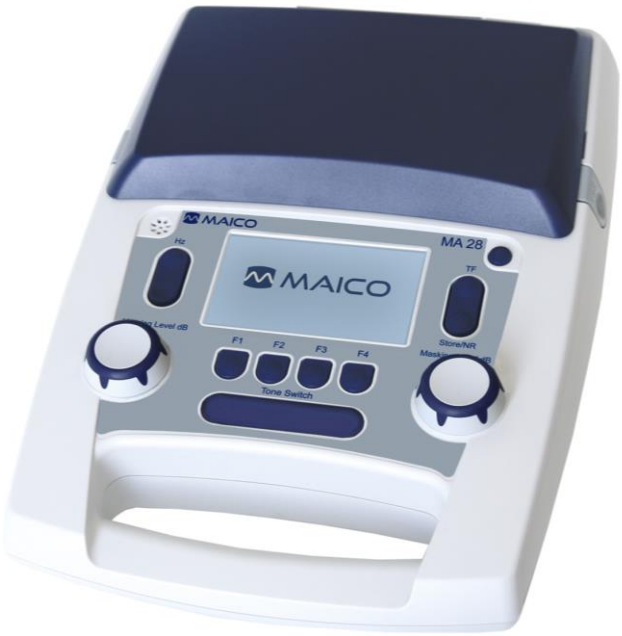
Operation Manual

MA 28



MAICO Diagnostics GmbH, Sickingenstr. 70-71 , D-10553 Berlin, Tel. +49 30 / 70 71 46-50, Fax -99

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Title: Operation Manual MA 28

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MAICO Diagnostics GmbH
Sickingenstr. 70-71
10553 Berlin
Germany
Tel.: + 49.30.70 71 46-50
Fax: + 49.30.70 71 46-99
E-mail: sales@maico.biz
Internet: www.maico.biz

Compliance

MAICO Diagnostics GmbH 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

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 selecting one of our quality products from the MAICO family range. The MA 28 is designed and manufactured to meet all quality and safety requirements.

Particular attention has been taken during the designing phase of the MA 28 to ensure its user-friendliness, meaning that its operation is simple, easy to learn and to understand. As all the functions are software-controlled, upgrading the software and/or adding additional functions at a later date will be simple and cost-effective. By purchasing the MAICO MA 28, you have made a decision towards long-term investment.

This operating manual aims to make learning and understanding the different MAICO MA 28 functions as quick and as easy as possible. Should you encounter any problems or have ideas for any further improvements, we are only a phone call away. Please do not hesitate to contact us.

Your MAICO-Team

1.2 Intended Use Statement

The MA 28 audiometer is designed to be a portable device for testing hearing loss. Output and specificity of this type of device are based on the test characteristics defined by the user, and may vary depending on environmental and operating conditions. Testing for hearing loss using this type of audiometer requires interaction with the patient.

Indications for Use:

The MA 28 is a portable or standalone audiometer intended to be used for the identification of hearing loss and the factors that contribute to the occurrence of the hearing loss in the age range of children to adults. It is used as part of a total test battery to determine hearing acuity by audiologists, ENTs, hearing healthcare professionals, or other trained technicians in a hospital, clinic, healthcare facility or other suitable quiet environment as defined in ISO 8253-1 or ANSI S3.1 or equivalent.

1.3 Contraindications of Use

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

1.4 Essential Performance

There is no essential performance as defined in IEC 60601-1.

1.5 Description

The MA 28 is an electroacoustic test device that produces sounds through a range of frequencies and intensities to test for hearing loss. It features pure tone audiometric testing with or without masking for measuring audibility thresholds. MA 28 is meant to be used with headphones that are calibrated to the specific audiometer and are not interchangeable with other devices.

Output and specificity of this type of device are based on the test characteristics defined by the user, and may vary depending on environmental and operating conditions. The testing for hearing loss using this kind of audiometer depends on the interaction with the patient.

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 device, the more stringent rules should take precedence.

This product and its components will perform 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).

NOTE: In the unlikely case of a serious incident, inform MAICO as well as your local distributor.

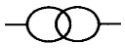
2.3 Manufacturer's Liability

Usage of the device in a way deviant from the intended use will lead 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
CE 0123	Conforms to European Medical Device Directive 93/42/EEC
ETL CLASSIFIED Intertek	ETL listed mark
MAICO	Logo

2.5 General Precautions

Before starting a measurement make sure, that the device works properly.

Use and store the device indoors only. For operation, storage and transport conditions see table in section Technical Data.

No modification of this equipment is allowed.

Equipment is not user repairable. Repairs must be performed by a qualified service representative only. No modifications of the equipment are allowed by anyone other than a qualified MAICO representative. Modification of the equipment could be hazardous. No part of the equipment can be serviced or maintained while in use with the patient.

Do not drop or otherwise cause undue impact to this device. If the device is dropped or otherwise damaged, return it to the manufacturer for repair and/or calibration. Do not use the device if any damage is suspected.

Calibration of the device: The audiometer and the transducers complement each other and share the same serial number (i.e. 7663252). Therefore, the device shall not be used with any other transducer prior to recalibration. Recalibration also needs to be conducted, when a defected headphone is replaced.

Uncalibrated devices 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 device conform to IEC 60601-1 Type B requirements.

In Case of Emergency

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

In Case of Emergency

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

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

Do not use the device if the power supply 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 60601-1shall 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 device is connected to a PC (IT equipment forming a system) ensure not to touch the patient while operating the PC.

If the device 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-series.

The device is not intended for operation in areas with an explosion hazard. Do NOT use the MA 28 in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc. If the device is not used switch it off and disconnect it from the power supply.

Never short-circuit the terminals.

To avoid the risk of electric shock, this equipment must only be connected to the medical power supply originally delivered by MAICO. Using another power supply can also lead to electrical damage on the device.

In order to maintain a high level of safety and to ensure the device works properly, it is necessary to have the device 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 3.2.

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

Prevent cable breakage: cables must not be bent 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 2.5 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 the power supply delivered by MAICO.

The device 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.

The use of the accessories, transducers and cables with medical equipment/system other than the MA 28 may result in increased emissions or decreased immunity of the medical equipment/system.

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**
- **handling disposables**
- **troubleshooting**
- **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 device 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 device to the original purchaser.

The device shall only be repaired and serviced by your distributor or by an authorized service center. Opening the device 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 device.

3.2 Maintenance

In order to ensure that the device 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 by a service center authorized by MAICO.

When returning the device 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 device.

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 the power supply.
- For cleaning use a lightly dampened cloth with soap water solution.
- Disinfect the plastic housing of the MA 28 and its accessories by wiping the surfaces with wet Sani-Cloth® Active wipes or a comparable product. Follow the instructions on the specific disinfection product.
    - Wipe before and after each patient
    - After contamination
    - After infectious patients

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.

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

For more detailed cleaning recommendations see the following sections 3.3 to 3.5.

3.4 Disposables

Operating the MA 28 with insert phones will require the use of Insert Foam Eartips. They are intended for single-use only. These should be discarded after use. They cannot be cleaned.

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

In case you want to purchase further disposables, please, contact MAICO or your local distributor.

3.5 Accessories/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 28 device configuration). Ask your authorized local distributor when accessories need to be replaced.

3.6 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 system**
- **components**
- **becoming familiar with the hardware inclusive connections**
- **how to store the device**

4.1 Unpacking the System

Check Box and Contents for Damage

- It is recommended that you unpack your MA 28 carefully making sure that all components are removed from the packing materials.
- Verify that all components are included as shown on the packing slip 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 MA 28 comes with different components (see Table 2). The availability of configurations with the following components are country specific. Contact your local distributor for more information. See also Table 3 for replacement parts and disposables.

Table 2 List of Components

Available Components
Base Unit
Database Software with Audiometry Module (CD and USB)
Power Supply UE10WCP1-050200SPA
USB Cable
DD45 Audiometric Headphones*
DD65 Audiometric Headphones*
DD450 High Frequency Headphones*
IP30 Insert Phones*
B71 Bone Conduction Headphones*
B81 Bone Conductor Headphones*
Patient Response Switch*
Operation Manual
Quick Guide

*Applied part according to IEC 60601-1.

Table 3 Replacement Parts and Disposables

Replacement Parts and Disposables
Ear Cushion Cover
Foam Eartips**
Audiogram Pad

**Only for use with Insert Phones.

4.2 Hardware and Accessories

4.2.1 Where to Setup

The MA 28 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 or ANSI S3.1. For use in noisier environments, headphones with optional sound insulation muffs are available.

Electro-medical 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.

WARNING

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

4.2.2 MA 28 Device

Figure 1 shows the MA 28 device. The device has a main device layout, a case to store headsets and cables and a handle to easily carry the device (Figure 2). The connections are located in the case (Figure 3).

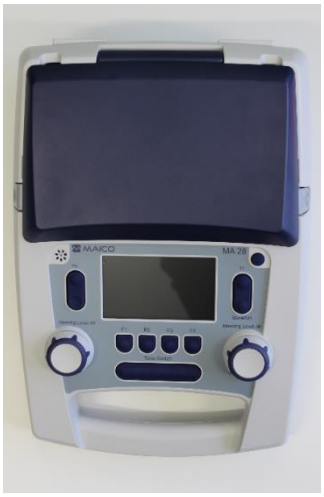


Figure 1

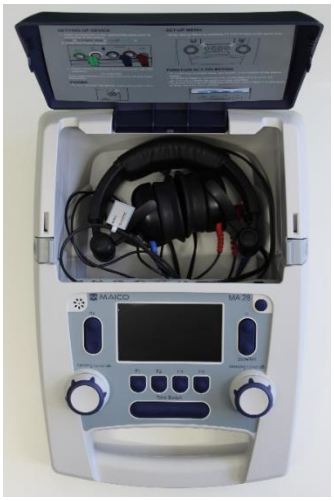


Figure 2

Figure 3

NOTE: See section 5.3 detailed information about the device layout.

Adjusting feet height

To adjust the height, turn the device over. Adjust the two feet by turning them in a counter clockwise to increase height, or in a clockwise direction to decrease height (Figure 4.)

Figure 4

4.2.3 Connections for Headphones, Power Supply and USB Devices

Figure 5 shows the connections on the inside panel of the device. The connections are explained in Table 4. Insert the plugs before turning on the device.

CAUTION

Insert plugs with care into the appropriate connection. Do not wiggle the plug or pull with force while connected. Disconnect plugs cautiously.

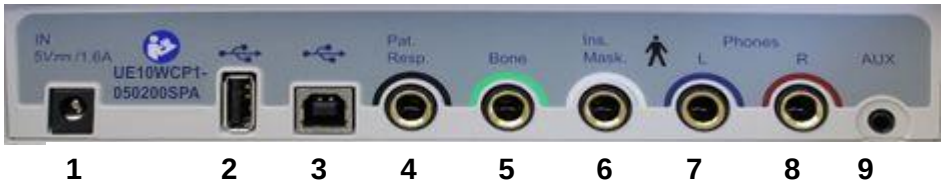


Figure 5

Table 4 Connections on Inside Panel of Device

CONNECTIONS	
1	Power Supply UE10WCP1-050200SPA
2	USB Host
3	USB Device for PC Communication
4	Patient Response Switch
5	Bone Conduction
6	No Function in Actual MA 28 Version
7	Left Phone or Left Insert
8	Right Phone or Right Insert
9	No Function in Actual MA 28 Version

4.2.4 Establishing a PC-Connection

To transfer data to a PC, establishing a PC-connection via USB is required. If the MA 28 is used with office equipment that is not a medical device itself (see Table 4,

PC-Connection 1), make sure to establish the PC-connection in one of the following ways (see Table 4, PC Connection 2, 3 or 4).

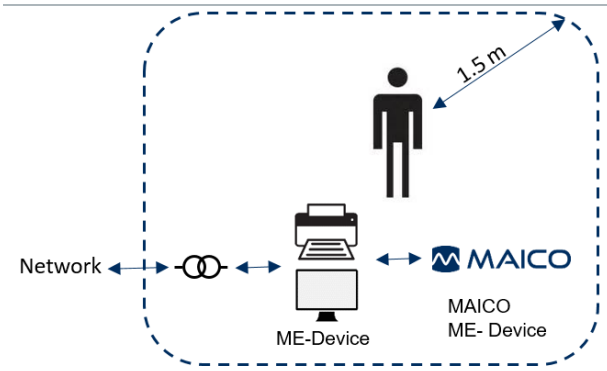
WARNING

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-series) a voltage transformer must be used (exception: a battery driven laptop is used).

PC CONNECTIONS

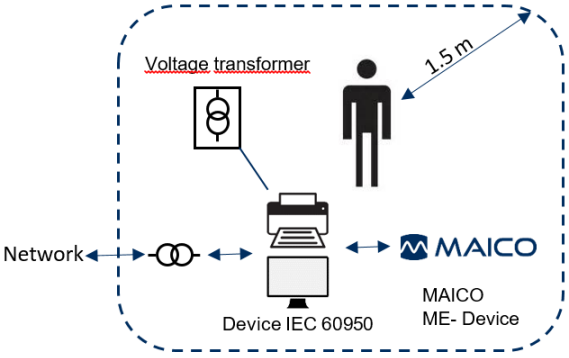
PC Connection 1

Medical device – Medical Device



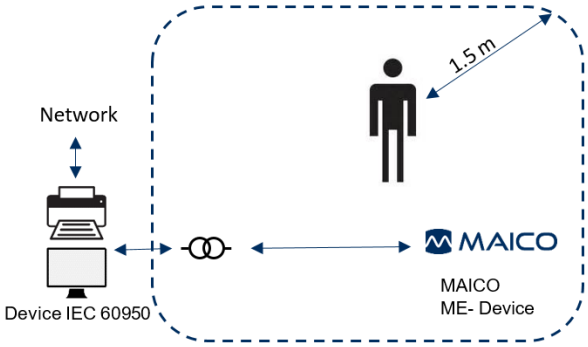
PC Connection 2

Medical device – Non Medical Device



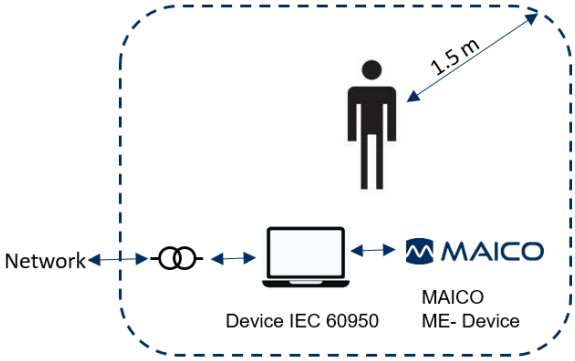
PC Connection 3

Medical device – Non Medical Device



PC Connection 4

Medical device –Laptop (battery driven)



4.2.5 PC-Interface

Please refer to the Audiometry Module operation manual for transferring of results to the PC.

4.2.6 Storage

When the MA 28 is not in use, store it in a location where it will be safe from damage to sensitive components such as the acoustic transducers and cables. Store according to the recommended temperature conditions described in section 4.2.1.

5 Operating the Device

This section offers you information about:

- **how to get started with the MA 28**
- **the device layout**
- **the display**
- **the function keys**
- **performing Tone Audiometric testing**
- **changing settings in the setup menu**

5.1 Getting started with the MA 28

Place the MA 28 on a stable counter or table. Plug the power cord into the power socket. Connect all accessories with the appropriate sockets as shown in Section 4.2.3. Plug the power cord into a grounded outlet.

5.2 Use of Equipment After Transport and Storage

Make sure the device is functioning correctly before use. If the device has been stored in a colder environment (even for shorter time) allow the device to become acclimatized. This can take a long time depending on the conditions (like environmental humidity). You can reduce the condensation by storing the device in its original packaging. If the device is stored under warmer conditions than the use conditions no special precaution are required before use. Always ensure proper operation of the device by following routine check procedures for audiometric equipment.

5.2.1 Switching On the Device

Figure 6

NOTE: The warm up time for the device including boot up process takes about 1 minute.

Briefly press the Power key on the MA 28 to turn on the device (Figure 6).

5.2.2 Switching Off the Device

The device can be shut down by pressing the ***Power*** key for about 3 seconds.

5.3 Device Layout

Figure 7 shows the device layout. Table 5 gives further explanation.

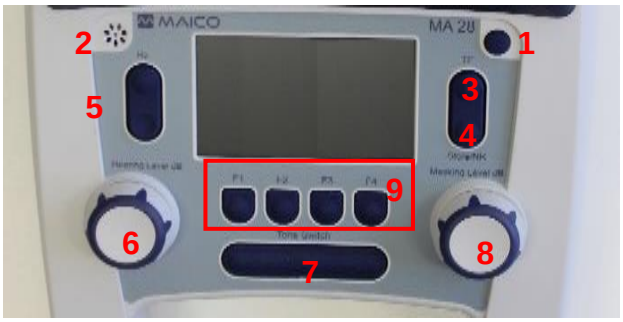
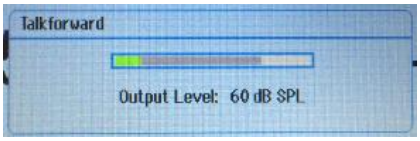


Figure 7

Table 5 Explanation of Device Layout

#	Name(s) / Function (s)	Description
1	**Power On/Off**	Turning the device on/off.
2	**Microphone Port**	To use the talk forward function.
3	**TF (Talk Forward)**	Press and hold while speaking to provide instruction to the patient. Increase/decrease the volume by simultaneously pressing ***TF*** and rotating one of the ***level dials*** (6 or 8). See Figure 8.  **Figure 8**
4	**Store** **NR (No Response)**	Press and release to store result. Press and hold to display a No Response (***NR***) result.
5	**Hz (+/-)**	Press + to increase the frequency (Hz). Press – to decrease the frequency (Hz).
6	**Hearing Level dB**	Turns the volume of the tone up/down.
7	**Tone Switch**	***Presenter mode:*** Press to present the signal. A tone presentation signal (i.e. ) will display on the screen. ***Interrupter mode***: Press to stop the signal being presented.
8	**Masking Level dB**	Turns on the masking/noise signal by rotating the wheel to the right. Once on, turns the masking/noise signal up/down. Turn off the noise by rotating the wheel to the left until the display on the right side no longer displays a number.
9	**Function Keys**	These keys (***F1*** to ***F4***) are dependent upon the label displayed on the display screen. See Table 4 and 5 for more details.

Display

Figure 9 shows the main display. See the explanation of the screen areas below.

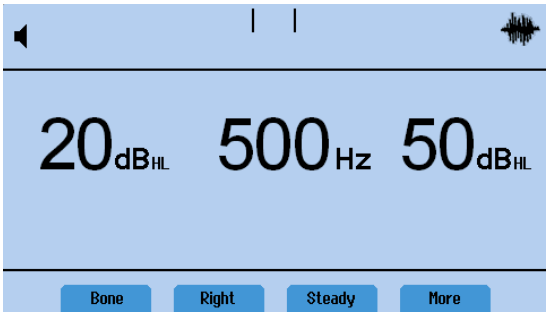


Figure 9

Tone: A tone presentation indicator is provided in the top left corner of the display.

Tone is presented (turned on).

Tone is not presented (turned off).

Response (Patient Response Switch required): When using the patient response switch, a response is indicated in the middle of the display header.

Patient response switch is being activated (pressed).

Patient response switch is not activated (not pressed).

Level:

Hearing Level: Displayed on the left side of the screen and indicates the level/volume of the tone presented. To change, rotate the left rotary wheel ***Hearing Level dB***.

Masking Level: Displayed on the right side of the screen and indicates the level/volume of the noise/masking presented. The noise is turned on by rotating the **Masking Level dB** rotary wheel to the right. It is turned off by rotating to the left until ***- - dB HL*** is displayed on the screen.

Frequency:

Frequency presented to the patient. To change, press the + to increase or – to decrease the test frequency.

NOTE: ***Result display****:* The device can be set to display stored results within a table as viewed in Figure 10. Review section 7: Setup Menu to change the display. Stored results are platted based on earside, transducer and level at the time of selecting **Store** button.

- Air: Level of air conductor transducer
- Mask Air: Non-test ear noise level
- Bone: Level of bone conductor transducer
- Mask Bone: Non-test ear noise level

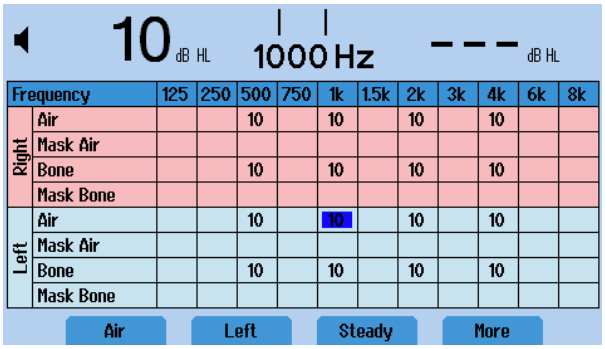


Figure 10

5.4 Function Keys

Function keys are the buttons below the screen. A label above the button displays the function of that key. These buttons are labeled ***F1***, ***F2***, ***F3*** and ***F4***. See Figure 11 and Table 6 for the selections available for each function key in the testing mode.

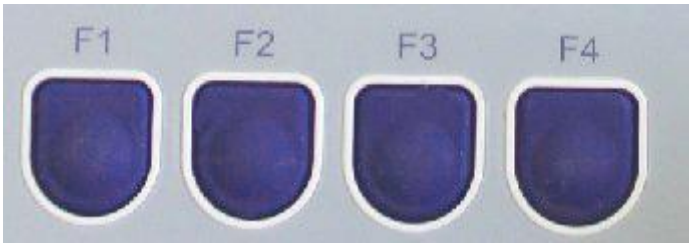


Figure 11

Table 6 Explanation of Functions Buttons

Menu Screen	Function button	Label	Description
1st menu screen	F1	Air Bone	Selection between ***Air*** or ***Bone*** conduction transducer.
	F2	Right Left	Selection between ***Right*** or ***Left*** ear.
	F3	Steady Pulse Warble P&W	Type of signal presented. Options include ***Steady***, ***Pulse***, ***Warble***, Pulse and Warble (***P&W***).
	F4	More	To move to the ***2nd menu screen.***
2nd menu screen	F1	Delete	To delete single stored measurement. Set device with the ear, test type and frequency to delete the measurement.
	F2	Del All	To delete all stored measurements for a selected transducer and ear.
	F3	New	To delete all stored results.
	F4	More	To move to the ***3rd menu screen***.
3rd menu screen	F1	HW	Activates ***Hughson-Westlake*** automatic air conduction threshold test.
	F2		No function
	F3		No function
	F4	Back	Returns the function key selection to the ***1st menu screen***.

5.5 Preparing for Testing

5.5.1 Preparing the Patient

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

Prior to hearing threshold level measurements, the following instructions should be given. ***"You will now hear a variety of tones with various loudness levels, raise your hand, or press the response switch, as soon as you hear the tone in either ear."***

5.5.2 Placement of Headphones (for Testing with Headphones)

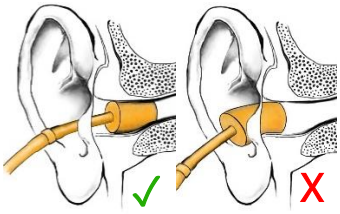
Eliminate any obstructions which will interfere with the placement of the earphone cushions on the ear (i.e. hair, eyeglasses).

Ensure that the headphones are positioned correctly: red phone on the right ear, blue phone on the left ear. Adjust the headband of the headphones so that the earphones are positioned at the correct height (i.e. the sound output grid exactly facing the ear canal).

5.5.3 Placement of Eartips (for Testing with Insert Phones Only)

First, place the eartip securely on the white adapter at the end of the insert earphone tubing. To prepare the foam eartip for insertion in the ear canal, you must compress the foam by rolling it in your fingers to narrow its diameter (Figure 12). Check to be sure that the foam does not obstruct the opening of the black sound tube.

Figure 12



Quickly, while the foam is still compressed, grasp the patient's ear and gently pull it up and back to open and straighten the ear canal. While holding the canal open, slide the compressed foam ear tip into the ear canal. The foam should be completely surrounded by the canal with virtually none of the foam sticking out of the canal (Figure 13).

Figure 13

5.6 Performing Tone Audiometric Tests

5.6.1 Air Conduction Testing

5.6.1.1 Pretest Set-up and Instructions

Hearing threshold levels can be determined by presenting test signals to the test subject with the included headphones (air conduction – AC). The purpose of AC audiometry is to establish the hearing sensitivity at various frequencies. The test can specify the AC loss but cannot distinguish between conductive versus a sensorineural abnormality.

5.6.1.2 Threshold Determination

The test normally starts at 1000 Hz on the patient's better ear. Select ***Right***/***Left*** (***F2*** key). A procedure of *"down 10 dB, up 5 dB*" is typically utilized to establish a threshold at each frequency.

NOTE: There is a safety feature within the device so that high volumes (i.e. 100 dB or more) are not accidently presented to a patient. When the volume of the tone or noise is 75 dB or higher and the user changes frequencies or ears, the device will automatically reset the level to 70 dB.

5.6.1.3 Screening

A hearing screening utilizes a ***Pass*** or ***Refer*** result and is used to determine if further testing is required as a hearing problem may exist. Patients are typically screened at a level of 20 dB HL at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz in each ear. If a patient hears all the tones in each ear, the result would be considered a ***Pass***. Failure to hear any of the tones in either ear would result in a ***Refer***.

NOTE: This is an example of one screening protocol. Each state may have their own screening protocol. Contact your state health department for guidelines in your area.

5.6.2 Bone Conduction Testing

Place the bone conduction oscillator on the patient's head 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 ***F1*** key to ***Bone*** and select the test ear.

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

5.6.3 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 dB 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 may increase the hearing threshold of the test ear. For bone conduction the masking signal is automatically routed to the opposite output of the phones or inserts, based on the test ear selected.

The masking is turned on by rotating the ***Masking Level dB*** level control dial to the right. The masking sound should be continuously presented for effective masking. 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.

Adjust the level of the masking noise for the appropriate level to be presented.

When the ***Store*** button is pressed, the hearing threshold value will be stored with the masking level.

5.6.4 Auto Threshold (Hughson-Westlake) – Air Only

In addition to traditional manual testing, the MA 28 incorporates a Hughson-Westlake patient controlled automatic threshold test complying with ISO 8253 for air conduction thresholds only. The test results are stored within a table display on the device.

Hughson-Westlake is a procedure used to determine pure tone thresholds. The MA 28 utilizes this procedure to perform an automatic pure tone test procedure (air conduction only). Threshold is defined as 2 out of 3 (or 3 out of 5) correct responses obtained at a certain level in a 10 dB decrease and 5 dB increase procedure. The test frequencies will start at 1000 Hz and continue through those frequencies activated within the settings. The device will re-test 1000 Hz before moving to the next ear or ending the test.

The test is accessed through the function keys in the 3rd menu selection. From the main test screen Press ***F4*** (**More**) until HW is displayed at ***F1***. The HW Test will always display a table for results to be viewable during the test and after.

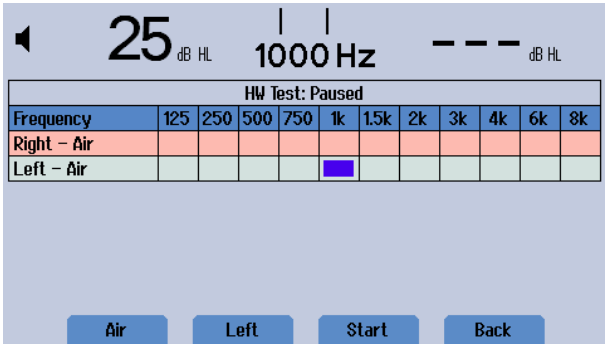


Figure 14

The function keys for test operation are defined in Table 7

Table 7 Explanation of function keys for HW test

Function key	Label	Description
F1	**Air**	Non-active function key (air only).
F2	**Right** **Left**	To choose the test ear.
F3	**Start** **Pause**	To start the HW test. To pause HW test during automatic operation
F4	**Back** **Cancel**	To exit HW test and return to main test screen. To stop test progression and return to main test screen.

NOTE: To delete the HW test, select ***New*** from the second function key menu. This will delete any results stored on the device.

An optional familiarization portion can be incorporated into the test process. See section 5.7 for more information on this setting.

5.7 Tone Setup Menu

To access the ***MA 28 Tone Setup menu*** press **F1** and **F4** simultaneously for 2-3 seconds. Once in the Menu (Figure 12), the different Setup options are listed and can be entered using the function keys. See Table 5 and Table 6 for further explanation.

Table 8 Explanation of Function Keys in Setup Menu

Function key	Label	Description
F1	Change	To change highlighted setting.
F2	↑	To browse up in the setup menu.
F3	↓	To browse down in the setup menu.
F4	Save	To save setting and go back to previous screen.

NOTE: A secondary way to manage the setting options is the Masking Level Control can scroll through the menu list and the Hearing Level Control to change the options. For the ease of reading the following explanations only refer to the function keys.

Table 9 Explanation of Options in the Setup Menu

Setup Menu	Description
Signal	To select the operation mode of the audiometer: • ***Presenter:*** Tone is presented as long as the Tone Switch is activated. • ***Interrupter*****:** Tone is interrupted/stopped when the Tone Switch is activated.
Power up ear	To select ***Right*** or ***Left*** ear as the default ear for Power Up.
Default signal	To select the default signal type (i.e. ***Steady***, ***Pulse***, ***Warble***, or Pulse & Warble – ***P & W***).
Diagram settings	The display of the test screen. Select between ***None***, see Figure 9, or ***Table***, see Figure 10. **NOTE**: HW test results are always displayed in the ***Table*** view.
Default intensity	To set the default intensity when changing transducer and ear side. Choose between: ***Off***, ***-10 dB*** to ***50 dB***.
Intensity steps	To change the intensity/volume level that changes with each rotation of the attenuator dial. Choose between ***1 dB*** and ***5 dB***.
Noise start intensity	To select the default intensity when the noise is turned on using the ***Masking Level dB level control dial***. Choose between ***0 dB*** to ***50 dB***.
Masking type	To select between Narrowband (**NB**) and White noise (**WN**).
Frequency roll	To define the movement to the next frequency choose: • ***None:*** Frequency roll is off. To change the frequency during testing, use the **+/-** buttons. Frequency stops when minimum or maximum levels are reached. • ***Wrap:*** When using the frequency buttons **+/-** or ***Store*** the frequency selection will cycle through all active frequencies. • ***Back:*** Frequency returns to 1000 Hz when minimum and maximum has been reached. Occurs when selecting ***Store*** or the frequency buttons **+/-**.
Bone masking	To select the transducer for masking: • **Opposite CH1:** masking noise is distributed to the opposite ear air conduction transducer. • **Insert masking:** transducer specific for masking. **NOTE**: ***Bone masking*** is only a viewable and selectable menu setting when an Insert Masker is calibrated to the device. As this is not an included component, this setting is defaulted to be hidden from view. Standard operation will deliver masking noise by the air conduction transducer.

Setup Menu	Description
Pulse length	To select the length of each tone when ***Pulse*** is selected. Choose between ***250 ms*** and ***500 ms***.
Language	To select the display language. Choose between ***English***, ***Deutsch***, ***Español***, ***Français, Italiano***, and ***Polski***.
Backlight	To select the intensity of the Backlight. Choose a value between ***30 %*** (very dark) to ***100 %*** (very bright).
Air Frequencies	To select the frequencies to be active during the air conduction test by setting them ***On/Off***. Press ***Change*** to toggle between the 10 frequencies that can be set to ***On*** or ***Off***: ***125 Hz, 250 Hz, 500 Hz, 750 Hz, 1500 Hz, 2000 Hz, 3000 Hz, 4000 Hz, 6000 Hz, and 8000 Hz***.
Bone Frequencies	To select the frequencies to be active during the bone conduction test by setting them ***On/Off***. Press ***Change*** to toggle between the 9 frequencies that can be set to ***On*** or ***Off***: ***250 Hz, 500 Hz, 750 Hz, 1500 Hz, 2000 Hz, 3000 Hz, 4000 Hz, 6000 Hz, 8000 Hz***.
Hughson/ Westlake (HW) test	See Table 10.
About	To view relevant information to the device (i.e. Serial number, firmware version, etc.). Press ***Change*** to access the license information of the MA 28.

Hughson Westlake Test (HW)

The MA 28 incorporates the ***Hughson Westlake test (HW)***. The automation of this test is configured in the Hughson/Westlake test setup menu. Press ***Change*** to access the ***Hughson Westlake Tests setup*** menu. Press ***Change*** again to enter the single setting options.

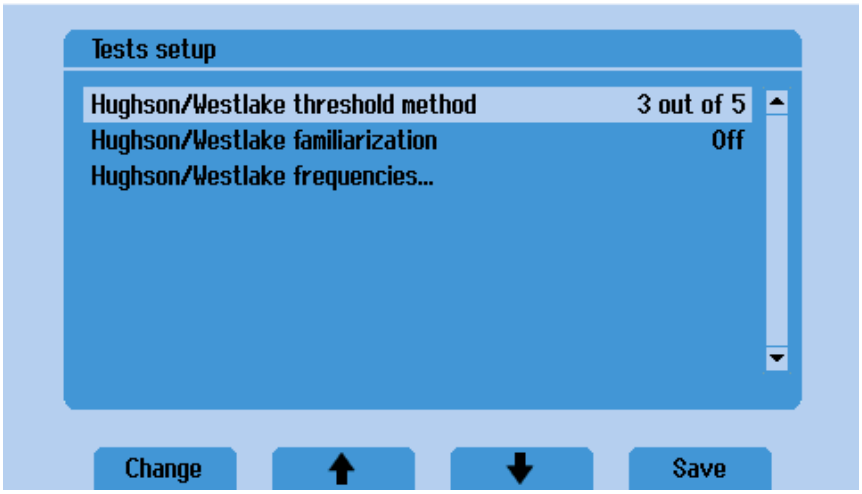


Figure 15

Table 10 Hughson/Westlake Test

HW Setup Menu	Description
Hughson/Westlake threshold method	The HW test can be automated to confirm ***3 out of 5*** or ***2 out of 3*** correct answers before moving to the next frequency.
Hughson/Westlake familiarization	To select if the patient shall be trained with a familiarization test (***On***), or not (***Off***).
Hughson/Westlake frequencies	The HW allows for test frequencies to be deactivated separate from the manual audiometric test process. Press ***Change*** to toggle between the 10 frequencies that can be set to ***On*** or ***Off***: ***125 Hz, 250 Hz; 500 Hz; 750 Hz; 1500 Hz, 2000 Hz, 3000 Hz, 4000 Hz, 6000 Hz, 8000 Hz***.

Press ***Save*** to return to the main ***Hughson/Westlake Tests Setup*** Menu.

5.7.1 Transferring Test Results to PC

Before transferring data to a PC make sure that you have installed the ***Audiometry Software Module*** properly according to the separately delivered operation manual. Before establishing the PC connection you will have to consider the recommendations given in section 4.2.4 in case the MA 28 is connected to a non-medical device.

To transfer the data, make sure the device is connected to the PC via USB connection and the ***Audiometry Software Module*** is open. When connected, the ***Request Measurement*** (Figure 16, 1) button appears. Click on ***Request Measurement*** and the tone audiometry values are transferred and displayed on the PC screen.

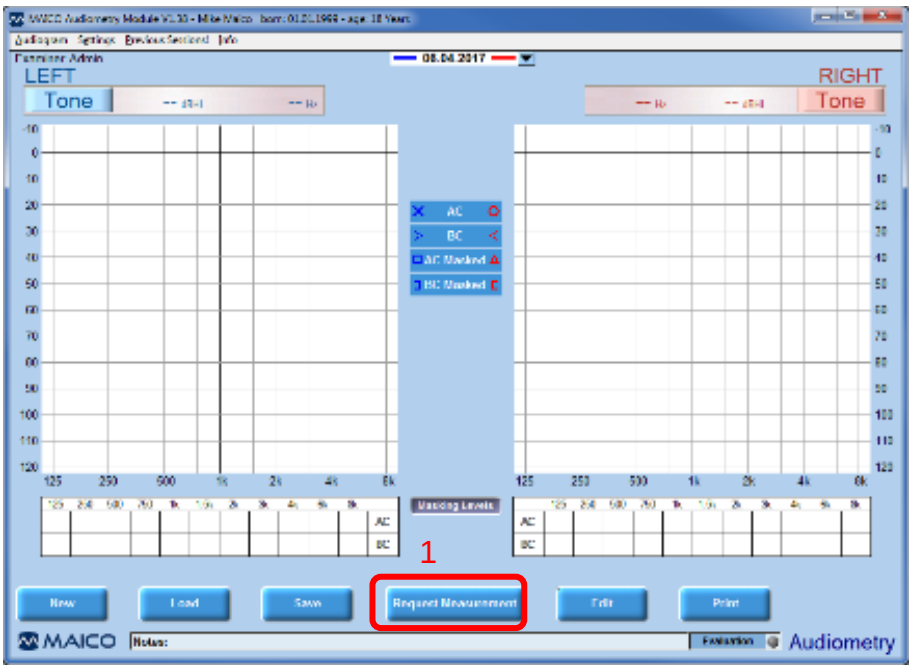


Figure 16

5.7.2 Deleting Test Results

Results are deleted by using the function keys of the device. The delete options are found within the 2nd menu screen of the Function Key list. Select ***More*** to access these functions. See section 5.4.

Table 11 Deleting Test Results

Function key	Description
Delete	To delete the current selection set by the device controls (i.e. Transducer, Ear, and Frequency).
Delete All	To delete the entire transducer selection set by the device controls (i.e. Transducer and Ear)
New	To clear all stored results to start a new test.

NOTE: If you select ***New*** for deleting all deleted test results a message box appears asking if you want to create a new session and discard data. In case you select ***Delete*** or ***Delete All*** the data will be deleted directly.

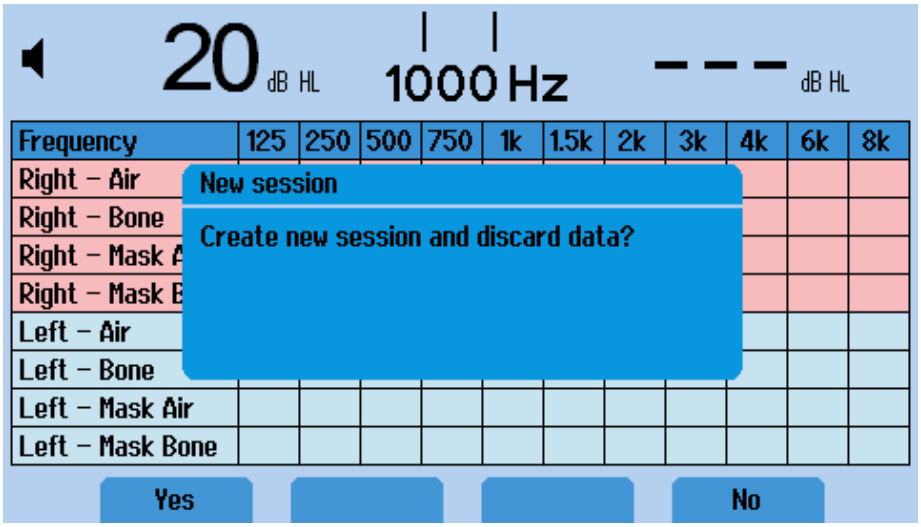


Figure 17

6 Technical Data

This section offers you important information about

- **the MA 28 hardware specifications**
- **connections**
- **the pin assignment**
- **audiometer calibration values**
- **electromagnetic compatibility (EMC)**
- **electrical safety, EMC and associated Standards**

6.1 MA 28 Hardware

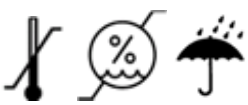
CE 0123

The Audiometer MA 28 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	Yes	
Safety Standards	IEC 60601-1: 2012 ANSI/AAMI ES60601-1: 2005 / A2:2010 CAN/CSA-C22.2 No. 60601-1:08 Class II, Type B applied parts	
EMC Standard	IEC 60601-1-2:2014	
Audiometer Standards	Tone: EN 60645-1:2012/ANSI S3.6:2010 Type 3	
DEVICE SPECIFICATIONS		
Power supply UE10WCP1-050200SPA	Consumption: 0.5 A rms. at 90 Vac input and maximum load supply voltages and fuses: 100 Vac to 240 Vac ± 10 % 50 Hz to 60 Hz ±10 %	
Environmental conditions: 	**Operation:**	+15 °C to +35 °C / + 59 °F to +95 °F
		Relative humidity 30 % to 90 % (non-condensing)
	Storage:	0 °C to + 50 °C / 32 °F to +122 °F Humidity 10 % to 95 % (non-condensing)
	Transport:	-20 °C to + 50 °C / -4 °F to +122 °F Humidity 10 % to 95 % (non-condensing)

Calibration	Calibration information and instructions are located in the MA 28 Service Manual.	
Air Conduction	DD45	MAICO Standard Values
	IP30	ISO 389-2, ANSI S3.6
	DD450	MAICO Standard Values
	DD65	MAICO Standard Values
Bone Conduction	B71	ISO 389-3, ANSI S3.6
	B81	ISO 389-3, ANSI S3.6
	Placement:	Mastoid
Effective masking	ISO 389-4, ANSI S3.6	
Transducers – Headband tension	DD45	Headband Static Force 4.5N ± 0.5N
	DD450	Headband Static Force 10.0 N ± 0.5 N
	B71/B81 Bone	Headband Static Force 5.4 N ± 0.5 N
	DD65	Headband Static Force: 10.0 N ± 0.7 N
Patient Response switch	One push button	
Patient communication	Talk Forward (TF)	
Special tests/test battery	• Auto threshold: ○ Hughson Westlake	
Inputs	Tone, Warble Tone +5%, 5 Hz (true sine wave frequency modulation)	
Outputs	Left, Right, Bone, Insert Masking	
Stimuli		
Tone	125 Hz -8000 Hz	
Warble Tone	5 Hz sine +/- 5 % modulation	
Pulse Tone	Pulse Length: 250 ms or 500 ms	
Masking	Narrow band noise: IEC 60645-1, 5/12 Octave filter with the same center frequency resolution as pure tone. Synchronous masking: Locks channel 2 attenuator to channel 1 attenuator Alternative: White noise	
Presentation	Presenter or Interruptor. Single, Pulse or Warble.	
Intensity	AC: -10 to 110 dB_{HL}, BC: -10 dB_{HL} to 80 dB_{HL} Available Intensity Steps are 1 dB or 5 dB Extended range function: Warning displayed when 100 dB_{HL} reached. Extended range is accessed automatically. Extended range only available when mains powered and not with USB-Cable connection.	
Frequency range	125 Hz to 8000 Hz. Frequencies can be freely deselected (except 1000 Hz)	
Weight MA 28:	1.9 kg / 4.1 lbs	
Dimensions MA 28:	380 mm x 270 mm x 140 mm 14.96 in x 10.62 in x 5.51 in	
Display:	4.3 in in in full color display with normally white LED back-light	
Language Settings:	English, Deutsch, Español, Français, Italiano, Polski.	
PC Connection:	1 x USB B for PC Connection (comparable with USB 1.1 and later)	
Warm up time:	Approx. 1 minute (incl. bootup-time)	

6.2 Connections

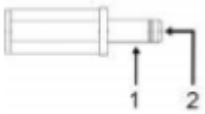
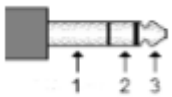
1 2 3 4 5 6 7 8 9

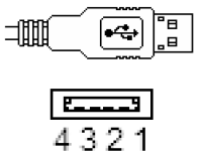
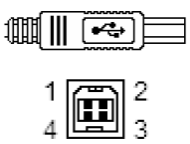
Figure 18

Table 12 Connections on Backside

CONNECTIONS No	Connection-socket	Specification
1	**DC**	5.0 V, 0,4 A Part No. Power Supply UE10WCP1-050200SPA
2	**USB out**	USB 2.0
3	**USB in**	USB 2.0
4	**Response**	RI = 330R
5	**Bone**	ZA= 10 Ω, UA= 3 Veff
6	**Insert Masking**	Not applicable in actual version
7	**Phone L**	ZA =10 Ω, UA = 3 Veff
8	**Phone R**	ZA =10 Ω, UA = 3 Veff
9	**AUX input**	Not applicable in actual version

6.3 Pin Assignment

SOCKET	CONNECTOR	PIN 1	PIN 2	PIN 3
IN 5V ⎓/1.6A	 DC Supply	Ground	DC	-
Left Right Bone	 6.3 mm Mono	Ground	Signal	-
Pat. Resp.		-		

USB A (OUT)		USB B (IN)	
	1. +5 VDC 2. Data - 3. Data + 4. Ground		1. +5 VDC 2. Data - 3. Data + 4. Ground

6.4 Calibration Values

Calibration values and Max Levels: Headphone DD45

Coupler IEC 60318-3

FREQUENCY [HZ]	TONE IEC 60318-3 RETSPL DB RE 20µPA	NBN IEC 60318-3 RETSPL DB RE 20µPA	TONE MAX LEVEL [DB_{HL}]	NBN MAX LEVEL [DB_{HL}]	SOUND ATTENUA-TION [DB] ISO 4869-1
125	47.5	51.5	85	65	3
250	27.0	31.0	105	85	5
500	13.0	17.0	110	100	7
750	6.5	11.5	110	105	-
1000	6.0	12.0	110	105	15
1500	8.0	14.0	110	105	-
2000	8.0	14.0	110	105	26
3000	8.0	14.0	110	105	-
4000	9.0	14.0	110	105	32
6000	20.5	25.5	110	95	-
8000	12.0	17.0	105	95	25
White Noise	-	0.0	-	110	-

Calibration values: Insert phone IP30

Coupler IEC 60318-4

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}]
125	26.0	30.0	90	85
250	14.0	18.0	105	100
500	5.5	9.5	110	105
750	2.0	7.0	110	110
1000	0.0	6.0	110	110
1500	2.0	8.0	110	110
2000	3.0	9.0	110	110
3000	3.5	9.5	110	110
4000	5.5	10.5	110	105
6000	2.0	7.0	100	95
8000	0.0	5.0	90	90
White Noise	-	0.0	-	110

Calibration values: High Frequency Headphone DD450

Coupler IEC 60318-1

FREQUENCY [HZ]	TONE IEC 60318-1 RETSPL DB RE 20µPA	NBN IEC 60318-1 RETSPL DB RE 20µPA	TONE MAX LEVEL [DB_{HL}]	NBN MAX LEVEL [DB_{HL}]	SOUND ATTENUA-TION [DB] ISO 4869-1
125	30.5	34.5	95	70	15
250	18.0	22.0	105	85	16
500	11.0	15.0	110	90	23
750	6.0	11.0	110	95	-
1000	5.5	11.5	110	95	29
1500	5.5	11.5	110	95	-
2000	4.5	10.5	110	95	32
3000	2.5	8.5	110	95	-
4000	9.5	14.5	110	95	46
6000	17.0	22.0	100	85	-
8000	17.5	22.5	100	85	44
White Noise	-	0.0	-	110	-

Calibration values: AC-Headphone Radioear DD65

Coupler IEC 60318-3

FREQUENCY [HZ]	TONE IEC 60318-3 RETSPL DB RE 20µPA	NBN IEC 60318-3 RETSPL DB RE 20µPA	TONE MAX LEVEL [DB_{HL}]	NBN MAX LEVEL [DB_{HL}]	SOUND ATTENUA-TION [DB ISO 4869-1
125	52.5	56.5	85	65	14.5
250	39.5	43.5	105	85	20
500	19.5	23.5	110	100	32.5
750	11.0	16.0	110	105	-
1000	8.5	14.5	110	105	39
1500	13.0	19.0	110	105	-
2000	9.0	15.0	110	105	36.5
3000	11.5	17.5	110	105	-
4000	10.5	15.5	110	105	34.5
6000	29.0	34.0	110	105	-
8000	14.5	19.5	105	95	40
White Noise	-	0.0	-	110	-

Calibration values: Bone conductor Radioear B71 / B81

Coupler IEC 60318-6, mastoid placement

FREQUENCY [HZ]	REFERENCE EQUIVALENT THRESHOLD FORCE LEVEL FOR TONE	AIR RADIATION	MAX LEVEL
	ISO 389 – 3 / ANSI S3.6 [DB] (RE 1µN)	MIN/MAX [DB]	TONE [DB_{HL}]
250	67.0	-	35
500	58.0	-	55
750	48.5	-	60
1000	42.5	-	60
1500	36.5	-	60
2000	31.0	-	65
3000	30.0	80	60
4000	35.5	-	60
6000	40.0	50	45
8000	40.0	-	35

6.5 Electromagnetic Compatibility (EMC)

Portable and mobile RF communications equipment can affect the MA 28. Install and operate the MA 28 according to the EMC information presented in this section.
The MA 28 has been tested for EMC emissions and immunity as a standalone device. Do not use the MA 28 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 28 is intended for use in the electromagnetic environment specified below. The customer or the user of the MA 28 should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The MA 28 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 28 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 28.			
The MA 28 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MA 28 can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MA 28 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 28 is intended for use in the electromagnetic environment specified below. The customer or the user of the ***Device*** 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	Power supply 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	Power supply 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% *U*T (>95% dip in *U*T) for 0.5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T (>95% dip in *U*T) for 5 sec	< 5% *U*T (>95% dip in *U*T) for 0.5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T	Power supply quality should be that of a typical commercial or residential environment. If the user of the MA 28 requires continued operation during power supply interruptions, it is recommended that the MA 28 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. supply voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The MA 28 is intended for use in the electromagnetic environment specified below. The customer or the user of the MA 28 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 28, 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 28 is used exceeds the applicable RF compliance level above, the MA 28 should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MA 28. [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. IEC 60601-1:2012/ ANSI/AAMI ES 60601-1: 2005 / A2:2010: Medical Electrical Equipment, Part 1 General Requirements for Safety
2. CAN/CSA-C22.2 No. 60601-1:2008: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
3. UL/IEC/EN 60950-1:2005: Information Technology Equipment - Safety - Part 1: General Requirements
4. IEC 60601-1-1:2000: General requirements for safety; Collateral standard: Safety requirements for medical electrical systems
5. IEC 60601-1-2:2014: Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and tests
6. DIN/EN/ISO 14971:2012 - Application of risk management to medical devices
7. Essential Requirements of the current European Union Medical Device Directive 93/42/EEC
8. DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2)
9. Directive 2002/96/EC 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 without notice.

MAICO Diagnostics GmbH
Sickingenstr. 70-71
10553 Berlin
Germany
Tel.: + 49 30 / 70 71 46-50
Fax: + 49 30 / 70 71 46-99
E-mail: sales@maico.biz
Internet: www.maico.biz