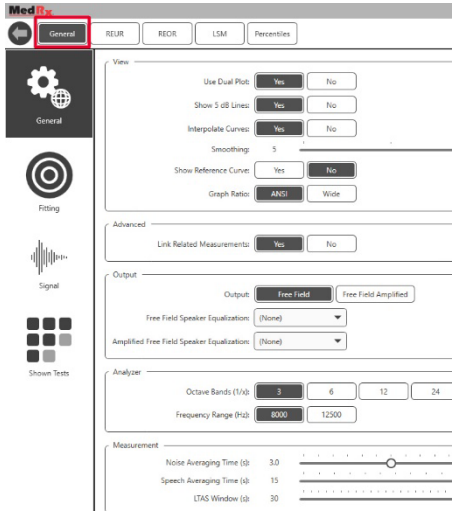
General LSM Options



Click the settings wheel in the top right menu bar.

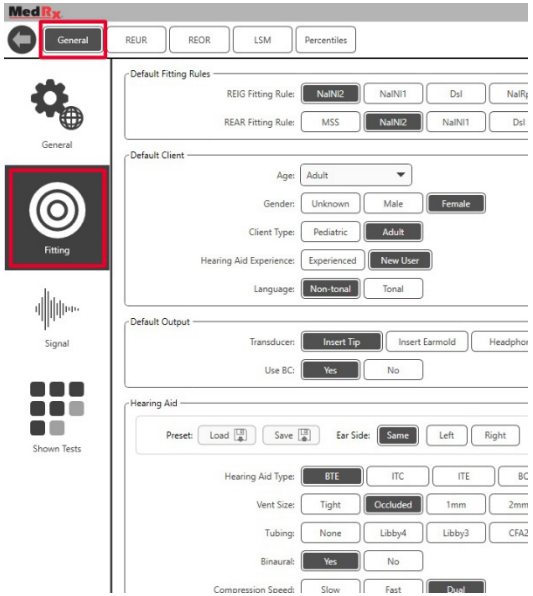


The **LSM tab** sets your default view and default target levels.

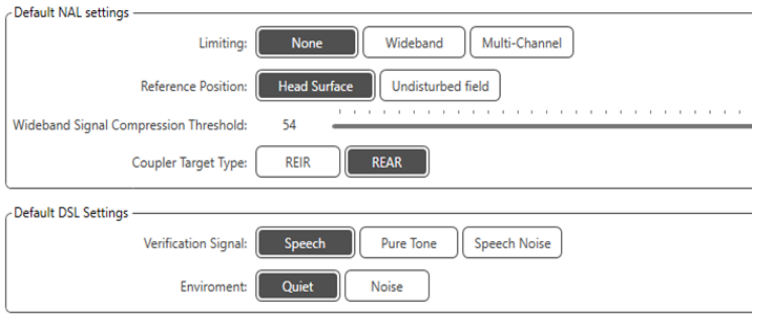


The **General tab** defines the default appearance of the Live Speech Mapping test environment.

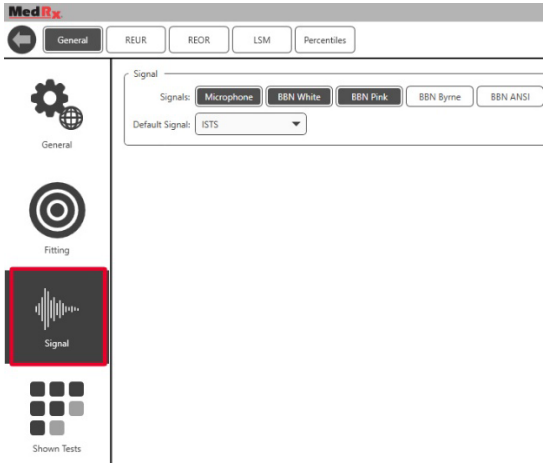
The **Fitting tab** sets the default fitting rule, client information, output and hearing aid parameters.



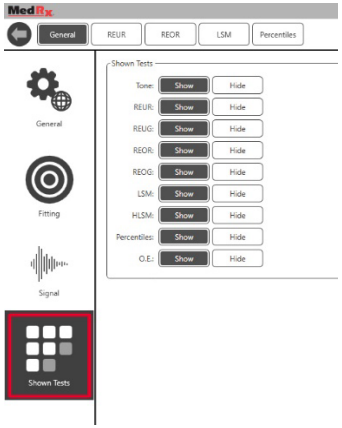
The **Fitting tab also** sets default NAL or DSL default settings.



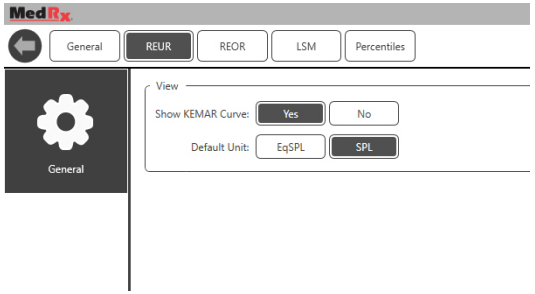
The **Signal** tab sets the signals displayed on the Live Speech Mapping Screen.



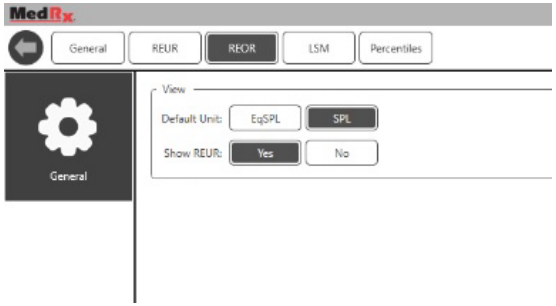
The **Shown Tests tab** sets the tests displayed in the Live Speech Mapping module.



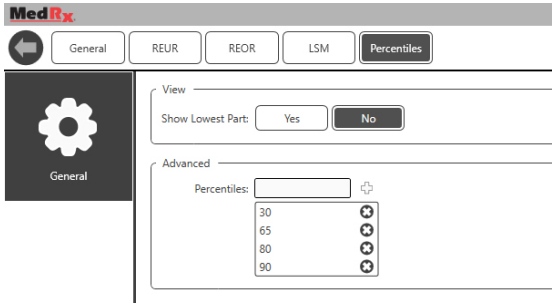
The **REUR** tab sets the default appearance and units displayed on the REUR graph.



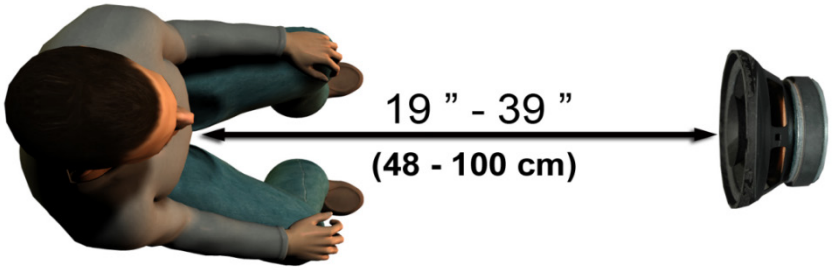
The **REOR** tab sets the default appearance and units displayed on the REOR graph.



The **Percentiles** tab sets the default appearance and percentiles displayed on the graph..



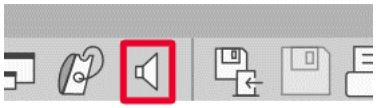
Positioning the Speakers



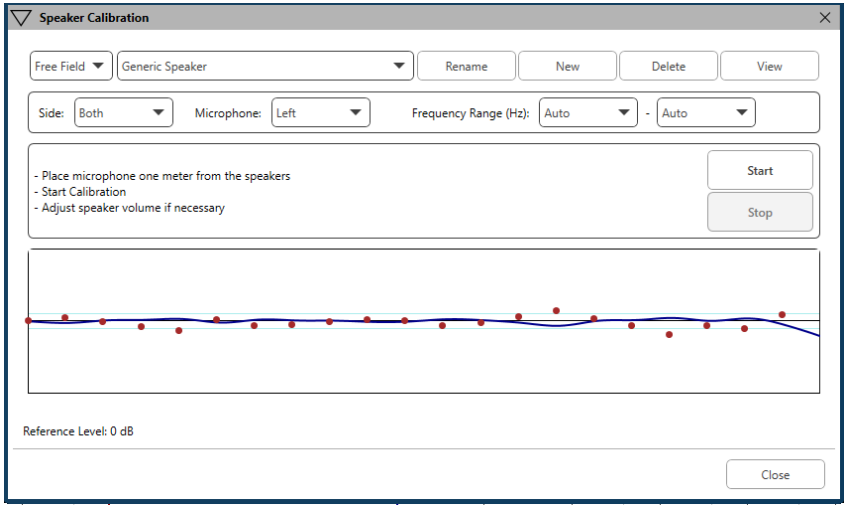
Proper positioning of the loudspeakers relative to the patient’s hearing aids is critical for making accurate and repeatable measurements. Seat the patient so their ear is between 19 and 39 inches from the loudspeaker.

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



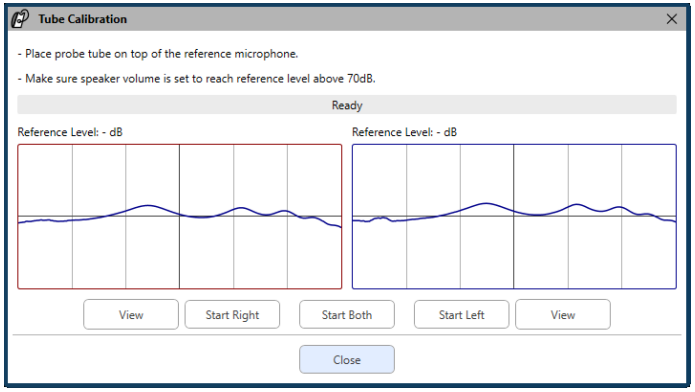
⚠ For reasons of infection control and reliability of results, MedRx recommends that a new probe tube be used with each patient. To ensure accurate measurements, it is necessary to calibrate the probe tube each time it is replaced.

1. Place a new probe tube on the probe micro-phone 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.

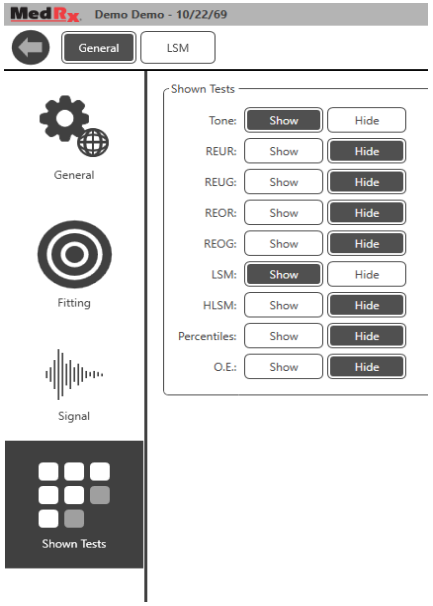
Return Probe Microphones to MedRx for annual re-calibration. Annual re-calibration of the Avant REM+ Probe Microphones is recommended. There are no user repairable components on this device.

Step-by-Step Guide to Live Speech Mapping

Ensure that the Audiogram is entered

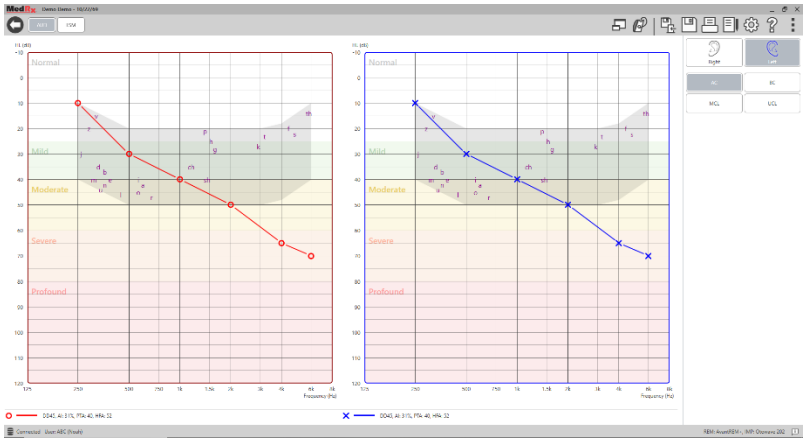
Before making Live Speech Mapping measurements, the patient's pure tone audiogram must be available to the software. This can occur several ways:

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.





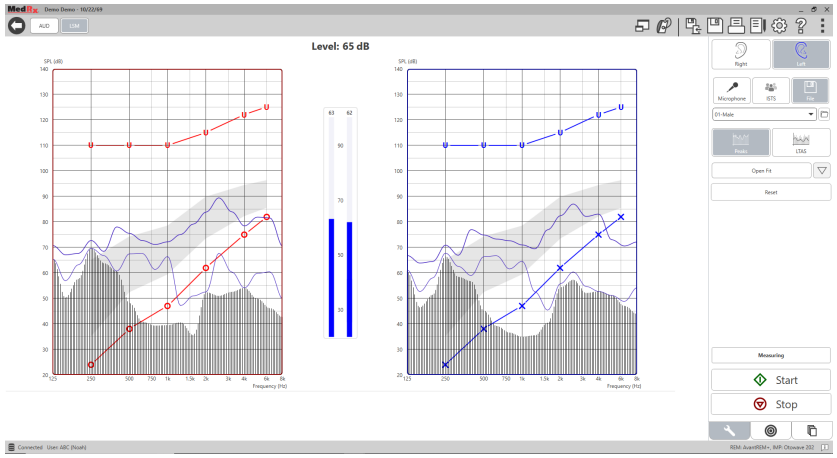
2. Select AUD module located at the top left of the software.
3. Using your mouse, select the test ear.
4. Select the test type AC.
5. Enter thresholds by clicking the intersection points with the mouse. (You may also enter the audiogram by selecting the audio tab in either the REM or HLS/MHA screens).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



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.

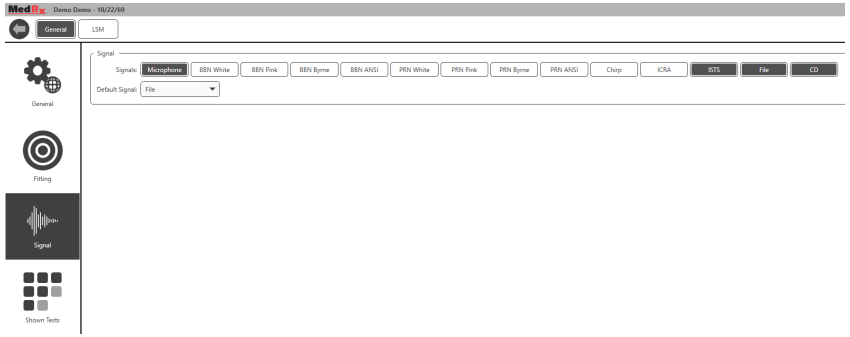
Speech Mapping with Recorded Inputs



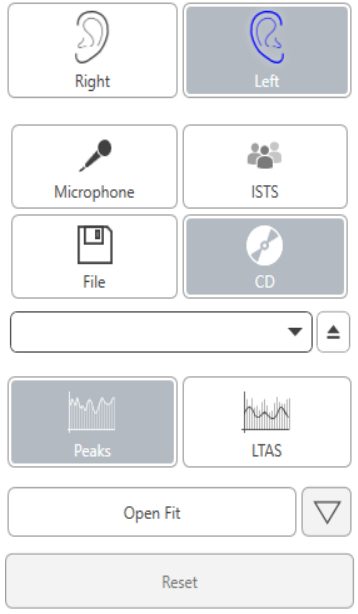
The Studio software provides several digital audio files to use as a repeatable stimulus for Speech Mapping. These are accessed by clicking the File button on the right and then selecting the desired track from the pull-down menu in the audio player. Peak measurements are recommended.

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.

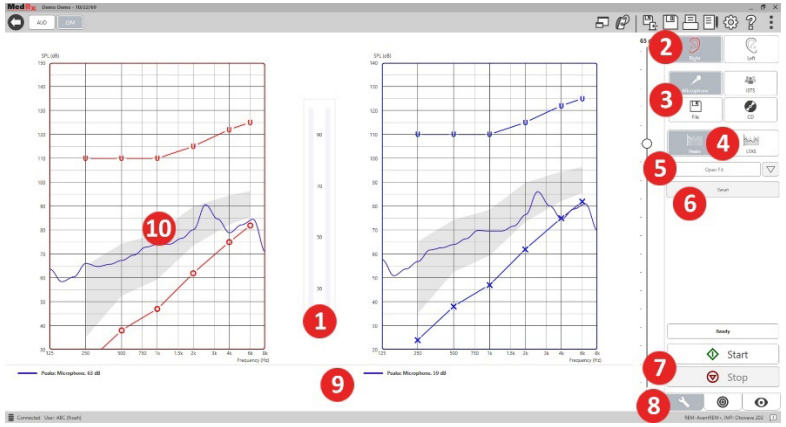


Select CD as an option under General and Signal.



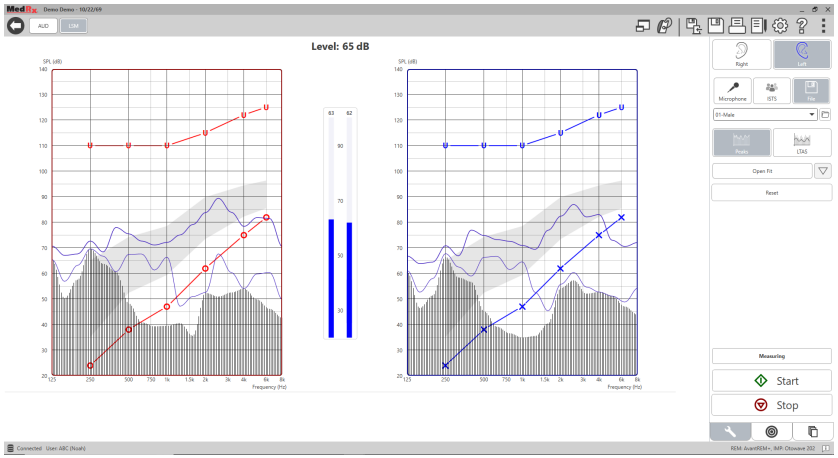
Select the CD button and then select a track. Use the sound level meter on screen to check the proper level. Adjust the output of the speaker to desired level using the sound level meter. (Remember conversational speech is 65 dB at 1 meter).

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. Ear Selection
3. Test Stimulus
4. Measurement Type
   - Peaks
   - LTAS
5. Open Fit Function
6. Reset Button
7. Start and Stop Buttons
8. Tools Tab, Target Selection Tab, and Display Tab
9. Legend
10. Target Area – can be any of the following:
    - MedRx Modified Speech Spectrum
    - DSL IO
    - NAL-NL2
    - NAL-NL1

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 36.

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 preform Speech Mapping measurements.

Completing the On-Top Mode Process

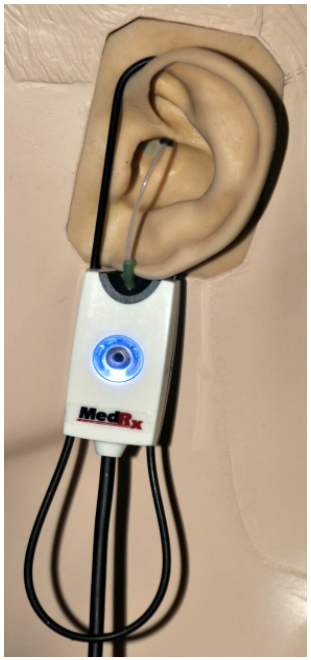
Close the REM module by clicking the X button or the back arrow in the top left. Save the session as normally.

MedRx Live Speech Mapping Protocol

Unlike other products, the AVANT REM+ 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.

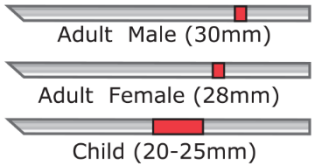
In order to get you “up and running” with the AVANT REM+ system, MedRx has developed the following protocol. This simple procedure has been found to be effective with both audiologists and hearing instrument specialists. After mastering the basic operation of the system utilized in this protocol, you 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 19.

4. Calibrate Probe Tube as described earlier in this manual on page 20.

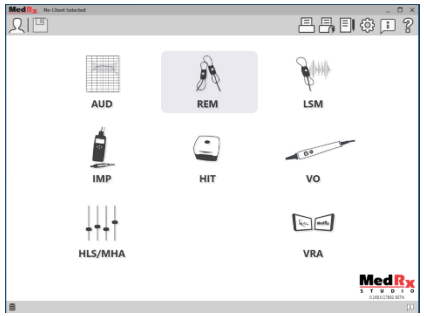
5. Option 1: Measure and place the probe tube in the ear canal. (Use chart to the left).

6. Option 2: Use the probe tube depth guide to accurately place the probe tube[1].

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





REM

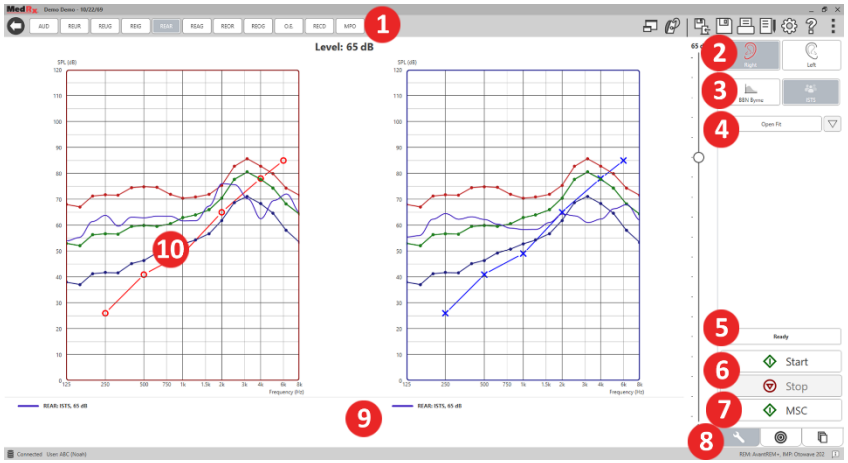
In addition to Live Speech Mapping, the Avant REM+ supports all conventional Real Ear Measurements (REM). All these tests are accessed from the main REM screen.

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.

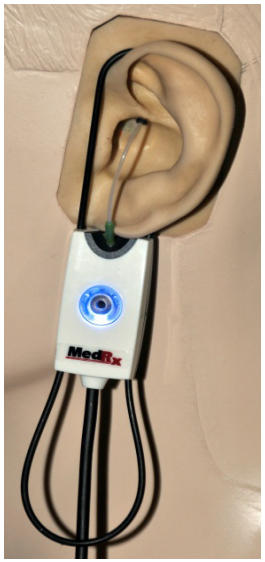


1. REM Test Options
2. Ear Selection
3. Test Stimulus
4. Open Fit Function
5. Time Indicator
6. Start and Stop Buttons
7. MSC
8. Tools Tab, Target Selection Tab, and Display Tab
9. Legend
10. Target Area – can be any of the following:
    a. DSL IO
    b. NAL-NL2
    c. NAL-NL1

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.

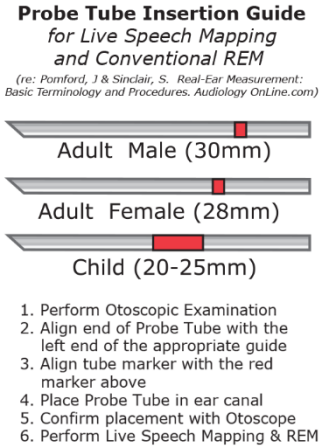
MedRx Real Ear Measures Protocol

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 19.



4. Calibrate Probe Tube as described earlier in this manual on page 20.

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 tube[1].

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

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.

the density of frequencies (individual cycles) raises with frequency, there is more energy in high octaves.

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.

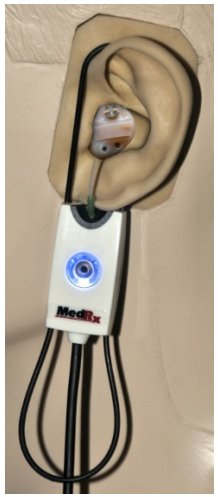
There are two ways to measure the REAR response with optional RECD coupler: using an insert headphone or a hearing instrument.

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.

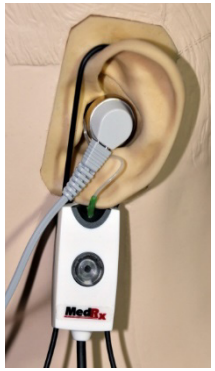
How to Perform the RECD Task

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.





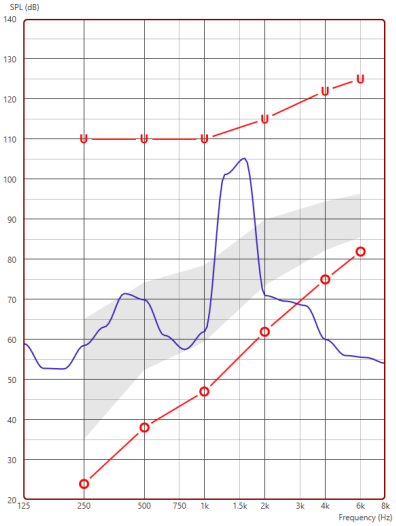
- Attach the hearing instrument or the insert headphone (must be the same as in the REAR test) to the appropriate coupler and place the probe tube inside the coupler.
- If a hearing instrument is used, be sure to perform this measurement at the same volume control setting as the first measurement.
- 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.

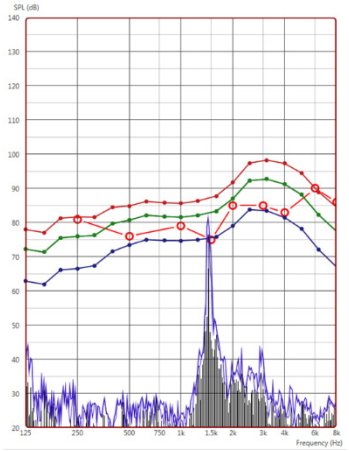
NOTE: After measuring RECD, it is possible to perform Live Speech Mapping in the coupler as well. Look for the “Measuring in” option on the LSM screen.

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 AVANT REM+ 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.



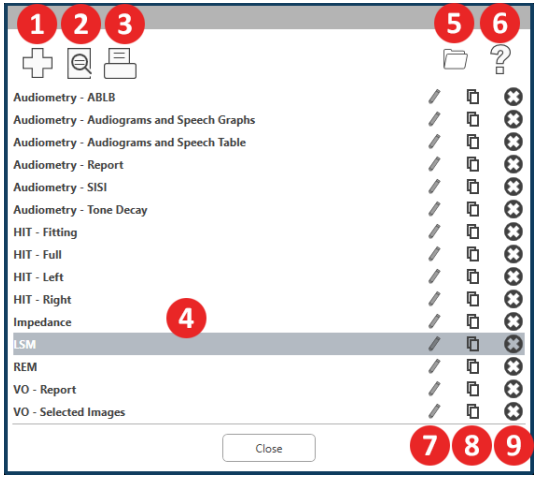
Hint: Use the track return icon on the player control panel to replay one track continuously.

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

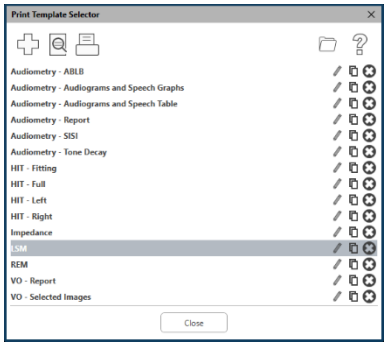


1. Create a new template.
2. Preview template icon.
3. Print template icon.
4. Select the template you would like to use.
5. Shortcut to templates folder on your desktop.
6. Studio Help icon.
7. Edit the template with the pencil icon. Editing a template will open the print editor and allow you to adjust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

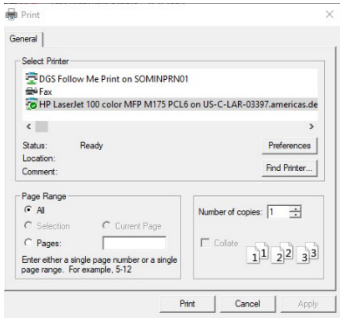


2. Select the template you would like to use.

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.



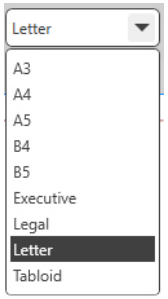
2. Select the + icon to create a new template.



3. Name the template you are creating.

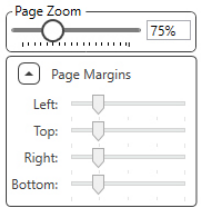


4. Choose page orientation.

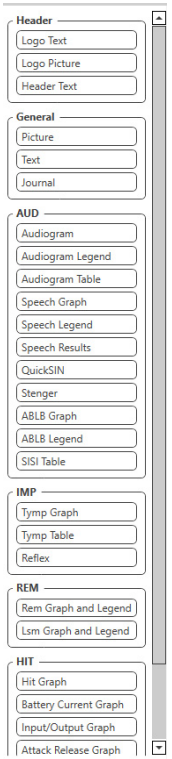


5. Use the drop-down menu to choose the size of paper you will be using.

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.

MedRx WREM EMC Precautions

MedRx WREM 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.

Bluetooth use 79 channels in the 2.4 GHz ISM band. This band ranges from 2400 MHz to 2483.5 MHz. Reception bandwidth 83.5MHz. Modulation GFSK. Maximum EIRP is 20 dBm.

Wireless Power Transfer (WPT) for Qi wireless charging has a frequency band range from 130-160 kHz. Qi resonant inductive coupling field strength measured is 76.4 dBµV/m.

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 Bluetooth lies between -20dBm and 20dBm

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

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

Transducer / Accessories	**Maximum Cable length**
USB Cable	≥2.9 meters
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 WREM as replacement parts for internal components, may result in increased emissions or decreased immunity of the MedRx WREM.
- The MedRx WREM should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the MedRx WREM should be observed to verify normal operation in the configuration in which it will be used.
- The MedRx WREM may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.
- The MedRx WREM 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 WREM, 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 WREM is intended for use in electromagnetic environment specific below. The customer or the user of the MedRx WREM should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1 Class A	The MedRx WREM 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 Conducted emissions	Group 1 Class A	The MedRx WREM 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	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The MedRx WREM is intended for use in electromagnetic environment specific below. The customer or the user of the MedRx WREM 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%.
Immunity to proximity fields from RF wireless communications equipment IEC 61000-4-3	Levels and modulation defined in table 9	As defined in table 9	RF wireless communications equipment should not be used close to any parts of the WREM.

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.
Voltage dips, short interruptions, and voltage variations on power supply lines IEC 61000-4-11	0% *U*T (100% dip in *U*T) for 0.5 cycle, @ 0, 45, 90, 135, 180, 225, 270 and 315° 0% *U*T (100% dip in *U*T) for 1 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles 0% *U*T (100% dip in *U*T) for 250 cycles	0% *U*T (100% dip in *U*T) for 0.5 cycle, @ 0, 45, 90, 135, 180, 225, 270 and 315° 0% *U*T (100% dip in *U*T) for 1 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles 0% *U*T (100% dip in *U*T) for 250 cycles	Mains power quality should be that of a typical commercial or residential environment. If the user of the MedRx WREM requires continued operation during power mains interruptions, it is recommended that the MedRx WREM be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated fields in close proximity — Immunity test IEC 61000-4-39	9 kHz to 13.56 MHz. Frequency, level and modulation defined in AMD 1: 2020, table 11	As defined in table 11 of AMD 1: 2020	If the MedRx WREM contains magnetically sensitive components or circuits, the proximity magnetic fields should be no higher than the test levels specified in Table 11
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The MedRx WREM is intended for use in electromagnetic environment specific below. The customer or the user of the MedRx WREM should assure that it is used in such an environment.			
Immunity test	**IEC 60601- test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 0.15 - 80 MHz 6 V_{RMS} (unmodulated) in ISM bands between 0.15–80 MHz	3 Vrms 0.15 - 80 MHz 6 V_{RMS} (unmodulated) in ISM bands between 0.15–80 MHz	Portable and mobile RF communications equipment should be used no closer to any parts of the MedRx WREM**,** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz	3 V/m 80 MHz to 2,7 GHz	
Surge IEC 61000-4-5	AC mains ± 0.5, 1 kV	AC mains ± 0.5, 1 kV	
NOTE 1 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 WREM is used exceeds the applicable RF compliance level above, the MedRx WREM should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MedRx WREM.			

MedRx WREM 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.

This device complies with the Canadian ICES-003 Class B specifications. CAN ICES-003(B) / NMB-003 (B).

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.

Cet appareil numérique de la Canadian ICES-003. Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.

MedRx WREM 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.

Cet équipement est conforme aux limites d'exposition aux radiations ISED CNR-102 établies pour un environnement non contrôlé. Une distance de séparation d'au moins 20 cm doivent 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 WREM 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.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

MedRx WREM 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.

MedRx WREM 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 is not protected from ingress of water. Power is supplied by an un-grounded mains power cable to a medical grade power supply and also supplied by the USB cable connected to a computer. The USB computer power must be able to supply at least 900mA at the standard USB voltage.
- Power is supplied by the USB cable connected to a computer.
- 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 WREM.
- 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.
- The wireless REM probes contain an internal battery that is not user-replaceable. Opening the probe may affect calibration and device performance. Battery replacement shall be performed by MedRx or authorized service personnel only.
- 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.

MedRx WREM Symbols that may be used



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



or SN

Indicates that the device serial number will follow



Type B applied part.



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

Avant REM+ EMC Precautions

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

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

Transducer / Accessories	**Maximum Cable length**
USB Cable	2,0 meters
REM Probe	2,0 meters
All Headsets	2,0 meters
All Speakers	2,0 meters



Warnings!

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

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

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

Guidance and manufacturer's declaration – electromagnetic immunity

The Avant REM is intended for use in electromagnetic environment specific below. The customer or the user of the Avant REM should assure that it is used in such an environment.

Immunity test	**IEC 60601- test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Avant REM, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM Band 1 kHz AC Mains	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM Band 1 kHz AC Mains	$d = 1{,}17 \times \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}17 \times \sqrt{P}$ 80 to 800 MHz $d = 2{,}33 \times \sqrt{P}$ 800 MHz to 2,5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency ranges applies.

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

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Avant REM is used exceeds the applicable RF compliance level above, the Avant REM should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Avant REM.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between

Portable and mobile RF communications equipment and the Avant REM

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

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

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

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

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

A medical grade computer is recommended, conforming to the requirements of IEC 60950-1 and IEC 60601-1-4.

Avant REM+ Safety

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

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

  This device provides Type B protection  (Type B equipment, Type B applied part)
- This device is not protected from ingress of water.
- Power is supplied by an un-grounded mains power cable to a medical grade power supply and also supplied by the USB cable connected to a computer. The USB computer power must be able to supply at least 500mA at the standard USB voltage.
- A USB Optical Isolator, with a minimum of 1500V AC isolation should be placed in-line between the computer's USB connection and the MedRx device. The Optical Isolator should be powered by a power supply that conforms to IEC 60601-1. The computer, Optical Isolator's power supply and the speaker's power supply should be connected to the Medical Grade isolation transformer that conforms to IEC 60601-1. Follow the manufacturer's instructions for installation and use. All connected equipment provides 2 MOPP per IEC 60601-1.
- This device is to be operated on non-conductive surfaces only.
- The computer used with this device should conform to the requirements of IEC 60601-1.
- A MULTIPLE PORTABLE SOCKET-OUTLET or extension cord shall not be connected to the system.
- The device warm-up time is less than 5 minutes.
- Use only the 15 VDC, 2A medical power supply supplied with your Avant REM.
- 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 are needed for each patient where applicable, and cleaning of the device and accessories should follow the procedure outlined below.
- The device is not intended to be operated in an environment with anesthetics, oxygen or NO. It is not an AP or APG device. This ME System is not intended for use with flammable anesthetics.
- This device uses Type B application parts temporarily placed on the patient during testing. They are nonconductive and can be immediately withdrawn from the patient at any time.
- The device is intended for continuous operation.
- The computer and the MedRx device or accessories may be located in the patient environment if required.
- The colored lights are as designated by ANSI S 3.6 and IEC 60645-1, conforming to the standard color designations for audiology. They signify that either the left (blue) channel is active or the right (red) channel is active, or no channel is active (green). The colors do not signify any dangerous or faulty condition.
- Contact the local MedRx distributor for safe and proper disposal of this equipment. Proper disposal may require that it be sent to collection facilities for recovery and recycling. 
- All repairs should be sent to MedRx for evaluation and / or repair. However, necessary diagrams and repair instruction will upon request be provided to authorized repair personnel.
- 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.
- There are no known contraindications for the use of this equipment.

Avant REM+ Symbols That May Be Used



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



or SN

Indicates that the device serial number will follow



Type B applied part. (Type B equipment)



Manufacturer (MedRx)



Authorized Representative in Europe



Non-ionizing electromagnetic radiation



Special Disposal Required



Humidity Limitation



Caution, General warning sign



Temperature limitation



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



Class II equipment



Start (of action)



Stop (of action)



Percentile Setup



Calibration



Loudspeaker (Speaker)



Headphones



Microphone



Recording



CAUTION
For Single Patient Use Only

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.

Recommended Procedures for Cleaning and Disinfection

1. 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 probe microphone, black ear loop and headphone pads with the 70% Isopropyl Alcohol. Clean other transducers in the same way. Do not let 70% Isopropyl Alcohol or water enter the microphone sound inlet.
5. The probe microphone cords and white device housing may also be wiped with 70% Isopropyl Alcohol. The speaker controls, headphone ear pads, head band and other components may be cleaned in a similar way.
6. Let all components that have been cleaned, thoroughly dry before use.
7. Cleaning of the computer should be performed using the methods suggested in the computer's manual.

Technical Information

The Avant REM+ is an active, diagnostic Class I Medical Device according to the EU Medical Device Regulation.

Standards:
IEC 60601-1 Class II
IEC 60601-1-2 Class A
IEC 60645-1
Medical Device Regulation

REM Speech+ Standards: ANSI S3.46, IEC 61669, EN 61669

Dimensions: Approx. 16 cm x 12 cm x 3 cm (L x W x H) Approx. 6.5" x 5" x 1.25" (L x W x H).

Weight: < 500 g < 1 lb

System Modality: Real Ear Measurement; Binaural Live Speech Mapping; Hearing Loss Simulator; Hearing Instrument Simulator.

Probe Microphones (L/R): Dual Electret Microphone Elements (2 Probe Microphones)

Probe Microphone Tube: Silicone 1.0 mm Nominal Diameter

Measurement Frequency Range: 125 – 12500 Hz

Test Stimuli: Broadband Noise and Synthesized Random Noise – Pink, White, Byrne LTASS and ANSI weighted; ICRA; ISTS; Microphone, File, CD-ROM for Live Speech Mapping, Chirp

Test Stimulus Levels at 1m: 45 – 90 dB SPL in 1 dB Steps – 200 Hz thru 8K Hz (depending on speaker wattage & efficiency)

Test Stimulus Accuracy: ± 3 dB SPL

Analysis Mode: User Selectable 1/3, 1/6, 1/12, 1/24, 1/48 Octave Bands

ANSI S3.46 Test Available IEC/EN 61669: Real Ear Unaided Response, Real Ear Unaided Gain; Real Ear Insertion Gain; Real Ear Occluded Response; Real Ear Occluded Gain; Real Ear Aided Response; Real Ear Aided Gain

Other Test Available: Live Speech Mapping with Peaks and LTASS analysis; Real Ear to Coupler Difference, Occlusion Effect, Percentile Analysis

Prescription Methods: NAL-RP; 1/3 Gain; 1/2 Gain; Berger; Pogo 1; Pogo 2; FIG6; DSL m[I/O] NAL-NL1; NAL-NL2

External Connections: Power Connection USB 2.0 Input 5.0 Volt Bus; Line-Output Jack (Speakers) 3.5 mm Stereo Jack; Speaker Output (Internal Amplifier) (2) 3.81mm Pluggable Spring Clamp; Probe Microphones Inputs (2) 8 Pin Mini-DIN; Operator Headset Jack 3.5 mm Stereo Jack; Patient Headset Jack 3.5 mm Stereo Jack; Power Jack 2.1 mm X 5.5 mm.

Data Connection: USB

Mode of Operation: Continuous

Warm up Time: Less than 5 min after USB connection

Weight: < 900 g < 2 lb

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
Operator Monitor headphone	ZA= 32Ω , UA= 3 Veff
Left Probe	ZI= 1 k Ω, UI= 0.38 – 500 mVeff
Right Probe	ZI= 1 k Ω, UI= 0.38 – 500 mVeff
Patient (Client) headphone	ZA= 32Ω , UA= 3 Veff
Line Level Stereo Speaker Output	ZA= 32Ω , UA= 3 Veff

The MedRx WREM is an active, diagnostic Class I Medical Device according to the EU Medical Device Regulation.

Standards:
IEC 60601-1 Class II
IEC 60601-1-2 Class A
IEC 60645-1
Medical Device Regulation

REM Speech+ Standards: ANSI S3.46, IEC 61669, EN 61669

Dimensions: Approx. 180 mm x 53 mm x 47 mm (L x W x H) Approx. 7" x 2" x 1.5" (L x W x H).

Weight: < 500 g < 1 lb

System Modality: Real Ear Measurement; Binaural Live Speech Mapping; Hearing Loss Simulator; Hearing Instrument Simulator.

Probe Microphones (L/R): Dual Electret Microphone Elements (2 Probe Microphones)

Probe Microphone Tube: Silicone 1.0 mm Nominal Diameter

Measurement Frequency Range: 125 – 12500 Hz

Test Stimuli: Broadband Noise and Synthesized Random Noise – Pink, White, Byrne LTASS and ANSI weighted; ICRA; ISTS; Microphone, File, CD-ROM for Live Speech Mapping, Chirp

Test Stimulus Levels at 1m: 45 – 90 dB SPL in 1 dB Steps – 200 Hz thru 12500 Hz (depending on speaker wattage & efficiency)

Test Stimulus Accuracy: ± 3 dB SPL

Analysis Mode: User Selectable 1/3, 1/6, 1/12, 1/24, 1/48 Octave Bands

ANSI S3.46 Test Available IEC/EN 61669: Real Ear Unaided Response, Real Ear Unaided Gain; Real Ear Insertion Gain; Real Ear Occluded Response; Real Ear Occluded Gain; Real Ear Aided Response; Real Ear Aided Gain

Other Test Available: Live Speech Mapping with Peaks and LTASS analysis; Real Ear to Coupler Difference, Occlusion Effect, Percentile Analysis

Prescription Methods: NAL-RP; 1/3 Gain; 1/2 Gain; Berger; Pogo 1; Pogo 2; FIG6; DSL m[I/O] NAL-NL1; NAL-NL2

External Connections: Power Connection USB 3.0 Input 5.0 Volt Bus; Line-Output Jack (Speakers) 3.5 mm Stereo Jack; Speaker Output (Internal Amplifier) (2) 3.81mm Pluggable Spring Clamp; Monitor Headset Jack 3.5 mm Stereo Jack; Power Jack 2.1 mm X 5.5 mm.

Data Connection: USB

Mode of Operation: Continuous

Warm up Time: Less than 5 min after USB connection

Power Connection: USB 3.0 Input 5.0 Volt Bus

USB 3.0 Input: Standard USB "C" Socket

Power Consumption:
Less than 1800 mA at 15 VDC / less than 900 mA at 5 VDC

WREM
Model: 3.7 V Li-Po Rechargeable Battery
Capacity: 2000 mAh
Chemistry: Lithium-Polymer (Li-Po)

Wireless Probe
Model: 3.7 V Li-Po Rechargeable Battery
Capacity: 150 mAh
Chemistry: Lithium-Polymer (Li-Po)

Connection Sockets:	**Specification**
Power/Communication	USB: 5.0 VDC
Power Int. Speaker Amp	15 VDC, 2A
Speaker left	ZA= 4Ω, UA= 8 Veff
Speaker right	ZA= 4 Ω, UA= 8 Veff
Operator Monitor headphone	ZA= 32Ω , UA= 3 Veff
Left Probe	ZI= 1 k Ω, UI= 0.38 – 500 mVeff
Right Probe	ZI= 1 k Ω, UI= 0.38 – 500 mVeff
Line Level Stereo Speaker Output	ZA= 32Ω , UA= 3 Veff

Limited Warranty

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

MedRx, Inc.
1200 Starkey Road #105
Largo, FL 33771 USA

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

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

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

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

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

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

1. A $300 deductible per repair.
2. Extended warranty does not include cables, connectors or peripherals.