MA 1
Operating Manual

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MAICO Diagnostics
10393 West 70th Street
Eden Prairie, MN 55344
Tel.: 888.941.4201
Fax: 952.278.4481
E-mail: info@maico-diagnostics.com
Internet: www.maico-diagnostics.com

Compliance

MAICO Diagnostics is an ISO 13485 certified corporation.

1. Introduction

Thank you for selecting one of our quality products from the MAICO family range. The MA 1 is designed and manufactured to meet all quality and safety requirements.

Particular attention has been taken during the designing phase of MA 1 to ensure its user-friendliness, meaning that its operation is simple, easy to learn and to understand. The MA 1 is an ultra-portable audiometer and a perfect choice for on-the-go hearing professionals.

This operating manual aims to make learning and understanding the different MAICO MA 1 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

2. Intended Use

The MA 1 audiometer is intended to be used by an audiologist, hearing healthcare professional, or trained technician in a quiet environment for the purpose of hearing screening.

The instrument is intended for all patient populations including children able to respond to a test signal.

The instrument is intended for professional use in clinics, hospitals or schools.

3. Description

The MA 1 screening audiometer is designed to be a device for screening for 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. The screening for hearing loss using this kind of audiometer depends on the interaction with the patient. As with any type of hearing screening, a "pass" result should not overrule any additional concerns regarding hearing ability. A full audiologic evaluation should be administered if concerns about hearing sensitivity persist.

3.1. Important Safety Note

The MA 1 should always be operated in a quiet room with minimal magnetic influence, to ensure that examinations are not disturbed by external noise.

Electro-medical instruments that emit strong electromagnetic fields (e.g. microwaves, radiotherapy devices) can affect the operation of the MA 1

Therefore, the operation of these instruments in close proximity to the MA 1 should be avoided at all times.

The examination room should have a normal temperature between 15˚C/ 59˚F and 35˚C/ 95˚F. If the instrument has cooled down during transportation, please wait for it to warm up to room temperature before operation.

Attention

PLEASE READ THE ENTIRE MANUAL CAREFULLY BEFORE OPERATING THIS INSTRUMENT.

Please only use this instrument as described in the manual.

Please familiarize yourself with the instrument and its operation before using.

Should defects or damages be suspected, please do not, under any circumstances, use or attempt to fix the instrument yourself.

Calibration of the instrument: The audiometer and the headphone complement each other and share the same serial number (i.e. 63252). Therefore, the instrument shall not be used with any other headphone prior to recalibration. Recalibration also needs to be conducted, when a defective headphone is replaced.

NOTE: Uncalibrated instruments may lead to faulty measurements.

Take note to ensure that all the accessories have been properly connected.

To avoid person-to-person cross contamination of communicable diseases, parts that come in direct contact with the patient (i.e. earphone cushions) should be disinfected using commercial disinfectant after each use.

In accordance with the Electronic Equipment Act for disposal of electronic equipment, the customer is obliged to dispose of the used consumables, according to appropriate regulation at own cost.

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.

3.2. Unpacking and Checking the MA 1

Checking for packaging and content damage

Thoroughly inspect the exterior of the shipping box for any sign of damage or tampering. Should any damage be noted, please notify the carrier immediately. If the content box has been damaged during transportation, the instrument should be checked for any electrical or mechanical defects. Should any defects be identified, please contact the responsible dealer. Keep all original packaging to facilitate any insurance claims against the damages.

PLEASE KEEP ALL ORIGINAL PACKAGING FOR FUTURE USE!

The MA 1 is packaged in a specially-designed box. Please keep the box as it will be useful for sending the instrument for the annual instrument check-up.

Please contact your nearest responsible dealer should the annual instrument check-up be needed.

3.3. Standard Accessories

- DD 45 Audiometric Headset with HB7 Headband
- Operation Manual
- Audiogram Pad
- Carry Case
- 2x AA Batteries
- MA 1 Stand

4. MA 1 Connections

The MA 1 has a single socket for both right and left earphones. While the instrument is off, insert the headphone into the socket ensuring is is completely seated prior to turning the device on.

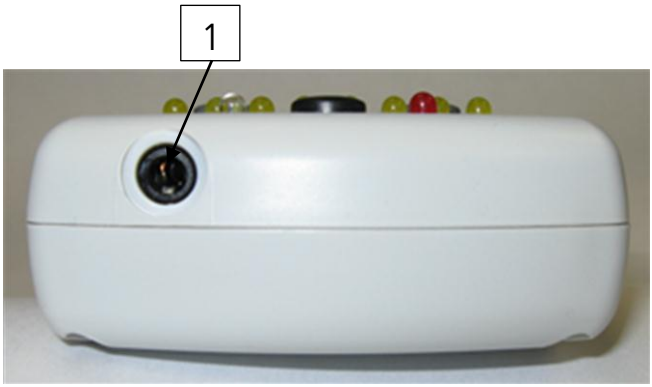

Figure 1

Position:	Function:
1	Socket for headphone

5. Battery Operation

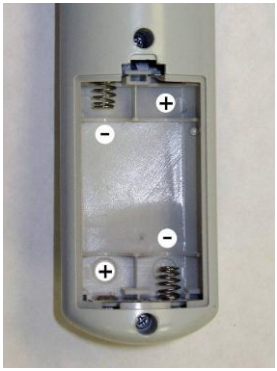

Figure 2

To install batteries:

1. Pull the tab on the battery compartment and remove panel.
2. Insert 2 AA batteries oriented as shown.
3. Reposition the panel and snap the tab back into place.

Battery Life

Maico Recommends using AA Alkaline Batteries

Batteries will last approximately 30,000 tone presentations. The MA 1 has an auto shut-off to conserve battery life. The device will power off after 30 seconds of inactivity. When batteries get too low to produce the proper signal, the unit will shut off and will not turn back on until batteries are replaced.

6. Front Panel Controls and Display

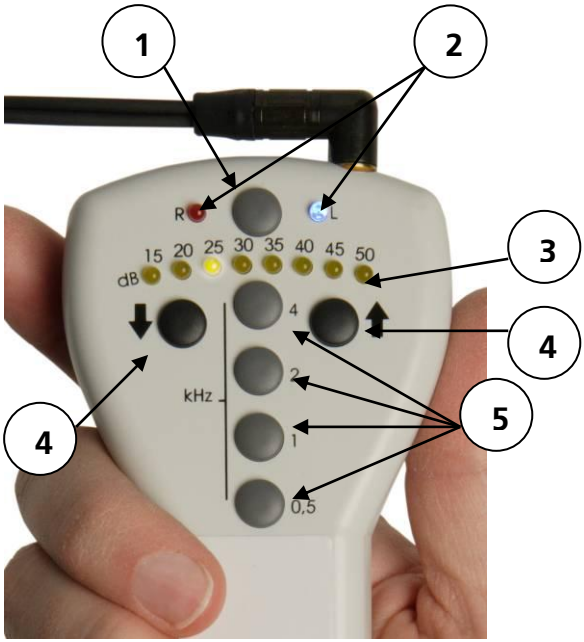

Figure 3

1. Power button and R/L Ear Selector
2. LED Ear Indicator
3. LED Level Indicator
4. dB Level selector buttons
5. Frequency selector buttons/stimulus presentation buttons.

7. Audiometric Testing

7.1. Instructing the Patient:

Place the patient at ease concerning the test. Explain the purpose of the test and what kind of sound or sounds will be heard. An unvarying and uniform explanation to the person being tested will help provide test results that are consistently high in reliability. Instructions might be expressed as follows: "I am going to place these headphones on your ears. You will hear a tone or beeping sound which may be loud or soft. Whenever you hear or think you hear one of these tones, raise your hand. Lower your hand when you no longer hear the tone. Remember, raise your hand when you hear the tone and lower your hand when you do not."

Proper placement of the earphones on the ears is essential to achieving good test results. Check the following before placing the earphones on the person to be tested.

a. Eliminate any obstructions which will interfere with placement of the earphone cushion on the ear (i.e. hair, earrings, eyeglasses, hearing aids, etc.)

b. Adjust the headband so the earphone cushions are centered over the ears and the head. The earphone cushions will put firm pressure on both ears.

7.2. Test Environment: Ambient Noise

Excessive sounds or noises in the chosen test environment can produce a masking effect and therefore affect test results. The selected site should be away from conversations, hallway traffic, outside auto traffic, and other noise producing environments.

The lower test frequencies are most affected by these types of noise. In some instances it may be necessary to treat the test site acoustically to achieve the necessary quietness for testing purposes.

Commercially available sound rooms, which are designed to provide an acoustically treated testing environment, are recommended where baseline or threshold audiometry is required. These rooms are available in a variety of sizes and isolation capabilities. Audiocup(TM) earphone enclosures fit over the DD-45 earphones and provide supplementary attenuation to noise. These can be used instead of, or in addition to, a sound room.

7.3. Conducting the Test

Press the black right/left button to turn on the MA 1. Use this same button to select the right (red LED) or left (blue LED) ear. Press the up or down arrow keys to select 20dBHL. Next press the 1 kHZ button to present the tone at 1kHZ to the patient. The tone will be presented as long as the corresponding frequency key (i.e .5, 1, 2, or 4 kHZ) is held down. If the patient does not respond to the tone, increase the tone by 5dB using the up arrow key and present again. Continue to increase the tone by 5dB until the patient responds. Once the patient responds, lower the tone by 10dB until he/she does not respond. Continue in this "down 10dB/up 5dB" pattern until a threshold is established, or screening protocol has been met. Continue the same procedure for the other frequencies. Record all results on the audiogram card provided.

Note: Most states define a normal hearing level for a pure-tone screening as 20dBHL. However, it is highly recommended that you check with your state health department, the American–Speech-Language-Hearing Association (ASHA), or the American Academy of Audiology (AAA) for specific guidelines.

NOTE: An automatic power shutoff occurs after 30 seconds of inactivity with the audiometer to conserve battery life. To turn the audiometer back on, press the black right/left button.

8. Warranty and Disclaimer

Warranty, Maintenance and After-Sales Service Hardware

The MA 1 audiometer is guaranteed for 1 year. This warranty is extended to the original purchaser of the instrument by MAICO through the Distributor from whom it was purchased and covers defects in material and workmanship for a period of one year from date of delivery of the instrument to the original purchaser.

The audiometer may be repaired only by your dealer or by a service center recommended by your dealer. We urgently advise you against attempting to rectify any faults yourself or commissioning non-experts to do so.

In the event of repair during the guarantee period, please enclose evidence of purchase with the instrument. In order to ensure that your instrument works properly, the audiometer should be checked and calibrated at least once a year. This check-up needs to be conducted by your dealer.

Calibration instrument or other information that will assist service personnel to repair those parts of the audiometer that is designated as repairable by service personnel will be available on request.

When returning the instrument for repairs it is essential to also send the headphone and other accessories. Send the device to your dealer or to a service center authorized by your dealer. Please also include a detailed description of the faults.

In order to prevent damage in transit, if possible please use the original packing when returning the instrument.

9. Care and Maintenance

Remove the unit's batteries before cleaning!

If the surface of the instrument or parts of it is contaminated, it can be cleaned using a soft cloth slightly damp with a mild solution of water and dish washing cleaner or similar. The use of organic solvents and aromatic oils must be avoided.

After each examination of a patient, it should be ensured that there is no contamination on the parts in connection with the patient. General precautions must be observed in order to avoid that disease from one patient is conducted to others. If ear cushions are severely contaminated, it is strongly recommended to remove them from the transducer before they are cleaned with a disinfectant. The use of organic solvents and aromatic oils must be avoided.

Always disconnect the unit's energy source before the cleaning process, and be careful that no fluid enters the inside of the instrument or the accessories; no alcohol or harsh chemicals should be used.

Leave the headset connected to the audiometer permanently to minimize straining the connections. Should it be necessary to unplug the headset, always grasp the barrel of the connecting plugs and pull straight out- never pull on the cords.

Avoid dropping the earphones or snapping them together. This could affect the calibration accuracy.

Store the audiometer and headset in the carrying case at the end of each day to minimize dust collection.

10. Recalibration

The length of time that an audiometer should be operated before recalibration varies depending upon the treatment given the instrument and its headset. Generally speaking, however, it is recommended that the instrument have a laboratory recalibration at least once a year. Since rough handling can easily cause calibration errors, it is advisable to establish a biological calibration check as soon as you receive the instrument.
This can be done as follows:

1. Make several careful tests of your own hearing, recording the results properly on the audiogram cards provided with the instrument.

2. Conduct similar tests with several young adults on whom you will be able to make subsequent retests, recording these on audiogram cards also.

3. File these audiogram cards where they will be readily available for comparison with subsequent retests.

Should you feel at any later date that the audiometer's calibration may be in error, proceed to make retests on yourself and the same young adults on whom you made audiograms previously. If all retests show changes of 10 dB or more in the same direction at the same frequencies, calibration is probably in error. If repair and recalibration is needed, be sure the work is done by a Maico Special Instrument Service Center. This assures the use of quality materials by trained and experienced technicians using accurate and reliable test equipment.

11. Safety Regulations

11.1. Measurement Safety:

In order to ensure safety and quality of the measurement, an annual inspection and calibration should be performed. The annual check-ups can be performed by one of MAICO's authorized service centers.

11.2. Instrument Handling:

The instrument should be checked once a week.

11.3. Operation:

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

12. Technical Data

Standards:
Audiometer : EN 60645-1/ANSI S3.6, Type 5

Frequencies and Maximum Intensities:

Freq. Hz.	AC (Air Condition) dB $_{HL}$
500	50
1000	50
2000	50
4000	50

Inputs:	None
Outputs:	AC headset, 10 ohm impedance
Attenuator:	15 to 50 dBHL in 5 dB steps
Tone Presentation:	Continuous
Distortion:	0.5% typical at full intensity 3% maximum at full intensity
Rise/fall Times:	~35 msec.
Calibration:	
Air Conduction:	ISO 389-1/ANSI S3.6
Warm Up Time:	None
Dimensions:	
W x D x H:	6.35 x 15.24 x 2.22cm / 2.5 x 6 x 7/8 inches
Weight:	2.1 lbs with accessories and carry case.
Operation (environment):	Temperature: 15°C to 35°C (59-95°F) Relative humidity: 30% to 90% (non cond.)
Storage (environment):	Temp: 0°C to 50°C (32-122°F) (Storage) Temp: -20°C to 50°C (-4-122°F) (Transport) Relative humidity: 10% to 95% (non cond.)
Power:	2 AA Alkaline batteries 3 VDC
Operating Environment:	Temperature 15-35°C/59-95°F Relative Humidity 30-90 %
Construction:	Plastic cabinet

13. Regulatory Symbols

Label or International Symbol	Reference	Placement
	Serial Number	Registration Label
	Date of Manufacture yyyy	Registration Label
	Address of Manufacturer	Registration Label Package Label IFU
	Return to Authorized Representative	Registration Label
	B Patient Applied Part according to IEC60601-1.	Registration Label
	Consult Operating Instructions	On device where appropriate
	Product Name	Rating Label IFU Package Label
	SKU	Rating Label Package Label
	Logo	Front Label

Specifications are subject to change without notice.

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