Operation Manual

MA 25/MA 25e
MA 27/MA 27e

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Title: Operation Manual MA 25/MA 25e – MA 27/MA 27e

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0123

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**
- **features and benefits**
- **a description of the device**

1.1 Intended Use Statement

Screening audiometers are designed for determine hearing thresholds levels. The instrument is intended for all patient populations over 3 years age and able to respond to test signal in a rational way.

1.2 Indications for Use Statement

The MA 25/MA 25e/MA 27/MA 27e 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 Features and Benefits of the MA 25/MA 25e and MA 27/MA 27e

1.4.1 General Information About the MA 25/MA 25e and MA 27/MA 27e

The MA 25/MA 25e and the MA 27/MA 27e gives you the benefit of:

- Portable audiometer
- Multiple transducer options
- Air Conduction
- Pure, Pulse and Warble Tone
- Built-in handle and storage compartment – MA 27 and MA 27e version

1.4.2 Extended Functions of the MA 25e and MA 27e

The MA 25e and the MA 27e extends the functionalities with the following extra features:

- Communication with a computer, to save and print results with the use of MAICO Software.
- Automatic Hughson-Westlake patient controlled automatic threshold test complying with ISO 8253. When the test is completed the results are easily recalled from the internal memory of the device.
- Talk Forward function allows easy communication with the patient while wearing the headphone and/or in sound booth installations.

1.5 Description

The MA 25/MA 25e and MA 27/MA 27e audiometers are 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.

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:

WARNING

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

CAUTION

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.

WARNING

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 the competent authority in the country where the user is established.

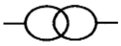
2.3 Manufacturer's Liability

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
MD	Medical Device
	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
	Do not reuse
CE	Conforms to Medical Device Regulation (EU) 2017/745
	ETL listed mark
MAICO	Logo

2.5 General Precautions

WARNING

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.

WARNING

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.

WARNING

Calibration of the device: The audiometer and the transducers complement each other and share the same serial number (i.e. MA1234567). 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.

WARNING

In Case of Emergency

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

WARNING

In Case of Emergency

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

Position the device in such a way that it can be easily disconnected from the power supply at any time.

Do not use the device if the power supply unit and/or the plug is damaged.

WARNING

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.

WARNING

A Separation Device (isolation device) is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. In particular such a Separation Device is required when a network connection is made. The requirement for the Separation Device is defined in IEC 60601-1 clause 16.

WARNING

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.

WARNING

Do not touch the contacts of the device and the patient at the same time.

If the device is connected to a PC (IT equipment forming a system) do not touch the patient and the IT equipment at the same time.

The consequence of not following this warning could be a too high leakage current to the patient.

WARNING

The device is not intended for operation in areas with an explosion hazard. Do NOT use the device 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.

WARNING

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.

WARNING

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)

WARNING

This device is suitable in hospital environments except for near active HF surgical equipment and RF shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.

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.

WARNING

Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this instrument and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

The list of accessories, transducers and cables can be found in the section 6.5 of this operation manual.

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the MA 25/MA 25e/MA 27/MA 27e, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result in improper operation.

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 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.

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 every 12 months.

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 25/MA 25e/MA 27/MA 27e and its accessories by wiping the surfaces with disinfectant wipes or a comparable product. Follow the instructions on the specific disinfection product.
  - Wipe before and after each patient
  - After contamination
  - After infectious diseases


CAUTION

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.

3.4 Disposables

Use only the Sanibel Supply disposable supplies that are supplied with your device.

Ear cushion covers are intended for single-use only. These should be discarded after use. They cannot be cleaned.


WARNING

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

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 25/MA 25e/MA 27/MA 27e 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 25/MA 25e/MA 27/MA 27e 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 ensure 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).

Components

The MA 25/MA 25e/MA 27/MA 27e comes with different components (see Table 2). The availability of configurations with the following components is country specific. Contact your local distributor for more information. See also Table 3 for replacement parts and disposables.

Table 2 Available Components

Available Components
Base Unit
AC Headphones DD45*
AC Headphones DD45 with RE-7 Headband*
DD65 v2 Headphones*
Power Supply Unit UES18LCPU-050200SPA
MAICO Sessions Kit (USB)
Operation Manual
Quick Guide
Patient Response Switch*
Only for MA 25/MA 25e:
Carrying Bag
3 AA Batteries

***Applied part according to IEC/EN 60601-1**

Table 3 Replacement Parts and Disposables

Replacement Parts and Disposables
Ear Cushion Cover
Audiogram Pad

4.2 Hardware Orientation

4.2.1 MA 25/MA 25e and MA 27/MA 27e Devices

MA 25/MA 25e

Figure 1 shows the MA 25/MA 25e device.

Figure 1

MA 27/MA 27e

Figure 2 shows the MA 27/MA 27e device. The device has a main device layout, a case to store headsets and cables and a handle to easily carry the device (Figure 3). The connections are located in the case (Figure 4).

Figure 2

Figure 3

Figure 4

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

Adjusting feet height (MA 27/MA 27e Only)

Figure 5

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 5.)

4.2.2 Connections for Headphones, USB Devices and Power Supply

Figure 6 and Figure 7 show the connections on the rear panel (MA 25/MA 25e) and the inside panel (MA 27/MA 27e) 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.

Connections

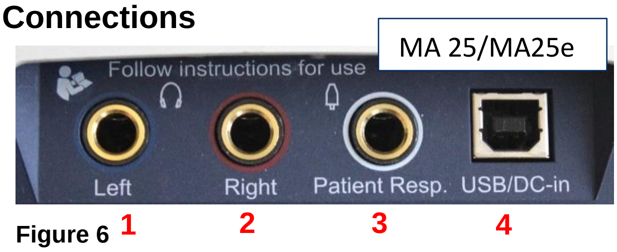


Figure 6

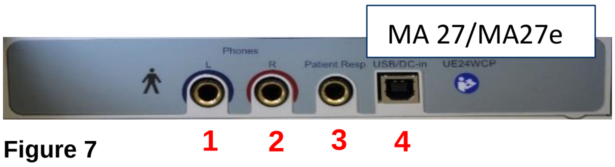


Figure 7

Table 4 Explanation of the Connections

CONNECTIONS	
1	Socket for left headphone jack (blue)
2	Socket for right headphone jack (red)
3	Socket for patient response switch
4	Socket for external power supply unit UES18LCPU-050200SPA

4.2.3 Only for MA 25/MA 25e: Battery Compartment

For battery driven use of the MA 25/MA 25e 3x AA batteries have to be placed in the battery compartment on the backside of the device (Figure 8 and Figure 9).

Figure 8

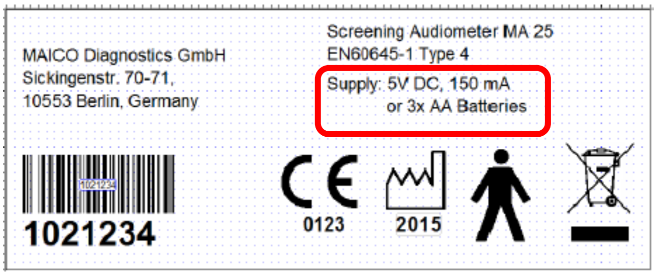


Figure 9

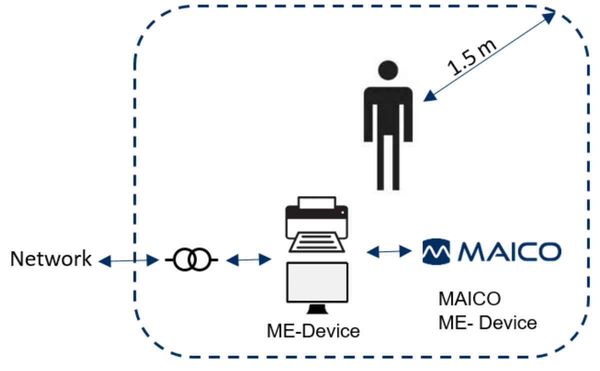
4.2.4 Establishing a PC-Connection (MA 25e/MA 27e Only)

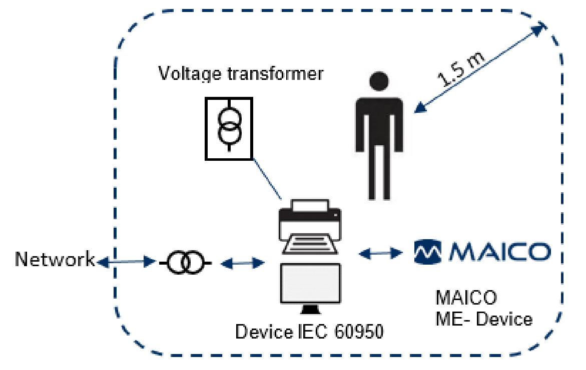
To transfer data to a PC, establishing a PC-connection via USB is required. If the MA25e/MA 27e is used with office equipment that is not a medical device itself (see Table 4, PC-Connection 1), make sure to establish the PC-connection in one of the following ways (see Table 5, PC Connection 2, 3 or 4).

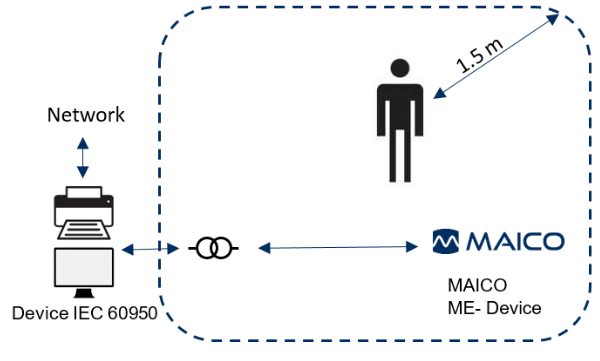
WARNING

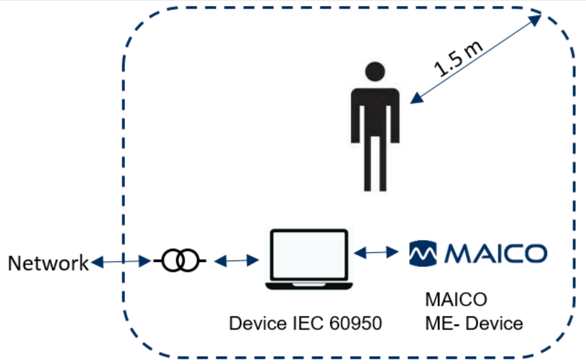
Make sure you use only office equipment with the device that is a medical device itself or meets the requirements of IEC 60950. If a non-medical device is used within the patient environment (1.5 m from patient as defined in IEC 60601) a voltage transformer must be used (exception: a battery driven laptop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

Table 5 PC-Connections

<table>
<tr><th colspan="2">PC CONNECTIONS</th></tr>
<tr><td>PC Connection 1:
Medical device – Medical Device</td><td>PC Connection 2:
Medical device – Non-Medical Device</td></tr>
<tr><td>


</td><td>


</td></tr>
<tr><td>PC Connection 3:
Medical device – Non-Medical Device</td><td>PC Connection 4:
Medical device – Laptop (battery-driven)</td></tr>
<tr><td>


</td><td>


</td></tr>
</table>

4.2.5 PC-Interface

Connecting the Audiometer to a PC for transferring the results is described in section 5.9.2.

4.2.6 Storage

When the MA 25/MA 25e/MA 27/MA 27e is not in use, store it in a location where it will be safe from damage to the 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 device**
- **the device layout**
- **the function keys and screens**
- **preparing the patient for testing**
- **performing Tone Audiometric testing**
- **changing settings in the tone setup menu**
- **managing the test results**

5.1 Getting started with the MA 25/MA 25e and the MA 27/MA 27e

5.1.1 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.

5.1.2 Where to Setup

The MA 25/MA 25e and MA 27/MA 27e 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..

Devices, which emit strong electromagnetic fields (e.g. cellphones, 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. For further information on use after transport and storage see section 6.1.

Place the device on a stable counter or table. Connect all accessories with the appropriate sockets as shown in Section 4.2.2. Plug the power cord into a grounded outlet.

5.2 Switching the Device On and Off

NOTE: All the cables and accessories have to be connected before the instrument is switched on. Power on is only possible if headphones are completely plugged-in!

NOTE: The warm-up time for the device including boot up process takes about 1 minute. For further information on use after transport and storage see Section 6.1.

To turn on the audiometer press the ***Tone Switch*** button (Figure 10/Figure 11, 1).

To power off the audiometer press and hold the ***Hearing Level dB*** dial (2) and ***Frequency Hz*** dial (3) for a few seconds or unplug the device.

5.3 Device Layout

Figure 10 and Figure 11 show the device layout. Table 6 gives further explanation.

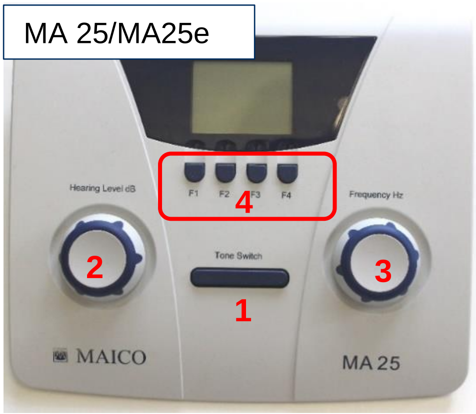


Figure 10

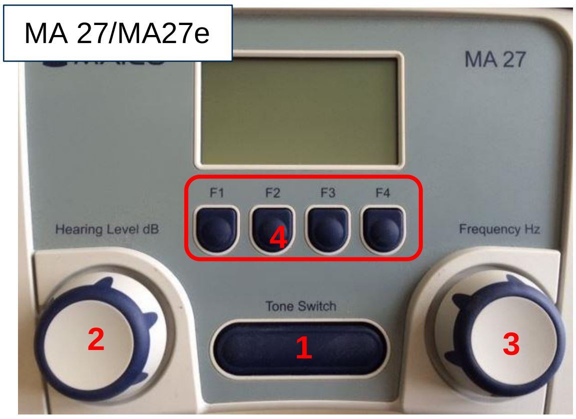


Figure 11

Table 6 Explanation of Device Layout

#	Name(s) / Function (s)	Description
1	**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.
2	**Hearing Level dB**	Dial to select hearing level of presented tone between -10 dB HL and 100 dB HL.
3	**Frequency Hz**	Dial to select frequency of presented tone.
4	**Function Keys F1-F4**	See section 5.4 for more details.

5.4 Function Keys

Function keys are the buttons below the display. Function of the button is displayed on the bottom of the display. These buttons are labeled ***F1***, ***F2***, ***F3*** and ***F4***. See Figure 10 and Figure 11 (4) well as Table 7 for the selections available for each function key in the testing mode.

NOTE: The function buttons are dependent upon the version obtained, MA 25/MA 27 and MA 25e/MA 27e.

Table 7 Explanation of Function Keys

Function key	MA 25/MA 27	MA 25e/MA 27e
F1	To select the ***Right*** ear.	To toggle between ***Left*** and ***Right*** ear.
F2	To select the ***Left*** ear.	To ***Store*** threshold.
F3	***Pulse*** – Pulse Off: Manual tone presentation; Pulse On: Pulsing Tone will be presented when tone switch is pressed.	
F4	***Warble*** – Warble Off: Pure tones will be presented. Warble On: Warble tones will be presented.	

5.5 MA 25e/MA 27e Special Functions

5.5.1 Talk Forward

Figure 12

On the MA 25e/MA 27e, Talk Forward is activated by holding down the ***Hearing Level dB*** (2) dial. Rotating the dial while in the talk-forward mode will adjust the level of the talk-forward to the patient (Figure 12).

5.5.2 Function Keys

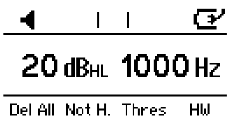
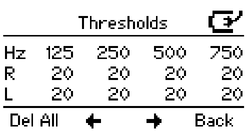


Figure 13

The additional function key options can be accessed by pressing the ***Frequency Hz*** dial (Figure 13). For explanation of the function keys see Table 8.

Table 8 Explanation of Function Keys

Function key	Label	MA 25e/MA 27e
F1	**Del All**	Deletes all thresholds stored in the internal memory of the MA 25e/MA 27e.
F2	**Not H.**	Stores a ***Not Heard*** threshold point.
F3	**Thres**	Displays the L/R thresholds stored in the internal memory of the MA 25e/MA27e (Figure 14).  **Figure 14**
F4	**HW**	Starts the automatic ***Hughson-Westlake (HW)*** test procedure. Refer to the section 5.8 on how to setup the HW test.

5.6 Screens

5.6.1 General

Figure 15 shows the main screen. See the explanation of the screen areas below.

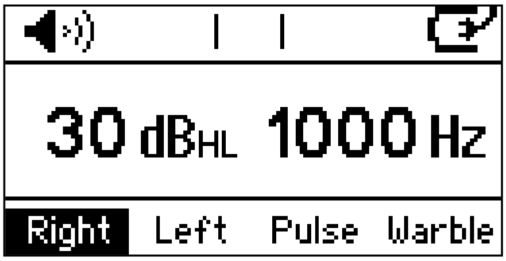
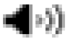


Figure 15

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

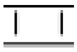
 Tone is presented (turned on).

 Tone is not presented (turned off).

5.6.2 Response (Patient Response Switch required)

When using the patient response switch, a response is indicated in the middle of the screen header.

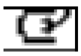
 Patient response switch is being activated (pressed).

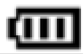
 Patient response switch is not activated (not pressed).

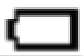
5.6.3 Powering of Device Icon

MA 25/MA 25e

The icon will change depending on whether the instrument is powered via an external source (power supply or USB connection to computer) or batteries.

 The device is plugged into a power source.

 When powered by batteries, the battery icon will change depending on the battery power level.

 When batteries are running low the screen will read Low Battery and flash (Figure 16).

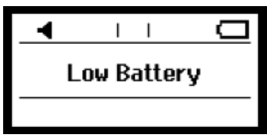
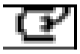


Figure 16

NOTE: The ***Power Off*** settings of the instrument can be adjusted at different time intervals or set to never power off. See section 5.8 for more information.

MA 27/MA 27e



The device is plugged into a power source.

5.6.4 Intensity

30 dBHL

Intensity displayed on the screen reflects the intensity/volume presented to patient. To change, rotate the ***Hearing Level dB*** dial.

5.6.5 Frequency

1000 Hz

Frequency displayed on the screen reflects the frequency presented to the patient. To change, rotate the ***Frequency Hz*** dial.

5.7 Preparing for Testing

5.7.1 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".***

5.7.2 Placement of Headphones (for Testing with Headphones)

Figure 17

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

Ensure that the headphones (Figure 17) 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).

5.7.3 Performing Tone Audiometric Tests (Air Conduction Testing)

5.7.3.1 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.

5.7.3.2 Threshold Determination

A threshold test is seeking the lowest level a tone is heard at least 50% of the time. 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. Vary the length of the tone and intervals between tone presentations to ensure the patient is responding to the tone not just repeating the behavior.

5.7.3.3 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 ***4000Hz*** in ***each ear***. If a patient hears all the tones in each ear, the result would be considered a ***Pass***. Failure to hear even one 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.

5.7.4 Automatic Threshold (Hughson-Westlake, MA 25e/MA 27e Only)

In addition to traditional manual testing, the MA 25e/MA 27e incorporates a Hughson-Westlake patient controlled automatic threshold test complying with ISO8253. When the test is completed the results are easily recalled from the internal memory of the MA 25e/MA 27e.

Hughson-Westlake is a procedure used to determine pure tone thresholds. The MA 25e/MA27e utilizes this procedure to perform an automatic pure tone test procedure. 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 device will re-test 1000 Hz before moving to the next ear or ending the test.

Prior to testing, the following instructions should be given. "***You will now hear a variety of tones with various loudness levels, please push the response switch when you hear a tone and release the button when you no longer hear it***“. The patient response can only be recorded during tone presentation.

The test frequencies will start at 1000 Hz and continue through those frequencies activated within the settings.

To start the automatic test, press the ***Frequency Hz*** dial. This will change the Function Key list to select HW with F4. For key selection see Table 8 in Section 5.5.2.

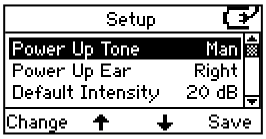
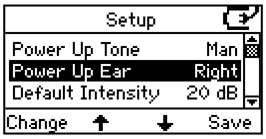
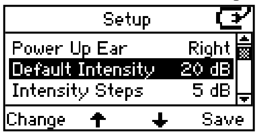
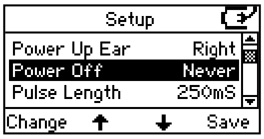
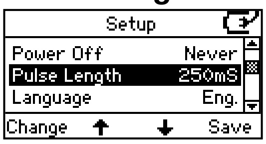
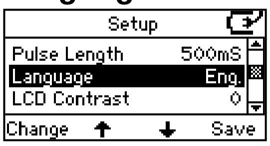
5.8 Tone Setup Menu

To access the ***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 or the ***Frequency Hz*** dial. See Table 9 and Table 10 for further explanation.

Table 9 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.

Table 10 Explanation of Options in the Setup Menu

Setup Menu	Description
Power Up Tone 	Press ***Change*** to toggle between ***Man (Manual)*** and ***Rev (Reverse)***: ***Man:*** Tone is presented as long as the ***Tone Switch*** is activated. ***Rev***: Tone will be interrupted if ***Tone Switch*** is activated.
Power Up Ear 	Press ***Change*** to toggle between ***Right*** and ***Left*** as the default ear for ***Power Up***.
Default Intensity 	The default intensity when changing ear side is 20 dB. Choose between: ***Off*** and values between ***-10 dB*** and ***50 dB*** (5 dB steps).
Intensity Steps 	The decible step size when turning the ***Hearing Level dB*** dial. Choose between ***1 dB***, and ***5 dB***.
Power Off 	**MA 25/MA 25e (Battery mode):** Press Change to toggle between ***Never***, and values between ***1 Min*** and ***5 Min*** (1 Min steps). The device will shut down after ***Power Off*** time as entered in the settings. **MA 25/MA 25e (USB power supply mode):** With power supplying from USB cable the device will <u>not</u> turn off. This setup is mainly to save the battery power. **MA 27/MA 27e**: The MA 27/MA 27e requires an electrical outlet or USB to computer connection and will not power off on its own.
Pulse Length 	Press ***Change*** to toggle between ***250 mS*** and ***500 mS***.
Language 	Press ***Change*** to toggle between ***Eng***. (***English***), ***Ger***. (***German***), ***Spa***. (***Spanish***), ***Fre***. (***French***) and ***Dut***. (***Dutch***).

<table>
<tr><th>Setup Menu</th><th>Description</th></tr>
<tr><td>

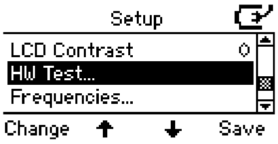
LCD Contrast

</td><td>

Press ***Change*** to toggle between settings ranging from ***0*** (low contrast) to ***7*** (strong contrast).

</td></tr>
<tr><td>

HW Test…

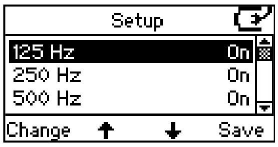


</td><td>

Hughson-Westlake test has a secondary menu. See Table 11 for more details.

</td></tr>
<tr><td>

Frequencies…



</td><td>

Press ***Change*** to access the menu for adjusting the default frequency range from ***125 Hz*** to ***8000 Hz***.

10 frequencies are available to change: ***125 Hz***; ***250 Hz***; ***500 Hz***; ***750 Hz***; ***1500 Hz***; ***2000 Hz***; ***3000 Hz***; ***4000 Hz***; ***6000 Hz***; and ***8000 Hz***.

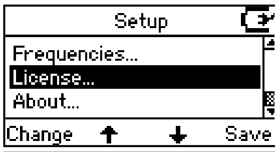
NOTE: 1000 Hz frequencies is not shown, since it cannot be deselected.

Press ***Change*** to toggle between ***On*** or ***Off***.

Press ***Save*** to return to the main ***Setup*** menu.

</td></tr>
<tr><td>

License



</td><td>

Press ***Change*** to access the license key of the device.Press ***Save*** to return to the main ***Setup*** menu.

For changing the license key ask your local distributor.

</td></tr>
<tr><td>

About

</td><td>

Press ***Change*** to access the information in the ***About*** section. This will display the model and version information.

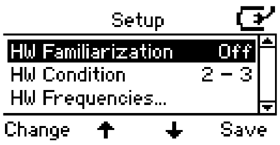
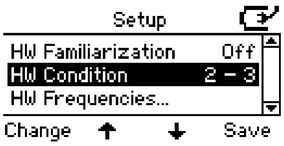
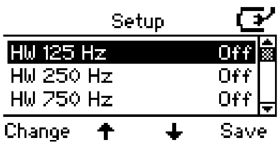
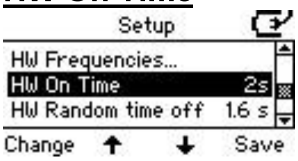
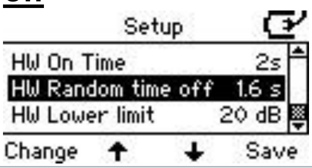
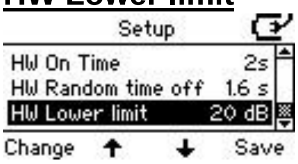
Press ***Save*** to return to the main ***Setup*** menu.

</td></tr>
</table>

Automatic Hughson-Westlake Test (HW)

The MA 25e and MA 27e incorporate the ***automatic 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. Press Save to return to the main setup menu.

Table 11 Hughson-Westlake Test

Setup Menu	Description
HW Familiarization 	To select if the patient shall be trained with a familiarization test (***On***), or not (***Off***).
HW Condition 	The HW test can be automated to confirm ***2 – 3*** (2 out of 3) or ***3 – 5*** (3 out of 5) correct answers before moving to the next frequency.
HW Frequencies… 	The HW allows for test frequencies to be deactivated separate from the manual audiometric test process. Press ***Change*** to toggle between the 7 frequencies that can be set to ***On*** or ***Off***: ***125 Hz, 250 Hz; 750 Hz; 1500 Hz, 3000 Hz, 6000 Hz, 8000 Hz***. Press ***Save*** to return to the main ***Hughson-Westlake Tests Setup*** Menu.
HW On Time 	Press ***Change*** to set the stimulus on time to 1 or 2 seconds.
HW Random time off 	Press ***Change*** to set the random time. The random time can be set between 0 and 1.6 seconds.
HW Lower limit 	Press ***Change*** to set the lower screening limit and define when to move on to the next frequency. The lower limit can be set between -10 and 20 dB.

5.9 Managing Test Results

5.9.1 Deleting Test Results

MA 25/MA 27

Deleting test results within the device is not possible.

MA 25e/MA 27e

Results are deleted by using the function keys of the device. Enter the F-key functions by pressing the ***Frequency Hz*** dial and press ***Del All*** to delete all results. Also, refer to section 5.5.2.

5.9.2 Transferring Test Results to PC (MA 25e/MA 27e Only)

Before transferring data to a PC make sure that you have installed ***MAICO Sessions*** properly according to the separately delivered operation manual on the USB. Before establishing the PC-connection you will have to consider the recommendations given in section 4.2.3 in case the MA 25e/MA 27e is connected to a non-medical device.

To transfer the data, make sure the device is connected to the PC via USB connection and ***MAICO Sessions*** is open before starting test. Click on ***(Get Measurement, 1)*** (Figure 14) and the tone audiometry values are transferred and displayed on the PC screen.

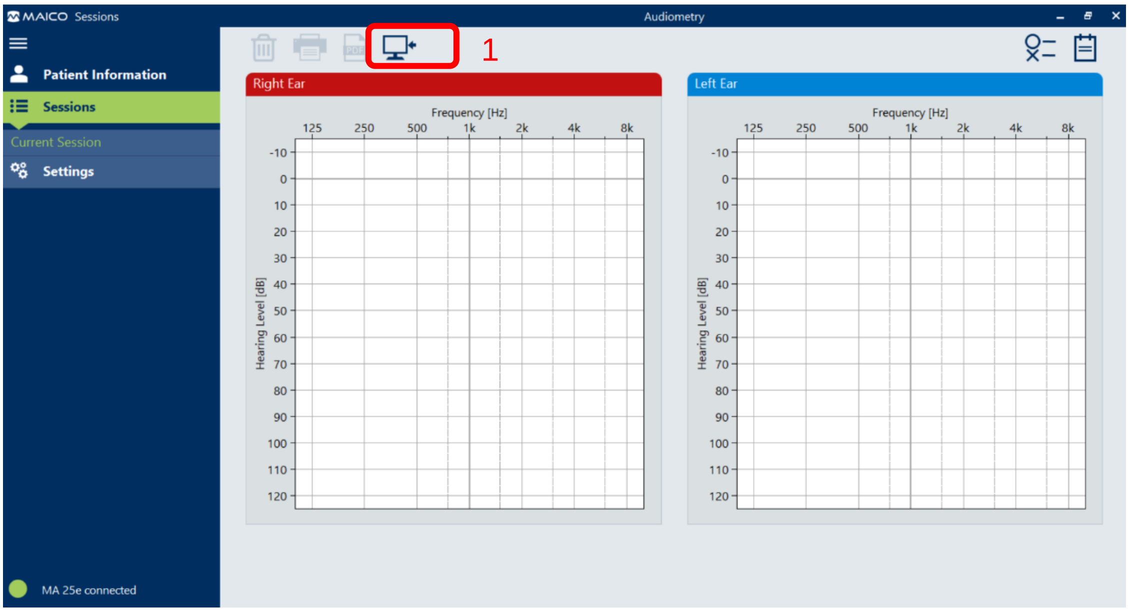


Figure 14

6 Technical Data

This section offers you important information about

- **the MA 25/MA 25e/MA 27/MA 27e hardware specifications**
- **connections**
- **the pin assignment**
- **audiometer calibration values**
- **electromagnetic compatibility (EMC)**
- **electrical safety, EMC and associated Standards**
- **checklist for subjective audiometer testing**

6.1 MA 25/MA 25e/MA 27/MA 27e Hardware

CE 0123

The MA 25/MA25e/MA27/MA 27e audiometer is an active, diagnostic medical product according to the class IIa of the Medical Device Regulation (EU) 2017/745.

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 every 12 months.

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

STANDARDS	
Safety Standards	IEC 60601-1: 2012 AAMI ES60601-1:2005+A2+A1 CAN/CSA-C22.2 No. 60601-1:14 Type B applied parts
EMC Standard	IEC 60601-1-2:2014
Audiometer Standards	Tone: IEC 60645-1:2017/ANSI S3.6-2018 Type 4

DEVICE SPECIFICATIONS		
Power supply	Type	UES18LCPU-050200SPA
	Input	100 to 240 V AC, 50/60 Hz, 0.5 A
	Output	5.0 V DC, 2.0A MAX
	Safety	IEC 60601-1, Class II
Mode of Operation	Continuous	
Batteries (MA 25/MA 25e)		
Battery Type	3 x AA	
Battery operation	Automatic battery on/off switching Automatic battery status indication	
Battery Life	Standby: 6 months, Tone presentations: 70,000	

Environmental conditions 	**Operation:**	+15 °C to +35 °C / + 59 °F to +95 °F
		Relative humidity 30 % to 90 % (non-condensing)
		Air pressure 98 kPa to 104 kPa Maximum altitude: 2000 m / 6561 ft above sea level
	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 25/MA 25e/MA 27/MA 27e Service Manual.	
Air Conduction	DD45:	RadioEar Standard Values
	DD65 v2:	RadioEar Standard Values
Transducers – Headband tension	DD45:	Headband Static Force: 4.5 N ± 0.5 N
	DD65 v2:	Headband Static Force: 10.0 N ± 0.7 N
Patient Response switch (MA 25e/MA 27e)	One push button	
Patient communication	MA 25e/MA 27e: Talk Forward (TF), built-in talk forward microphone. 60-100 dB SPL, Continuously adjustable on operation panel	
Special tests/test battery	MA 25e/MA 27e: Automatic-recording audiometer according ISO 8253-1 Mode of Operation: Patient controlled modified Hughson-Westlake procedure Rate of Change of Sound Pressure Level: • Randomized with a maximum rate of dB step/5.6 s depending on settings and patient response Initial familiarization: 10 dB up and 20 dB down steps • Threshold determination (ascending method): 5 dB up and 10 dB down steps Time window for patient response = On time (selection between 1 s or 2 s in device settings)	
Inputs	Tone, Warble Tone +5%, 5 Hz (true sine wave frequency modulation)	
Accuracy	Frequency ± 2 %, Level ± 3 dB	
Precision	Available Level Steps are 1 dB or 5 dB (chosen in Setup Menu)	
Outputs	Left, Right	
Stimuli		
Warble Tone	5 Hz sine +/- 5 % modulation	
Pulse Tone	Multiple pulses 250 ms or 500 ms; On/Off; pure tone or warble tone	
Presentation	Manual or reverse. Single, Pulse or Warble.	

Intensity	AC: -10 dB HL to 100 dB HL
Frequency range	125 Hz to 8000 Hz. Frequencies can be freely deselected (except 1000 Hz)
Weight	MA 25/MA 25e: 1.0 kg/2.2 lbs – including batteries and headset. (1.6 kg/3.5 lbs – including carrying bag headset, audiogram charts etc.) MA 27/MA 27e:2.4 kg/5.28 lbs – including power supply, headset and audiogram pad.
Dimensions	MA 25/MA 25e: 225 mm x 180 mm x 55 mm / 8.9 in x 7.1 in x 2.2 in MA 27/MA 27e: 255 mm x 370 mm x 150 mm / 10 in x 14.5 in x 6 in
Display	MA 25/MA 25e: 38.1 mm x 50.8 mm / 1.5 in x 2 in, Monochrome MA 27/MA 27e: 38.1 mm x 76.2 mm / 1.5 in x 3 in, Monochrome
Language Settings	English, Deutsch, Español, Français, Dutch
PC Connection	1 x USB B for PC Connection (comparable with USB 1.1 and later)
Warm up-time	1 minute incl. boot-up time
Store Function	MA 25e/MA 27e only: Soft key (function key) store button and internal memory for AC L/R. Stored measurements can be viewed on built-in display.
Distortion	0.3% typical at full intensity
Rise/fall Times	~35 ms

6.2 Connections

MA 25/MA25e

1 2 3 4

Figure 18

MA 27/MA27e

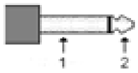
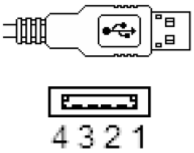
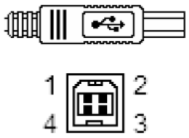
1 2 3 4

Figure 19

Table 12 Connections on Backside

CONNECTIONS		
No	Connection-socket	Specification
1	**Phone L**	ZA =10 Ω, UA = 7 Veff
2	**Phone R**	ZA =10 Ω, UA = 7 Veff
3	**Patient Resp.**	RI = 330R
4	**USB/DC-in**	USB 2.0

6.3 Pin Assignment

SOCKET	CONNECTOR	PIN 1	PIN 2
Left	 6.3 mm Mono	Ground	Signal
Right			
Pat. Resp.			
USB A (OUT)		**USB B (IN)**	
	1. +5 VDC		1. +5 VDC
	2. Data -		2. Data -
	3. Data +		3. Data +
	4. Ground		4. Ground

6.4 Calibration Values and Maximum Levels

Table 13 Coupler Types

COUPLER TYPES USED DURING CALIBRATION	
DD45:	Calibrated using a IEC 60318-3 (6cc) acoustic coupler. Tested in accordance with ANSI S3.6:2010 / ISO 389-1:1998, Impedance: 10Ω
DD65 v2:	Calibrated using a IEC 60318-1 acoustic coupler. Tested in accordance with ANSI S3.6:2010 / ISO 389-1:1998, Impedance: 10Ω

Table 14 Sound attenuation values

SOUND ATTENUATION		
Frequency [Hz]	Reference equivalent threshold sound pressure level [RETSPL, dB re. 20µPa]	
	DD45	DD65 v2
125	3.0	8.3
250	5.0	15.5
500	7.0	26.1
1000	15.0	32.4
2000	26.0	43.6
4000	32.0	43.8
8000	24.0	45.6

Table 15 Reference Values for Stimulus Calibration

REFERENCE VALUES FOR STIMULUS CALIBRATION		
Fre-quency [Hz]	Reference equivalent threshold sound pressure level [RETSPL, dB re. 20 µPa] according to:	
	PTB Report 2009, DTU Report 2010 Coupler IEC 60318-3	PTB Report 2018, DTU Report 2018 Coupler IEC 60318-1
	DD45	DD65 v2
125	47.5	30.5
250	27.0	17.0
500	13.0	8.0
750	6.5	5.5
1000	6.0	4.5
1500	8.0	2.5
2000	8.0	2.5
3000	8.0	2.0
4000	9.0	9.5
6000	20.5	21.0
8000	12.0	21.0

Table 16 Frequencies and Maximum Intensities: AC (Air Condition) dB HL

TRANSDUCER MAXIMUM HEARING LEVELS		
Frequency [Hz]	Intensities [dB HL]	
	DD45	DD65 v2
	Tone	Tone
125	70	70
250	90	90
500	100	100
750	100	100
1000	100	100
1500	100	100
2000	100	100
3000	100	100
4000	100	100
6000	100	85
8000	90	70

6.5 Electromagnetic Compatibility (EMC)

ESSENTIAL PERFORMANCE for this device is defined by the manufacturer as:

- This device does not have an ESSENTIAL PERFORMANCE.
- Absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk. Final diagnosis shall always be based on clinical knowledge.

This instrument is in compliance with IEC60601-1-2:2014, emission class B group 1.

NOTE: There are no deviations from the collateral standard and allowances uses.

NOTE: All necessary instruction for maintaining compliance with regard to EMC can be found in the general maintenance section in this instruction. No further steps required.

To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the accessories listed in the following table. Conformance to the EMC requirements as specified in IEC 60601-1-2 is ensured if the cable types and cable lengths are as specified.

ITEM	MANUFACTURER	MODEL	CABLE	
			LENGTH [M]	SCREENED (YES/NO)
Audiometric Headphones	Radioear	DD45	2.0	Yes (MA 27 only)
Audiometric Headphones	Radioear	DD65 v2	2.0	No
Patient response switch	Radioear	APS3	2.0	Yes
Power Supply (Wall plug)	UE / Fuhua	UES18LCPU-050200SPA	1.5	No
USB cable Type A/B	Sanibel	8011241	2.0	Yes

Electromagnetic Compatibility (EMC)

Portable and mobile RF communications equipment can affect the ***MA 25/MA27.*** Install and operate the ***MA 25/MA27*** according to the EMC information presented in this chapter.
The ***MA 25/MA27*** has been tested for EMC emissions and immunity as a standalone ***MA 25/MA27.*** Do not use the ***MA 25/MA27*** 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 25/MA 27 is intended for use in the electromagnetic environment specified below. The customer or the user of the *MA 25/MA 27* should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ***MA 25/MA 27*** 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 25/MA 27*** 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 25/MA 27*.			
The ***MA 25/MA 27*** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ***MA 25/MA 27*** can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ***MA 25/MA 27*** 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 2.7 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 25/MA 27*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***MA 25/ MA 27*** 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	+8 kV contact +15 kV air	+8 kV contact +15 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% *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 for 5 sec	Mains power quality should be that of a typical commercial or residential environment. If the user of the ***MA 25/MA 27*** requires continued operation during power mains interruptions, it is recommended that the ***MA 25/MA 27*** 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 25/MA 27*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***MA 25/MA 27*** should assure that it is used in such an environment,			
Immunity test	**IEC / EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any parts of the ***MA 25/MA 27,*** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC / EN 61000-4-6	3 Vrms 150kHz to 80 MHz	3 Vrms	$d = 1{,}2\sqrt{P}$
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,7 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,7 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: 
NOTE1 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 25/MA 27*** is used exceeds the applicable RF compliance level above, the ***MA 25/MA 27*** should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ***MA 25/MA 27.*** **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: Medical Electrical Equipment, Part 1 General Requirements for Safety and Essential Performance
2. AAMI ES60601-1:2005+A2+A1: Medical Electrical Equipment, Part 1 General Requirements for Safety and Essent ial Performance
3. CAN/CSA-C22.2 No. 60601-1:14: Medical Electrical Equipment, Part 1 General Requirements for Basic Safety and Essential Performance
4. UL/IEC/EN 60950-1: Information Technology Equipment - Safety - Part 1: General Requirements
5. IEC/EN 60601-1-1 General requirements for safety; Collateral standard: Safety requirements for medical electrical systems
6. IEC/EN 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
7. DIN/EN/ISO 14971 - Application of risk management to medical devices
8. General Safety and Performance Requirements of the current REGULATION (EU) 2017/745
9. DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2)
10. Legislation 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.

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