MA 41

Operating Instructions

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Operating Instructions MA 41

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1 Introduction

Thank you for purchasing a quality product from MAICO Diagnostics. The Audiometer MA 41 is manufactured to meet all quality and safety requirements, and has been certified with the CE-symbol according to Medical Directive 93/42/EEC.

In designing the MA 41 we placed particular importance on making it a user-friendly device, meaning its operation is simple and easy to understand. All functions of the MA 41 are software controlled, allowing for easy upgrades of new features and functions in the future.

The user manual should make it as easy as possible for you to become familiar with the functions of the MA 41.

If you have questions or ideas for further improvements, please contact us.

Your MAICO Team

1.1 Intended Use Statement

The MA 41 is a portable or standalone audiometer intended to be used for the identification of hearing loss and the factors that contribute to the occurrence of the hearing loss in the age range of children to adults. It is intended to be used by audiologists, ENTs, hearing healthcare professionals, or other trained technicians in a hospital, clinic, healthcare facility or other suitable quiet environment as defined in ANSI S3.1 or equivalent.

1.2 Essential Performance

The following is considered essential performance:

- To generate and present stimulus signals in the audio range as specified in the applicable IEC 60645 series in normal condition
- Record and store a patient response

2 Description

The MA 41 is a portable one and half channel audiometer with pure tone, speech, and optional sound field audiometric testing. Additionally, it has limited special audiology test capabilities such as Stenger and Master Hearing Aid. It can be used as a portable audiometer or a desktop unit for ENT diagnostics, hearing aid fittings in the office, and for mobile audiometry.

The MA 41 audiometer delivers 11 air conduction (AC) test frequencies from 125 Hz to 8 kHz, with levels from -10 dB_{HL} to 120 dB_{HL}. Bone conduction (BC) can be tested with 10 test frequencies from 250 Hz to 8 kHz with levels from -10 dB_{HL} to 80 dB_{HL} (using the B 71 bone conductor). As an upgrade option, the MA 41 is also capable of high frequency audiometry up to 16 kHz.

The large back lighted LCD-color display shows level, frequency, transducer, signal type, audiograms, and other information for each channel.

The MA 41 performs tests using DD 45 headphones, B 71 bone conduction oscillator, optional insert phones, and optional speakers. Built-in test signals include pure tone, pulse tone, warble tone, narrow band and speech noise. Inputs include ports for a live speech microphone and a CD player for speech test material. Speech tests can also be imported via a removable SD memory card. Outputs have separate jacks for air conduction headphones, bone conduction transducer, optional insert phones and optional sound field speakers. Optional transducers available include: TDH 39, insert phones, B 71W, B 81, HAD 200, HDA 300.

Furthermore, the patient management feature provides the ability to store results in the device for further evaluation and documentation.

Results can print directly via the USB printer or stored as a PDF file on the included SD memory card or USB flash drive. The MA 41 can be connected to the PC via USB to track the session and store the results in NOAH or the MAICO Database.

In order to remain current with present and future technologies the MA 41 is compatible with PCs, easy to use, extremely reliable, and is adaptable to future developments. It is also designed to be easily serviced as the need arises. Automatic test programs make trouble shooting and the yearly calibration as effortless as possible.

The speaker outputs can also be used as line level outputs for an external amplifier or active speaker. Please contact your authorized service center to change to line output levels.

3 Getting Started

3.1 Unpacking the Instrument

Prior to shipping, the MA 41 was carefully packed and inspected. However, it is good practice to thoroughly inspect the outside of the shipping box for signs of damage. If any damage is noted, please notify the carrier immediately.

Please remove the MAICO instrument from the shipping box by lifting the case completely out of the box. The instrument can now be easily removed from the plastic packaging without the use of scissors or other sharp tools.

SAVE ALL THE ORIGINAL PACKING MATERIAL AND THE SHIPPING CONTAINER SO THE INSTRUMENT CAN BE PROPERLY PACKED IF IT NEEDS TO BE RETURNED FOR SERVICE OR CALIBRATION.

Notify the carrier immediately if any mechanical damage is noted. This will insure that a proper claim is made. Save all packing material so the claim adjuster can inspect it as well. Notify your dealer or MAICO when the adjuster has completed the inspection.

Please check that all accessories listed below have been received in good condition. If any accessories are missing or damaged, immediately notify your dealer or MAICO.

Standard Accessories:

See page 43 for accessory listing.

3.2 Calibration of the Device

The instrument, headphones, bone conduction oscillator, as well as the optional insert phones and speakers, will come calibrated to the instrument and have the same serial number (e.g. 0021520). Use of transducers not calibrated to this particular instrument will likely lead to incorrect thresholds causing incorrect test results which will invalidate the test. If a transducer needs to be replaced, the instrument must be recalibrated with the new transducer.

The use of non-calibrated audiometers can lead to incorrect measurements!

3.3 Where to Setup

The MA 41 should be operated in a quiet room, so that the audiometric examinations are not influenced by outside noises. Ambient sound pressure levels in an audiometric test room shall not exceed the values specified in the norm ISO 8253-1:2010 or ANSI S3.1-1999. For use in noisier environments, headphones with optional sound insulation muffs are available.

Electro-medical instruments, which emit strong electromagnetic fields (e.g. microwaves or radiotherapy devices), can influence the function of the audiometer. Therefore, it is not recommended to the use these instruments in close proximity to the audiometer as it may lead to incorrect test results.

The test room must be at a normal temperature, usually from 15° C / 59° F to 35° C / 95° F, and the instrument should be switched on approximately 10 minutes before the first measurement. If the device has been cooled down (e.g. during transport), please wait until it has warmed to room temperature before using.

Caution: External devices such as a computer, printer or Ethernet which are connected to the device must meet electrical safety requirements, such as IEC/EN 60601-1 or UL 60601-1. This is to avoid electrical shock to the user or the patient.

3.4 Rear Panel Connections

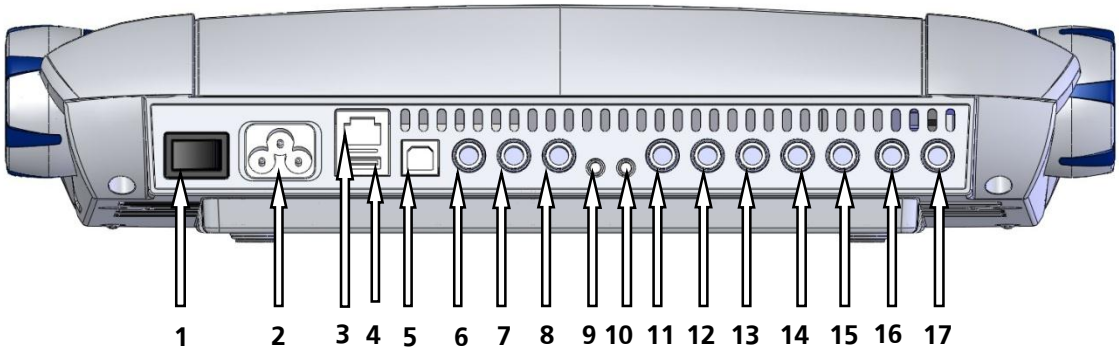

Figure 1– Rear View of the MA 41

1: Power switch	**10**: CD Input
2: Power socket 100-240VAC / 50-60Hz	**11**: Speaker left channel
3: Network socket	**12**: Speaker right channel
4: USB out socket	**13**: Bone conduction receiver
5: USB in socket	**14**: Insert phone left channel
6: Patient response switch socket	**15**: Insert phone right channel
7: Talk-back microphone socket	**16**: Phone left channel
8: Mic live voice microphone socket	**17**: Phone right channel
9: Monitor phone output socket	

Place the MA 41 on a stable counter or table. Plug the power cord into the power socket on the rear panel. Connect all accessories with the appropriate sockets as shown above. Plug the power cord into a grounded outlet.

Turn on the instrument with the power switch, which is located on the rear panel of the MA 41. The device will perform its initialization and boot up. Please wait until the test screen appears, this can take up to 60 seconds. If an error is detected the startup is stopped and a description of the error will be shown on the display. In this case please contact your local dealer for service.

4. Working with the MA 41

The hearing level can be easily adjusted with the level dials on each side of the instrument (1). The instrument's default setting is in 5 dB steps and can be adjusted to 2 dB or 1 dB steps, as needed.

Figure 2 - Control Buttons

The Stimulus Presenter buttons (2) and Store buttons (3) are located beside the left and right level control dials (1). With the STIM mode button (8) you can change from presenter to interrupter mode. The corresponding LED lights up when a signal is presented. The frequency can be adjusted with the Plus (4) and Minus (5) buttons on both sides of the instrument. The ergonomic design of the MA 41 makes it easy to control the dB level, signal presentation, and frequency adjustments with one hand.

4.1 Using the Control Panel of the MA 41

The main functions of the MA 41 are directly accessible by using the Function buttons which are located around the display. As the buttons have changing functionality, the actual function of each button is shown in the blue boxes on the screen above the button. To change the function of buttons (9), (11), (13) and (15), which have several functions, press the corresponding button and a list of alternative functions will appear. Quickly press and release the button until the desired function is selected.

An extensive user menu for the customization of the MA 41 is available for advanced users (see chapter 7).

4.2 Functionality of Operating Elements

The following table describes the main functions of each button for the tone and speech audiometry screens:

Figure 3 - Control Panel MA 41

(1) Level control: adjusts the hearing level for the left/right ear

(2) STIM bar: presents or interrupts the signal for the left/right ear

(3) STORE button: stores results for the left/right ear

(4) Frequency up: change to higher frequency for tone audiometry, enters a correct answer for word recognition score (WRS) testing, or selects the next word in the word list for speech recognition threshold (SRT) testing with wave files

(5) Frequency down: change to lower frequency for tone audiometry, enters an incorrect answer for WRS testing, or selects a previous word in the word list for SRT testing with wave files

(6) Monitor with options to adjust monitor and talk back settings; for speech, the input calibration for microphone or CD player can be adjusted

(7) Function button: function is displayed on the screen based on test screen

Tone: Select New, to delete all stored results and start a new session

Speech: Reset the result percentage counter or Play wave file

(8) Channel STIM Mode button/TALK: to change from presenter to interrupter mode, or to talk to the patient by pressing and holding the button down

(9) Function button: to select left, right or both ears

(10) Transducer selector button: to choose between Phones, Insert, Bone and, Speaker (only calibrated transducers are available)

(11) Function button: function is displayed on the screen based on test screen

Tone: No response, stores value with arrow below the symbol

Speech: Select microphone, external CD player or wave file as signal source

(12) Test Signal selector button: Steady, Pulse, Warble, or P&W (pulse and warble tone)

(13) Function button: function is displayed on the screen based on test screen

Tone: Selects test for selected receiver, either the pure tone threshold, Hearing Level (HL) or Uncomfortable Loudness (UCL); if Speaker is selected as the transducer an option for aided sound field threshold (Aided) is also made available

Speech: Select Speech Recognition Threshold (SRT), Word Recognition Score (WRS), UCL or Master Hearing Aid (MHA).

(14) Select Unlock: Lock (locks the presentation of the signal in both channels), Track (activates the masking noise to automatically increase and decrease level in relationship to the signal), L&T (Lock and Track)

(15) Function button: function is displayed on the screen: Masking on/off, activates masking in the opposite ear

(16) Function button: to switch from tone to speech and back; the current function is displayed on the screen

(17) Function button - Menu: to enter the user menu, where settings can be adjusted, results can be printed out or stored as PDF on SD memory card or USB flash drive or the patient list can be entered

(18) SD memory card slot

(19) Level meter

Note: When a Function button is grey, this identifies it as an inactive button with the current test set-up (ex. 

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4.3 The Display of the MA 41

The instrument is set up by default to display the tone audiometry screen.

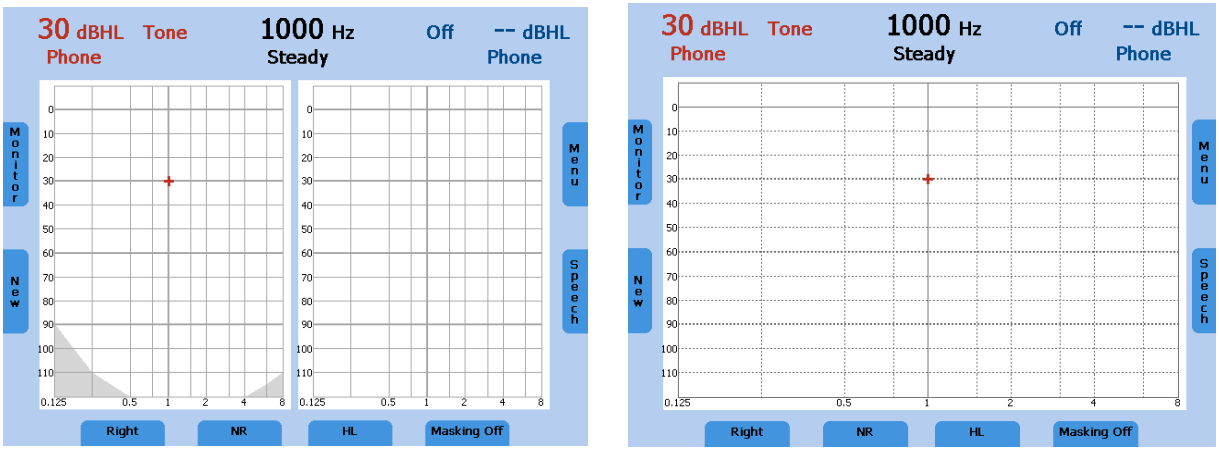

Figure 4 - Start Screen Tone Audiometry Examples (Dual and Single Audiogram)

The default frequency is set to 1 kHz and the level of the tone is set to 30 dB_{HL} in the right ear, masking in the other ear is switched off. All channel information is shown on the display, as well as the type of the function buttons shown on the display.

The display has an energy saving function; the backlight of the display is automatically dimed after approximately three minutes. Any action with the MA 41, such as pressing a button or rotating the dial, will immediately illuminate the backlight.

5 Measurement Methods of Audiometry

Remove any obstructions that will interfere with the earphone cushion placement over the ear (e.g. hats, eyeglasses). Always use the headphones with appropriate padded ear cushions.

Ensure the headphones are placed correctly over the patient's ears and that the red is over the right ear and the blue is over the left ear. Adjust the headband of the headphones so that the receivers are at the correct height (the sound output grid on the inside of the headphone should be directly over the ear canal).

Ask the patient to press the button on the patient response switch when the tone is heard, even if it is barely audible.

For hygienic reasons it is important to disinfect the ear cushions on the headphone between patients (see chapter 8).

5.1 Tone Audiometry

The MA 41 supports tone audiometric testing methods. The following testing methods can be started in the tone audiometry mode and the results can be saved to the instrument.

- Air conduction testing
- Bone conduction testing
- Sound field testing
- Pure tone hearing threshold
- Uncomfortable Loudness (UCL)
- Aided sound field thresholds (Aided)

5.1.1 Pure Tone Testing

During pure tone audiometry, the patient's hearing threshold is measured. Typically the threshold search begins with air conduction testing in the ear with better hearing.

While viewing the tone screen the following settings will be displayed.

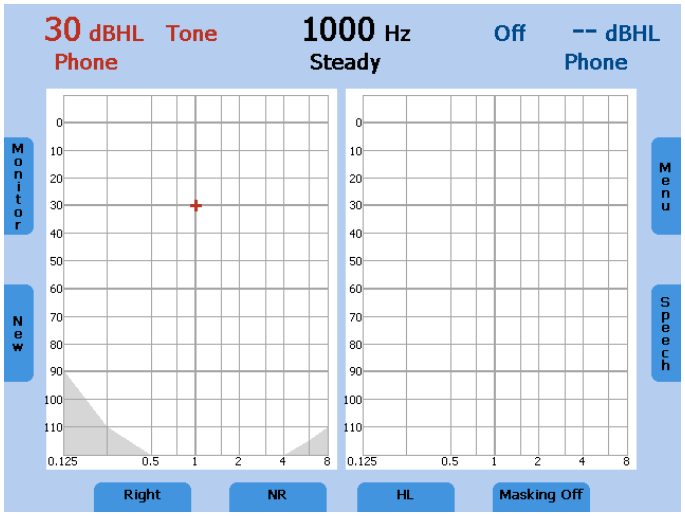

Figure 5 - Pure Tone Audiometry Screen Example

The default setting is the right channel set to air conduction pure tone and the left channel is switched off. The frequency is automatically set at 1,000 Hz.

The audiometer provides one and a half channels, one for the test signal, and the other for the masking signal. The test signal can be routed to the left, right, or both ears. If masking is on, the masking signal is routed to the non-test ear, through the primary transducer established in the set-up menu.

Select the ear to be tested by pressing the function button (9) on the control panel underneath the screen. Press several times to toggle between Right, Left and Both.

Next, select the transducer to be used, headphones (Phones), insert phones (Insert), bone conductor (Bone), or sound field speaker (Speaker) by pressing the appropriate button (10). Press the button several times until the LED indicates the required transducer. Only calibrated transducers are available.

The level and frequency is displayed as a numerical value at the top of the screen and is also indicated by the cursor within the audiogram.

The dB_{HL} can be changed with the attenuator dials on both sides (1) of the instrument.

Use the frequency plus (4) or minus (5) keys to increase or decrease the frequency. Press the STIM button (the blue button touching the attenuator dials) to present

or interrupt the tone. The status LED for the stimulus mode button (8) will illuminate when the tone is presented.

Follow your preferred procedure for the hearing threshold evaluation.

Note: A warning prompt appears on the display in the event that the hearing level exceeds 100 dB_{HL}. The warning prompt disappears after approximately 3 seconds. As long as the prompt is visible on the display, no further entries can be made.

Test the frequencies: Starting at 1,000 Hz, test the higher frequencies first, then the lower frequencies.

Use the frequency up key (4) to select the next higher frequency and use the frequency down key (5) to select the next lower frequency.

Once a threshold value is established at the desired frequency, press the store button (3) to store the threshold. The appropriate symbol will be plotted in the audiogram on the display.

Once all frequencies are tested, select the other ear and repeat the hearing threshold test.

Pulse Tone

If required, the test can also be performed with a pulsed tone. Set the test signal button (12) on PULSE and the pure tone will be switched to a pulsating tone.

Warble Tone

If required, the test can also be performed with a warble (frequency modulated) tone. Press the test signal button (12) and the pure tone will frequency modulate. The warble tone can also be pulsed as described above.

5.1.1.1 Masking

Masking is required if there is a notable threshold difference between the left and right ears. It is possible for sound to be transmitted to both ears via bone conduction while testing the poorer ear. This is called "crossover."

Crossover occurs often while testing bone conduction, but it can also occur during air conduction testing. Relevant to crossover is the sound level received by the opposite ear. The difference between the original test signal in the test ear and the received signal in the opposite ear is called "interaural attenuation."

For bone conduction measurements the interaural attenuation is 0 to 15 dB. Bone conduction crossover is therefore possible even with a slight difference in hearing loss between ears.

To ensure that the patient will not experience crossover, mask the opposite ear. Masking increases the hearing threshold of the opposite ear. For bone conduction the masking signal is automatically routed to the opposite output of the phones or inserts.

The masking is done with a noise signal which is transmitted by the headphone. For pure tone audiometry a narrowband noise is used. This noise changes its center frequency according to the frequency of the test signal.

Note: Masking is only available in when **Right** or **Left** ear is selected. When **Both** is selected, the **Masking Off** key is greyed out (i.e. 

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Manual Masking

The masking is switched on by pressing the Masking On/Off button (15). The channel of the non-test ear is switched on and set to noise with a level of 0 dBHL.

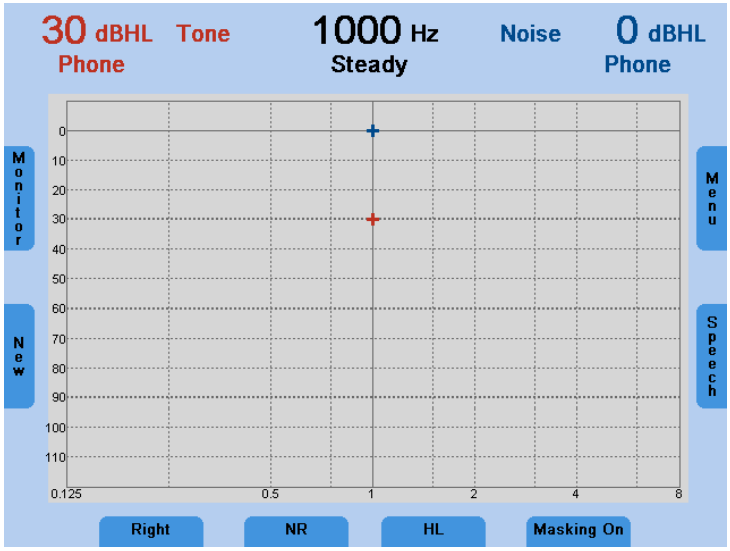


Figure 6 - Tone Audiometry with Masking

Adjust the level of the masking noise by the right-hand level control dial. If the Store button on either side of the instrument is pressed, the hearing threshold value will be stored in the audiogram with the corresponding masking symbol.

The masking sound should be continuously presented for effective masking by pressing the STIM button. You can interrupt the masking signal by pressing the corresponding stimulus button (2).

Automatic Masking

With the manual masking, as described before, the masking level should be adjusted every time you change the test signal level. The MA 41 has a tracking function for easy masking.

Set the tone level and the masking level to a desired difference for effective masking. Press the TRACK button (14) to implement the automatic masking feature. The masking level is automatically changed if you adjust the test signal level (e.g. if the test level is at 30 dBHL and the masking level 50 dBHL and you change the test level to 45 dBHL the masking level will automatically adjust to 65 dBHL).

5.1.2 Bone Conduction Testing

Place the bone conduction oscillator so that the flat, circular side of the transducer is placed on the mastoid, at the noticeable ledge of the cranial bone behind but not touching the pinna. The other side of the headband is placed in front of the opposite ear. Set the receiver selector to Bone and select the testing ear.

Perform the test utilizing the same method as air conduction testing.

For hygienic reasons it is important to disinfect the bone conduction oscillator following each patient (see chapter 8).

5.1.3 Sound Field Testing (optional)

Set the transducer selector (10) to Speaker. Perform the test utilizing the same method as air conduction testing.

Warble tones should be used in the sound field as pure tones may provide inaccurate results in the typical test room.

Perform the test in the same way as described in the air conduction section above.

5.1.4 Uncomfortable Loudness (UCL) Testing

Testing of UCL can be measured using pure tone or speech stimuli. The purpose is to determine the dB_{HL} level at which the stimuli becomes uncomfortable to the patient. The UCL is described as the level between very loud and too loud as perceived by the patient when listening to the test signal. This information is valuable for determining the limits of a patient's dynamic range.

Warning! Because this test uses high sound pressure levels, it is extremely important to perform this test using the utmost caution to avoid causing hearing loss. To prevent the possibility of extreme discomfort by the patient, it is important to start the test at a comfortable level.

Press and release the test mode selector key (13) below the display to select UCL. The LCD-display in the bottom row changes from HL to UCL. Start with a test level of 60 dB_{HL} and present the tone briefly (max. 1s). If the signal was recognized by the patient as "not uncomfortable," increase the level and proceed as described before. If the signal was uncomfortable for the patient store the value. Proceed accordingly with other test frequencies.

5.1.5 Stenger

The Stenger test is a test to confirm the presence of pseudohypacusis. During this test, two tones of the same frequency will be presented simultaneously to both ears, and only the louder tone will be perceived. Select HL to perform the Stenger test and select both ears (9). Instruct the patient to press the response button when the tone is heard. Present a tone to the better hearing ear 10 dB above threshold and wait for the patient to indicate the tone has been heard. Now present the tone to the poorer ear 10 dB below the indicated threshold (the patient may "ignore" this tone). Present the tones simultaneously by pressing the lock function button (14) and the STIM Mode button (8) to set it to interrupter mode. If the patient responds it is a negative. If the patient does not respond it is a positive Stenger, indicating that the tone is heard in the poorer ear and the patient is ignoring the stimulus.

5.2 Speech Audiometry

The MA 41 supports speech audiometry. To conduct speech tests using speech test material you can use a CD player, wave files from the SD memory card, or a microphone.

Caution: If you are using a CD player powered by electrical current, the player must meet electrical safety requirements, such as IEC 60601-1 or UL. This is to avoid electrical shock of either the patient or you. If you are not sure if your player meets these requirements it is safer to use battery power.

5.2.1 Input Calibration

The MA 41 must be calibrated to the particular speech test to ensure valid test levels. That means every time you change the speech test CD you must recalibrate the instrument.

To calibrate the CD speech input, select CD with the signal selector key (11). Press the Monitor button (6) and then InCal (17) and the calibration screen appears (see figure 7b).

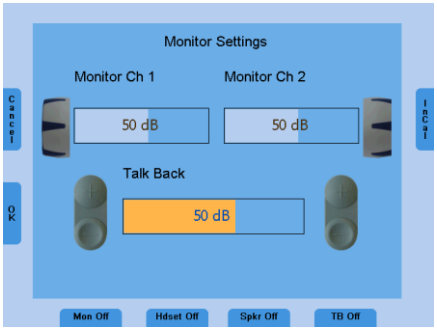


Figure 7a – Monitor Settings

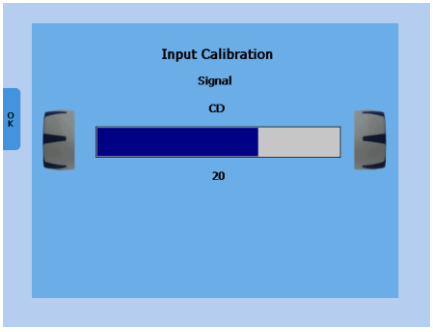


Figure 7b – Input Calibration

On every CD with speech test material there is a reference signal, such as a reference tone or speech simulating noise. Play back the reference signal with the CD. Use the left or right level control (1) and adjust the levels until the VU-meter (19) shows all yellow lights and one green light.

If one or more red lights are on, reduce the level using the level control dial (1).

To calibrate the microphone for live voice testing, select MIC with the signal selector key (11). Press the Monitor button (6) and then InCal (17) and the calibration screen appears. Use the left or right level control (1) and adjust the levels until the VU-meter (19) shows all yellow lights and one green light.

Store the calibration and leave the calibration mode by pressing the OK button on the left side of the display.

5.2.2 Performing Speech Testing

Use the function button for Speech on the right side of the tone screen (16) to switch to speech testing. The speech test screen will open, and the unit will default to the right ear and the level will be set to the default value.

The speech recognition threshold (SRT) is a test indicating the lowest level in which speech is understood using a closed set of spondaic words. Speech testing can be done via recorded speech test material from CD or wave files or with the microphone and live voice using standardized word lists.

Ask the patient to repeat each word. Often times a carrier phrase such as, "Say the word _____" may be used. The patient should sit at a distance of at least 1 meter from the device. Additionally, any obstructions which may interfere with the placement of the earphone cushions on the ear (i.e. hair, eyeglasses) should be removed. Ensure the headphones are put on correctly. Adjust the headband of the headphones so that the receivers are at the correct height (the sound output grid should be placed directly over the ear canal).

Select the ear to be tested by pressing Right, Left, or Both by the function button (9) on the control panel underneath the screen.

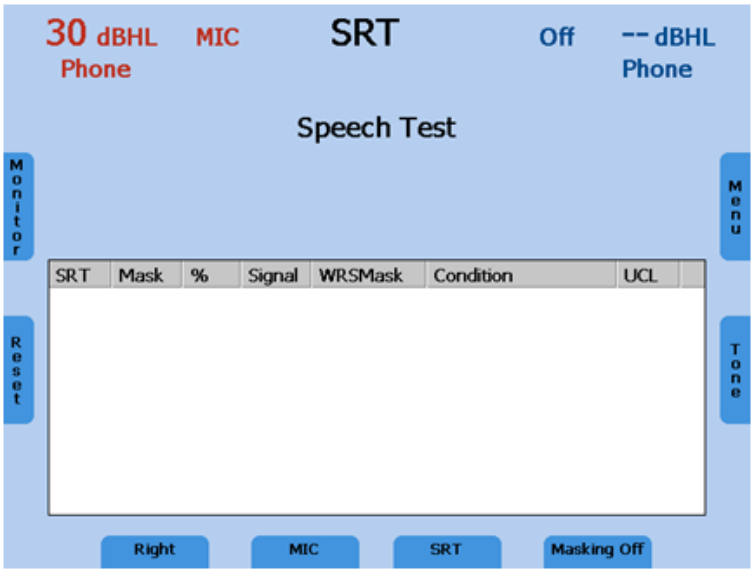


Figure 8 - Speech Test Screen

Next, select the transducer to be used, Phones, Insert, or Speaker by pressing the Transducer button (10). Toggle to the required signal by the selector button (11) to MIC/CD/Wave.

5.2.3 Speech Audiometry with Microphone or CD player

Connect the microphone or CD player to the corresponding input (10). Select the test ear (9) and MIC or CD as signal source by the function button (11). Make sure that the input signal is calibrated correctly, as described above. Select the test SRT, WRS or UCL with the function button (13).

For the SRT test familiarize the patient with a closed set of spondaic words at a level loud enough for them to hear and understand. Begin the test and decrease the level as the patient repeats the word. Once the threshold has been found press the Store button (3) to save the result.

For the WRS test, the level remains fixed and correct or incorrect answers can be entered by the Frequency Plus (4) and Frequency Minus (5) button. Once the word list has been completed by the patient, press the Store button to save the established WRS score. To clear the word counter, press the Reset key (6) on the left side of the display. If no counter is set the Reset key (6) is displayed grey.

For the UCL testing the level is increased until the patient indicates the level is uncomfortable and the result can be saved by pressing the Store button (3).

5.2.4 Speech Audiometry with Wave Files

If Wave is selected by the speech signal selector (11) a menu will pop-up with the available word lists, stored on the SD memory card. A word list can be selected by using the level controls (1) to scroll through the list. A list can be loaded by pressing the Stimulus button (2). The word list will then be displayed on the speech audiometry screen.

The level is displayed as a numerical value at the top of the screen. The level can be changed with the level controls (1) on both sides of the instrument. Before starting the playback of the wave files, the first word can be selected by the Frequency Up and Down buttons (4) and (5). Press the function button Play (7) to start. Once the speech test is started the test can only be stopped by pressing the Cancel (16) or Store (3).

The procedure for the SRT, WRS and UCL test is the same as the procedure for CD or microphone testing. For the SRT test, a word needs to be selected in the wordlist by the frequency up (4) or down (5) key. When the Play button (7) is pressed, the selected word is presented.

For the WRS test score, tally the correct words by pressing the frequency up (4) key and the incorrect words by pressing the frequency down (5) key. The next word will be played back automatically. The correct word is displayed green, while incorrect word is displayed red. By pressing Repeat (7), the word will be repeated. Once a wave file has been selected, the intensity cannot be changed. Select the presentation level before selecting Play (7).

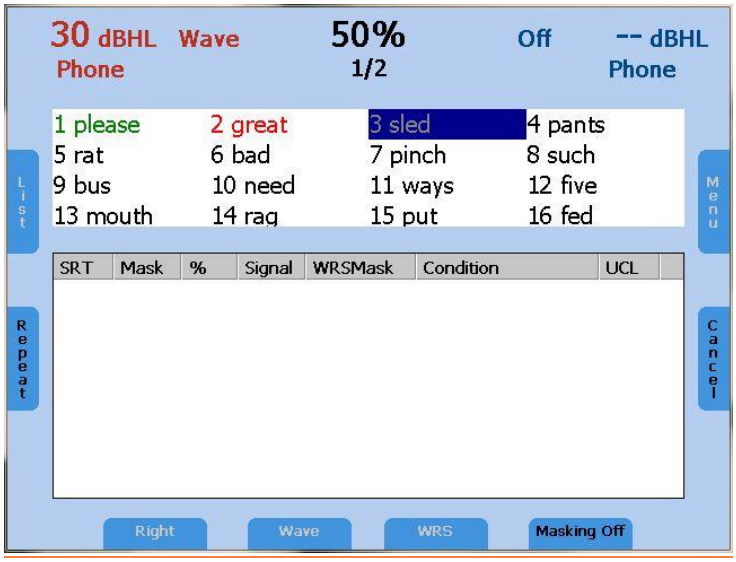


Figure 9 – Speech Audiometry with Wave Files

The percentage of the speech discrimination score will be displayed and stored in the speech table or audiogram as soon as the Store button (3) is pressed.

Press the function button List (6) to load another word list.

UCL measurements are best performed with the Passage wave file include with the device. Select the ear for testing (9). Press the function button Play (7) to start the presentation to the patient. Rotate the attenuator wheel (1) to increase the volume until the patient reports this is uncomfortable loud. Press Store (3) to save the results.

5.2.5 Masking

Speech audiometry masking can be used in the same manner as described in chapter 5.1.1.1 for pure tone audiometry. Instead of narrowband noise, speech noise (SN) is applied when masking is turned on. Masking noise is activated in the non-test ear by pressing the function button Masking On/Off (15). Adjust the level of the masking channel by the corresponding level control (1) for effective masking.

5.2.6 Master Hearing Aid (MHA)

The Master Hearing Aid (MHA) feature utilizes input signals from the Live Voice (Mic), external CD/MP3 player or with the wave files. These signals are then filtered by various high pass filters to simulate a hearing aid.

Begin by selecting a signal source in the speech mode with the function button (11). Start the MHA function by pressing the Test Selection button (13). When using wave files begin testing by pressing the Play button (7) to play back the imbedded wave files. Press the stimulus mode (8) indicator to alternate between signal sources like the microphone or the CD. Change the dB presentation levels with the level control dials (1), and control the filtering options by using the frequency Up (4) and Down (5) keys.

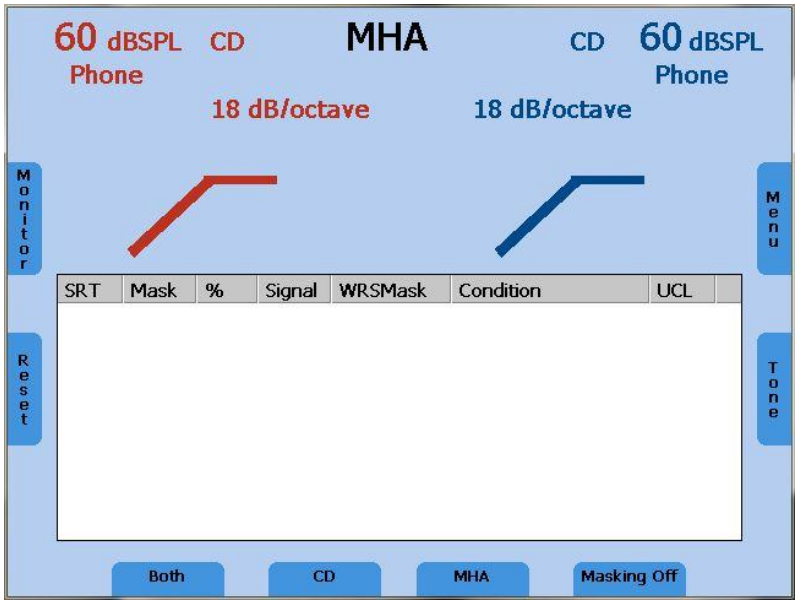


Figure 10 - Display Master Hearing Aid

5.3 Monitoring

All signals presented to the patient can be monitored by the examiner via a monitoring headset or the internal speakers. For this purpose, press the Monitor button (6) and the monitor screen will appear.

Enable monitoring by pressing the function button Monitor On/Off (9). Monitoring by the integrated speaker is switched on by pressing the button (13) and the external headset is activated for monitoring via button (11). Then the monitor level of the left and right channel can be adjusted with the corresponding level control dial (1). In order to hear the signal given to the patient, make sure to activate monitoring (9).

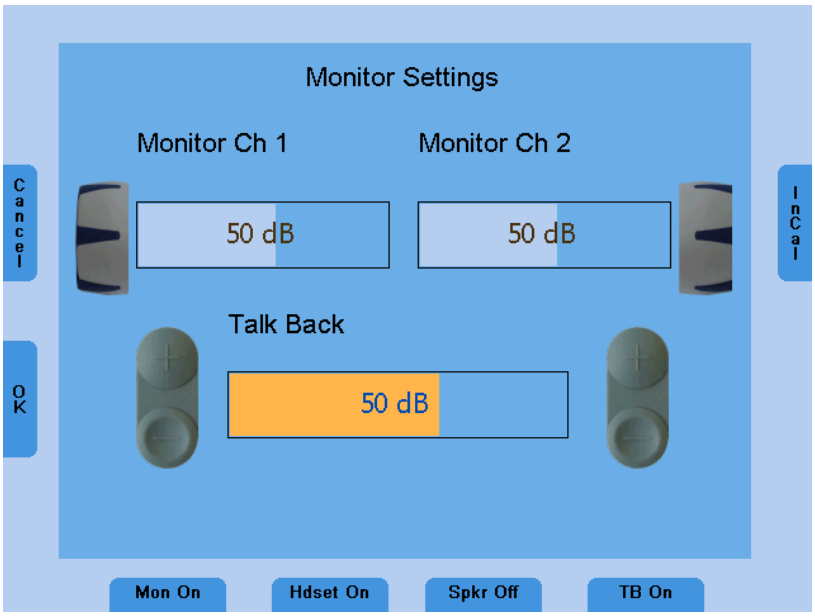


Figure 11 - Display Monitor Settings

The talk back microphone is activated by the button (15) and its level adjusted by the frequency up and down buttons (4), (5).

5.4 Talk Forward

Connect the microphone headset (or optional gooseneck microphone) to the microphone socket (8) on the rear side of the device. To talk to the patient press and hold the STIM mode/TALK button and speak into the microphone. Adjust the level by turning the left or right level control (1) while the STIM mode/TALK button is pressed and held.

5.5 Documentation of the Results

All stored results can be directly printed via the USB printer. Make sure that a compatible printer is connected via the USB port (4) and the device is configured according to the connected printer settings; refer to menu settings in chapter 7.2.

The results can also be stored as a PDF file on a SD memory card or USB flash drive to be later transferred to a PC for further usage. The PDF file contains the measurement results. An SD memory card needs to be inserted in the SD card slot (20) or a USB flash drive connected to the USB socket (4) on the rear side of the device.

When the examination has been completed, press the Menu button (17) in the tone or speech test mode. The user menu is opened and the functionality of the function buttons (11), (13) and (15) changes to PDF, Print, and Patients, respectively.

To printout the results press the Print button (13). Make sure that a compatible printer is connected and the printer settings are correct.

To store the results on the SD memory card or USB flash drive, press the PDF button (11). A PDF will be created and stored on for further transfer to a PC or printout via a PC connected printer. Make sure that a SD memory card is inserted in the SD memory card slot (18).

After printing or creating a PDF you will automatically return to the tone or speech test mode. Enter the patient list by pressing the Patient button (15) to store the results.

5.6 Patient Management

The patient management option allows the results of the audiological tests to be stored on the SD memory card. The results can be reloaded at a later time to be reviewed, edited, or printed. Patients can be stored by a number ID or by entering the name and birth date. The demographic patient information can be entered using the level controls (1) or a connected USB keyboard.

Enter the User Menu by pressing the Menu button (17) in the tone or speech audiometry screen. Press the button Patients (15) to display the patient list.

To comply with patient privacy laws the option to add a PIN code for entry to this list has been offered. To activate this feature press the New Patient button (15) followed by the Login button (15). Enter the desired 4 digit PIN using the level control dials (1) and the Stim button (2). Once the 4 digits have been entered press the Set button (9) and the device will return to the patient list. Moving forward the PIN will be required to enter the patient list. To deactivate the PIN, select Login Off after following the same steps as listed above.

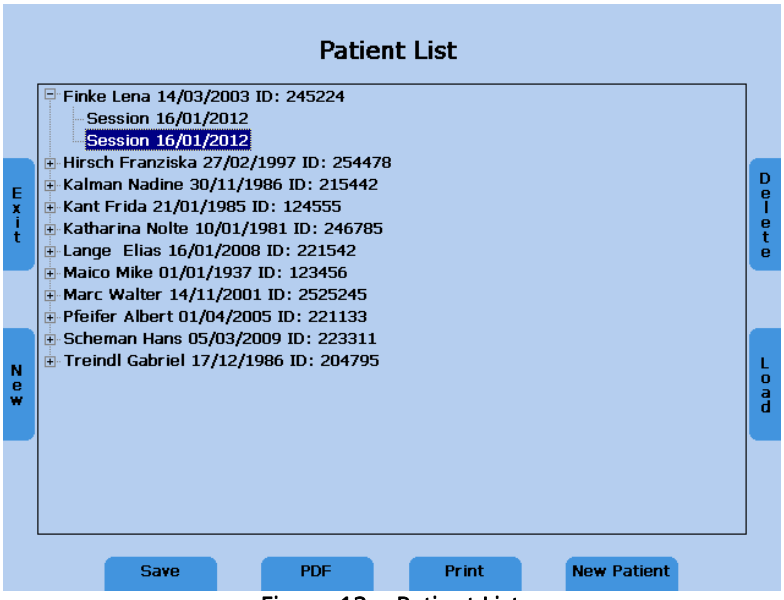


Figure 12 – Patient List

Select a patient using the level controls and press the Stimulus button (2) to display the stored sessions. Select a session and press the PDF button (11) to save the PDF on the SD memory card or USB flash drive. To print the results to a connected printer press Print (13). The patient information will only be included on the printout if it is done in the patient list, or if the PDF is created in the patient list screen.

Current results can be stored to a numbered patient or to a named patient. Entering the Patient List, automatically a new numbered patient with a new

number will be selected. Just press the Save button (9) to save the current session to the new patient number. To save the results to an existing patient, select a patient by the level controls and press the Save button.

To save the current results to a new patient with a new patient name, press the button New Patient (15) and a screen appears to enter the patients last name, first name, ID and date of birth.

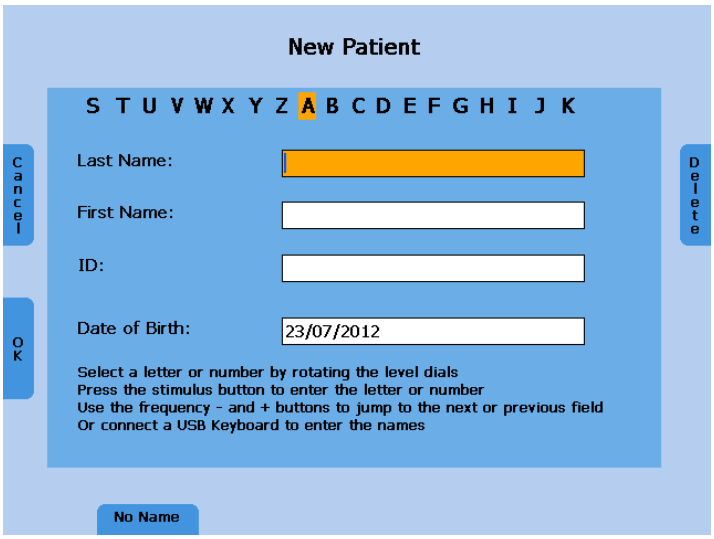


Figure 13 – New Patient

Enter the characters of the name by scrolling through the alphabet with the level controls and enter the selected character by using the Stimulus button (2). Jump to the next or previous field by using the Frequency Up (4) or Down (5) button. The date can be entered in the same manner with the level controls. Delete the last character or number by pressing the Delete button (17).

A USB keyboard can also be utilized to enter the patient information. Connect it to the USB connector (4) and type in the characters. Jump to the next field with the tab key. Press the function button OK (6) to save the new patient and go back to the patient list. The new patient is selected and the current measurement results can be saved to this new patient by pressing the function button Save (9).

Press the button No Name (9) to store the results only by a patient number, without entering a name or use Cancel (6) to go back to the Patient List without saving.

6 Quick Reference Guide

6.1 General Setup

6.1.1 Startup Settings

Air conduction

Pure tone on the right channel, left channel is switched off

30 dB_{HL} tone

Presenter mode

6.1.2 Transducer Selection

Select the transducer to be used, headphones (Phones) or insert phones (Insert), by pressing the appropriate button (10). The display shows the selected transducer at the top of the display screen below the presentation levels.

6.1.3 Signal Selection

For tone testing the test signal is always tone. For speech audiometry the signal can be selected by the SIGNAL key (11). The type of NOISE signal is dependent upon the opposite channel's signal.

6.1.4 Masking

Use the Masking On/Off button (15) to activate masking in the non test ear.

For tone audiometry narrow band noise is used as the masking signal and for speech audiometry, speech noise is used.

6.2 Tone and Speech Audiometry

6.2.1 How to Select Tone or Speech Audiometry Mode

There are two audiometry modes.

Tone audiometry: shows level and frequency on the display

Speech audiometry: shows level, correct and incorrect words, and speech discrimination percentage on the display

Use the MODE button (16) to switch between tone and speech mode.

6.2.2 Tone Audiometry

Frequency Selection

Use one of the two sets of frequency keys (4) or (5) to select the frequency. The maximum and minimum frequency depends on the transducer you have selected.

Warble Tone

Press the Test Signal button (12) to activate the warble tone. The LED will highlight Warble.

Pulse Tone

Press the Test Signal button (12) to activate the pulse tone. The LED will highlight Pulse.

Tracking Function

Press the TRACK key (14) to activate tracking. Both channels will adjust when only one attenuator is adjusted.

Lock Function

Press the LOCK/UNLOCK (14) key to activate the interlock function. Signals from both channels will be presented simultaneously with the press of only one STIM button (2). If both ears are selected, LOCK is automatically activated.

Select L&T (14) to interlock the stimulus presentation of both channels as well as the tracking of the levels.

STIM Mode Selection

Press STIM MODE (8) key to switch between continuous presentation and presentation by pressing the STIM button (2). When in continuous presentation mode the STIM buttons function as interrupters. The light above the STIM MODE key is on if continuous presentation is selected.

CD and Wave speech signals are always in continuous presentation.

Talk Forward Microphone

Press and hold the STIM MODE (8) to activate Talk Forward. Adjust the level by turning one of the attenuator dials (1) while in the mode.

Talkback Microphone and Monitor Volume Control

Press the Monitor key on the left side of the display and the volume control bars for talkback and monitor are shown.

Adjust the monitor volume with the right and left dials (1). Adjust the talkback microphone volume with the plus/minus keys (4) or (5).

To store the actual settings press OK (19).

6.2.3 Speech Audiometry

To select speech audiometry, select Speech (16) and the test SRT or WRS (13). Use the frequency up (4) and down (5) key to select a word in the word list.

For the WRS test the display shows the percentage of correctly repeated words.

To count the word as correct press the frequency key (4) up.

To count the word as incorrect press the frequency key (5) down.

To clear the counter, press the Reset key (7) on the left side of the display.

Speech Calibration

To calibrate the MIC or CD speech input, select the input with the SIGNAL selector key (11). Press the Monitor button (6), so that the monitor setting screen appears. Now press the InCal button (17) on the right side of the display and the calibration screen appears.

Play the reference signal with the CD player or speak into the microphone. Use the left or right intensity dial (1) and adjust the levels until both VU-meters show all yellow and one green light. If one or more red lights are displayed, reduce the level using the corresponding dial (1).

Store the calibration and leave the calibration mode by pressing the OK (6) button on the left side of the display.

6.2.4 Documentation of the Results

Printout

Enter the user Menu by pressing the function button (17) and press the Print (13) button to printout the results.

Store Results as a PDF

Enter the user Menu by pressing the function button (17) and press the button PDF (13) to save the results as PDF file on SD memory card or USB flash drive.

Store the Result in the Patient List

Enter the User Menu by pressing the function button (17) and press the button Patient (15) to enter the patient list. Enter a new patient by pressing the button New Patient (15). It is also possible to print a result from the patient list or to create a PDF of the result. Select a stored session of a patient in the patient list and press then the button PDF (11) or Print (13). In this case, the patient information will be included in the PDF or printout. Press the button New (7) in the patient list to start a new session.

7 User Menu

The User Menu enables the user to customize the device to meet their specific needs. Additionally, the menu allows the user to printout the results via USB printer, store the results as a PDF on an SD memory card or USB flash drive, and the ability to enter the patient list. To enter the User Menu press the Menu button (17) on the right side of the display.

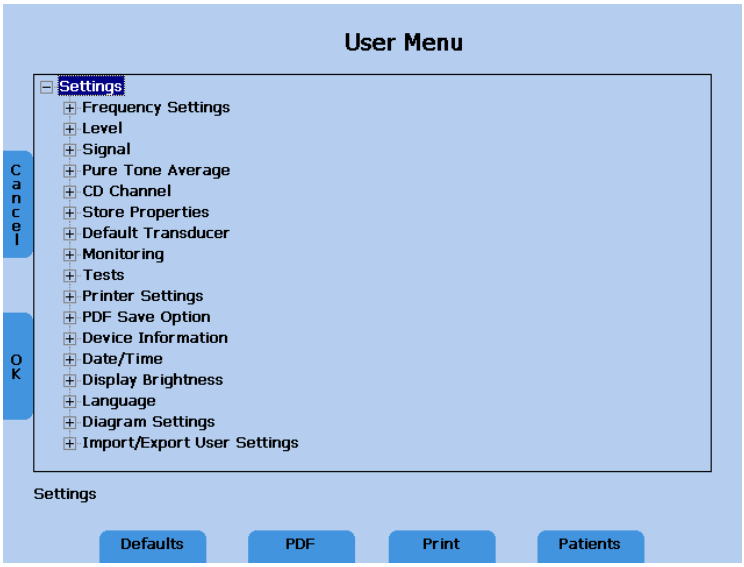


Figure 14 - User Menu Screen

To choose an item from the menu use the level control dials. A short description of the selected setting item will be displayed below the user menu list.

To display the sub items or change the setting of the selected item press the STIM Presenter button (2).

To confirm the change press the OK button (7) on the left side of the display, or press Cancel (6) to return without any change.

Note: When changes have been made to the menu and saved, restart the device to confirm all changes are implemented.

These menu items are available (Bold represents default setting):

Frequency Settings	Frequency	Default Frequency Set (On/**Off**): Set default frequency if side, transducer or signal type has changed
	Frequency Roll	Back: Frequency control jumps to 1,000 Hz if the highest and lowest frequency was reached
		Stop: Frequency control function stops at highest and lowest frequency
		Wrap: Jumps to the lowest/highest frequency when the highest/lowest frequency
	Standard Frequencies	Select/deselect
Level	Default Level	On/**Off**: Set default level after changing signal type
	Level Steps	**5**; 2; 1
	Inverse Dialing	Change effect on dialing an encoder: **Dial Down**
	Speech Level Unit	dBSPL/**dBHL**: Select the level unit for speech signals

Signal	Controller Assignment	Assign ear side fixed to the left or right controller;
		- Same, left dial controls level of the left ear, right dial the level of the right ear
		- Interchanged, left and right dial controls the level of the opposite ear
		Assign signals fixed to the left and right controller
		- Test signal always on the left hand side or always on the right hand side
		This setting requires a restart
	Presenter Duration	Unlimited, signal is presented as long as the STIM bar is pressed
		1.5 Seconds, signal is switched off after 1.5 seconds
		User defined duration, user can define a maximum presentation duration
	Interrupter / Presenter Mode	Default Presenter or Interrupter Mode
	Pulse	500 ms, slow pulsing
		250 ms, fast pulsing
PTA		Select/deselect frequencies for the calculation of the PTA value for the default transducer
CD Channel	Select the CD Channel	Both/Channel A/Channel B

Store Properties	Change Frequency After Store	Moves to next test frequency after storing a threshold (**on**) or stays on same frequency after storing (off)
	Change Level After Store	Change in level after storing a threshold (stay at the same test level (**0**) or decrease by 10, 20, or 30 dB)
Default Transducer	Selection of Default Transducer	**Headphones** or Inserts
Monitoring	Monitoring	Monitor only speech signals (off) or **all signals (on)**
Tests	Start Test	**Tone**/Speech, defines test which will load after start-up
Printer Settings	Set Printer Settings	Opens a dialog to select a printer and configure its settings
PDF Save Option	Save on SD Card	Stores PDF files to an SD memory card
	Save on USB	Stores PDF files to a USB flash drive
Device Information	Show Information	Shows device information
Date/Time	Set Date/Time	Opens a dialog to change the date, time, and the date format to US or International
Display Brightness		Change the display brightness from 1 – 100%, store new value by pressing the Store button (3)
Language		**English**/German/Italian/ French/Spanish, etc.

Diagram Settings	Diagram in Speech Test	Diagram or Table
	Number of Diagrams in Tone Test	No audiogram, only the level and frequency, one combined audiogram or two separate audiograms for left and right
	Bone Lines	On/Off, displays a dotted line, connecting the bone conduction results
	Bone Symbol Setting	Int Symbols/US Symbols/
		UK Symbols
Import/Export User Settings		Export User Settings to SD Card/Import User Settings from SD Card.

7.1 Setup Date and Time

Select Date/Time in the user menu by scrolling down with the left or right level control (1) and select Set Date/Time by using the stimulus presenter bar. The following screen will appear:

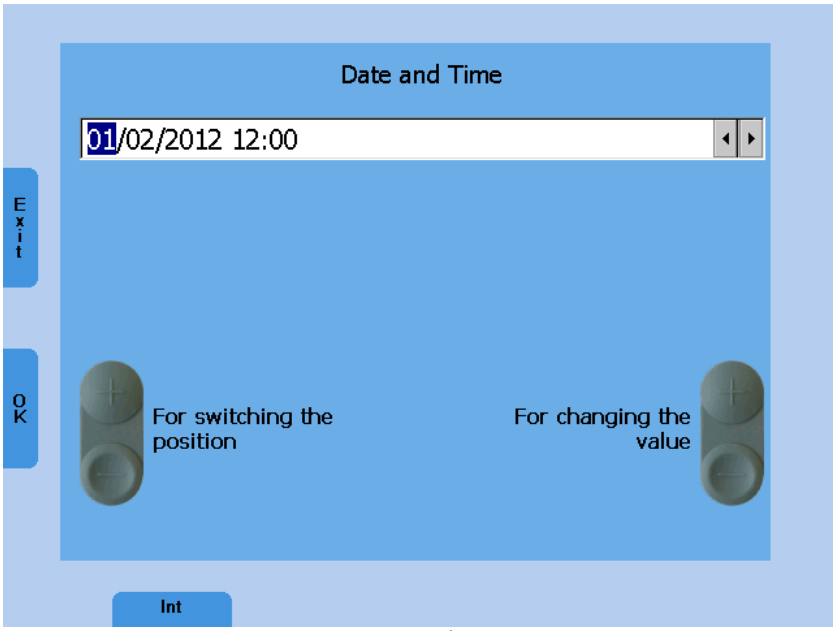


Figure 15 - Date and Time Settings

Set the date format to International or US by the function button (9). Jump to the required position of the date or the time by the left Frequency Up/Down button (4) or (5) and change the value by the right Frequency Up/Down button (4) or (5) or left level control. Press the function button OK (6) to store the changes or Exit (7) to leave the Date/Time setting screen without saving the changes.

7.2 Set Printer Settings

Select the printer by turning the left or right level control (1) down. The color mode is automatically adjusted. If the color mode is wrong adjust the color mode as well. Jump to the field paper format by pressing the stimulus presenter bar several times and select A4 or Letter format by using the level controls. If the printer is connected to your Ethernet network select Ethernet as port. Additionally, the IP address of the printer needs to be entered in the field "IP Address." Select the number of the IP address by rotating the level controls and press the STORE button to enter the selected number.

Save the settings and return to the user menu by pressing the function button OK (7).

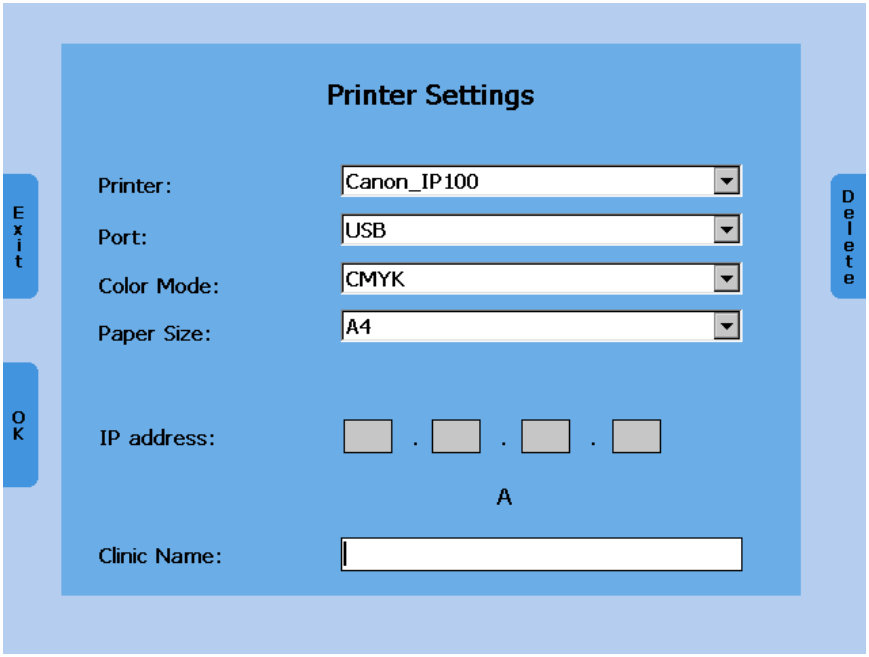


Figure 16 - Printer Settings

Test your printer settings by a sample print before starting the audiological assessment. Incorrect settings may require a restart of the device.

Enter the field clinic name by using the STIM button. Select letters by rotating the level control and enter the selected letter by pressing the STORE button (3). Save the settings and return to the user menu by pressing the function button OK (7).

8 Cleaning and disinfection recommendations

It is recommended that parts (device and accessories like headphones, ear cushions) which come in direct contact with the patient be subjected to standard cleaning and disinfecting procedure between patients. Please disinfect the instrument and its accessories in dependence on the specific existing infection potential.
Recommendations for cleaning and disinfection of MAICO device presented in this document are not intended to replace or contradict policies in effect or procedures required for infection control at the facility.
If there is not a high infection potential, MAICO recommends:

Before cleaning always switch off and disconnect the device from power supply.

For cleaning use a lightly dampened cloth with soap water solution

Disinfect the instrument and its accessories by wiping the surfaces with wet Sani-Cloth® Active wipes or a comparable product and allow them to take effect for the duration related to the specific disinfection aim listed in product data sheet of the disinfection product. Please follow also its instructions for cleaning.

- Wipe before and after each patient
- After contamination
- After infectious patients

Disinfect computer, keyboard, transport trolley etc. with Sani-Cloth® Active wipes:

- once a week
- after contamination
- when polluted

To avoid damage of the device and its accessories, please mind the following:

Do not autoclave or sterilize.
Do not use the device in the presence of fluid that can come into contact with any of the electronic components or wiring.

Should the user suspect fluids have contacted the system components or accessories, the unit should not be used until deemed safe by a MAICO certified service technician.

9 Device Update

Insert the SD memory card into your computer and copy the update file MaicoMA4xseries.CAB to the SD memory card. Switch off the MA 41, insert the SD memory card into the MA 41, and then switch the device on. The update will be installed automatically. Wait until the update is finished and follow the instructions. Remove the SD memory card from the MA 41, it will boot up normally. Following the update, please use your computer to delete the update file from the SD memory card in order to have normal use of the card.

10 Connection to the PC

Install the included software on your PC. This will allow you to use your device with NOAH™ and the MAICO Database. The driver for the device will be installed automatically. Connect the MA 41 by USB cable to the PC and turn on the device. The required driver will be installed. Please follow the installation procedure. When the installation program asks you how to search for software, choose "Yes, this time only" and click on the Next button.

Figure 17 - Installation Advice

Select automatic installation in the next dialog window and click the Next button. Wait till the MAICO MA4x family driver is installed and the operating system updated. Click on the Finish button when the installation of the driver is completed. The new hardware is now ready to use.

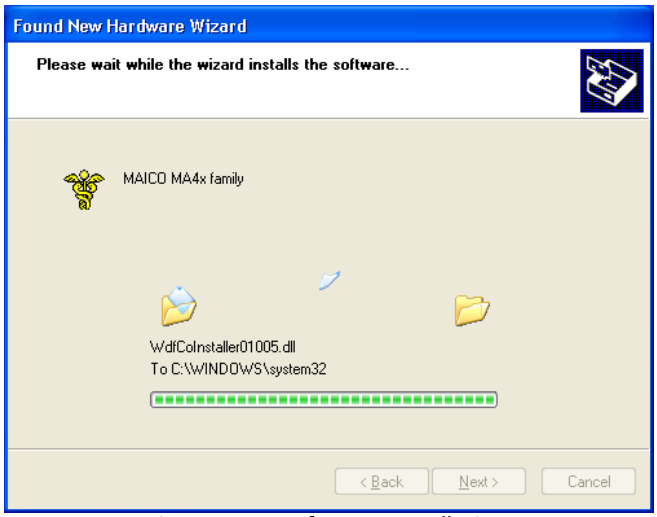


Figure 18 - Software Installation

Once the instrument is linked to the PC audiometry software, you are able to record the results while performing your audiological assessment. Make sure that the software is running and that a connection is built up before starting a new session.

Review the Audiometry Module User Manual for complete instructions of software use. This is located on the included CD and USB.

11 Regulatory Symbols

Symbol	IEC Pub.	Description
	980 & 60601-1	Serial Number
	980 & 60601-1	Date of Manufacture
	980 & 60601-1	Manufacturer
	980 & 60601-1	Caution, Consult Accompanying Documents
	980 & 60601-1	Return to Authorized Representative, Special Disposal Required
	980 & 60601-1	Reference Number
	60601-1	B Patient Applied Part According to IEC60601-1
	980 & 60601-1	Consult Operating Instructions
	60601-1	Keep Dry
	60601-1	Transport and Storage Temperature range
		Logo
	980 & 60601-1	EU Authorized Representative
 Intertek 4005727	Medical Equipment Classified by Intertek Testing Services NA Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 60601-1. Classified under the Medical Device Directive (93/42/EEC) as a Class IIa device.	Registration Label

12 Technical Data

EU Authorized Representative: EC REP	MAICO Sickingenstr. 70-71 D-10553 Berlin Germany
Standards:	ANSI S3.6, ANSI S3.43, IEC 60645-1, IEC 60645-2, ISO 389 UL 60601-1 American Standards for Medical Electrical Equipment IEC/EN 60601-1 International Standards for Medical Electrical Equipment CSA C22.2 # 601-1-M90 Medical Device Directive (MDD) to comply with "EC Directive" 93/42/EEC
Test Frequencies:	125 Hz – 8,000 Hz 9,000 Hz – 16,000 Hz (upgrade)
Level Step:	5 dB, 2 dB or 1 dB level steps (user selectable)
Maximum Sound Pressure Level:	
AC with earphone DD 45:	- 10 dB_{HL} to 120 dB_{HL}
BC with B 71/B 71W Bone Conduction Oscillator:	- 10 dB_{HL} to 80 dB_{HL}
Insert earphones Ear 3A:	- 10 dB_{HL} ... 120 dB_{HL}
Sound field speaker from Amp:	
Tones:	- 10 dB_{HL} ... 100 dB_{HL}
Speech:	- 10 dB_{HL} ... 90 dB_{HL}

Sound field speaker from MA 41:
(using SP90 Speaker Kit):

Tones:	- 10 dB_{HL} ... 90 dB_{HL}
Speech:	- 10 dB_{HL} ... 70 dB_{HL}
Test Signal:	Pure tone, Pulse tone, Warble tone
Masking Signals:	Narrow Band Noise: 5/12 Octave filter with the same center frequency resolution as pure tone
	Speech Noise: 125 to 6,000 Hz falling 12 dB/octave above 1 kHz (+/-5 dB)
Modulation:	
Pulse Tone:	0.25/0.5 s on time
Warble Tone:	5% sinus frequency modulation, repetition rate 5 Hz
Tests:	
Tone:	HL, UCL
Speech:	SRT, WRS, UCL
Patient Response:	Handheld response switch
Monitor:	Build in monitor speaker, headset
Communication:	Talk forward and talk back
Data Connection:	USB, LAN Ethernet

External Devices:	USB keyboard CD player Supported USB printers: HP (PCL 3 and PCL 5e) Epson (ESC/P2, LQ, Stylus Color) Canon (iP100, iP90, BubbleJet)
Stimulus Functions:	Tone Presenter / Interrupter Interlock (tone presentation of both channels simultaneously) Tracking (fixed level difference between both channels) Masking
Warm-up Time:	Less than 10 min after power on
Mode of Operation:	Continuous
Environment Conditions:	15 - 35℃ / 59 - 95℉ (operation) 5 - 50℃ / 41 - 122℉ (transport) Humidity: 30-90%
Dimensions:	W x D x H: 34.5 x 20 x 8 cm / 13.4" x 7.9" x 3.2"
Weight:	1.5 kg / 2.7 lbs
Power Supply:	100 - 240 V~ 50/60 Hz ±10 %
Power Consumption:	Approximately 60 VA
Device Fuses:	2 x 1A slow blow

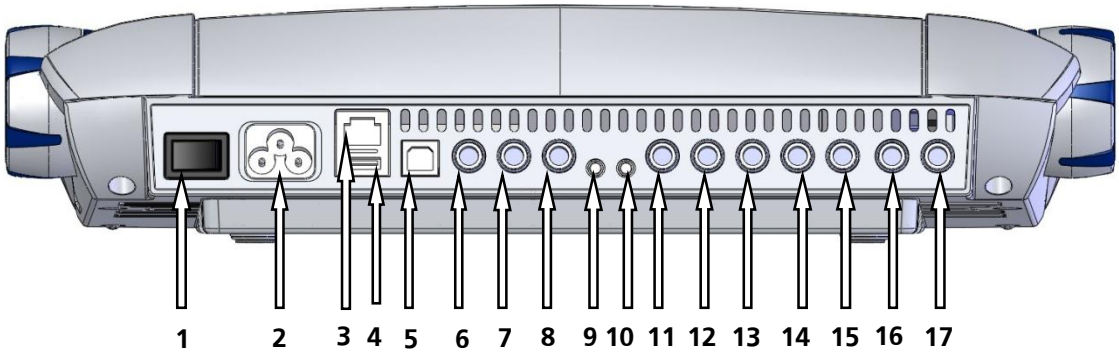


Figure 19 – Connection Sockets of the MA 41

Connection sockets:	Specification:
1: On/Off	Power
2: Power	(100 ... 240 V~ 50/60 Hz)
3: Network	Ethernet
4: USB out	USB 2.0
5: USB in	USB 2.0
6: Patient response switch	R_I= 500 Ω
7: Talk Back Microphone	Z_I= 1 kΩ, U_I= 0.38 - 500 mV_{eff}
8: Mic Microphone	Z_I= 1 kΩ, U_I= 0.38 - 500 mV_{eff}
9: Monitor phone	Z_A= 250 Ω, U_A= 8 V_{eff}
10: CD Input	Z_I= 47 kΩ, U_I= 0.04 - 5 V_{eff}
11: Speaker left	Z_A= 4 Ω, U_A= 8 V_{eff}
12: Speaker right	Z_A= 4 Ω, U_A= 8 V_{eff}
13: Bone (bone conductor)	Z_A= 4 Ω, U_A= 8 V_{eff}
14: Insert phone left	Z_A=10 Ω, U_A=1 V_{eff}
15: Insert phone right	Z_A=10 Ω, U_A=1 V_{eff}
16: Phone left (headphone)	Z_A=10 Ω, U_A=1 V_{eff}
17: Phone right (headphone)	Z_A=10 Ω, U_A=1 V_{eff}

Standard Accessories:

Items	Part Number
DD45 Headphones	8010880
B71 Bone Conductor	8010800
Patient Response Switch	8011091
Power Cable	8011392
Mic/Monitor Headset	8010870
Adaptor, Stereo, 1/8" to 1/4"	8010402
SD Memory Card w/ Wave Files (2 GB)	8100885
CD, Noah Module and Maico DB	8105958
USB Flash Drive	8102480
1 Meter USB Cable	8004381
Carrying Case	8100797
MA 41 Manual	8120525
MA 41 Quick Guide	8102407

Optional Accessories:

Items	Part Number
High Frequency Option (HDA200 and High Tone License)	1000057
EAR 3A Insert Phones	8010959
TDH 39 Headphones	8010820
Monitor Phone	8111857
Talk-Back Microphone	8110026
Gooseneck Microphone	8006479
Sound Room Patch Cords (each)	8004383
Sound Room Kit	8120006
SP90 Free Field Speaker Kit	8121128
SP90 Speaker Kit with AP70 Amplifier	8121130

13 Warranty, Maintenance and After-Sales Service

The MAICO MA 41 is guaranteed for 1 year.

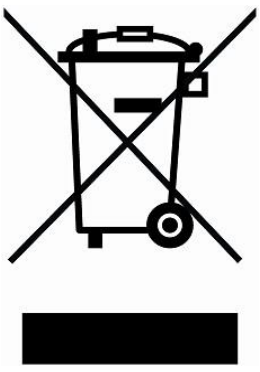
This warranty is extended to the original purchaser of the instrument by MAICO through the distributor from whom it was purchased and covers defects in material and workmanship for a period of one year from date of delivery of the instrument to the original purchaser.

The MA 41 may be repaired and serviced only by your dealer or by an authorized service center. We urgently advise you against attempting to rectify any faults yourself or commissioning non-experts to do so.

In the event of repair during the guarantee period, please enclose evidence of purchase with the instrument.

In order to ensure that your instrument works properly, the MA 41 should be checked and calibrated at least once a year. This check should be carried out by your dealer.

When returning the instrument for repairs it is essential that all transducers (headphones, inserts, and bone conduction oscillators) are sent in as well. Please send the device to your dealer or to a service center authorized by your dealer, and include a detailed description of any defects the equipment is exhibiting. In order to prevent damage in transit, please use the original packing whenever possible to return the instrument.



Within the European Union it is illegal to dispose electric and electronic waste as unsorted municipal waste. According to this, all MAICO products sold after August 13, 2005, are marked with a crossed-out wheeled bin. Within the limits of Article (9) of DIRECTIVE 2002/96/EC on waste electrical and electronic equipment (WEEE), MAICO has changed their sales policy. To avoid additional distribution costs we assign the responsibility for the proper collection and treatment according legal regulations to our customers.

Date of Manufacture.

14 Safety Regulations

Consult operating instructions before using this device.

14.1 Electrical Safety

The MA 41 audiometer is a B patient applied part according to international standard IEC 60601-1 (EN 60601-1). The instruments are not intended for operation in areas with an explosion hazard.

Electrostatic discharge (ESD) according to IEC 61000-4-2. It is recommended that you use this device in an electrostatically controlled environment. To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.

14.2 Measuring Security

To guarantee that the audiometer works properly, the instrument has to be checked and calibrated at least once a year.

The service and calibration must be performed by an authorized service center. In accordance with the regulations of the EU Medical Directive, warranties may be void if these checks are not done.

The use of non-calibrated audiometers can lead to incorrect test results and is not advisable.

14.3 Device Control

The user of the instrument should perform a subjective instrument check once a week.

14.4 Operation

The instrument should only be handled and operated by trained personnel (audiologists, ENT doctors or personnel with similar qualifications).

14.5 Warnings and Statements

No modification of this equipment is allowed.

Maico will make available instructions and diagrams to repair devices that it deems appropriate to be repaired in the field.

No adverse effects have been reported from the materials used in this device based on 50 plus years of use with many different patient populations.

The operation of the device can be safely terminated by using the power switch found on the rear of the device or by disconnecting the power cable.

Appendix A: QuickSIN™ Speech-in-Noise Test Manual

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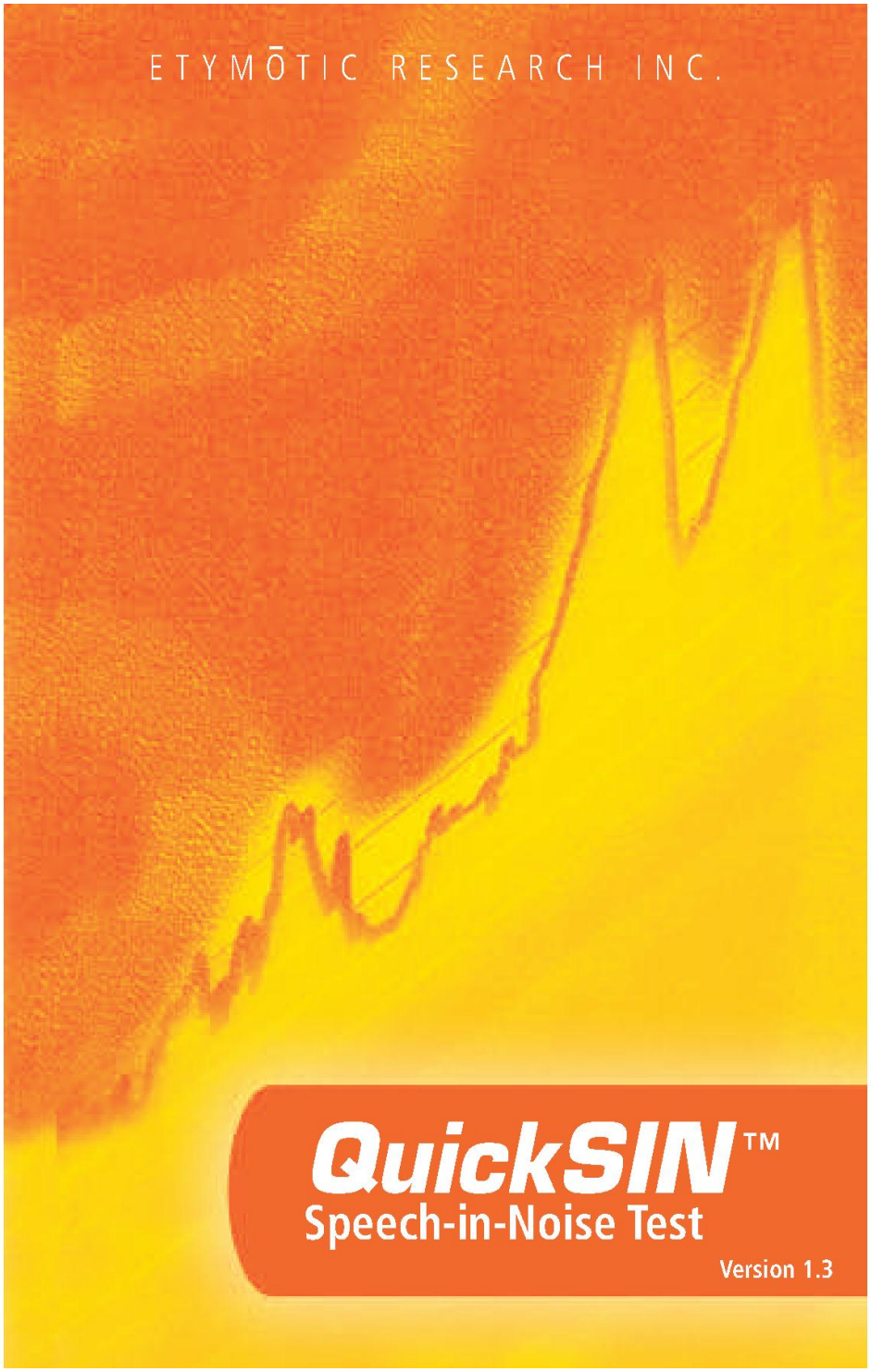

TABLE OF CONTENTS

QUICK START (for full instructions, see page 6)

- Connect a CD player to the speech circuit of a standard audiometer.
- Using the calibration tone on Track 1, adjust both channels of the audiometer to read 0 VU. NOTE: Except for tracks 24-35, the target speech and background talkers were recorded together on both channels.
- Present the test with earphones or in a sound field, with the attenuator dial set to 70 dB HL. For subjects with PTA hearing losses greater than 45 dB HL, set the attenuator dial to a level that is "loud but OK."
- Instruct the patient to repeat the sentences spoken by the target (female) talker.
- When testing in a sound field, have the patient hold the talkback microphone close enough so that responses are clearly audible to the tester.
- Score the five key words underlined in each sentence, giving one point for each word repeated correctly.
- Add the number of words repeated correctly, totalled across all 6 sentences. Subtract the total correct from 25.5 to obtain SNR loss.

SNR Loss = 25.5 – Total Correct.

- To interpret the SNR loss score, see Table 1.

Table 1

SNR LOSS	DEGREE OF SNR LOSS	EXPECTED IMPROVEMENT WITH DIRECTIONAL MIC
0-3 dB	Normal/near normal	May hear better than normals hear in noise
3-7 dB	Mild SNR loss	May hear almost as well as normals hear in noise
7-15 dB	Moderate SNR loss	Directional microphones help. Consider array mic
>15 dB	Severe SNR loss	Maximum SNR improvement is needed. Consider FM system

PURPOSE OF THE *QuickSIN*

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

The ***QuickSIN*** test was developed to:

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

QuickSIN METHODOLOGY

A list of six sentences with five key words per sentence is presented in four-talker babble noise. The sentences are presented at pre-recorded signal-to-noise ratios which decrease in 5-dB steps from 25 (very easy) to 0 (extremely difficult). The SNRs used are: 25, 20, 15,10, 5 and 0, encompassing normal to severely impaired performance in noise.

WHAT'S ON THIS CD?

The ***QuickSIN*** CD contains lists of sentences in noise (4-talker babble) that can be used to determine SNR Loss (signal-to-noise ratio loss). Each list takes about one minute to administer. There are eight blocks of recordings on this CD:

- 12 **standard** equivalent lists—**for basic SNR Loss testing**
- 3 pairs of **standard** lists—**additional list pairs for research**
- 3 practice lists (not equivalent to lists 1-12)—**for practice only**

- 12 lists with speech on channel 1 and constant-level babble on channel 2 (separated)—**to demonstrate directional microphone effectiveness**

- 12 lists recorded with 30 dB high frequency emphasis (**HFE**)—**for use with ski-slope losses**
- 2 pairs of **HFE** lists—**additional list pairs for research**
- 12 lists recorded with 30 dB **HFE** and low pass filtering (**HFE-LP**)—**for use in combination with the HFE lists to determine whether hearing aids with extended HFE will help or degrade speech intelligibility in noise**
- 2 pairs of **HFE-LP** filtered lists—**additional list pairs for research**

TRACKS:

Track 1 1-kHz calibration tone
Track 2 Identification
Tracks 3-14 Standard ***QuickSIN*** lists 1-12. These twelve lists are equivalent.
Tracks 15-20 List pairs. Lists 13/14, 15/16 and 17/18.
Tracks 21-23 Practice lists A, B and C. These lists are for practice only and are not equivalent to the standard lists or list pairs.
Tracks 24- 35 Lists 1-12 recorded with sentences on channel 1 and constant-level babble on channel 2. These lists can be used to demonstrate directional microphone performance (see page 11).
Tracks 36-47 Lists 1-12 recorded with 30 dB high-frequency emphasis (HFE). The HFE is used to make speech sounds audible for persons with ski-slope loss.
Tracks 48-51 Two list pairs with 30 dB **HFE**. List pairs 13/14 and 15/16.
Tracks 52-63 Lists 1-12 recorded with HFE plus 3-kHz low-pass brickwall filter; to be used in combination with the HFE lists to predict the outcome of fitting hearing aids with extended HFE (see page 10).
Tracks 64-67 Two list pairs with **HFE-LP.** List pairs 13/14 and 15/16.
Track 68 Speech spectrum noise recorded at 0 VU re: 1-kHz cal tone.
Track 69 Pink noise recorded at 0 VU re: 1-kHz cal tone.

HOW TO USE THIS CD

Every CD has two channels: channel one (left) and channel two (right). The ***QuickSIN*** CD contains the identical recording on left and right channels on all tracks, except for Tracks 24-35, which have the target talker on the left and the 4-talker babble on the right.

Setup:
Connect a CD player to the external input of the audiometer. The ***QuickSIN*** test may be presented via loudspeaker, insert earphones or TDH earphones. When presenting the ***QuickSIN*** test via loudspeaker, present it through one loudspeaker only, with the subject seated facing the loudspeaker (0° azimuth). When using insert earphones or TDH earphones, you may present the test either monaurally or binaurally. Most normative data were collected using binaural presentation.

Calibration:
Using the 1-kHz calibration tone on Track 1, adjust the audiometer so that the VU meter reads "0." Some audiometers have two VU meters, one for each channel. When presenting the test via loudspeaker, it is only necessary to set the VU meter for the channel being directed to the loudspeaker. When presenting the test via earphones, it may be necessary with some audiometers to adjust both VU meters. NOTE: Tracks 24-35 were recorded with speech on one channel and babble on the other. When using these tracks, calibrate both channels.

Presentation Level:
For pure tone average (PTA) $\leq$45 dB HL, set the attenuator dial to 70 dB HL. For PTA of 50 dB HL or greater, set the attenuator dial to a level that is judged to be "loud, but OK." The sound should be perceived as loud, but not uncomfortably loud. (See Appendix A.) The practice lists on Tracks 21-23 can be used to determine the correct presentation level.

Test Instructions:
"Imagine that you are at a party. There will be a woman talking and several other talkers in the background. The woman's voice is easy to hear at first, because her voice is louder than the others. Repeat each sentence the woman says. The background talkers will gradually become louder, making it difficult to understand the woman's voice, but please guess and repeat as much of each sentence as possible." NOTE: When testing via loudspeaker, the talkback microphone should be held close to the patient's mouth so that responses are clearly audible to the tester.

Pausing:
Use the **PAUSE** button between sentences if the patient responds slowly.

PRACTICE LISTS

Tracks 21-23 contain Practice Lists A-C. They can be used to familiarize the patient with the test protocol or to determine the "loud but OK" presentation level for persons with hearing loss of 50 dB HL and greater. These lists are NOT equivalent to lists 1-12 or list pairs, and do not reliably predict SNR Loss.

TRACK 21

Practice List A

		Score
1. The lake sparkled in the red hot sun.	S/N 25	_____
2. Tend the sheep while the dog wanders.	S/N 20	_____
3. Take two shares as a fair profit.	S/N 15	_____
4. North winds bring colds and fevers.	S/N 10	_____
5. A sash of gold silk will trim her dress.	S/N 5	_____
6. Fake stones shine but cost little.	S/N 0	_____
	TOTAL	_____

TRACK 22

Practice List B

		Score
1. Wake and rise, and step into the green outdoors.	S/N 25	_____
2. Next Sunday is the twelfth of the month.	S/N 20	_____
3. Every word and phrase he speaks is true.	S/N 15	_____
4. Help the weak to preserve their strength.	S/N 10	_____
5. Get the trust fund to the bank early.	S/N 5	_____
6. A six comes up more often than a ten.	S/N 0	_____
	TOTAL	_____

TRACK 23

Practice List C

		Score
1. One step more and the board will collapse.	S/N 25	_____
2. Take the match and strike it against your shoe.	S/N 20	_____
3. The baby puts his right foot in his mouth.	S/N 15	_____
4. The pup jerked the leash as he saw a feline shape.	S/N 10	_____
5. Leave now and you will arrive on time.	S/N 5	_____
6. She saw a cat in the neighbor's house.	S/N 0	_____
	TOTAL	_____

WHAT IS SNR LOSS?

We are interested in the patient's performance in noise compared to normal-hearing persons' performance in noise. We consider this difference in performance the **SNR Loss**.

Similar to the definition of pure tone hearing loss, SNR Loss is defined as the dB increase in signal-to-noise ratio required by a hearing-impaired person to understand speech in noise, compared to someone with normal hearing. A normal-hearing person requires about +2 dB signal-to-noise ratio (speech louder than the background noise by 2 dB) to identify 50% of key words in sentences on the ***QuickSIN*** test. The value of SNR Loss is derived from the SNR-50 (signal-to-noise ratio for 50% correct) score. A hearing-impaired person who requires speech to be 8 dB higher than the noise to achieve a 50% correct score would have a 6 dB SNR Loss (see Figure 1).

Different tests will give different values of SNR-50 for the same patient. We have found that changing from a female to male talker and using easier sentences decreases the normal SNR-50 by 5 dB from +2 to –3 dB, even though the babble noise is identical in both tests. Similarly, when continuous speech-spectrum noise is used, the reported SNR will differ by about 7 dB between computed rms calibration and traditional frequent-peak VU-meter readings (Ludvigsen and Killion, 1997). We've chosen to report ***QuickSIN*** scores in *SNR Loss* because it is substantially independent of calibration and test material. Calibration and/or test material differences that affect the SNR-50 values equally for normal and hearing-impaired subjects will cancel out in the SNR Loss calculation.

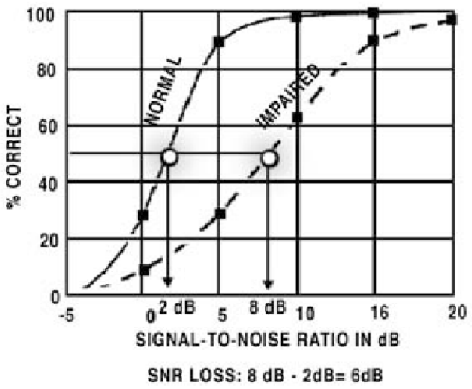

Figure 1 (From Killion, 2002)

SCORING:

Five key words are scored in each sentence. The key words are underlined on the score sheets. One point is given for each key word repeated correctly. The number of

correct words for each sentence should be written in the space provided at the end of the sentence and the total correct calculated for the list. SNR Loss is calculated for each list by using the formula: SNR Loss = 25.5 – Total Correct.

Note: For greater accuracy, two or more lists should be averaged (see pp 19-20).

WHERE DOES THE NUMBER 25.5 COME FROM?

First we need to explain where the number 27.5 comes from. Following the Tillman-Olsen (1973) recommended method for obtaining spondee thresholds, we have a simple method for estimating SNR-50 using nothing more than the total number of words correct. In the Tillman-Olsen method, two spondees are presented at each level, starting at a level where all spondees are repeated correctly and decreasing in two dB steps until no responses are obtained for several words. The starting level plus 1 dB, minus the total number of spondees repeated correctly, is the spondee threshold. The simple arithmetic comes from the use of 2 dB steps and 2 words per step. If the audiometer only has 5 dB steps, the corresponding method would use 5 words per step and take the starting level plus 2.5 dB (half of the step size, just as in the case of 2 dB steps), minus the total number of spondees repeated correctly.

The ***QuickSIN*** has five words per step and 5 dB per step. Our highest SNR is 25 dB so we take 25 + 2.5 = 27.5 minus the total number of words repeated correctly. This gives what we call **SNR-50**, the signal-to-noise ratio required for the patient to repeat 50% of the words correctly. For example, if someone repeats all the words correctly down to 15 dB SNR and then misses everything beyond that point, they gave 15 correct responses (five each at 25, 20, and 15 dB SNR). Since they scored 100% correct at 15 dB SNR and 0% correct at 10 dB SNR, their SNR-50 would be about 12.5 dB, halfway between 15 and 10. This is the value given by the formula 27.5-15 = 12.5 dB.

THE FORMULA FOR SNR LOSS:

Since ***SNR-50*** for normal-hearing persons is 2 dB, we subtract 2 dB to derive the formula for a patient's **SNR LOSS**: **25.5 – (Total words correct in 6 sentences)**

SNR loss = *SNR-50* – 2 dB
= 27.5 – (total words correct) – 2 dB
= 25.5 – (total words correct)

GUILT-FREE *QuickSIN* TEST: for ski-slope loss

High-Frequency Lists & Low-Pass-Filtered Lists

Figure 2 shows the high-frequency emphasis added to the ***QuickSIN*** lists to obtain the recordings labeled **HFE**. This frequency response was obtained from FIG 6 (1997) for 65 dB (normal speech) inputs for a patient with 60-70 dB ski-slope loss.

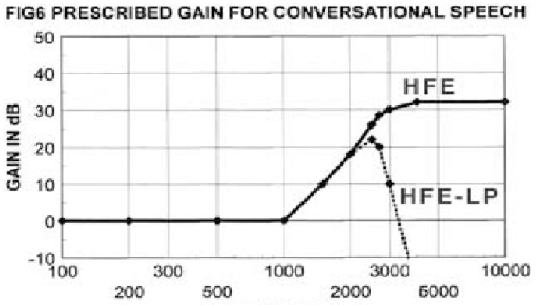

Figure 2

Data on ski-slope hearing loss from Skinner (1980), Rankovic (1991), and Turner and Cummings (1999) indicate that some patients do worse with the extended high frequency emphasis prescribed by popular formulae than if the emphasis is restricted to regions of better hearing. Other patients with similar audiograms seem to benefit from the extended high-frequency amplification.

A new set of recordings labeled **HFE-LP** were generated by low-pass filtering the **HFE** recordings with a brickwall filter set at 2.5 kHz. The resulting frequency response is also shown in Figure 2.

By comparing the SNR results obtained with the **HFE** and **HFE-LP** lists, it is possible to determine whether or not extended high-frequency amplification is useful. For a test accurate to 1.9 dB (95% confidence interval for the difference between the two conditions), four **HFE** and four **HFE-LP** lists are required, a total of 8 independent lists used alternately.

Example: Track 36 (list 1 with HFE) and Track 53 (list 2 with HFE-LP)
Track 38 (list 3 with HFE) and Track 55 (list 4 with HFE-LP)
Track 40 (list 5 with HFE) and Track 57 (list 6 with HFE-LP)
Track 42 (list 7 with HFE) and Track 59 (list 8 with HFE-LP)

Note: The same list is never used twice in this example.

SEPARATED SPEECH & NOISE CHANNELS

Tracks 24-35 contain the 12 standard ***QuickSIN*** lists recorded with the speech and noise on two separate channels (target speech on channel one and 4-talker babble on channel two). The purpose of these lists is to provide a quick way to verify the effectiveness of hearing aids that have switchable directional microphones. On these tracks, both speech and babble were recorded at constant levels; therefore, the tester must establish and control the signal-to-noise ratios by selecting the presentation levels for both speech and babble channels, and manually change the level of the babble channel for each sentence to adjust the signal-to-noise ratio.

Directional Comparisons

A complete measurement of a directional hearing aid requires extensive laboratory facilities, but a good demonstration of the ability of directional hearing aids to reject sound from the sides and rear can be obtained in a standard test booth with loudspeakers located in the corners (at +45° and -45° or 0° and 180° azimuth).

It is important to remember that any test conducted in a sound booth will not precisely reflect results in the real world. By design, sound booths have minimal reverberation, and testing is conducting using a limited number of loudspeakers (usually two) that are in fixed locations. In this setup, it is possible that the location of the speakers may interact with the null of the directional microphone(s). Therefore, these measures should not be used to assess effectiveness of one directional microphone design vs. another (where differences are usually small) but rather as a general measure comparing OMNI to Directional, to verify that the directional microphones are working and providing directivity (rejection of sound from the sides and rear).

Procedure:
If the loudspeakers are located at +45° and -45°, test each ear separately. Position the patient in the sound booth so that speech is presented from in front at 45° and babble from behind at approximately 135°. Direct the speech (channel one) to the loudspeaker at 45° and direct the babble (channel two) to the loudspeaker at 135°.

Note: There are two possible "45 degree" orientations for the patient. The desired orientation places the aided ear between the loudspeakers. See Figure 3. When the other ear is tested, the patient will need to be rotated to face the opposite wall and the speech and babble switched to the opposite speakers.

Directional Comparisons Continued

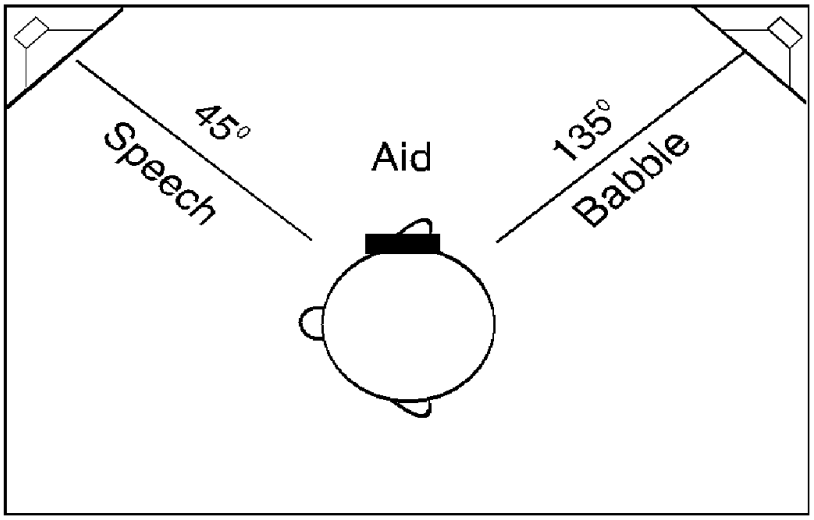

Figure 3

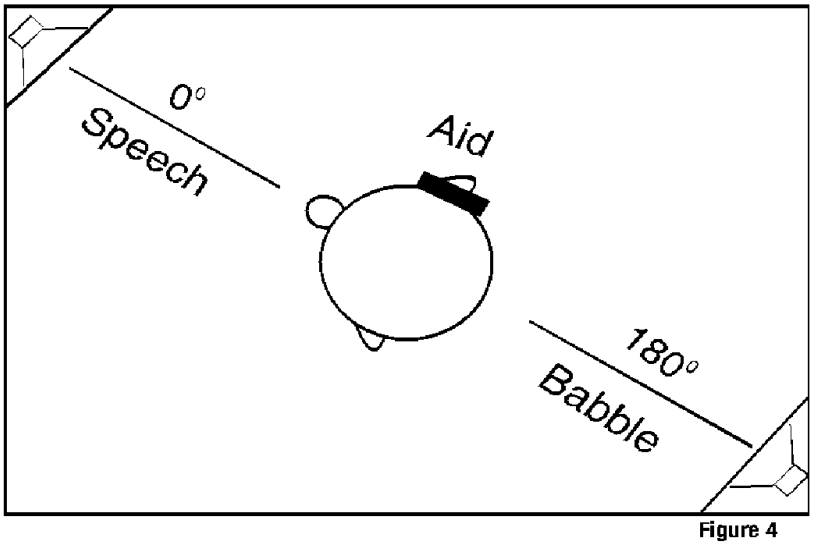

Figure 4

12

If the loudspeakers are located at 0° and 180°, you may test each ear separately or both ears together. Position the patient in the sound booth so that speech is presented from in front at 0° and babble from behind at 180°. See Figure 4.

Since the babble noise on Tracks 24-35 is at a constant level, two types of demonstrations are possible:

1. **Subjective.** Calibrate both channels. Have the patient set the hearing aid/s to OMNI. Adjust the speech to 50 dB HL (65 dB SPL conversational speech level) and then adjust the noise to the level where the patient reports that it just prevents understanding the speech. Have the patient switch back and forth between OMNI and Directional positions on the hearing aid/s. The improved intelligibility in the directional mode should be obvious.

2. **Objective.** Calibrate both channels. Set the dial for channel one (front speaker) to 50 dB HL. Set the dial for channel two to 25 dB HL for the first sentence, and increase the dial setting for channel two (babble) by 5 dB for each succeeding sentence (see Table 2). Score each list as before to obtain SNR Loss. Test in OMNI and Directional. A minimum of three lists in each condition (six total) is required for a valid comparison to an accuracy of 1.5 dB at the 80% confidence level (see page 20). If you find a difference greater than 4 dB with one list in each condition, you have already reached the 95% confidence level.

Table 2

	Channel 1 Dial (dB HL)	Channel 2 Dial (dB HL)	SNR (dB)
Sentence 1	50	25	25
Sentence 2	50	30	20
Sentence 3	50	35	15
Sentence 4	50	40	10
Sentence 5	50	45	5
Sentence 6	50	50	0

TEST DEVELOPMENT

The Original SIN Test

The original Etymotic Research Speech-In-Noise (SIN) Test was designed to assess word recognition performance in noise, with and without hearing aids. Test results are reported as signal-to-noise ratio (SNR) for 50% correct. This is consistent with normal audiometric practice, where threshold is defined as the level at which the patient responds 50% of the time. The recommended presentation levels for the SIN Test (70 dB HL and 40 dB HL) were selected to represent the range of typically loud and quiet speech levels encountered by most people in everyday life.

SIN Test Format

Sentence materials were used in the SIN Test because sentences spoken with natural dynamics have greater dynamic range than monosyllabic words, and are thus a more valid representation of real speech (Villchur, 1982). In the real world, the speech dynamic range is increased by the stress given to some words and syllables vs. the drop in level given to others. The effects of co-articulation are not well represented on monosyllabic word lists. Monosyllabic words, recorded and played back at specific intensity levels, are not representative of speech in the real world.

One drawback of using sentence materials, however, is that tests which use sentence formats sometimes present an entire sentence to obtain one scorable item (i.e. one word or the entire sentence is scored as correct or incorrect). The result is that significantly greater test time is needed for a given reliability compared to word scoring. The SIN and ***QuickSIN*** tests are "words in sentences" tasks, in which 5 words are scored in each sentence, providing a larger amount of scorable material in a given amount of time. The sentence materials used in the SIN and ***QuickSIN*** tests (IEEE sentences) use words that are typically not highly predictable from the surrounding context, resulting in a performance-intensity function that is not unlike that obtained with NU-6 monosyllables (Rabinowitz et. al., 1992). Indeed, an analysis of the relative independence of these words indicated that 25 words in five sentences, using half-word scoring, give the equivalent of 27 independent words with whole-word scoring.

Origin of SIN Test Sentence Materials

The IEEE (Institute of Electrical and Electronics Engineers) sentences were derived from the Harvard Phonetically Balanced Sentences, developed at Harvard University during World War II (Braida, 2000). The IEEE formed a subcommittee that was charged with developing practice guidelines for speech quality measurements to help communication engineers assess speech transmission systems. The 720 IEEE

sentences (72 lists of 10 sentences each, with five key words in each sentence) were published as Appendix C in the 1969 document, "IEEE Recommended Practice for Speech Quality Measurements." According to Silbiger (2000), the sentences used in the IEEE document were originally published in 1944 (Egan, 1944). The IEEE sentences were designed to have few contextual cues to aid in understanding, i.e. if a listener hears the first part of the sentence, s/he cannot likely "fill in" the remainder based on contextual cues and knowledge of the language.

As part of her doctoral dissertation, Fikret-Pasa (1993) obtained recordings of the IEEE sentences (female talker) from the Massachusetts Institute of Technology on DAT, and equalized them to correct for the high-frequency attenuation caused by the chest position of the recording microphone used at MIT. This recording was used in generating sentences for both the SIN and the ***QuickSIN*** tests.

Problems with the SIN Test:
Many practitioners reported that administration of the SIN Test was too time-consuming for clinical use, and scoring the test was difficult and cumbersome. After several in-depth analyses of the SIN Test, it was discovered that several of the lists were not equivalent, resulting in too few lists available for some clinical comparisons and research purposes (Bentler 2000). Some subjects could not attain a 50% correct score, even at the best (+15 dB) signal-to-noise ratio.

Background Noise
The choice of background noise is an important component of any test. The purpose of the SIN test was to obtain an estimate of difficulty hearing in noise that is representative of real-world performance. Sperry, Wiley & Chial (1997) found that a meaningful speech competitor had a significantly more adverse effect on word recognition performance compared to non-meaningful competitors (e.g. shaped noise or backward multitalker). While the spectrum and masking effects of speech-shaped noise are much easier to control, speech-shaped noise is not representative of the type of noise encountered by normal-hearing persons in their everyday environments.

The SIN and ***QuickSIN*** tests use a four-talker babble recording (Auditec of St. Louis) with one male and three females. The four-talker babble represents a realistic simulation of a social gathering, in which the listener may "tune out" the target talker and "tune in" one or more of the background talkers. It provides a good representation of the difficulty that patients face—the situation in which what they want to hear is speech, and what they don't want to hear is also speech. During the ***QuickSIN*** test development, research subjects frequently commented, "This is what it sounds like to me; this is what it sounds like to have a hearing loss and try to listen in a noisy place!"

***QuickSIN* Search for Sentence Equivalence**

Alpha Versions

The original SIN Test used the first 360 sentences (lists 1-36) of the 720 IEEE sentences. The ***QuickSIN*** sentences were selected from among the remaining 360 sentences (lists 37-72) and were re-recorded, along with the four-talker babble, on separate tracks of an eight-track digital recorder. Thus, all subsequent re-recordings of a given sentence had the same time-locked sequence of babble. This was important because the conversational ebb and flow of the natural conversational speech produced by the four babble talkers meant that the overall noise level varied from moment to moment. Moreover, not all of the IEEE sentences are equivalent in terms of difficulty.

In order to determine the SNR-50 of each sentence *in its accompanying babble segment*, IEEE sentence lists 37-72 were recorded on the "Alpha-1 version" set of three CDs at nominal signal-to-noise-ratios of -1, +2, and +5 dB. The sentences were presented to sixteen normal-hearing subjects at 70 dB HL via ER-3A insert earphones. The three signal-to-noise ratios (-1, +2, and +5 dB) were presented in that order. An across-subject average SNR-50 was obtained for each sentence. This value was used to adjust the SNR on a sentence-by-sentence basis to an expected value of 2 dB, the grand average value. The resulting set of recordings became the Alpha-2 set of CDs.

At this point, the sentences were subjected to a taste test committee that required the sentences to be grammatically acceptable and contemporary (as opposed to the 1940s when the IEEE sentences were created). Sentences surviving the taste test were subjected to the following statistical criteria for SNR equivalence:

1. The standard deviation of the SNR-50 values across six normal-hearing adult subjects was less than 1.5 dB on the Alpha-2 recordings;
2. The mean SNR-50 value on six normal-hearing adult subjects was within 1.5 dB of their grand average on the Alpha-2 recordings;
3. The mean SNR-50 value on eight high-frequency-loss adult subjects was within 2 dB of their grand average on the Alpha-2 recordings;
4. The range of individual-word SNR-50 values within a given sentence exceeded 2 dB (data from six randomly-selected subjects from the 16 normal-hearing adult subject pool on the Alpha-1 recordings).

Beta Version

Starting with the original 360 sentences, the procedure just described eliminated all but 89 sentences, giving enough sentences for 14 lists of six sentences, one each at 25, 20, 15, 10, 5, and 0 dB SNR. Lists 1-14 on the Beta version used these 14 lists. Since we wanted at least 20 lists, we obtained another seven lists by opening up the standard deviation in #2 from 1.5 to 2.0 dB. Lists 15-21 on the Beta version of the ***QuickSIN*** test used the more lax criteria.

Beta Site Protocol
CD recordings of the beta version ***QuickSIN*** lists (21 lists of six sentences each) were sent to approximately two dozen sites. The test protocol controlled for order and learning effects. Test/retest data were required for all 21 lists for both normal and hearing-impaired subjects.

Normal subjects
Beta version ***QuickSIN*** tests were analyzed for 26 normal-hearing listeners (14 subjects from eleven sites, and 12 subjects from a University of Iowa clinic) and 18 hearing-impaired subjects from ten sites. Some data were excluded from analysis if the test protocol was not followed correctly. Analysis of list presentation order indicated that adequate counter-balancing for list order was achieved. The across-subject average across lists for normal-hearing subjects was SNR-50 = 1.9 dB, nearly identical to the original SIN Test average of 2 dB.

Hearing-Impaired (simulated):
Normal-subject results alone are not adequate to determine list equivalence, since performance for normal-hearing listeners is typically determined primarily by the sentences recorded at 0 and 5 dB SNR. In order to check list equivalence for higher SNR levels, we simulated varying degrees of high-frequency hearing loss using filtering.

The 21 Beta-test lists were re-recorded using low-pass brickwall filter settings of 750 Hz, 850 Hz, 1100 Hz, 1400 Hz, and 2000 Hz. Each recording was presented to 25 normal-hearing subjects. Subjects were tested in three sessions over several days, and list number presentation order was varied to counterbalance for potential order effects. The most difficult condition (750 Hz low pass) was presented first, followed in order by the less difficult conditions. Testing was completed over several days, thus "learning effects" were not expected despite repeated presentations of the same lists.

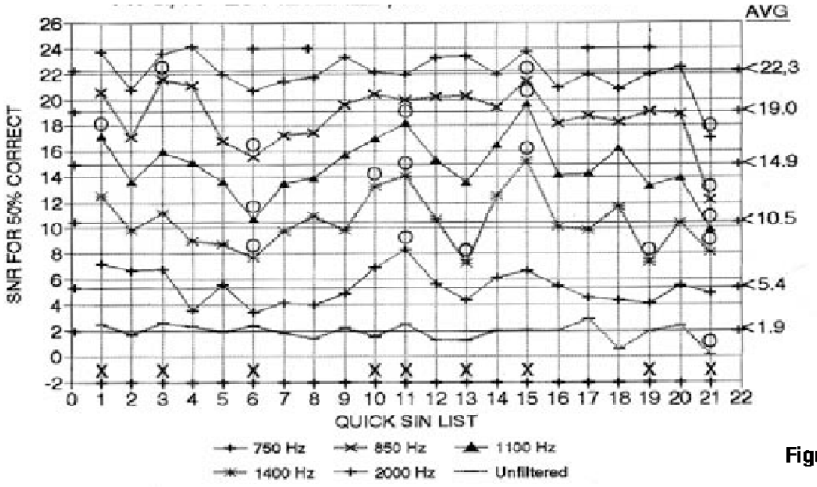

Figure 5

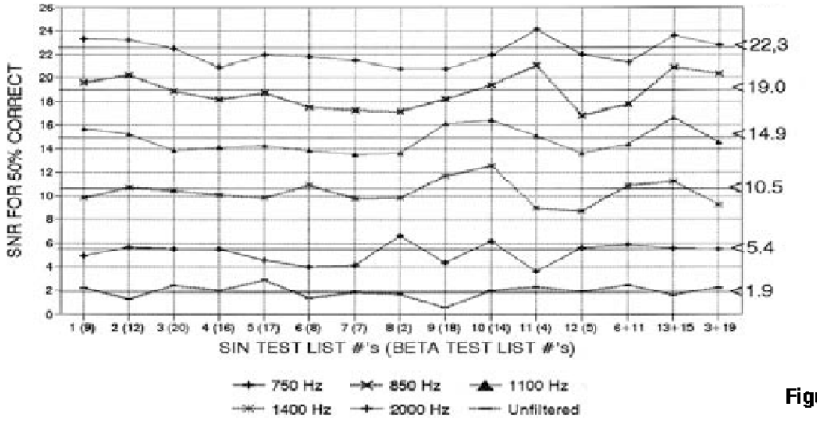

Figure 6

Figure 5 shows a plot of across-subject QuickSIN Beta averages for 25 normal-hearing adult subjects at each filtering condition. The twelve lists without an X exhibited SNR-50 values at *each* filtering condition that fell within ± 2.2 dB of the grand average. ***In addition, three pairs of lists were found whose pair average met those criteria. (Typically one list score would be high and the other would be low under similar conditions.) By adding those paired lists, a total of 15 equivalent lists became available (12 lists plus 3 list pairs).***

Figure 6 shows a plot of the across- subject average data (renumbered lists) for the lists included on the final ***QuickSIN*** CD.

RELIABILITY (STATISTICS MADE USEFUL)

A ***QuickSIN*** score obtained in one minute from a single list is accurate to about 1.8 dB at the 80% confidence level. By "about" we mean that 80% of the time (four times out of five) the "true" score (obtained from many lists) will be within 1.8 dB of the single-list test score. Statisticians would say we have "an 80% confidence level" that the true ***QuickSIN*** score will be within + 1.8 dB of the measured score. To put these numbers in perspective, a typical clinical threshold is accurate to about 5 dB at the 80% confidence level. In other words, one time out of five a threshold can be expected to be 5 dB or more above or below the recorded value. An 80% confidence level is normally adequate for clinical testing, where the results of any one test are used in context with other factors. In the case of a test of SNR Loss, for example, the clinician will already have formed an idea of the patient's communication difficulty from conversations with the patient. A 95% confidence level is common for research reporting, where a reduced risk of error is normally required. Using a statistical criterion that gives a 95% confidence level reduces the probability of error to one time in twenty.

Table 3 below shows the number of lists required for a given accuracy for confidence levels of 80%, 90% and 95%.

Table 3

Number of Lists	1	2	3	4	5	6	7	8	9
95% C.I. ±, in dB	2.7	1.9	1.6	1.4	1.2	1.1	1.0	1.0	0.9
90% C.I. ±, in dB	2.2	1.6	1.3	1.1	1.0	0.9	0.8	0.8	0.7
80% C.I. ±, in dB	1.8	1.3	1.0	0.9	0.8	0.7	0.7	0.6	0.6

The numbers in Table 3 are based on the rms average standard deviation of 1.4 dB in SNR found for the hearing-impaired subjects included in the Beta-site testing. This figure comes from two numbers: a) the 1.3 standard deviation derived from the combined individual test-retest scores, and b) the across-list standard deviation of 0.6 dB. If only normal-hearing subjects are used, the appropriate standard deviation drops from 1.4 dB to 1.25 dB. A standard deviation of 1.4 dB is slightly better than the standard deviation which would have been expected based on the original SIN Test. That standard deviation of 0.7 dB, multiplied by the square root of five, would predict a standard deviation of 1.6 dB for the ***QuickSIN*** test which uses only one sentence at each level compared to five sentences at each level on the SIN Test. The more careful preselection of sentences used in the ***QuickSIN*** test may have contributed to the slightly better result.

COMPARISON BETWEEN TWO CONDITIONS

Averaging the results of several ***QuickSIN*** lists improves the reliability compared to a single list. This is particularly important when ***QuickSIN*** lists are used to compare two conditions, often two hearing aids or hearing aid adjustments. In this case, the real differences may not be large.

Table 4 below gives the number of lists required for the *comparison between two conditions* at an 80%, 90% or 95% confidence level. For a critical difference of 1.9 dB, for example, four lists are required for *each* condition at the 95% level. For a critical difference of 1.4 dB at the 95% confidence level, eight lists are required for each condition. For a simple example, one list in each condition with the assumed standard deviation of 1.4 dB gives a 95% confidence level of 1.96 x 1.41 x 1.4 = 3.9 dB.

To improve from 80% to 95% confidence level at a given criterion requires an approximate doubling of test time. Example: Two lists in each condition gives a 1.8 dB critical difference at the 80% confidence level; four lists in each condition provide 1.9 dB at the 95% confidence level, and five lists in each condition provide 1.7 dB at the 95% confidence level.

Table 4

Lists per Condition	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
95% C.D. ±, in dB	3.9	2.7	2.2	1.9	1.7	1.6	1.5	1.4	1.3
90% C.D. ±, in dB	3.2	2.2	1.8	1.6	1.4	1.3	1.2	1.1	1.1
80% C.D. ±, in dB	2.5	1.8	1.5	1.3	1.1	1.0	1.0	0.9	0.8

When comparing HFE and HFE-LP conditions for a patient with ski-slope loss, one might well accept an 80% confidence level (one in five chance of being wrong), and consider anything less than 1.5 dB as not practically significant. In this case, Table 4 indicates that three lists in each condition would suffice. This will typically take six minutes, which is relatively small compared to the time often taken fighting feedback. (A relaxed criterion of 1.8 dB would require only two lists in each condition, or four minutes of testing). If the test results indicate that high-frequency emphasis which ends at about 2.5 kHz gives as good or better scores, the clinician can abandon the feedback fight without guilt.

LISTS 1-6

List 1

TRACKS 3, 24, 36, 52 **Score**

1. A white silk jacket goes with any shoes. S/N 25 _____
2. The child crawled into the dense grass. S/N 20 _____
3. Footprints showed the path he took up the beach. S/N 15 _____
4. A vent near the edge brought in fresh air. S/N 10 _____
5. It is a band of steel three inches wide. S/N 5 _____
6. The weight of the package was seen on the high scale. S/N 0 _____

25.5 - TOTAL =_____ SNR loss **TOTAL** _____

List 2

TRACKS 4, 25, 37, 53 **Score**

1. Tear a thin sheet from the yellow pad. S/N 25 _____
2. A cruise in warm waters in a sleek yacht is fun. S/N 20 _____
3. A streak of color ran down the left edge. S/N 15 _____
4. It was done before the boy could see it. S/N 10 _____
5. Crouch before you jump or miss the mark. S/N 5 _____
6. The square peg will settle in the round hole. S/N 0 _____

25.5 - TOTAL =_____ SNR loss **TOTAL** _____

List 3

TRACKS 5, 26, 38, 54 **Score**

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

25.5 - TOTAL =_____ SNR loss **TOTAL** _____

List 4

TRACKS 6, 27, 39, 55 **Score**

1. The sense of smell is better than that of touch. S/N 25 _____
2. He picked up the dice for a second roll. S/N 20 _____
3. Drop the ashes on the worn old rug. S/N 15 _____
4. The couch cover and hall drapes were blue. S/N 10 _____
5. The stems of the tall glasses cracked and broke. S/N 5 _____
6. The cleat sank deeply into the soft turf. S/N 0 _____

25.5 - TOTAL =_____ SNR loss **TOTAL** _____

List 5

TRACKS 7, 28, 40, 56 **Score**

1. To have is better than to wait and hope. S/N 25 _____
2. The screen before the fire kept in the sparks. S/N 20 _____
3. Thick glasses helped him read the print. S/N 15 _____
4. The chair looked strong but had no bottom. S/N 10 _____
5. They told wild tales to frighten him. S/N 5 _____
6. A force equal to that would move the earth. S/N 0 _____

25.5 - TOTAL =_____ SNR loss **TOTAL** _____

List 6

TRACKS 8, 29, 41, 57 **Score**

1. The leaf drifts along with a slow spin. S/N 25 _____
2. The pencil was cut to be sharp at both ends. S/N 20 _____
3. Down that road is the way to the grain farmer. S/N 15 _____
4. The best method is to fix it in place with clips. S/N 10 _____
5. If you mumble your speech will be lost. S/N 5 _____
6. A toad and a frog are hard to tell apart. S/N 0 _____

25.5 - TOTAL =_____ SNR loss **TOTAL** _____

LISTS 7-12

List 7

TRACKS 9, 30, 42, 58 **Score**

1. The kite dipped and swayed, but stayed aloft. S/N 25 _____
2. The beetle droned in the hot June sun. S/N 20 _____
3. The theft of the pearl pin was kept secret. S/N 15 _____
4. His wide grin earned many friends. S/N 10 _____
5. Hurdle the pit with the aid of a long pole. S/N 5 _____
6. Peep under the tent and see the clown. S/N 0 _____

25.5 - TOTAL =_____ SNR loss **TOTAL** _____

List 8

TRACKS 10, 31, 43, 59 **Score**

1. The sun came up to light the eastern sky. S/N 25 _____
2. The stale smell of old beer lingers. S/N 20 _____
3. The desk was firm on the shaky floor. S/N 15 _____
4. A list of names is carved around the base. S/N 10 _____
5. The news struck doubt into restless minds. S/N 5 _____
6. The sand drifts over the sill of the old house. S/N 0 _____

25.5 - TOTAL =_____ SNR loss **TOTAL** _____

List 9

TRACKS 11, 32, 44, 60 **Score**

1. Take shelter in this tent, but keep still. S/N 25 _____
2. The little tales they tell are false. S/N 20 _____
3. Press the pedal with your left foot. S/N 15 _____
4. The black trunk fell from the landing. S/N 10 _____
5. Cheap clothes are flashy but don't last. S/N 5 _____
6. At night the alarm roused him from a deep sleep. S/N 0 _____

25.5 - TOTAL =_____ SNR loss **TOTAL** _____

List 10

TRACKS 12, 33, 45, 61 **Score**

1. Dots of light betrayed the black cat. S/N 25 _____
2. Put the chart on the mantel and tack it down. S/N 20 _____
3. The steady drip is worse than a drenching rain. S/N 15 _____
4. A flat pack takes less luggage space. S/N 10 _____
5. The gloss on top made it unfit to read. S/N 5 _____
6. Seven seals were stamped on great sheets. S/N 0 _____

25.5 - TOTAL =_____ SNR loss **TOTAL** _____

List 11

TRACKS 13, 34, 46, 62 **Score**

1. The marsh will freeze when cold enough. S/N 25 _____
2. A gray mare walked before the colt. S/N 20 _____
3. Bottles hold four kinds of rum. S/N 15 _____
4. He wheeled the bike past the winding road. S/N 10 _____
5. Throw out the used paper cup and plate. S/N 5 _____
6. The wall phone rang loud and often. S/N 0 _____

25.5 - TOTAL =_____ SNR loss **TOTAL** _____

List 12

TRACKS 14, 35, 47, 63 **Score**

1. The hinge on the door creaked with old age. S/N 25 _____
2. The bright lanterns were gay on the dark lawn. S/N 20 _____
3. He offered proof in the form of a large chart. S/N 15 _____
4. Their eyelids droop for want of sleep. S/N 10 _____
5. There are many ways to do these things. S/N 5 _____
6. We like to see clear weather. S/N 0 _____

25.5 - TOTAL =_____ SNR loss **TOTAL** _____

LISTS 13-18 (PAIRS)

Lists 13-18 do not meet the criteria for equivalence as individual lists, but do in the pairs shown. The *average* scores from list pairs 13/14, 15/16 and 17/18 are equivalent to lists 1-12.

List 13

TRACKS 15, 48, 64

		Score
1.	The dusty bench stood by the stone wall.	S/N 25 _____
2.	We dress to suit the weather of most days.	S/N 20 _____
3.	The water in this well is a source of good health.	S/N 15 _____
4.	That guy is the writer of a few banned books.	S/N 10 _____
5.	The door was barred, locked and bolted as well.	S/N 5 _____
6.	A big wet stain was on the round carpet.	S/N 0 _____
	25.5 - TOTAL =_____ SNR loss	**TOTAL** _____

List 14

TRACKS 16, 49, 65

		Score
7.	The team with the best timing looks good.	S/N 25_____
8.	Sit on the perch and tell the others what to do.	S/N 20_____
9.	The early phase of life moves fast.	S/N 15_____
10.	Tea in thin china has a sweet taste.	S/N 10_____
11.	The latch on the back gate needs a nail.	S/N 5_____
12.	A whiff of it will cure the most stubborn cold.	S/N 0 _____
	25.5 - TOTAL =_____ SNR loss	**TOTAL**_____

List 15

TRACKS 17, 50, 66

		Score
1.	Poached eggs and tea must suffice.	S/N 25 _____
2.	They sang the same tunes at each party.	S/N 20 _____
3.	A gold vase is both rare and costly.	S/N 15 _____
4.	Cod is the main business of the north shore.	S/N 10 _____
5.	A round mat will cover the dull spot.	S/N 5 _____
6.	A good book informs of what we ought to know.	S/N 0 _____
	25.5 - TOTAL =_____ SNR loss	**TOTAL** _____

List 16

TRACKS 18, 51, 67

		Score
7.	The thaw came early and freed the stream.	S/N 25_____
8.	It takes a lot of help to finish these.	S/N 20_____
9.	Roads are paved with sticky tar.	S/N 15_____
10.	It's a dense crowd in two distinct ways.	S/N 10_____
11.	Raise the sail and steer the ship northward.	S/N 5_____
12.	Jerk the dart from the cork target.	S/N 0 _____
	25.5 - TOTAL =_____ SNR loss	**TOTAL**_____

List 17

TRACK 19

		Score
1.	The point of the steel pen was bent and twisted.	S/N 25_____
2.	There is a lag between thought and act.	S/N 20_____
3.	Seed is needed to plant the spring corn.	S/N 15_____
4.	This horse will nose his way to the finish.	S/N 10_____
5.	The dry wax protects the deep scratch.	S/N 5 _____
6.	Twist the valve and release hot steam.	S/N 0 _____
	25.5 - TOTAL =_____ SNR loss	**TOTAL** _____

List 18

TRACK 20

		Score
7.	Read just what the meter says.	S/N 25_____
8.	Clams are small, round, soft, and tasty.	S/N 20_____
9.	The line where the edges join was clean.	S/N 15_____
10.	A round hole was drilled through the thin board.	S/N 10_____
11.	The cloud moved in a stately way and was gone.	S/N 5_____
12.	A plea for funds seems to come again.	S/N 0 _____
	25.5 - TOTAL =_____ SNR loss	**TOTAL**_____

APPENDIX A

CATEGORIES OF LOUDNESS

7. Uncomfortably Loud
6. Loud, But OK
5. Comfortable, But Slightly Loud
4. Comfortable
3. Comfortable, But Slightly Soft
2. Soft
1. Very Soft

Valente and Van Vliet (1997)

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APPENDIX B
TECHNICAL NOTE: CROSSTALK

On Tracks 24-35, the target speech and the babble are recorded on separate channels, but a small amount of interchannel crosstalk (-65 dB) exists on the ***QuickSIN*** CD. The typical CD player with a 1/8th-inch stereo plug can increase the crosstalk another 20-30 dB, and most cassette players have even greater crosstalk between their magnetic playback heads. Under normal conditions none of these levels will be audible, but during silent periods on the sentence channel, a faint babble can sometimes be heard in the background. None of these crosstalk levels will affect normal usage of these tracks.

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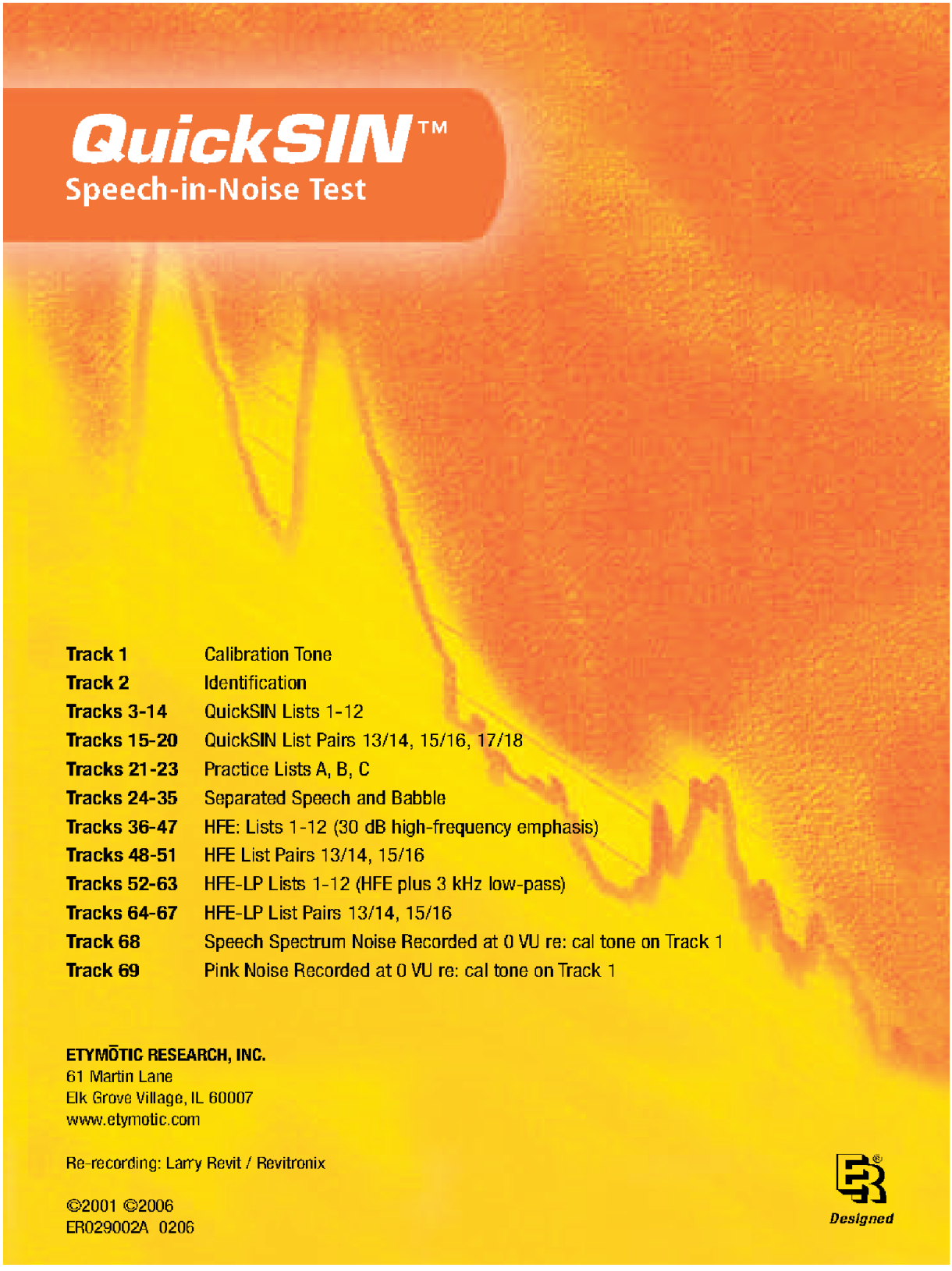
QuickSIN™
Speech-in-Noise Test
Track 1 Calibration Tone
Track 2 Identification
Tracks 3-14 QuickSIN Lists 1-12
Tracks 15-20 QuickSIN List Pairs 13/14, 15/16, 17/18
Tracks 21-23 Practice Lists A, B, C
Tracks 24-35 Separated Speech and Babble
Tracks 36-47 HFE: Lists 1-12 (30 dB high-frequency emphasis)
Tracks 48-51 HFE List Pairs 13/14, 15/16
Tracks 52-63 HFE-LP Lists 1-12 (HFE plus 3 kHz low-pass)
Tracks 64-67 HFE-LP List Pairs 13/14, 15/16
Track 68 Speech Spectrum Noise Recorded at 0 VU re: cal tone on Track 1
Track 69 Pink Noise Recorded at 0 VU re: cal tone on Track 1
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Appendix B: EMC Compatibility

Portable and Mobile RF communications equipment can affect the MAICO MA41. Install and operate the MAICO MA41 according to the EMC information presented on this page and the next 4 pages.

The MAICO MA41 has been tested for EMC emissions and immunity as a standalone instrument. Do not use the MAICO MA41 adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.

The use of accessories, transducers and cables other than those specified, with the exception of servicing parts sold by MAICO as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device. Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

Electromagnetic Compatibility

Although the instrument fulfils the relevant EMC requirements precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g. from mobile phones, etc. If the device is used adjacent to other equipment it must be observed that no mutual disturbance appears.

Electrical Safety, EMC and Associated Standards

1. UL 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety

2. IEC/EN 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety

3. CAN/CSA-C22.2 No. 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety Electrical Equipment for Laboratory Use

4. IEC/EN 60601-1-1: Collateral Standard, Safety Requirements for Medical Electrical Systems

5. IEC/EN 60601-1-2: Medical Electrical Equipment, Part 1 - Electromagnetic Compatibility - Requirements and Tests

6. Essential Requirements of the current European Union Medical Device Directive 93/42/EEC

7. RoHS (Restriction of the use of certain Hazardous Substance)

8. WEEE (Waste Electrical & Electronic Equipment) Legislation

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The MAICO MA41 is intended for use in the electromagnetic environment specified below. The customer or the user of the MAICO MA41 should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment - Guidance
RF Emissions CISPR 11	Group 1	The MAICO MA41 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B Limits	The MAICO MA41 is suitable for use in all commercial, industrial, business, hospital, and residential environments.
Harmonic Emissions IEC 61000-3-2	Class A Category	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the MAICO MA41

The MAICO MA41 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MAICO MA41 can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MAICO MA41 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 m		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

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 transmitters, 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 higher frequency range applies.

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

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The MAICO MA41 is intended for use in the electromagnetic environment specified below. The customer or the user of the MA41 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment-Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be greater than 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, hospital, or residential environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial, hospital, or residential environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Lines IEC 61000-4-11	<5% *UT* (>95% dip in *UT*) for 0.5 cycle 40% *UT* (60% dip in *UT*) for 5 cycles 70% *UT* (30% dip in *UT*) for 25 cycles 5% *UT* (>95% dip in *UT*) for 5 sec	<5% *UT* (>95% dip in *UT*) for 0.5 cycle 40% *UT* (60% dip in *UT*) for 5 cycles 70% *UT* (30% dip in *UT*) for 25 cycles 5% *UT* (>95% dip in *UT*) for 5 sec	Mains power quality should be that of a typical commercial, hospital, or residential environment. If the user of the MAICO MA41 requires continued operation during power mains interruptions, it is recommended that the MA41 be powered from an uninterrupted power supply.
Power Frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: *UT* is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The MAICO MA41 is intended for use in the electromagnetic environment specified below. The customer or the user of the MA41 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment-Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the MA41, 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 2.5 GHz	3 V/m	Recommended separation distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 1.17\sqrt{P}$ 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 Strengthens 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: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply to 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 MA41 is used exceeds the applicable RF compliance level above, the MA41 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MA41.

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

Specifications are subject to change without notice.

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