MAICO Diagnostic GmbH

Operating Instructions MA 41

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Operating Instructions MA 41

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1 Introduction

Thank you for purchasing a quality product from MAICO Diagnostic. 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

2 Intended Use

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 is intended to be used by hearing healthcare professionals (i.e. ENT doctors, audiologists) and/or technicians, and school nurses who have been trained by a hearing healthcare professional.

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 B71W bone conductor). As an upgrade option, the MA 41 is also capable of high frequency audiometry up to 20 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 DD45 headphones, B71W 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.

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

Results can also 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 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 cardboard package on the end flaps. Holding the package securely, fold the side flaps upwards to loosen the tension in the plastic film. 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:

- Headphones DD45
- Bone conduction receiver B71W with headband
- Gooseneck microphone
- SD memory card – inserted into the SD card slot
- Patient response switch
- Power cable
- Operating Instructions

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 results!

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

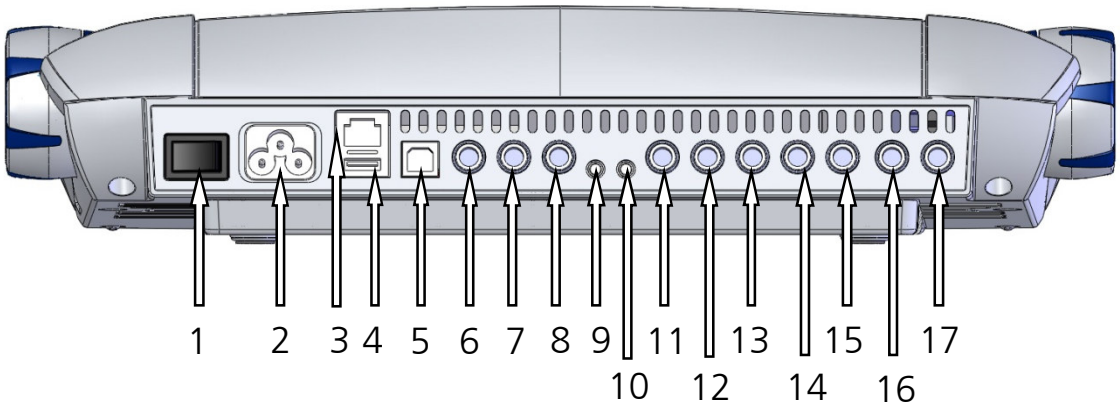


Figure 1– Rear View of the MA 41

1: Power switch

2: Power socket 100-240VAC / 50-60Hz

3: Network socket

4: USB out socket

5: USB in socket

6: Patient response switch socket

7: Talk-back microphone socket

8: Mic live voice microphone socket

9: Monitor phone output socket

10: CD Input

11: Speaker left channel

12: Speaker right channel

13: Bone conduction receiver

14: Insert phone left channel

15: Insert phone right channel

16: Phone left channel

17: Phone right channel

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 Functional 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 selector button: function is displayed on the 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) Functional selector 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) Functional selector button: function is displayed on the 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 selector button: function is displayed on the 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); if Speaker is selected as the transducer Aided can be selected to record aided sound field test results

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

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

(17) Functional selector 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

4.3 The Display of the MA 41

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

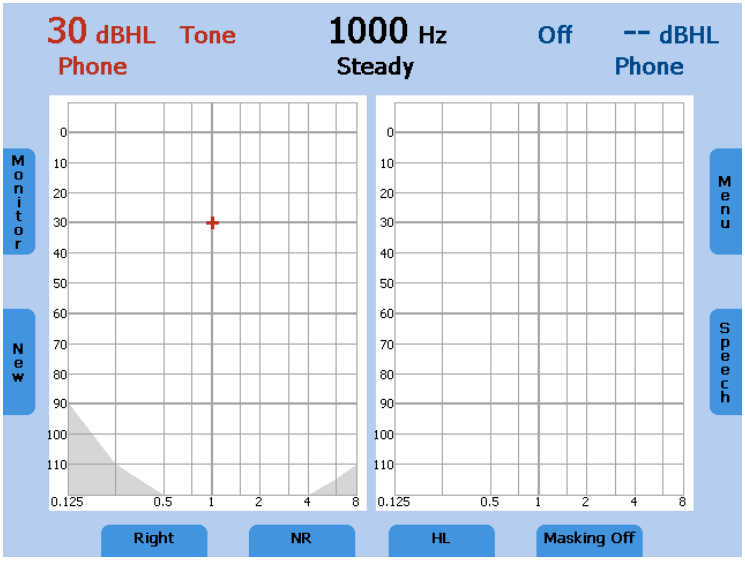


Figure 4 - Start Screen Tone Audiometry Example

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 selector 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 which 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.

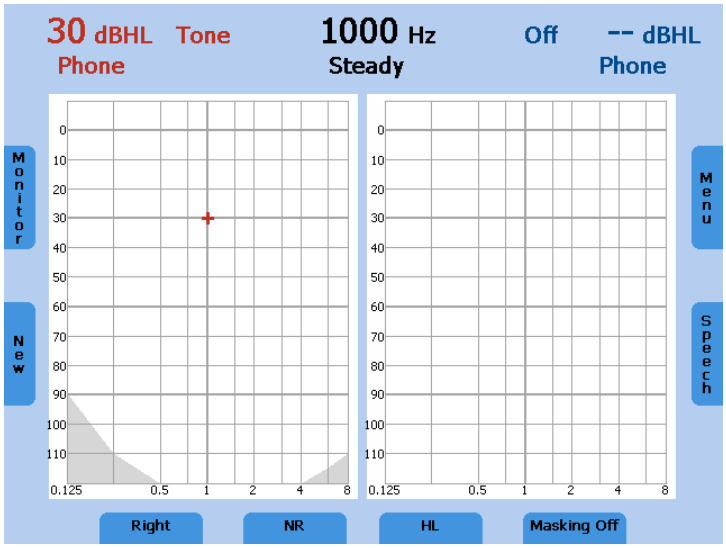


Figure 5 - Pure Tone Audiometry Screen Example

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.

Select the ear to be tested by pressing the functional selector 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 dBHL. 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.

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 dB_{HL}.

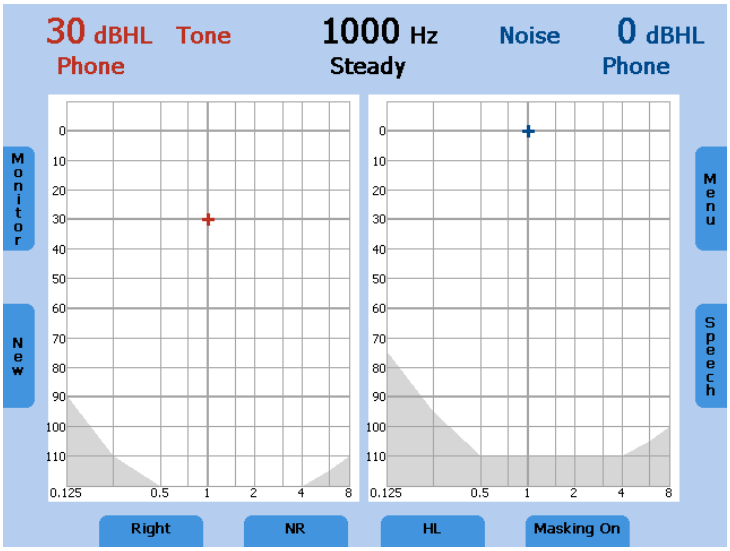


Figure 6 - Tone Audiometry with Masking

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 dB_{HL} and the masking level 50 dB_{HL} and you change the test level to 45 dB_{HL} the masking level will automatically adjust to 65 dB_{HL}).

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.

If you are using bone conductor with contra lateral masking like the BKH 10, connect the contra phone to the left insert phone socket (14, Fig. 1). If masking is switched on, the masking noise will be routed to this output.

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 functional 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 601-1 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).

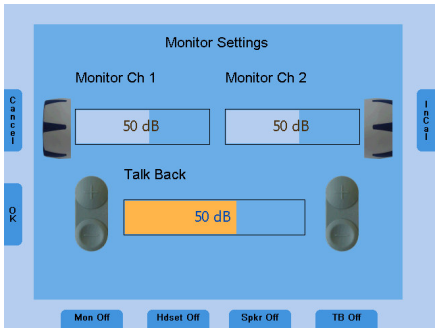


Figure 7a – Monitor settings

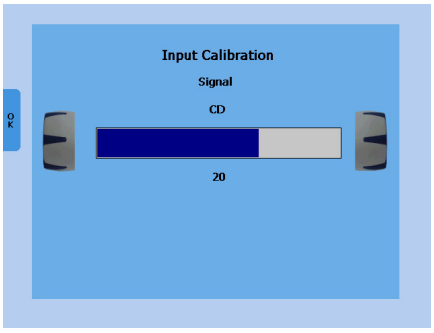


Figure 7b – Input Calibration

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 functional 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 will 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 selector button (9) on the control panel underneath the screen.

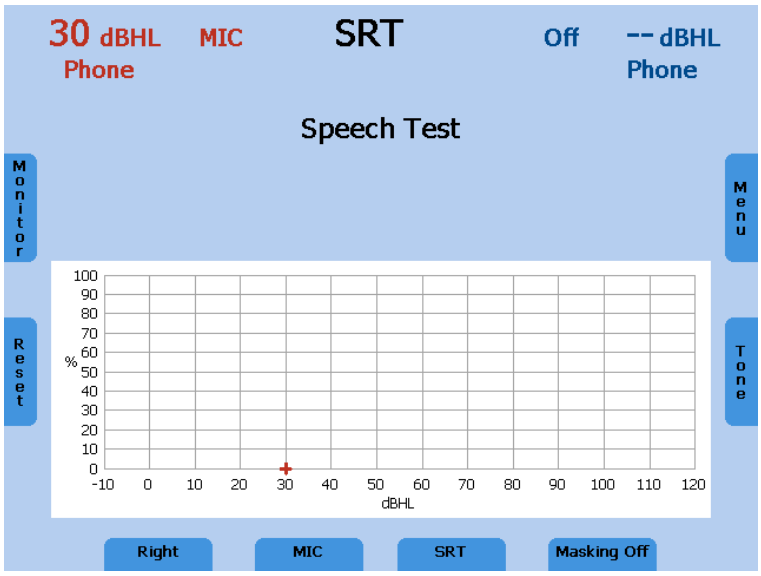


Figure 8 - Speech Test Screen

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 functional button (11). Make sure that the input signal is calibrated correctly, as described above. Select the test SRT, WRS or UCL with the functional 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.

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 to scroll through the list. A list can be loaded by pressing the Stimulus button. The word list will then be displayed on the speech audiometry screen.

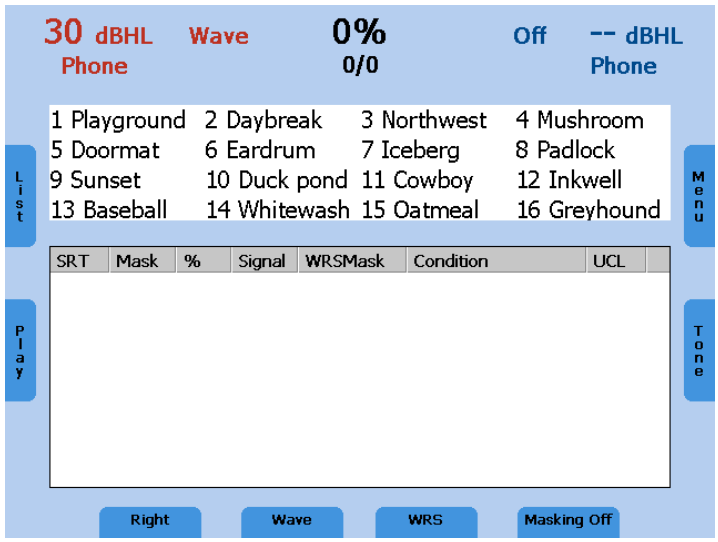


Figure 9 – Speech Audiometry with Wave Files

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 functional button Play (7) to start or pause the wave file playback.

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. Press the functional button Pause (7) to interrupt the playback.

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 functional button List (6) to load another word list.

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 functional 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)

After you have completed the speech audiometry testing you may wish to demonstrate to the patient the difference a hearing aid can make. Use the MA 41 master hearing aid to adjust various frequency slopes for speech.

The Master Hearing Aid (MHA) feature utilizes input signals from the Live Voice (Mic), external CD/MP3 player or with Wave files. These signals are then filtered to simulate the benefit of hearing aids in the case of a high frequency hearing loss. The level of the low frequencies can be reduced by 6 dB, 12 dB, 18 dB per octave.

Begin by selecting a signal source in the speech mode with the functional selector button (11). Start the MHA function by pressing the Test Selection button (13). Change the dB presentation levels with the level control dials (1). The influence of the filters can be changed by using the Frequency Up (4) and Down (5) keys. The MHA function can be performed using monaural or binaural presentations.

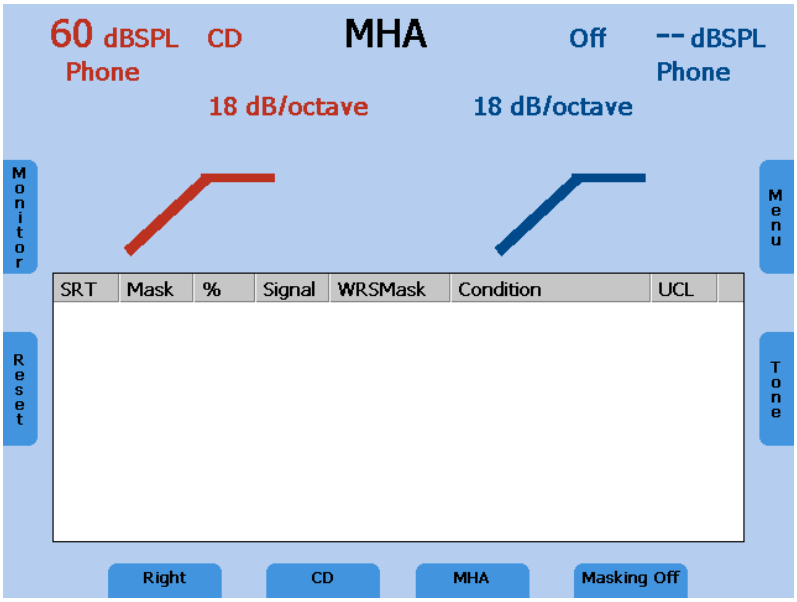


Figure 10 - Display Master Hearing Aid

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 functional 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).

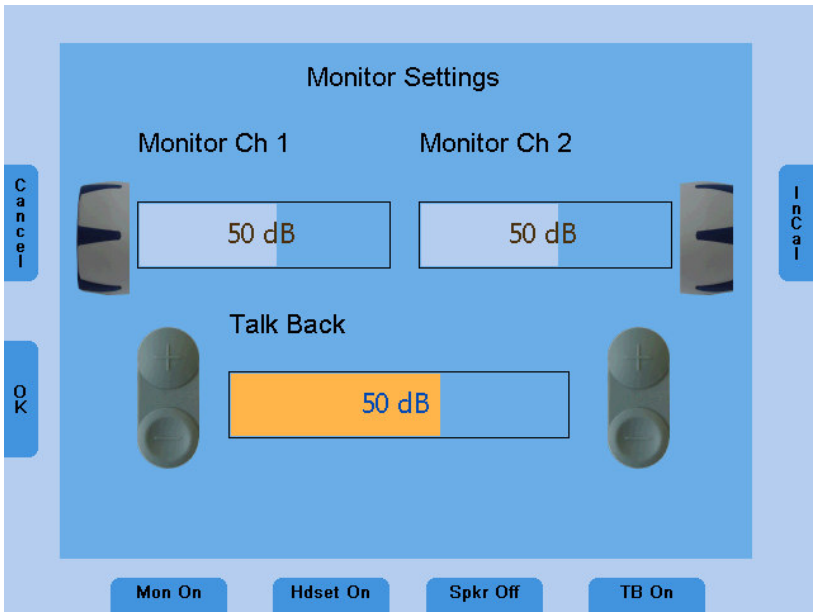


Figure 11 - Display Monitor Settings

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 gooseneck microphone or the microphone headset 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 functional 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.

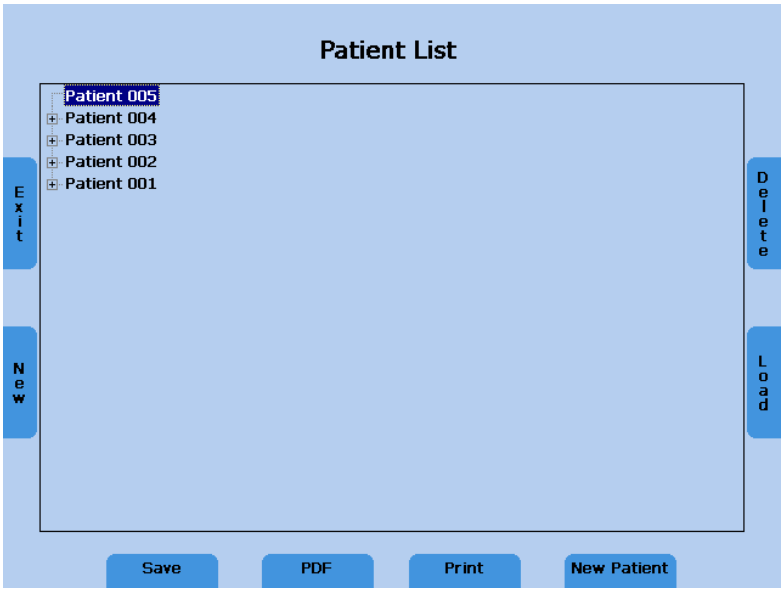


Figure 12 – Patient List

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.

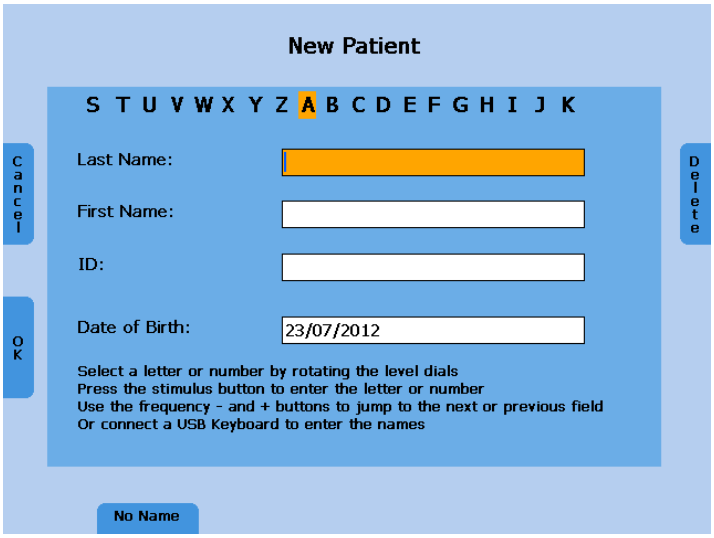


Figure 13 – New Patient

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 functional 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 functional 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.

There is a possibility available to lock the database and to enter a log-in PIN if the language is set to English. Enter the Patient List and select New Patient by pressing the New Patient button (15). Select Log-In On by pressing the functional button Log-In On/Off (15). A screen will appear to set your personal four digit log-in PIN. Select four numbers between 0 and 9 by the level dial and enter each by pressing the STIM bar (2) and confirm your personal log-in PIN by pressing the button Set (9). Remember the PIN very well otherwise it is not possible to enter the patient list anymore! Each time you enter the patient list this PIN need to be entered by selecting the digit by the level dial and entering it by pressing the STIM bar (2).

Enter the New Patient screen and select Log-In Off by button (15) to switch off the patient list log-in.

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 dBHL 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 functional button (17) and press the Print (13) button to printout the results.

Store Results as a PDF

Enter the user Menu by pressing the functional 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 functional 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.

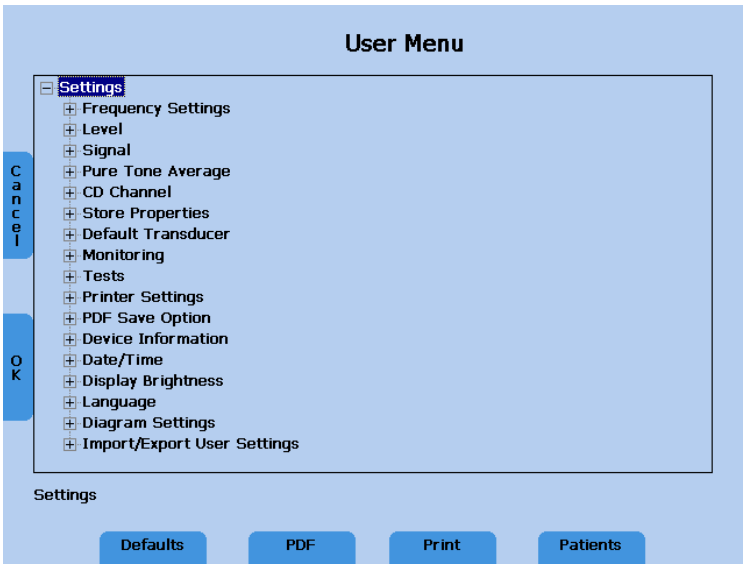


Figure 14 - User Menu Screen

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.

These menu items are available:

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
	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 Set up 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:

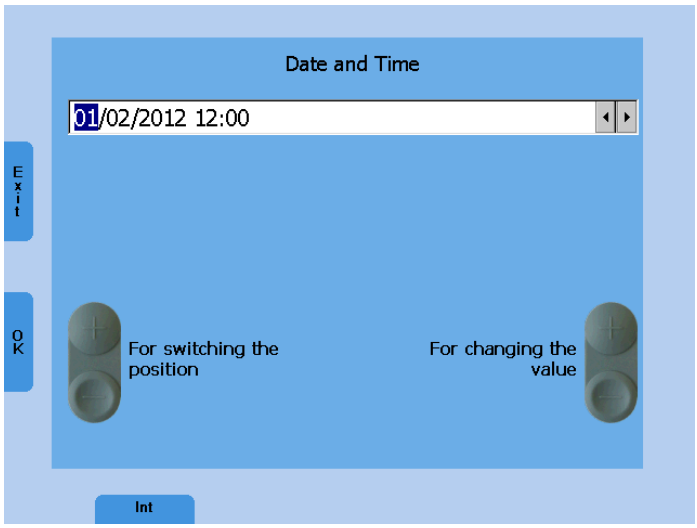


Figure 15 - Date and Time Settings

Set the date format to International or US by the functional 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 functional 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 functional button OK (7).

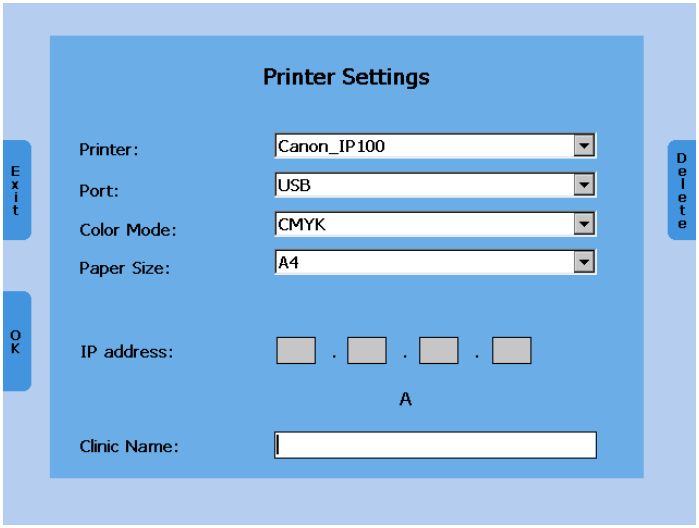


Figure 16 - Printer Settings

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 functional button OK (7).

8 Disinfection

It is recommended that parts which are in direct contact with the patient (e.g. earphone cushions or patient response switch) be disinfected between patients. This includes physically wiping down the equipment which comes in contact with the patient using a recognized disinfectant. Individual manufacturer's instruction should be followed for use of this disinfecting agent to provide an appropriate level of cleanliness. If ear cushions are contaminated, it is strongly recommended that you remove them from the transducer before they are cleaned.

To avoid person-to-person cross contamination of communicable diseases, ear tips should only be used one time for insert earphones.

9 Activation of Optional Features

Optional features like the MHA or Patient Management can be activated by a license key. Contact your local MAICO dealer and provide the serial number of your audiometer to obtain the required license key.

After receiving the key, store it as text file with the name Key.txt on your SD memory card, then insert the card to the SD card slot of your MA 41 and switch it on. The feature will be activated automatically and the functionality will be available.

10 Device Update

Insert the SD memory card into your computer and copy the update file Maico MA 4x series.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.

11 Connection to the PC

Install the included software on your PC. 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 MA 4x 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.

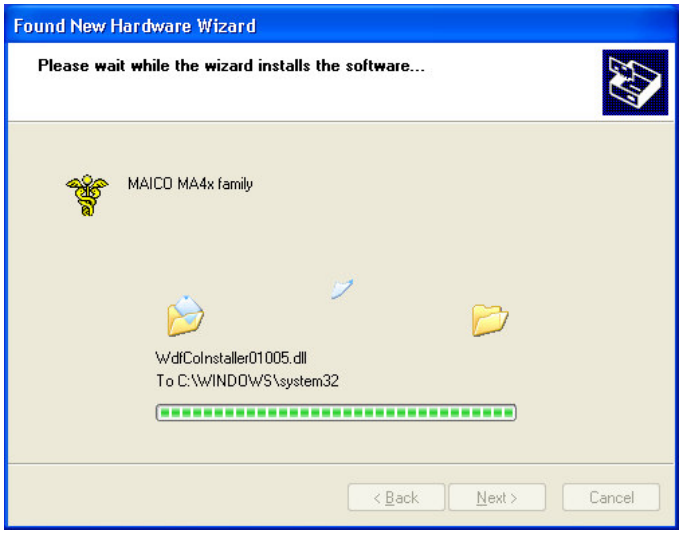


Figure 18 - Software Installation

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.

12 Technical Data

CE 0123 **The MA 41 audiometer is an active, diagnostic medical product according to the class IIa of the EU medical directive 93/42/EEC.**

Standards:	IEC60645-1 / EN 60645-1: Type 2
	IEC60645-2: Type B
	ANSI S3.6-1996 / ANSI S3.6-2010: Type 3 B
	ISO 389
	UL 60601-1 American Standards for Medical Electrical Equipment
	IEC/EN 60601-1 class I, protection class B, International Standards for Medical Electrical Equipment
	CAN/CSA C22.2 NO. 60601-1-08
	Medical Device Directive (MDD) to comply with "EC Directive" 93/42/EEC
Test Frequencies:	125 Hz – 8,000 Hz
Level Step:	5 dB, 2 dB or 1 dB level steps (user selectable)
Maximum Sound Pressure Level:	
AC with earphone DD45:	- 10 dB_{HL} to 120 dB_{HL}
BC with B71W Bone Conductor:	- 10 dB_{HL} to 80 dB_{HL}

Insert earphones Ear 3A:	- 10 dB_{HL} ... 120 dB_{HL}
Sound field speaker:	- 10 dB_{HL} ... 90 dB_{HL}, for CD 220
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)
Speech Signals:	External CD-Player, Microphone, Wave file from SD memory card
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:	Supported printers: HP (PCL 3 and PCL 5e) Epson (ESC/P2, LQ, Stylus Color) Canon (iP100, iP90, BubbleJet) USB keyboard
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°C / 59 - 95°F (operation) 5 - 50°C / 41 - 122°F (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

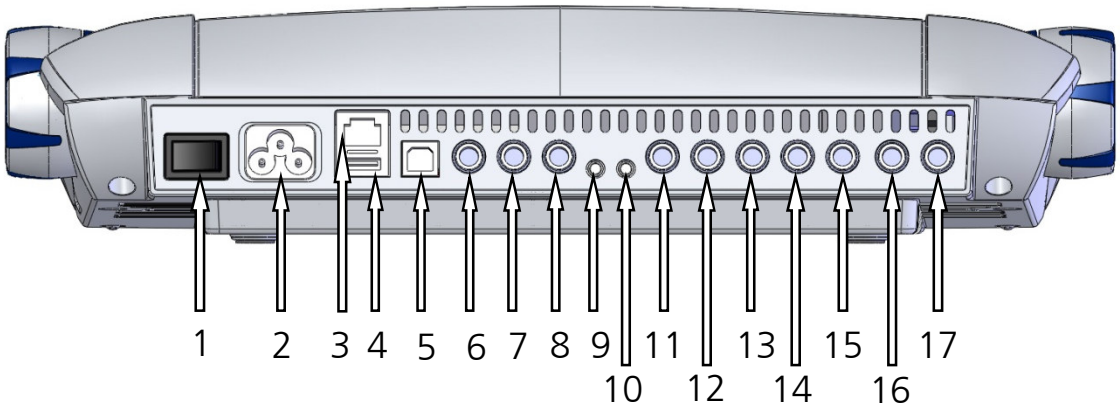


Figure 19 – Connection Sockets of the MA 41

Connection sockets		Specification
1	Power switch on/off	
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	RI= 500
7	Talk Back microphone	ZI= 1 k , UI= 0.38 - 500 mVeff
8	Microphone	ZI= 1 k , UI= 0.38 - 500 mVeff
9	Monitor phone	ZA= 250 , UA= 8 Veff
10	CD Input	ZI= 47 k , UI= 0.04 - 5 Veff
11	Speaker left	ZA= 4 , UA= 8 Veff
12	Speaker right	ZA= 4 , UA= 8 Veff
13	Bone (bone conductor)	ZA= 4 , UA= 8 Veff
14	Insert phone left	ZA=10 , UA=1 Veff
15	Insert phone right	ZA=10 , UA=1 Veff
16	Phone left (headphone)	ZA=10 , UA=1 Veff
17	Phone right (headphone)	ZA=10 , UA=1 Veff

Standard Accessories:

Items	Item Number
MA 41 audiometer includes:	8013739
DD45 headphones	88010880
B71W bone conductor	8102514
Patient response switch	8011091
Power cable	8011237
Gooseneck microphone	8006479
SD memory card (2 GB)	8010775

Optional Accessories:

Item	Item Number
HDA300 headphones	8103867
HOLMCO 8103 headphones	8010878
TDH39 headphones	8010806
Ear 3A insert phones	8010959
Canton CD220 speaker (single unit)	8110906
Cable for Canton CD 220	8004229
SBC speakers	8111951
Monitor headset with microphone	8010870
Single ear monitor phone	8111857
USB cable	8011241
Carrying case	8100797
Sound room patch cords	8111839
Talk-back microphone	8011233
NOAH audiometry module	8112043
MHA License	8110670

13 Warranty, Maintenance and After-Sales Service

The MAICO MA 41 is guaranteed for 2 years.

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 two years 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 by yourself or commissioning non-experts to do so.

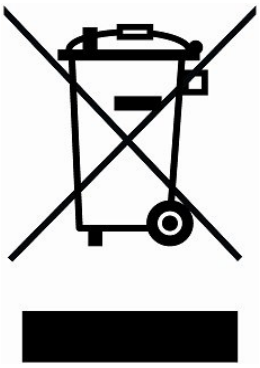
Do not modify this equipment without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

WARNING: No modification of this equipment is allowed.

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 has to be carried out by your dealer.

When returning the instrument for repairs it is essential to send the headphones and bone conductor, as well. Send the device to your dealer or to a service center authorized by your dealer. Please include a detailed description of faults. In order to prevent damage in transit, please use the original packing if possible when returning 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

READ THIS ENTIRE MANUAL BEFORE ATTEMPTING TO USE THIS SYSTEM.

14.1 Electrical Safety

The MA 41 audiometer is constructed to comply with protection class I of the international standard IEC 601-1 (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. Use the device only in an electrostatic 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).

Appendix A: Checklist for subjective audiometer testing

- Clean the ear and head cushion! - Untangle all lines when necessary! - Are the headphone cushions in good condition? If not → replace. - Are plugs and leads in good condition/ undamaged? - Are all controls working properly? - Is the Patient Response Key working properly (if available)? - Check batteries and renew if necessary!	Instrument:..... Manufacturer:..... Serial No.:..... Examiner:.....

Test Signal Quality

All the test frequencies in the below table indicate typical hearing level and can be changed when necessary:
Masking: "B" for Buzz tone, "G" for Noise, "V" for signal distortion, "S" for switching masking noise.

	Right Ear								Level	Left Ear								
kHz	0,25	0,5	1	2	3	4	6	8		0,25	0,5	1	2	3	4	6	8	kHz
AC									30 dB_{HL}									
									50 dB_{HL}									
									70 dB_{HL}									
BC									30 dB_{HL}									
									50 dB_{HL}									

* When noise "B", "G", "V" or "S" is blocked, inform the service center!
* When the test tone is heard at the masking ear, contact the service center!

Air Conduction Audiogram

	Right Ear								Level	Left Ear								
kHz	0,25	0,5	1	2	3	4	6	8		0,25	0,5	1	2	3	4	6	8	kHz
									Should dB_{HL}*									
Left Earpiece									Is dB_{HL}									Left Earpiece
Right Earpiece **									Is dB_{HL}									Right Earpiece **

* Should is the last measurement of the patient
**For inverted measurement please reattach the headphone
If the frequency difference between „Should" and „Is" for one ear averages more than 10 dB, contact the SERVICE CENTER!

Bone Conduction Audiogram

	Right Ear								Level	Left Ear								
kHz	0,25	0,5	1	2	3	4	6	8		0,25	0,5	1	2	3	4	6	8	kHz
									Should dB_{HL}*									
									Is dB_{HL}									

If the frequency difference between „Should" and „Is" for one ear averages more than 10 dB, contact the SERVICE CENTER!

Tested..... Date.....

Appendix B: Calibration values and maximum levels

Headphone DD45 with Coupler IEC 60318-3, Force 4-5 N, ANSI and IEC

Frequency Hz	Tone RETSPL dB re 20µPa	NBN RETSPL dB re 20µPa	Max Tone dB_{HL}	Max NBN dB_{HL}
125	47.5	51.5	90	75
250	27.0	31.0	110	95
500	13.0	17.0	120	110
750	6.5	11.5	120	110
1000	6.0	12.0	120	110
1500	8.0	14.0	120	110
2000	8.0	14.0	120	110
3000	8.0	14.0	120	110
4000	9.0	14.0	120	110
6000	20.5	25.5	120	110
8000	12.0	17.0	110	100

Signal	IEC60645-2 RETSPL	IEC Max Level dBHL	ANSI S3.6 RETSPL	ANSI Max Level dBHL
Speech	20.0	110	18.5	100
SN	20.0	110	18.5	100

Headphone TDH39 withCoupler IEC 60318-3, Force 4-5 N, ANSI and IEC

Frequency Hz	Tone RETSPL dB re 20µPa	NBN RETSPL dB re 20µPa	Max Tone dB_{HL}	Max NBN dB_{HL}
125	45.0	49.0	90	75
250	25.5	29.5	110	95
500	11.5	15.5	120	110
750	7.5	12.5	120	110
1000	7.0	13.0	120	110
1500	6.5	12.5	120	110
2000	9.0	15.0	120	110
3000	10.0	16.0	120	110
4000	9.5	14.5	120	110
6000	15.5	20.5	120	110
8000	13.0	18.0	110	100

Signal	IEC60645-2 RETSPL	IEC Max Level dB_{HL}	ANSI S3.6 RETSPL	ANSI Max Level dB_{HL}
Speech	20.0	110	19.5	110
SN	20.0	110	19.5	110
WN	0.0	110	0.0	110

Headphone Holmco 8103 with Coupler IEC 60318-3, Force 4-5 N, ANSI and IEC

Frequency Hz	Tone RETSPL dB re 20µPa	NBN RETSPL dB re 20µPa	Max Tone dB_{HL}	Max NBN dB_{HL}
125	39.5	43.5	90	80
250	25.0	29.0	105	95
500	18.5	22.5	110	100
750	13.5	18.5	120	105
1000	12.0	18.0	120	110
1500	10.0	16.0	120	110
2000	9.5	15.5	120	110
3000	9.0	15.0	115	110
4000	9.0	14.0	110	110
6000	19.5	24.5	100	110
8000	20.0	25.0	100	110

Signal	IEC60645-2 RETSPL dB_{SPL}	IEC Max Level dB_{HL}	ANSI S3.6 RETSPL dB_{SPL}	ANSI Max Level dB_{HL}
Speech	20.0	110	24.5	110
SN	20.0	110	24.5	110
WN	0.0	110	0.00	110

Headphone HDA 300/ Ear simulator IEC60318-1 with adapter,
Force 8.8 N ± 0.5 N, ANSI and IEC

Frequency Hz	Tone RETSPL dB_{SPL}	NBN RETSPL dB_{SPL}	Max Tone dB_{HL}	Max NBN dB_{HL}
125	27.0	31.0	115	80
250	20.0	24.0	120	90
500	8.0	12.0	120	100
750	4.5	9.5	120	100
1000	2.0	8.0	120	105
1500	3.0	9.0	120	105
2000	0.0	6.0	120	105
3000	-3.0	3.0	120	110
4000	-0.5	4.5	120	110
6000	21.0	26.0	110	95
8000	23.0	28.0	110	95
9000	27.5	32.5	100	90
10000	18.0	23.0	105	95
11200	22.0	27.0	105	90
12500	27.0	32.0	100	85
14000	33.5	38.5	90	75
16000	45.5	50.5	75	60
18000*	83.0	88.0	35	20
20000*	105.0	110.0	10	0

*Calibration values for 18 kHz and 20 kHz are not covered by the norm ISO389-5 and defined by MAICO Diagnostic GmbH

Signal	IEC60645-2 RETSPL	IEC Max Level dB_{HL}	ANSI S3.6 RETSPL	ANSI Max Level dB_{HL}
Speech	20.0	95	18.0	100
SN	20.0	90	18.0	95
WN	0.0	115	0.0	115

Insert phone Eartone 3A
Reference equivalent threshold sound pressure level

Frequency Hz	Tone IEC 60318-5 RETSPL dB re 20µPa	NBN IEC 60318-5 RETSPL dB re 20µPa	Tone Max Level dB_{HL}	NBN Max Level dB_{HL}	sound damping dB
125	26.0	30.0	90	90	32.5
250	14.0	18.0	105	105	36
500	5.5	9.5	110	110	37.5
750	2.0	7.0	115	110	-
1000	0.0	6.0	120	110	36.5
1500	2.0	8.0	120	110	-
2000	3.0	9.0	120	110	33
3000	3.5	9.5	120	110	-
4000	5.5	10.5	115	110	39.5
6000	2.0	7.0	100	100	-
8000	-1.0	4.0	95	95	42.5

Signal	IEC60645-2 RETSPL	IEC Max Level dB_{HL}	ANSI S3.6 RETSPL	ANSI Max Level dB_{HL}
Speech	20.0	100	12.5	100
SN	20.0	100	12.5	100
WN	0.0	100	0.0	100

Bone conductor Radioear B71W Force: 4.9 ... 5.9 N, ANSI and IEC
Mastoid placement

Frequency Hz	Reference equivalent threshold force level for tone		Air radiation	Max level
	ISO 389 - 3 dB (re 1□N)	ANSI S3.6 dB (re 1□N)	mean/max dB	Tone dB_{HL}
250	67	67	-	45
500	58	58	-	60
750	48.5	48.5	-	70
1000	42.5	42.5	-	70
1500	36.5	36.5	-	70
2000	31	31	-	75
3000	30	30	4 / 18	80
4000	35.5	35.5	-	80
6000	40	40	10.5 / 31	50
8000	40	40	-	50

Signal	IEC60645-2 RETSPL	IEC Max Level dB_{HL}	ANSI S3.6 RETSPL	ANSI Max Level dB_{HL}
Speech	35.00	75	55.00	75
SN	35.00	75	55.00	75

Sound field (0 degree incidence)
Reference equivalent threshold sound pressure level and maximum hearing levels
For Canton CD 220 / Maico SBC speaker
ISO 389 – 7 and ANSI S3.6-1996

Frequency Hz	Tone RETSPL dB_{SPL}	NBN RETSPL dB_{SPL}	Max level Tone dB_{HL} CD220 / SBC	Max level NBN dB_{HL} CD220 / SBC
125	22.0	22.0	65 / -	55 / -
250	11.0	11.0	75 / -	70 / -
500	4.0	4.0	85 / 85	75 / 75
750	2.0	2.0	85 / 85	75 / 75
1000	2.0	2.0	85 / 85	75 / 75
1500	0.5	0.5	90 / 85	80 / 75
2000	-1.5	-1.5	90 / 85	85 / 75
3000	-6.0	-6.0	90 / 90	85 / 80
4000	-6.5	-6.5	95 / 90	85 / 80
6000	2.5	2.5	85 / 90	80 / 80
8000	11.5	11.5	80 / 75	70 / 65

Signal	IEC60645-2 RETSPL dB_{SPL}	IEC Max Level dB_{HL} CD220 / SBC	ANSI S3.6 RETSPL dB_{SPL}	ANSI Max Level dB_{HL} CD220 / SBC
Speech	0.0	90 / 80	14.5	90 / 80
SN	0.0	90 / 75	14.5	90 / 75
WN	0.0	90 / 75	0.0	90 / 75

Specifications are subject to change without notice.

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