Operation Manual
MA 41

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Compliance

MAICO Diagnostics is an ISO 13485 certified corporation.

Caution for USA: Federal Law restricts this device to sale by or on the order of a licensed medical professional.

Trademark Notice

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1 Introduction

This section offers you important information about:

- **the intended use of the device**
- **indications and contraindications of use**
- **essential performance**
- **features and benefits**
- **a description of the device**

1.1 General

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 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

1.2 Intended Use Statement

The MA 41 is a portable or stand-alone 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 / ISO 8253-1 or equivalent.

1.3 Indications for Use Statement

The MA 41 is a portable one and half channel air, bone, and speech audiometer. This audiometer is used to screen, test, and diagnose hearing loss.

1.4 Contraindications of Use Statement

The patient is too young, sick or uncooperative to perform the tasks.

1.5 Essential Performance

The following is considered essential performance:

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

1.6 Description

The MA 41 is a portable one and half channel audiometer with pure tone and speech testing. Additionally, it has limited special audiology test function which include 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 in clinics and abroad.

The MA 41 audiometer delivers 11 air conduction (AC) test frequencies from 125 Hz to 8 kHz, with transducer dependent 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 included bone oscillator). 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 headphones, bone conduction oscillator, configuration dependent insert phones and 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, configuration dependent insert phones and sound field speakers.

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

Results can be printed directly via a 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.

The speaker outputs are used with the internal amplifies. For use with an external amplifier or active speaker, contact your authorized service center to change to line output levels.

2 For your Safety

This section offers you important information about:

- **how to read the operation manual**
- **where to spend special attention**
- **the customer responsibility**
- **the explanation of all regulatory symbols used**
- **important cautions and warnings that have to be considered during the whole time handling and operating your device**

2.1 How to read this Operation Manual

This Operation Manual contains information pertinent to the use of the MAICO device system including safety information as well as maintenance and cleaning recommendations.

READ THIS ENTIRE MANUAL BEFORE ATTEMPTING TO USE THIS SYSTEM!

Use this device only as described in this manual.

All images and screenshots are only examples and may differ in appearance from the actual device settings.

In this manual, the following two labels identify potentially dangerous or destructive conditions and procedures:

The WARNING label identifies conditions or practices that may present danger to the patient and/or user.

The CAUTION label identifies conditions or practices that could result in damage to the equipment

NOTE: Notes help you identify areas of possible confusion and avoid potential problems during system operation.

2.2 Customer Responsibility

All safety precautions given in this operation manual must be observed at all times. Failure to observe these precautions could result in damage to the equipment and injury to the operator or subject.

The employer should instruct each employee in the recognition and avoidance of unsafe conditions and the regulations applicable to his or her work environment to control or eliminate any hazards or other exposure to illness or injury.

It is understood that safety rules within individual organizations vary. If a conflict exists between the material contained in this manual and the rules of the organization using this instrument, the more stringent rules should take precedence.

This product and its components performs reliably only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and/or inserts. A defective product should not be used. Make sure all connections to external accessories are snug and secured properly. Parts which may be broken or missing or are visibly worn, distorted, or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from MAICO.

NOTE: Customer responsibility includes proper maintenance and cleaning of the device (see Sections 3.2 and 3.3). Breach of the customer responsibility can lead to limitations of Manufacturer's Liability and Warranty (see Sections 2.3 and 3.1).

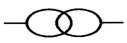
2.3 Manufacturer's Liability

Usage of the device in a way deviant from the intended use leads to a limitation or termination of the manufacturer's liability in case of damage. Improper use includes disregarding the operation manual, the operation of the device by underqualified personnel as well as making unauthorized alterations on the device.

2.4 Regulatory Symbols

The following Table 1 gives an explanation of the symbols used on the device itself, on the packaging and the accompanying documents including the Operation Manual.

Table 1 Regulatory Symbols

REGULATORY SYMBOLS SYMBOL	DESCRIPTION
SN	Serial number
	Date of manufacture
	Manufacturer
	Caution, consult accompanying documents
	Warning, consult accompanying documents
	Return to authorized representative, special disposal required
REF	Reference number
	Patient applied part type B according to IEC 60601-1
	Refer to instruction manual (mandatory)
	Keep away from rain
	Transport and storage temperature range
	Transport and storage humidity limitations
	Voltage transformer
	Electrostatic sensitive devices
	Do not reuse
REP	Authorized representative
	Conforms to European Medical Device Directive 93/42/EEC
	ETL listed mark
MAICO	Logo

2.5 General Precautions

Before starting a measurement make sure, that the device works properly.
Use and store the instrument indoors only. For operation, storage and transport conditions see Table in Section 6 Technical Data.
For operation in certain places, a recalibration may be necessary.

No modification of this equipment is allowed.
Do not drop or otherwise cause undue impact to this device. If the instrument is dropped or otherwise damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.

Calibration of the instrument: The audiometer and the headphone complement each other and share the same serial number (i.e. 7663252). Therefore, the instrument shall not be used with any other headphone prior to recalibration. Recalibration also needs to be conducted, when a defected headphone is replaced.
Uncalibrated instruments may lead to faulty measurements and sometimes even damage the hearing of the examinee.

2.6 Electrical Safety and Measuring Security

This icon indicates that patient applied parts of the instrument conform to IEC 60601-1 Type B requirements.

In Case of Emergency

In case of emergency, disconnect the instrument from the computer.

In Case of Emergency

In case of emergency, disconnect the instrument from power supply.

Do not position the instrument in a way that it is difficult to operate the disconnection device. The supply mains and the power socket shall be accessible at all times.

Do not use the instrument if the mains cable and/or the outlet is damaged.

To transfer data to a PC, establishing a PC-connection via USB is required. See Section 4.2.4 on how to safely establish a connection with a power supplied PC or laptop (medical device/non-medical device) or to a battery-driven laptop.

This equipment is intended to be connected to other equipment thus forming a Medical Electrical System. External equipment intended for connection to signal input, signal output or other connectors shall comply with the relevant product standard e.g. IEC 60950-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations – Medical Electrical Systems – shall comply with the safety requirements stated the general standard IEC 60601-1, edition 3, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support or shall be supplied via a separation transformer to reduce the leakage currents. Any person who connects external equipment to signal input, signal output or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements. If in doubt, contact qualified medical technician or your local representative. If the instrument is connect to a PC (IT equipment forming a system) ensure not to touch the patient while operating the PC.

If the instrument is connected to a PC (IT equipment forming a system) assembly and modifications shall be evaluated by qualified medical technician according to safety regulations in IEC 60601.

The instrument is not intended for operation in areas with an explosion hazard.

Never short-circuit the terminals.

In order to maintain a high level of safety and to ensure the instrument works properly, it is necessary to have the instrument and its power supply checked according to the medical electrical safety standard IEC 60601-1 by a qualified service technician at least once a year. For more information see Section 3.

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

Prevent cable breakage: cables must not be bend or buckled.

2.7 Device Control

The user of the device should perform a subjective device check once a week according ISO 8253-1. See Section 6.7 for a checklist.

For annual calibration please see Sections 2.6 and 3.1.

2.8 Electromagnetic Compatibility (EMC)

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.

The instrument fulfills the relevant EMC requirements. 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.

Please also refer to EMC consideration in Section 6.5.

3 Warranty, Maintenance and After-Sales Service

This section offers you important information about:

- **warranty conditions**
- **maintenance**
- **cleaning and disinfection recommendations**
- **accessory and replacement parts**
- **recycling and disposal of the device**

3.1 Warranty

The MAICO device is guaranteed for at least one year. Ask your authorized local distributor for more information.

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 at least one year from date of delivery of the instrument to the original purchaser.

The device shall only be repaired and serviced by your distributor or by an authorized service center. Opening the instrument case will void the warranty.

No modification of this equipment is allowed.

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

3.2 Maintenance

In order to ensure that the instrument works properly, it has to be checked and calibrated at least once a year.

The service and calibration must be performed by your dealer or to a service center authorized by MAICO.

When returning the instrument for repairs or calibration it is essential to send the acoustic transducers with the device. Please include a detailed description of faults. In order to prevent damage in transit, please use the original packing when returning the instrument.

3.3 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.

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 device 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.

Do not use hard or pointed objects on the device or its accessories

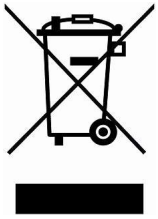
Use 70 % isopropyl alcohol only on hard cover surfaces

Discard single-use equipment after use! In case of re-use of the single-use equipment you enhance the risk of cross contamination!

3.4 Accessories and Replacement Parts

Some reusable components are subject to wear with use over time. MAICO recommends that you keep these replacement parts available (as appropriate for your MA 41 device configuration). Ask your authorized local distributor when accessories need to be replaced.

3.5 Recycling and Disposal



Within the European Union it is illegal to dispose of 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 to legal regulations to our customers.

Non-European countries Outside the European Union, local regulations should be followed when disposing of the product after its useful life.

4 Unpacking and Hardware Orientation

This section provides information on:

- **unpacking the device**
- **components**
- **becoming familiar with the hardware inclusive connections**
- **how to store the device**
- **rear panel**

4.1 Unpacking the System

Check Box and Contents for Damage

- It is recommended that you unpack your MA 41 carefully making sure that all components are removed from the packing materials.
- Verify that all components are included as shown on the packing list included with your shipment.
- If any component is missing, contact your distributor immediately to report the shortage.
- If any component appears to be damaged in shipment, contact your distributor immediately to report it. Do not attempt to use any component or device that appears to be damaged.

Reporting Imperfections

Notify the carrier immediately if any mechanical damage is noted. This will insure that a proper claim is made. Save all packaging material so the claim adjuster can inspect it as well.

Report Immediately any Faults

Any missing part or malfunction should be reported immediately to the supplier of the device together with the invoice, serial number, and a detailed report of the problem.

Keep Packaging for Future Shipment

Save all the original packing material and the shipping container so the device can be properly packed if it needs to be returned for service or calibration (see Section 3.2).

The availability of configurations with the following components is country specific. Contact your local distributor for more information.

Components
DD45 Headphones *
TDH39 Headphones *
DD450 Headphones for high frequency audiometry (with High Tone License) *
B71 Bone Conductor *
B81 Bone Conductor *
BKH10 Bone Conductor with contra masking phone *
Holmco 8103 Headphones *
IP30 Insert Phones *
Canton CD220 Free Field Speaker *
Cable for Canton CD220 Free Field Speaker
Patient Response Switch
Carrying Case
Gooseneck Microphone
USB Cable
USB Flash Drive
SD Memory Card (2 GB)
Sennheiser PC 131 Headset for monitoring and talk forward
Stereo Adaptor, 1/8” to 1/4”
Monitor Phone for examiner
Talk-Back Microphone
Sound Room Patch Cords (single)
Sound Room Kit
CD Player incl. power supply and connecting cable
Operation Manual
Quick Guide

*** Calibration required**

4.2 Hardware Orientation

4.2.1 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.

Electronic devices, which emit strong electromagnetic fields (e.g. microwaves or radiotherapy devices), can influence the function of the audiometer. Therefore, it is not recommended to use these devices 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 device 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.

External devices such as a computer, printer or Ethernet which are connected to the device must meet electrical safety requirements, such as IEC 60601-1 or UL 60601-1. This is to avoid electrical shock to the user or the patient. See Section 2 for more information

4.2.2 MA 41 Device

The ergonomic design of the MA 41 makes it easy to control the hearing level, signal presentation, and frequency adjustments with one hand.

Figure 1

4.2.3 Rear Panel Connections

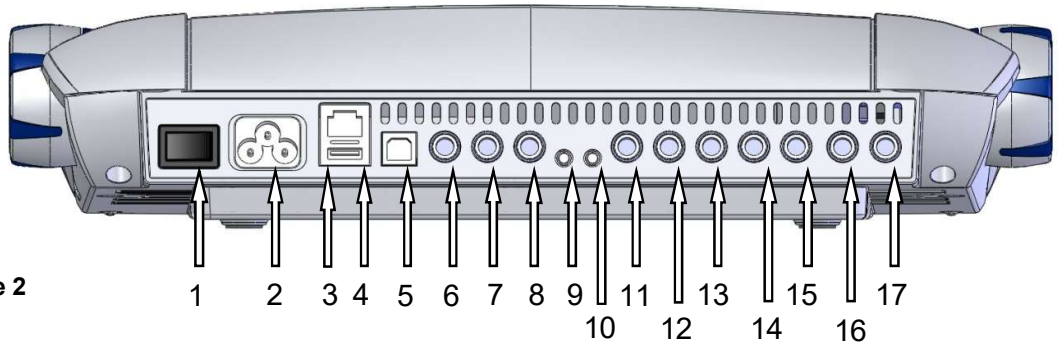


Figure 2

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: Mon - monitor phone output socket	

4.2.4 Establishing a Connection to a PC, USB Printer or CD Player

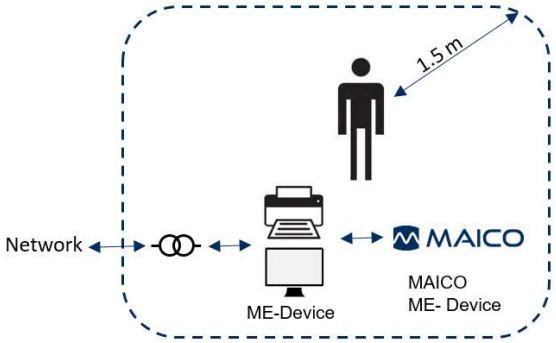
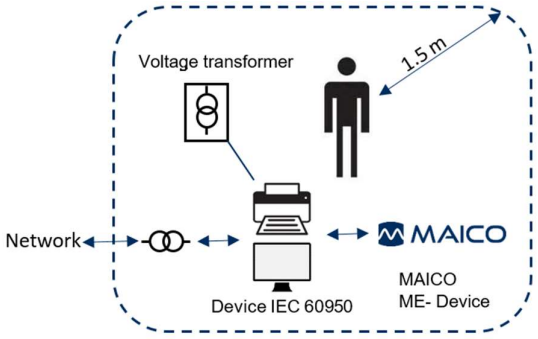
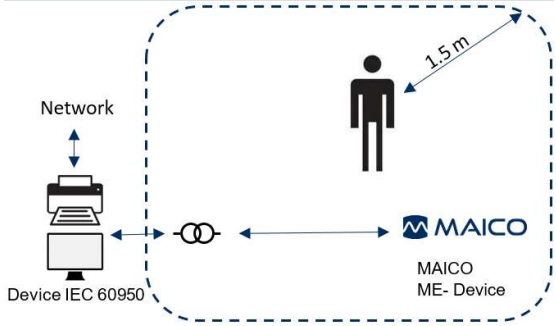
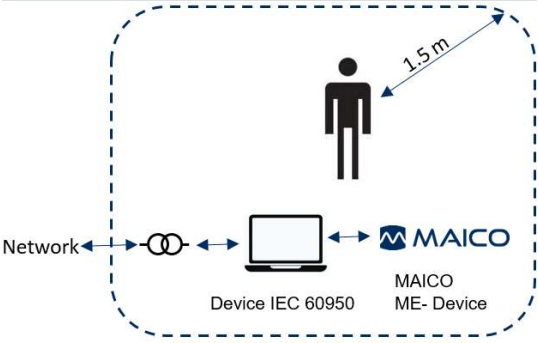
To transfer data to a PC, establishing a PC connection via USB is required. If the MA 41 is used with office equipment that is not a medical device itself (see Table 2, PC Connection 1), make sure to establish the PC connection in one of the following ways (see Table 2, PC Connection 2, 3 or 4).

In case a CD player shall be connected proceed accordingly to PC Connection 3 (if used with a CD player with power supply) or 4 (if used with a battery driven CD player).

WARNING

Make sure you use only office equipment with the device that is a medical device itself or meets the requirements of IEC 60950. If a non-medical device is used within the patient environment (1.5 m from patient as defined in IEC 60601) a voltage transformer must be used (exception: a battery driven laptop is used).

Table 2 PC-Connections

PC CONNECTIONS	
PC Connection 1: Medical device – Medical device	PC Connection 2: Medical device – Non-Medical device
	
PC Connection 3: Medical device – Non-Medical device	PC Connection 4: Medical device – Laptop (battery-driven)
	

4.2.5 Storage

When the MA 41 is not in use, store it in a location where it will be safe from damage to the screen or other sensitive components such as the acoustic transducers and cables. Store according to the recommended temperature conditions described in Section 6.1.

5 Operating the Device

This section offers you information about:

- **how to get started with the MA 41**
- **the device layout**
- **the function keys**
- **performing the measurement methods of Audiometry**
- **patient management**
- **documentation of results**
- **changing settings in the user menu**

5.1 Getting started with the MA 41

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 in Section 4.2.3. Plug the power cord into a grounded outlet.

Turn On: The device can be turned on with the power switch, which is located on the rear panel of the MA 41.

NOTE: A device should always be off when inserting or removing an accessory from the rear panel connectors.

The device performs its initialization and boot up. Please wait until the test screen appears, this can take up to 90 seconds. If an error is detected the startup is stopped and a description of the error is shown on the display. In this case please contact your local dealer for service.

Turn Off: 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.

5.2 Functionality of Operating Elements

The main functions of the MA 41 are directly accessible by using the Function buttons which are located around the display (see Figure 3). As the buttons have changing functionality, the actual function of each button is shown in the blue boxes on the screen above the button.

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

Figure 3

(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: changes 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: changes 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) Function button: 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/TALK button: 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 (NR), 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: Select test for selected receiver, either the pure tone threshold, Hearing Level (HL), Most Comfortable Loudness (MCL), 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), MCL, 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. 

).

5.3 The Display of the MA 41

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

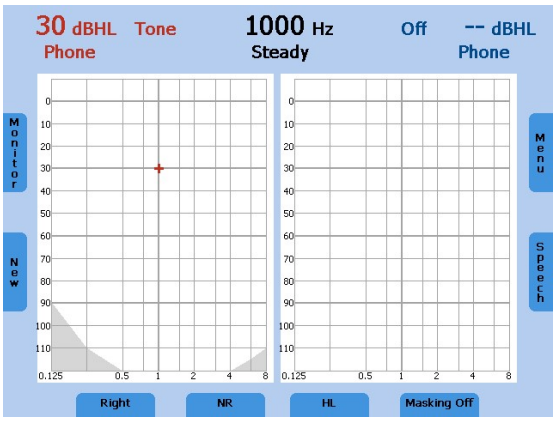


Figure 4

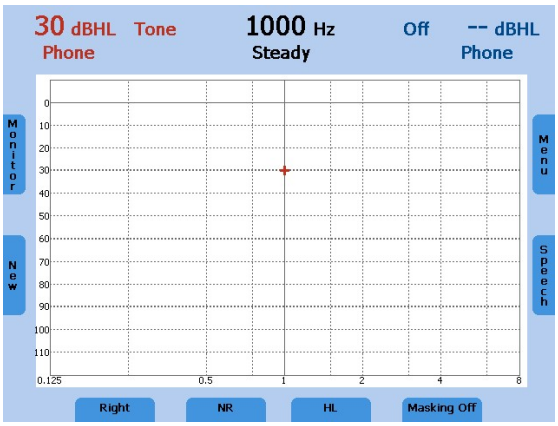


Figure 5

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.

NOTE: Once the default settings are changed, the device applies the new settings.

Reset the device to return to the default settings.

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

5.4 Measurement Methods of Audiometry

The patient should sit at a distance of at least 1 m from the device.

Remove any obstructions that interferes 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 side is over the right ear and the blue side 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 clean and disinfect the ear cushions on the headphone between patients (see Section 3.3).

5.4.1 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 device.

- Air conduction testing
- Bone conduction testing
- Sound field testing
- Uncomfortable Loudness (UCL)
- Most Comfortable Loudness (MCL)
- Aided sound field thresholds (Aided)

5.4.1.1 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.

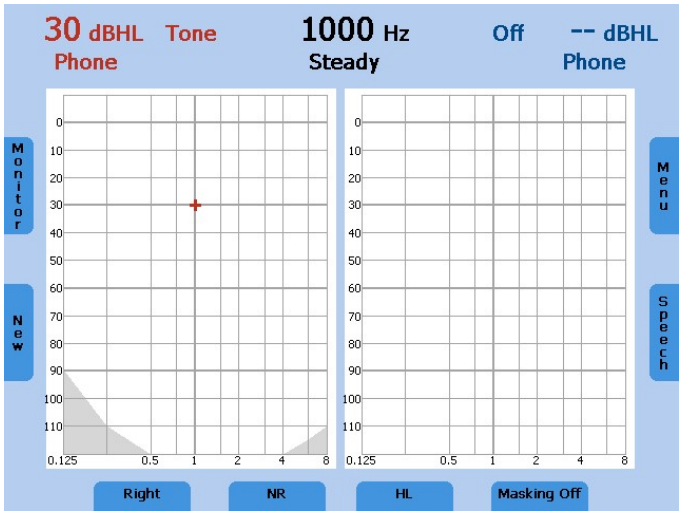


Figure 6

The default setting is that 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. 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 for selection.

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} level can be changed with the Level control dials on both sides (1) of the device.

Use the Frequency Up (4) or Down (5) keys to increase or decrease the frequency. Press the STIM button (the blue part next to the Level control dials) to present or interrupt the tone. The status LED for the Stimulus Mode button (8) illuminates 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 plots in the audiogram on the display.

To delete a stored test point, select the corresponding frequency and then press both frequency down keys (5) at the same time. The symbol of the stored test point disappears from the audiogram. Make sure, that the correct transducer and test type (HL, MCL or UCL) is selected before deleting.

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 is 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 is frequency modulated. The warble tone can also be pulsed as described above.

5.4.1.2 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 is 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 primary transducer established in the set-up menu.

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

).

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.

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

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

Automatic Masking

With the manual masking, as described above, 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 adjusts automatically to 65 dB_{HL}).

5.4.1.3 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 in the same way as described in the air conduction section above.

For hygienic reasons it is important to clean and disinfect the bone conduction oscillator after each patient (see Section 3.3).

5.4.1.4 Sound Field Testing (optional)

Set the Transducer selector (10) to Speaker. Perform the test in the same way as described in the air conduction section above.

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

5.4.1.5 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.

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.

5.4.1.6 Most Comfortable Loudness (MCL)

Testing of MCL can be measured using pure tone stimuli or speech. The purpose is to determine the most comfortable listening level for the patient for a given stimulus. The dB level at which the stimulus is the most comfortable is determined. This level might be described as the level at which the patient would be comfortable listening for an extended period of time. Press the test mode selector key (13) underneath the display and select MCL in order to test and store the Most Comfortable Loudness.

5.4.1.7 Stenger

The Stenger test is used to confirm the presence of pseudohypacusis. During this test, two tones of the same frequency are presented simultaneously to both ears, and only the louder tone is perceived. Select HL to perform the Stenger test and select both ears (9). Ask 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.

5.4.2 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 60601-1. 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.

5.4.2.1 Input Calibration

The MA 41 must be calibrated to the particular speech signal when CD or MIC is used to ensure valid test levels. That means every time you change the speech test CD you must recalibrate the device.

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 (Figure 8).

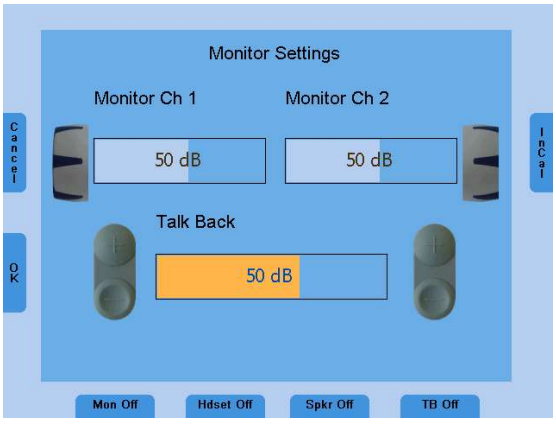


Figure 7

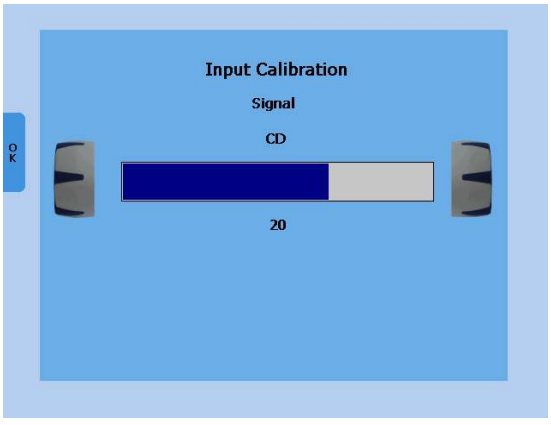


Figure 8

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 from 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 (19) 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.

NOTE: When multiple individuals use the device, input calibration is required when switching to a new user. The device does store that last input calibration for ease of use.

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

The Wave files included with the device have been pre-calibrated and no input calibration is required.

5.4.2.2 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 opens, the right ear is selected, and the level is set to the default value.

The Speech Recognition Threshold (SRT) is a test indicating the lowest level at which a 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.

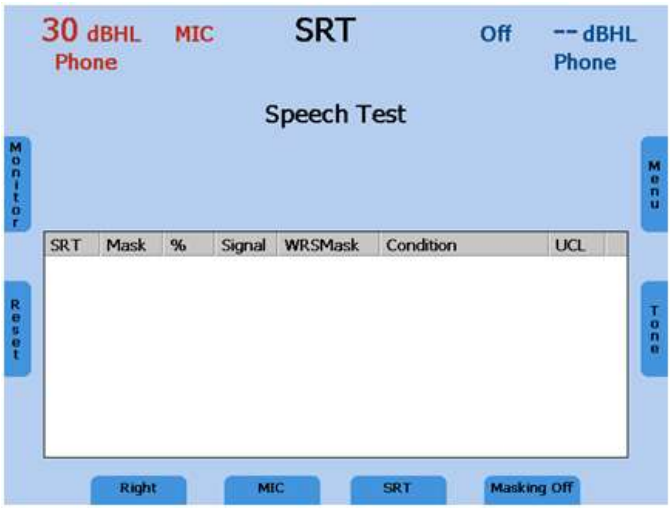


Figure 9

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.

5.4.2.3 Speech Audiometry with Microphone or CD player

Connect the microphone or CD player to the corresponding input (10) on the rear side of your MA 41. 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, MHA, MCL or UCL by 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 (7) on the left side of the display. If no counter is set, the Reset key (7) 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).

If MCL is selected, the level is increased until the patient indicates the level is comfortable to listen to. Store the value by pressing the Store button (3).

To delete a stored test result, select the corresponding level, then press both frequency down keys (5) at the same time. The test result disappears from the speech audiogram or table. Make sure, that the correct transducer and test type (SRT, WRS, MCL or UCL) is selected before deleting.

5.4.2.4 Speech Audiometry with Wave Files

If Wave is selected by the Speech Signal selector (11) a menu pops 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 is 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 device. Before starting the playback of the Wave files, the first word can be selected by the Frequency Up (4) and Down (5) buttons. 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, MCL 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 word list 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 is played back automatically. The correct word is displayed green, while incorrect word is displayed red. By pressing Repeat (7), the word is repeated. Once a Wave file has been selected, the intensity cannot be changed. Select the presentation level before selecting Play (7).

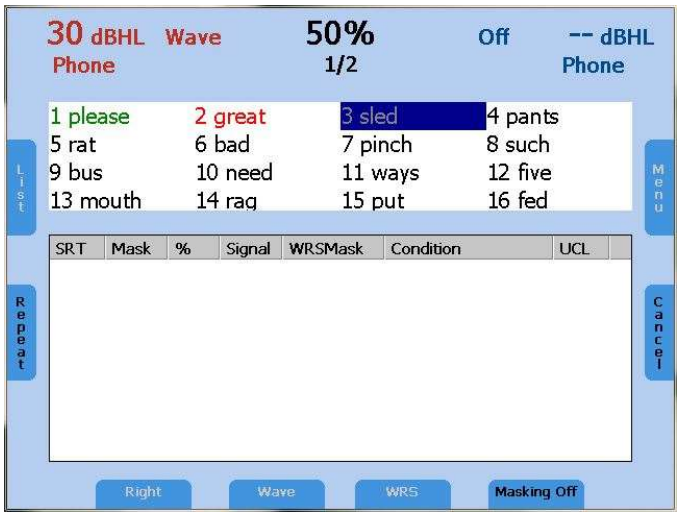


Figure 10

The percentage of the speech discrimination score is 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.

MCL and UCL measurements are best performed with the Passage Wave file included with the device. Select the ear for testing (9). Press the function button Play (7) to start the presentation to the patient. Rotate the Level control (1) to increase the volume until the patient reports this is uncomfortably loud. Press Store (3) to save the results.

5.4.2.5 Masking

Speech audiometry masking can be used as described in Section 5.4.1.1 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.

5.4.2.6 Speech in Noise Tests – QuickSIN® (configuration dependent)

Speech-in-noise test, the QuickSIN®, was developed to provide a quick estimate of signal-to-noise ratio (SNR) loss. Configuration dependent, this test is incorporated into the MA 41, with selection made in the speech testing screen under the Wave file lists (11) or (15). For more information refer to Etymotic Research's QuickSIN® Speech-in-Noise Test manual. MA 41 does not incorporate the entire QuickSIN® lists but provides Standard QuickSIN® lists 1-12 (i.e. Track 3-14 from the CD recording).

NOTE: Pre-calibration of the QuickSIN® lists was implemented into the recording and installation of the Wave files on the MA 41. No input calibration is required.

5.4.2.7 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). Press the Stimulus mode (8) indicator to alternate between signal sources like the microphone, CD or Wave file. When using Wave files begin testing by pressing the Play button (7) to play back the imbedded Wave files 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.

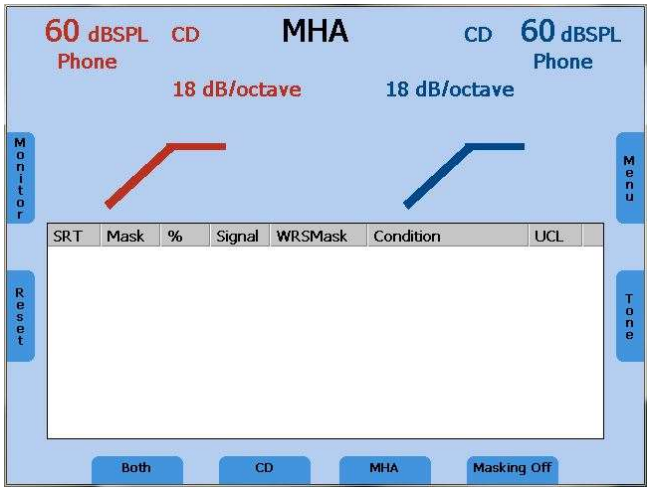


Figure 11

5.4.3 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 appears. The monitor level of the left and right channel can be adjusted with the corresponding Level control dial (1). Enable monitoring by pressing the function button Monitor (9), while Mic or CD is selected. The integrated speaker is switched on by pressing the button (13) and the external headset via the Function button (11). In order to hear the signal given to the patient, make sure to activate the monitoring (9).

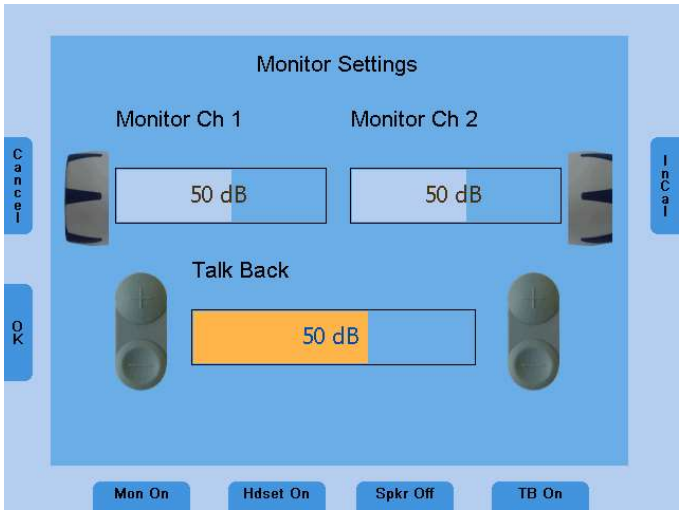


Figure 12

The talk back microphone is activated by the button (15) and its level adjusted by the Frequency Up (4) and Down (5) buttons.

5.4.4 Talk Forward

Connect the microphone headset (or optional gooseneck microphone) to the microphone socket (8) on the rear side of the device.

NOTE: Only connect the microphone when the unit is off.

To talk to the patient press and hold the STIM/TALK button (8) and speak into the microphone. Adjust the level by turning the left or right Level control (1) while pressing and holding the STIM/TALK button.

5.5 User Menu

The User Menu enables the user to customize the device to meet their specific needs. Additionally, the menu allows the user to print out 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.

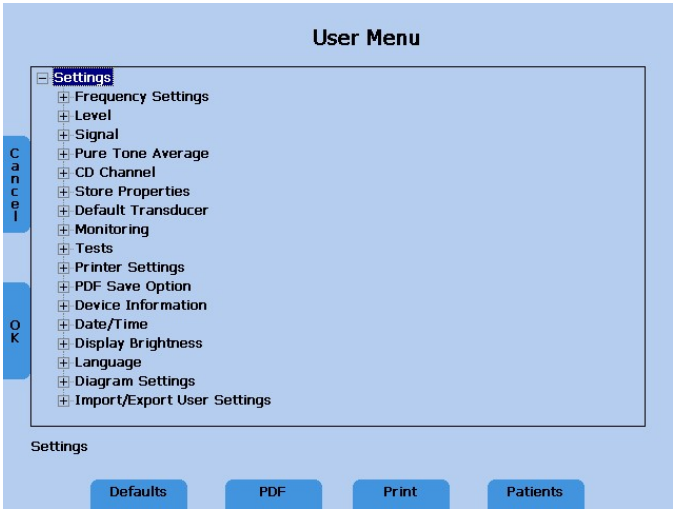


Figure 13

To choose an item from the menu use the Level control dials (1). A short description of the selected setting item are 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 changes 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:

Setup Menu		Description
Frequency Settings	Default Frequency	Default Frequency Set (On/Off): set default frequency to 1,000 Hz 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 is reached.
	Standard Frequencies	Select/Deselect single frequencies
Level	Default Level	On/Off: Set default level after changing signal type. Set Default Levels: Set the default level for tone, noise and speech signals.
	Level Steps	5 dB**;** 2 dB; 1 dB
	Inverse Dialing	Change effect on dialing an encoder: Dial Up / 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 L, Noise R - Test signal R, Noise L 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	Presenter: Signal is presented upon pushing the Stimulus button (2). Interrupter: Signal is stopped upon pushing the Stimulus button (2).
	Pulse	500 ms, slow pulsing 250 ms, fast pulsing

Setup Menu		Description
Pure Tone Average (PTA)		Select/Deselect frequencies for the calculation of the PTA value for the default transducer (500, 1000, 2000).
CD Channel	Select the CD Channel	Both / Channel A / Channel B
Store Properties	Change Frequency after Store	Next: Move to next test frequency after storing a threshold. Remain: Stay on same frequency after storing (Remain).
	Change Level after Store	Change the level after storing a threshold. Stay at the same test level (0 dB) or increase/decrease by (10, 20, or 30 dB).
Default Transducer	Selection of Default Transducer	Headphones (on) or Inserts (off)
Monitoring	Monitoring	Monitor Speech only or All Signals
Tests	Start Test	Tone/Speech defines test which is loaded 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 SD memory card
	Save on USB Flash Drive	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 % to 100 % by using the Level controls (1), store new value by pressing the Store button (3).
Language		English/Deutsch/Italiano/Français/ Español, etc. Language change requires a restart of the device.
Diagram Settings	Display in Speech Test	Diagram or Table
	Number of Diagrams in Tone Test	None: No audiogram displayed, only the level and frequency. One: one combined audiogram Two: two separate audiograms for left and right
	Bone Lines	On/Off, displays a dotted line, connecting the bone conduction results
	Symbol Setting	Int Symbols / US Symbols / UK Symbols / DE Symbols
Import/Export User Settings		Export User Settings to SD Card or Import User Settings from SD Card.

5.5.1 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 (2). The following screen appears:

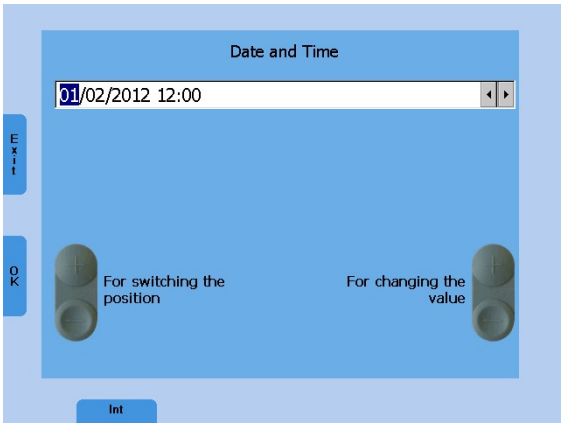


Figure 14

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 (1). Press the Function button OK (6) to store the changes or Exit (7) to leave the Date/Time setting screen without saving the changes.

5.5.2 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 (2) 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).

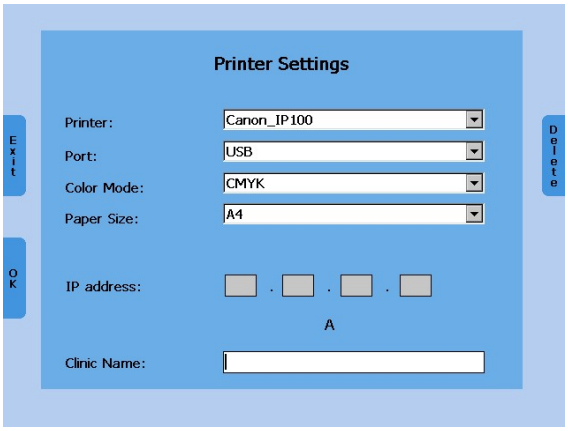


Figure 15

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

Enter the field clinic name by using the STIM button (2). Select letters by rotating the Level control (1) 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).

5.6 Managing Test Results

All stored results can be directly printed via a USB connected printer, saved as a PDF to the SD card or USB flash drive or stored internally to the Patient Management of the device.

To print to a 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 Section 5.5.2.

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.

NOTE: It is recommended using the USB flash drive for storing PDF results.

NOTE: Please refer to the Audiometry Module operation manual for transferring of results to the PC. This is located on the included CD and USB.

Before transferring data to a PC make sure that you have installed the PC software properly according to the separately delivered operation manual.

When the examination is complete, 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 print out 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 is created and stored on for further transfer to a PC or print out via a PC connected printer. Make sure that a SD memory card or USB flash drive is inserted in the appropriate slot (18).

After printing or creating a PDF you return automatically to the tone or speech test mode.

To store the results within the Patient Management, review Section 5.7.

5.7 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. The 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 entering to this list has been offered when the language is set to English. Enter the Patient List and select New Patient by pressing the New Patient button (15). Select Login On by pressing the functional button Login On/Off (15). A screen appears to set your personal four digit login PIN. Select four numbers between 0 and 9 by the level dial and enter each by pressing the STIM button (2) and confirm your personal login PIN by pressing the button OK (9).

Caution: 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 must be entered by selecting the digit by the Level control dial and entering it by pressing the STIM bar (2). Moving forward, the PIN is required to enter the patient list. To deactivate the PIN, select Login Off after following the same steps as listed above.

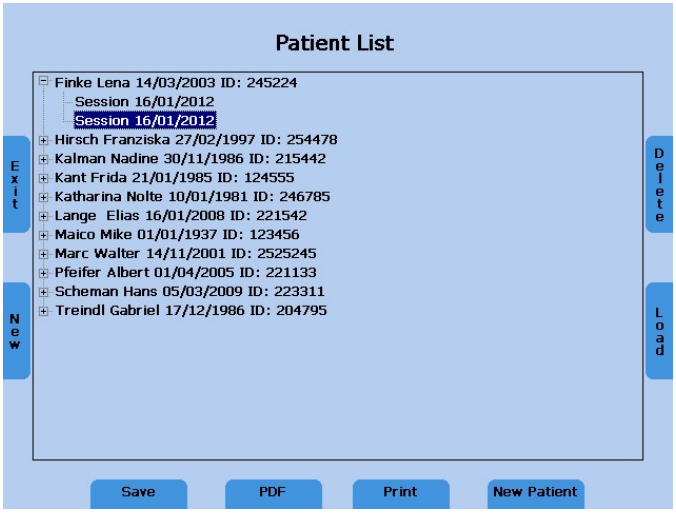


Figure 16

Select a patient using the Level controls (1) 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 is only included on the print out, 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, a patient with a new number is selected automatically. 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.

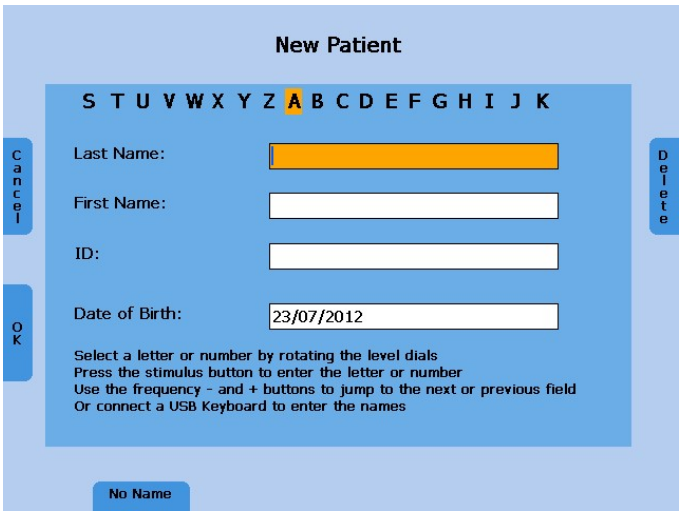


Figure 17

Enter the characters of the name by scrolling through the alphabet with the Level controls (1) 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 Technical Data

This section offers you important information about

- **the MA 41 hardware specifications**
- **connections**
- **the pin assignment**
- **calibration values**
- **electromagnetic compatibility (EMC)**
- **electrical safety, EMC and associated Standards**

6.1 The MA 41 Hardware

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.

General Information About Specifications

The performance and specifications of the device can only be guaranteed if it is subject to technical maintenance at least once per year.

MAICO Diagnostics puts diagrams and service manuals at the disposal of authorized service companies.

STANDARDS	
Medical CE mark	
Standards:	ANSI S3.6: Type 3B IEC 60645-1: Type 2 IEC 60645-2: Type B ISO 389 Acoustics – Reference zero for calibration of audiometric equipment IEC 60601-1 class I, protection class B, International Standards for Medical Electrical Equipment Medical Device Directive 93/42/EEC

DEVICE SPECIFICATIONS		
Power supply:	100 - 240 V~ 50/60 Hz ±10 %	
Power Consumption:	Approximately ~60 VA	
Environmental conditions:	**Operation:**	+15 °C … +35 °C / +59 °F … +95 °F Humidity: 30 % … 90 %, non-condensing
	Storage:	0 °C … +50 °C / +32 °F … +122 °F Humidity: 10 % … 95 %, non-condensing
	Transport:	-20 °C … +50 °C / -4 °F … +122 °F Humidity: 10 % … 95 %, non-condensing

Weight:	1.5 kg / 2.7 lbs
Dimensions:	W x D x H: 34.5 x 20 x 8 cm / 13.4” x 7.9” x 3.2”
Monitor:	Build in monitor speaker, headset
Device Fuses:	2 x 1A slow blow
Warm-up Time:	Less than 10 min after power on
Communication:	Talk forward and talk back
Mode of Operation:	Continuous
Stimulus Functions:	Tone Presenter/Interrupter Interlock (tone presentation of both channels simultaneously) Tracking (fixed level difference between both channels) Masking
Data Connection:	USB, LAN Ethernet
External Devices:	CD Player, USB Printer, USB Keyboard
Supported Printers:	HP (PCL 3 and PCL 5e) Epson (ESC/P2, LQ, Stylus Color)

AUDIOMETRY

Test signals:	Pure tone, Pulse tone, Warble tone
Level Steps:	5 dB, 2 dB or 1 dB level steps (user selectable)
Test Frequencies:	125 Hz to 8,000 Hz 9,000 Hz to 16,000 Hz (optional)
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)
Maximum Sound Pressure Level:	
AC with Headphone:	-10 dB_{HL} to 120 dB_{HL}
BC with Bone Conduction Oscillator:	-10 dB_{HL} to max. 80 dB_{HL}
Insert earphones:	-10 dB_{HL} to 120 dB_{HL}
Sound field speaker from Amp:	Tone: -10 dB_{HL} to 100 dB_{HL} Speech: -10 dB_{HL} to 90 dB_{HL}
Modulation:	
Pulse Tone:	0.25/0.5 s on time
Warble Tone:	5 % sinus frequency modulation, repetition rate 5 Hz
Tests:	
Tone:	HL, MCL, UCL
Speech:	SRT, WRS, MCL, UCL, MHA
Patient Response:	Handheld response switch

6.2 Connections

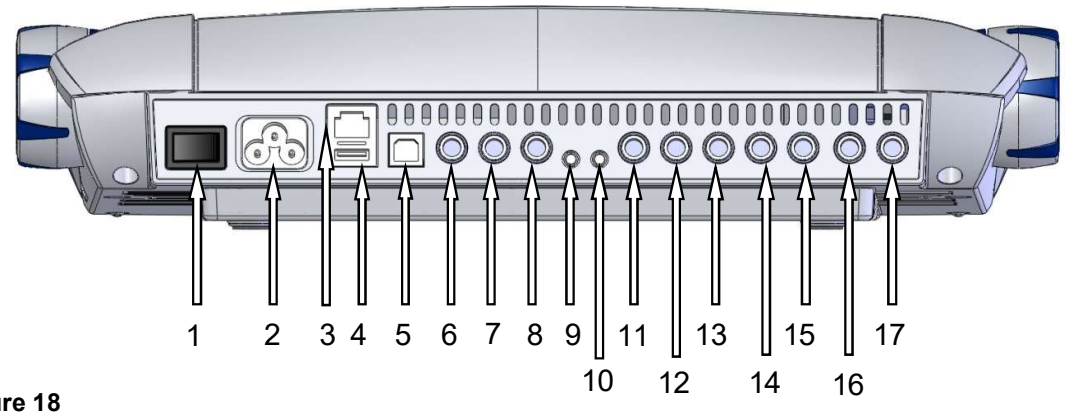
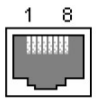
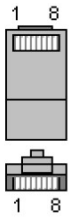
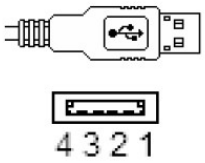
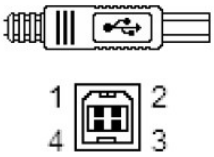
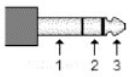
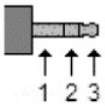


Figure 18

Table 3 Connections on Backside

CONNECTIONS		
No	**Connection socket**	**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 (Microphoney)**	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}

6.3 Pin Assignment

Socket No.	Connector	Pin L (left)	Pin G (top)	Pin N (right)
2	 DC socket Rated current international: 250 V/2,5 A	L (Live)	G (Ground)	N (Neutral)
Socket No.	**LAN Ethernet**			
3	 RJ45 Socket	 RJ45 Cable Plug		TX + Transmit Data TX- Transmit Data- RX+ Receive Data+ Not connected RX- Receive Data
4				1. +5 VDC 2. Data - 3. Data + 4. Ground
5				1. +5 VDC 2. Data - 3. Data + 4. Ground
Socket No.	**Connector**	**Pin 1**	**Pin 2**	**Pin 3**
6; 7; 8; 11; 12; 13; 14; 15; 16; 17	 6.3 mm Stereo	Ground	DC bias	Signal
		-		
9; 10	 3.5 mm Stereo	Ground	DC bias	Signal
		Ground	Right	Left

6.4 Calibration Values and Maximum Levels

Calibration values and Max Levels: Headphone DD45

Coupler IEC 60318-3, Force 4-5 N, PTB-DTU Report 2009-2010

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	IEC 60645-2 RETSPL	IEC Max Level [dB_{HL}]	ANSI S3.6 RETSPL	ANSI Max Level [dB_{HL}]
Speech	20.0	110	18.5	100
SN	20.0	110	18.5	110
WN	0.0	110	0.0	110

Calibration values and Max Levels: Headphone TDH39

Coupler IEC 60318-3, Force 4-5 N, ANSI S3.6 and ISO 389-1

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	8/7.5	13/12.5	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	IEC 60645-2 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

Calibration values and Max Levels: Headphone Holmco 8103

Coupler IEC 60318-3, Force 4-5 N, PTB

Frequency [Hz]	Tone RETSPL dB re 20µPa	NBN RETSPL dB re 20µPa	Max Tone [dBHL]	Max NBN [dBHL]
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	IEC 60645-2 RETSPL [dBHL]	IEC Max Level [dBHL]	ANSI S3.6 RETSPL	ANSI Max Level [dBHL]
Speech	20.0	110	24.5	110
SN	20.0	110	24.5	110
WN	0.0	110	0.00	110

Calibration values and Max Levels: Headphone DD450

Ear simulator IEC60318-1 with adapter, Force 8.8 N ± 0.5 N, ANSI 3.6 and ISO 389-8/ISO 389-5

Frequency [Hz]	Tone RETSPL [dB_{SPL}]	NBN RETSPL [dB_{SPL}]	Max Tone [dB_{HL}]	Max NBN [dB_{HL}]
125	30.5	34.5	100	75
250	18.0	22.0	110	85
500	11.0	15.0	115	95
750	6.0	11.0	120	100
1000	5.5	11.5	120	100
1500	5.5	11.5	115	100
2000	4.5	10.5	115	100
3000	2.5	8.5	115	100
4000	9.5	14.5	115	100
6000	17.0	22.0	105	90
8000	17.5	22.5	105	90
9000	19.0	24.0	100	85
10000	22.0	27.0	100	85
11200	23.0	28.0	95	80
12500	27.5	32.5	90	75
14000	35.0	40.0	80	70
16000	56.0	61.0	60	60

Signal	IEC 60645-2 RETSPL	IEC Max Level [dB_{HL}]	ANSI S3.6 RETSPL	ANSI Max Level [dB_{HL}]
Speech	20	90	19	90
SN	20	85	19	85
WN	0.0	115	0.0	115

Calibration values: Insert phone Eartone 3A and IP30

Reference equivalent threshold sound pressure level

Coupler IEC 60318-5, ANSI 3.6 and ISO 389-2

Frequency Hz	Tone IEC 60318-5 RETSPL dB re 20µPa	NBN IEC 60318-5 RETSPL dB re 20µPa	Tone Max Level dBHL	NBN Max Level dBHL
125	26.0	30.0	90	90
250	14.0	18.0	105	105
500	5.5	9.5	110	110
750	2.0	7.0	115	110
1000	0.0	6.0	120	110
1500	2.0	8.0	120	110
2000	3.0	9.0	120	110
3000	3.5	9.5	120	110
4000	5.5	10.5	115	110
6000	2.0	7.0	100	100
8000	0.0	5.0	95	95

Signal	IEC 60645-2 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

Calibration values: Bone conductor Radioear B71/B71W/B81/BKH10
Force: 4.9 ... 5.9 N Mastoid placement

Coupler IEC 60318-6, ANSI 3.6-2010 and ISO 389-3

Frequency [Hz]	Reference equivalent threshold force level for tone	Air radiation	Max level
	[dB] (re 1µN)	Min - max [dB]	Tone [dB$_{HL}$]
125 (ONLY for BKH10)	82.5	-	-
250	67	-	45
500	58	-	65
750	48.5	-	70
1000	42.5	-	70
1500	36.5	-	70
2000	31	-	75
3000	30	4-18	80
4000	35.5	-	80
6000	40	10.5-31	50
8000	40	-	50

Signal	IEC 60645-2 RETSPL	IEC Max Level [dB$_{HL}$]	ANSI S3.6 RETSPL	ANSI Max Level [dB$_{HL}$]
Speech	55.00	60	55.00	65
SN	55.00	60	55.00	65
WN	-	-	-	-

Calibration values: Sound field (0 degree incidence)

Reference equivalent threshold sound pressure level and maximum hearing levels

For Canton CD220

ISO 389 – 7 and ANSI S3.6-1996

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

Signal	IEC60645-2 RETSPL [dBSPL]	IEC Max Level [dBHL] CD220	ANSI S3.6 RETSPL [dBHL]	ANSI Max Level [dBSPL] CD220
Speech	0.0	90	14.5	75.5
SN	0.0	90	14.5	75.5
WN	0.0	90	0.0	75.5

6.5 Electromagnetic Compatibility (EMC)

Portable and mobile RF communications equipment can affect the MA 41. Install and operate the MA 41 according to the EMC information presented in this section.
The MA 41 has been tested for EMC emissions and immunity as a standalone MA 41. Do not use the MA 41 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.

Guidance and manufacturer's declaration - electromagnetic emissions		
The MA 41 is intended for use in the electromagnetic environment specified below. The customer or the user of the MA 41 should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The MA 41 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	The MA 41 is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Complies Class A Category	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the MA 41.			
The MA 41 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MA 41 can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MA 41 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 transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note 1** At 80 MHz and 800 MHZ, the 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 MA 41 is intended for use in the electromagnetic environment specified below. The customer or the user of the ***Instrument*** 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 IEC61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	+2 kV for power supply lines +1 kV for input/output lines	Mains power quality should be that of a typical commercial or 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 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	Mains power quality should be that of a typical commercial or residential environment. If the user of the MA 41 requires continued operation during power mains interruptions, it is recommended that the MA 41 be powered from an uninterruptable power supply or its battery.

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 residential environment.
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The MA 41 is intended for use in the electromagnetic environment specified below. The customer or the user of the MA 41 should assure that it is used in such an environment,			
Immunity test	IEC/EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC/EN 61000-4-6 Radiated RF IEC/EN 61000-4-3	3 Vrms 150kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any parts of the MA 41, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range (b) Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] 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 MA 41 is used exceeds the applicable RF compliance level above, the MA 41 should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MA 41. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

6.6 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. 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
8. Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE)

6.7 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:.....

Specifications are subject to change

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