# Operation Manual
# MA 25/MA 25e


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**TABLE OF CONTENTS**

Title: Operation Manual MA 25/MA 25e

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All available operation manuals can be found in the download center on the MAICO homepage:

Germany:

https://www.maico-diagnostics.com/german/support/resources/

International:

https://www.maico-diagnostics.com/support/resources/



**Compliance**

MAICO Diagnostics is an ISO 13485 certified corporation.

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

# 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

The audiometer is designed to quantitatively measure and monitor an individual's hearing threshold across different frequencies.

## 1.2 Indications for Use Statement

There are no medical indications for this device.

## 1.3 Patient Population

The target population is children to adults.

## 1.4 Contraindications

A discharging ear, acute external auditory canal trauma, discomfort (e.g., severe otitis externa) or occlusion of the external auditory canal, or if the patient is too young, sick or uncooperative to perform the tasks.

## 1.5 Intended Operator

The MA 25/MA 25e is intended to be used by audiologists, hearing healthcare professionals, and trained personnel responsible for assessing and managing the hearing health of individuals.

## 1.6 Features and Benefits of the MA 25/MA 25e

### 1.6.1 General Information About the MA 25/MA 25e

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

- Portable audiometer
- Multiple transducer options
- Air Conduction
- Pure, Pulse and Warble Tone

### 1.6.2 Extended Functions of the MA 25e

The MA 25e 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.

## 1.7 Description

The MA 25/MA 25e audiometers are designed to be a device for screening for hearing loss. The 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 Reading this Operation Manual

This operation manual contains information pertinent to the use of the MA 25/MA 25e system including safety information as well as maintenance and cleaning recommendations.

READ THIS ENTIRE OPERATION MANUAL BEFORE ATTEMPTING TO USE THIS SYSTEM!

Use this device only as described in this Operation Manual.

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

In this Operation 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 always observed. 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 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 failure to follow the operating instructions, operation by unqualified personnel, and unauthorized modifications to the equipment.

## 2.4 Regulatory Symbols

The following Table 1 explains the symbols used on the device itself, on the packaging and the accompanying documents including the Operation Manual.

**Table 1 Regulatory Symbols**

| REGULATORY SYMBOLS<br>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 |
| (01)04260176127444<br>(11)201020<br>(21)MA0123456 | UDI information: (01) GTIN (Global Trade Item Number), (11) Date, (21) Serial number |
| | Applied part type BF according to IEC 60601-1 |
| | Refer to operation manual (mandatory) |
| | Keep away from rain |
| | Transport and storage temperature range |
| | Transport and storage humidity limitations |
| | Transport and storage atmospheric pressure limitations |
| | Voltage transformer |
| | Do not reuse |
| CE<br>0123 | CE label with notified body ID |
| | Non-ionizing electromagnetic radiation |
| | Direct Current (DC) |
| | 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 6.

For operation in certain places, a recalibration may be necessary.


Do not open the case of the MA 25/MA 25e. Refer servicing to qualified personnel.


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.


Do not modify this equipment without authorization of the manufacturer.

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.


Calibration of the device: The device and the transducers complement each other and share the same serial number (i.e., MA7663252). Therefore, the device shall not be used with any other transducer prior to recalibration. Recalibration also needs to be conducted when defective headphones are replaced.

Uncalibrated devices may lead to faulty measurement results and could even damage the hearing of the examinee.


The device is not intended to be used in environments exposed to fluid spills. Ingress of any fluids is considered a single fault condition. No means specified for fluid protection (not IP classed).


Connect only accessories purchased from MAICO to the MA 25/MA 25e. Only accessories which have been stated by MAICO as being compatible are allowed to be connected to the device.

## 2.6 Electrical and Electrostatic Safety

This icon indicates that 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.

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


Do not use the device if the power supply unit and/or the plug is damaged.
To transfer data to a PC, establishing a PC connection via USB is required. See Section 0 on how to safely establish a connection with a power supplied PC or laptop (medical electrical equipment/nonmedical electrical equipment) 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 62368-1 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 in 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 a qualified medical technician or your local representative.


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.


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.


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.


The device is not intended for operation in areas with an explosion hazard. Do NOT use the device in a highly oxygen rich 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 unit originally delivered by MAICO. Using another power supply unit can also lead to electrical damage on the device.


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

## 2.7 Electromagnetic Compatibility (EMC)


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.


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 device 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 Section 6.5.


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, including cables specified by the manufacturer.

Otherwise, degradation of the performance of this equipment could result in improper operation.

## 2.8 Device Control

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

For annual calibration, see Sections 2.5 and 3.2.

# 3 Warranty, Maintenance and After-Sales Service

**This Section offers you important information about:**

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

## 3.1 Warranty

The MAICO device is guaranteed for at least 1 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 1 year from date of delivery 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, enclose evidence of purchase with the device.

## 3.2 Maintenance

To ensure that the device works properly, it must be checked and calibrated at least every 12 months.

The service and calibration must be performed by your distributor, or 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. Include a detailed description of faults. To prevent damage in transit, use the original packaging when returning the device.

## 3.3 Cleaning and Disinfection Recommendations

It is recommended that parts (device and accessories like headphones, and 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.
- Remove the headphones from the device.
- For cleaning use a lightly dampened cloth with soap water solution.
- Disinfect the plastic housing of the device and its accessories by wiping the surfaces with wet disinfection 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, 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.

For more detailed cleaning recommendations see the following sections and follow the instructions on the items that are relevant for your system.

## 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.


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

## 3.5 Components/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 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 2012/19/EU of the European Parliament and of the Council of 4 July 2012 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 carefully making sure that all components are removed from the packaging materials.
- Verify that all components are included as shown on the packing list included with your shipment.
- If any component is missing, contact your distributor immediately to report the shortage.
- If any component appears to be damaged in shipment, contact your distributor immediately to report it. Do not attempt to use any component or device that appears to be damaged.

### Reporting Imperfections

Notify the carrier immediately if any mechanical damage is noted. This will 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 packaging material and the shipping container, so the device can be properly packed if it needs to be returned for service or calibration.

The MA 25/MA 25e 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.

**Table 2 List of Components**

| Available Components |
|---|
| Base Unit |
| AC Headphones |
| DD45* |
| DD65 v2* |
| Power Supply Unit UES18LCPU-050200SPA |
| MAICO Sessions Kit (USB) |
| Operation Manual** |
| Quick Guide** |
| Patient Response Switch* |
| Carrying Bag |
| 3 AA Batteries |

***Applied part according to IEC/EN 60601-1**
****As download from the download center – see accompanying leaflet**

**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 Devices

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


**Figure 1**

### 4.2.2 Connections for Headphones, USB Devices and Power Supply

Figure 2 show the connections on the rear 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.

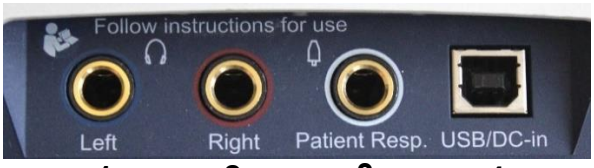



**Figure 2**

**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 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 3 and Figure 4).


**Figure 3**

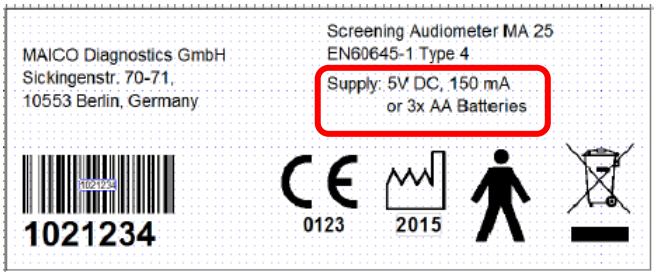



**Figure 4**

### 4.2.4 Establishing a PC Connection via USB (MA 25e Only)

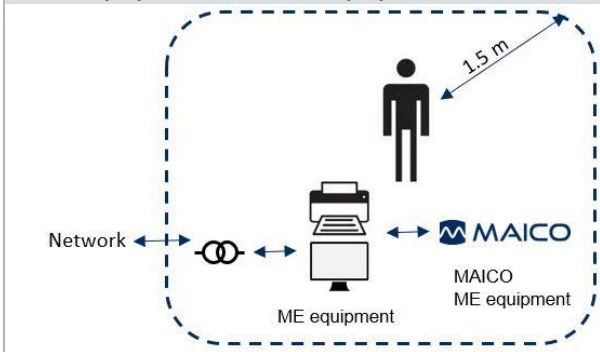
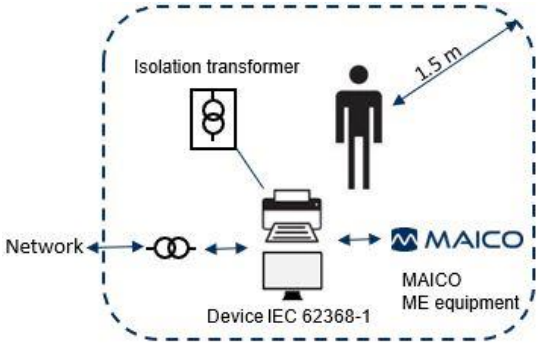
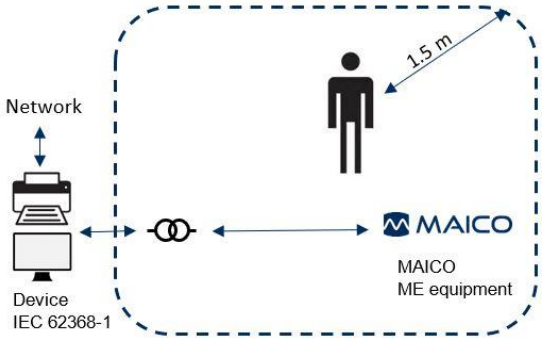
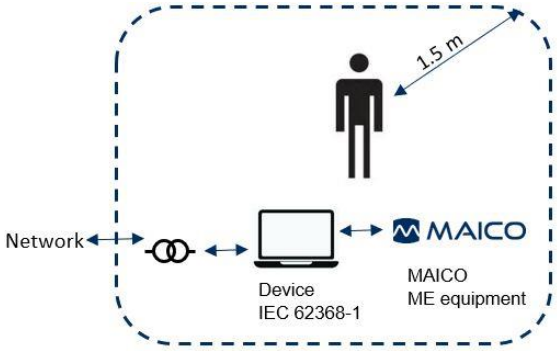
Data transfer to a PC can be done via USB connection.

If the MA 25/MA 25e is used with office equipment that is not medical electrical equipment (ME equipment) itself (see Table 5, 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 medical electrical equipment itself or meets the requirements of IEC 62368-1. If nonmedical electrical equipment is used within the patient environment (1.5 m from patient as defined in IEC 60601-1) an isolation transformer must be used (exception: a battery-driven laptop is used).

**Table 5 PC Connections**

| PC CONNECTIONS | |
|---|---|
| PC Connection 1:<br>ME equipment – ME equipment | PC Connection 2:<br>ME equipment – Non-ME equipment |
|  |  |
| PC Connection 3:<br>ME equipment – Non-ME equipment | PC Connection 4:<br>ME equipment – Laptop (battery-driven) |
|  |  |

## 4.3 Storage

When the MA 25/MA 25e is not in use, store it in a location where it will be safe from damage to the screen or other sensitive components. Store according to the recommended temperature conditions described in Section 6.

CAUTION

Leaking batteries can cause damage to the device.

Remove batteries from the device if you will not be using it for a longer period.

# 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

### 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 is 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 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 ISO 8253 series or ANSI S3.1.

Electronic devices, which emit strong electromagnetic fields (e.g., microwaves or radiotherapy devices), can influence the audiometric function. Therefore, it is not recommended to use these devices near 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 min before the first measurement. If the device has been cooled down (e.g. during transport), wait until it has warmed up to room temperature before using.

**NOTE**: For temperature and warm-up time see Section 6.1.

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

## 5.2 Switching the Device On and Off

**NOTE:** All the cables and accessories must be connected before the device is turned on. The device can only be turned on when the headphones are completely plugged in!

**NOTE:** The warm-up time for the device including boot up process takes about 1 min. For further information on use after transport and storage see Section 5.1.1.

To turn on the audiometer press the ***Tone Switch*** button (Figure 5, **1**).

To turn 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 5 shows the device layout. Table 6 gives further explanation.


**Figure 5**

**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. The function of the button is displayed on the bottom of the display. These buttons are labeled ***F1***, ***F2***, ***F3*** and ***F4***. See Figure 5 (**4**) and 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 and MA 25e.

**Table 7 Explanation of Function Keys**

| Function key | MA 25 | MA 25e |
|---|---|---|
| **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.<br>***Warble On***: Warble tones will be presented. | |

## 5.5 MA 25e Special Functions

### 5.5.1 Talk Forward

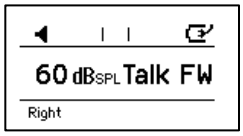



**Figure 6**

On the MA 25e, 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 6).

### 5.5.2 Function Keys

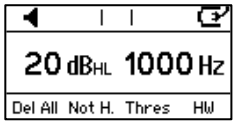
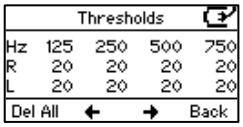



**Figure 7**

The additional function key options can be accessed by pressing the ***Frequency Hz*** dial (Figure 7). For explanation of the function keys see Table 8.

**Table 8 Explanation of Function Keys**

| Function key | Label | MA 25e |
|---|---|---|
| **F1** | **Del All** | Deletes all thresholds stored in the internal memory of the MA 25e. |
| **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 (Figure 8).<br>  <br>**Figure 8** |
| **F4** | **HW** | Starts the automatic ***Hughson-Westlake (HW)*** test procedure. Refer to the Section 5.9 on how to setup the HW test. |

## 5.6 Screens

### 5.6.1 General

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

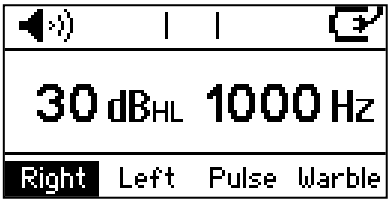



**Figure 9**

**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

The icon will change depending on whether the device 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 10).

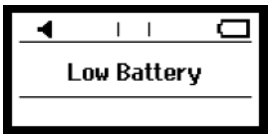



**Figure 10**

**NOTE**: The ***Power Off*** settings of the device can be adjusted at different time intervals or set to never power off. See Section 5.9 for more information.

### 5.6.4 Intensity

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

### 5.6.5 Frequency


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."***

**NOTE**: This is an example of patient preparation. Each state may have their own preparation procedure. Contact your state health department for guidelines in your area.

### 5.7.2 Placement of Headphones (for Testing with Headphones)

**Figure 11**

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 11) 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).

## 5.8 Performing Tone Audiometric Tests

### 5.8.1 Air Conduction Testing

#### *5.8.1.1 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 disorder.

#### *5.8.1.2 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.

### 5.8.2 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.

### 5.8.3 Automatic Threshold (Hughson-Westlake, MA 25e Only)

In addition to traditional manual testing, the device incorporates a 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.

Hughson-Westlake is a procedure used to determine pure tone thresholds. The device 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***.

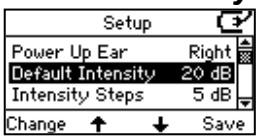
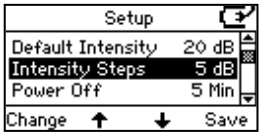
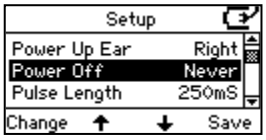
## 5.9 Tone Setup Menu

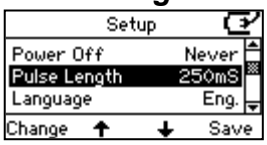
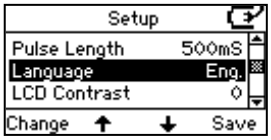
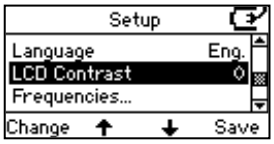
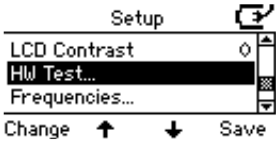
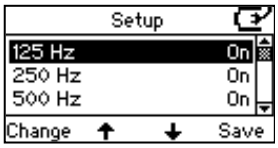
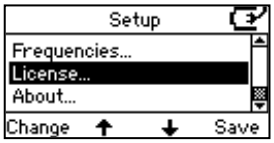
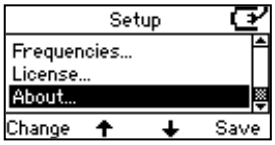
To access the ***Tone Setup menu*** press **F1** and **F4** simultaneously for 2 s to 3 s. Once in the Menu (Figure 12), the different Setup options are listed and can be entered using the function keys or the ***Frequency Hz*** dial. See Table 9 and Table 10 for further explanation.

**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**

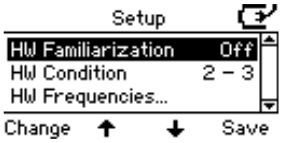
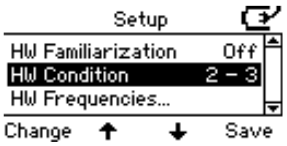
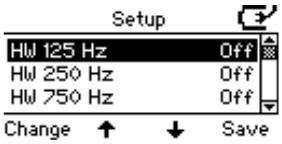
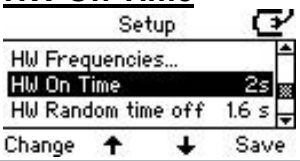
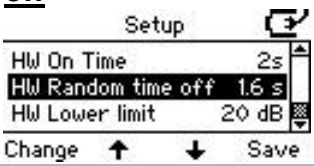
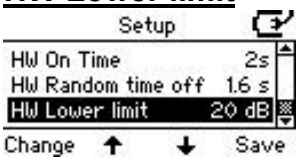
| Setup Menu | Description |
|---|---|
| ***Power Up Tone***<br>  | Press ***Change*** to toggle between ***Man*** **(*Manual*)** and ***Rev (Reverse)***:<br>***Man:*** Tone is presented as long as the ***Tone Switch*** is activated.<br>***Rev****:* Tone will be interrupted if ***Tone Switch*** is activated. |
| ***Power Up Ear***<br>  | Press ***Change*** to toggle between ***Right*** and ***Left*** as the default ear for ***Power Up***. |
| ***Default Intensity***<br>  | The default intensity when changing ear side is 20 dB.<br>Choose between: ***Off*** and values between ***-10 dB*** and ***50 dB*** (5 dB steps). |
| ***Intensity Steps***<br>  | The decible step size when turning the ***Hearing Level dB*** dial.<br>Choose between ***1 dB***, and ***5 dB***. |
| ***Power Off***<br>  | **Battery mode:**<br>Press ***Change*** to toggle between ***Never***, and values between ***1 Min*** and ***5 Min*** (1 min steps). The device will turn off after ***Power Off*** time as entered in the settings.<br>**USB power supply mode:**<br>With power supplying from USB cable the device will not turn off. This setup is mainly to save the battery power. |

| Setup Menu | Description |
|---|---|
| ***Pulse Length***<br>  | Press ***Change*** to toggle between ***250 mS*** and ***500 mS***. |
| ***Language***<br>  | Press ***Change*** to toggle between ***Eng***. (***English***), ***Ger***. (***German***), ***Spa***. (***Spanish***), ***Fre***. (***French***) and ***Dut***. (***Dutch***). |
| ***LCD Contrast***<br>  | Press ***Change*** to toggle between settings ranging from ***0*** (low contrast) to ***7*** (strong contrast). |
| ***HW Test…***<br>  | Hughson-Westlake test has a secondary menu. See Table 11 for more details. |
| ***Frequencies…***<br>  <br>  | Press ***Change*** to access the menu for adjusting the default frequency range from ***125 Hz*** to ***8000 Hz***.<br>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***.<br>**NOTE**: 1000 Hz frequency is not shown, since it cannot be deselected.<br>Press ***Change*** to toggle between ***On*** or ***Off***.<br>Press ***Save*** to return to the main ***Setup*** menu. |
| ***License***<br>  <br>  | Press ***Change*** to access the license key of the device. Press ***Save*** to return to the main ***Setup*** menu.<br>For changing the license key, ask your local distributor. |
| ***About***<br>  | Press ***Change*** to access the information in the ***About*** section. This will display the model and version information.<br>Press ***Save*** to return to the main ***Setup*** menu. |

### Automatic Hughson-Westlake Test (HW)

The MA 25e incorporates 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***<br>  | To select if the patient shall be trained with a familiarization test (***On***), or not (***Off***). |
| ***HW Condition***<br>  | 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…***<br>  | 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**<br>  | Press ***Change*** to set the stimulus on time to 1s or 2 s. |
| **HW Random time off**<br>  | Press ***Change*** to set the random time. The random time can be set between 0 s and 1.6 s. |
| **HW Lower limit**<br>  | 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 dB and 20 dB. |

## 5.10 Managing Test Results

### 5.10.1 Deleting Test Results

**MA 25**

Deleting test results within the device is not possible.

**MA 25e**

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.

### 5.10.2 Transferring Test Results to PC (MA 25e 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.

To transfer the data, make sure the device is connected to the PC via USB connection and ***MAICO Sessions*** is open before starting the test. Press  ***(Get Measurement, 1)*** ***(***Figure 8***)*** and the tone audiometry values are transferred and displayed on the PC screen.

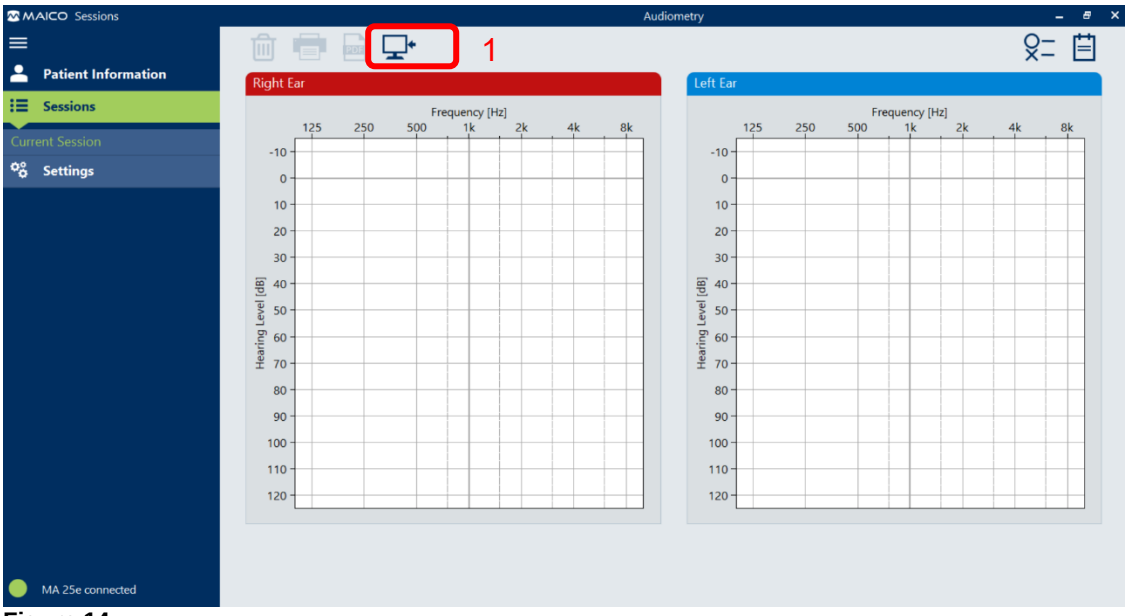



**Figure 14**

# 6 Technical Data

**This section offers you important information about**

- **the MA 25/MA 25e hardware specifications**
- **connections and pin assignment**
- **calibration and maximum values**
- **electromagnetic compatibility (EMC)**
- **electrical safety, EMC, and associated standards**

## 6.1 MA 25/MA 25e Hardware

CE 0123

The MA 25/MA 25e is an active, diagnostic medical product according to 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 subjected to technical maintenance at least every 12 months.

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

| STANDARDS | |
|---|---|
| **Safety Standards** | IEC 60601-1: 2012<br>AAMI ES60601-1:2005+A2+A1<br>CAN/CSA-C22.2 No. 60601-1:14<br>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 | |

## DEVICE SPECIFICATIONS

| | | |
|---|---|---|
| **Batteries** | | |
| **Battery Type** | 3 x AA | |
| **Battery operation** | Automatic battery on/off switching<br>Automatic battery status indication | |
| **Battery Life** | Standby: 6 months, Tone presentations: 70,000 | |
| **Environmental conditions**  | **Operation** | +15 °C to +35 °C /<br>+ 59 °F to +95 °F |
| | | Relative humidity 30 % to 90 % (non-condensing) |
| | | Air pressure 98 kPa to 104 kPa<br>Maximum altitude: 2000 m / 6561 ft above sea level |
| | **Storage** | 0 °C to + 50 °C / 32 °F to +122 °F<br>Humidity 10 to 95 % (non-condensing) |
| | **Transport** | -20 °C to + 50 °C / -4 °F to +122 °F<br>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** | One push button | |
| **Patient communication** | MA 25e: Talk Forward (TF), built-in Talk Forward microphone. 60-100 dB SPL, continuously adjustable on operation panel | |
| **Special tests/test battery** | MA 25e:<br>Automatic recording audiometer according ISO 8253-1<br>Mode of Operation: Patient controlled modified Hughson-Westlake procedure<br>Rate of Change of Sound Pressure Level:<br>• Randomized with a maximum rate of dB step/5.6 s depending on settings and patient response<br>Initial familiarization: 10 dB up and 20 dB down steps<br>• Threshold determination (ascending method): 5 dB up and 10 dB down steps<br>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) | |

## DEVICE SPECIFICATIONS

| | |
|---|---|
| **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** | 1.0 kg/2.2 lbs – including batteries and headphones. (1.6 kg/3.5 lbs – including carry case, headphones, audiogram charts, etc.) |
| **Dimensions** | 225 mm x 180 mm x 55 mm / 8.9 in x 7.1 in x 2.2 in |
| **Display** | 38.1 mm x 50.8 mm / 1.5 in x 2 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 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

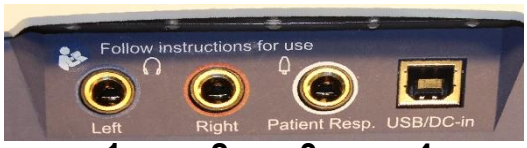


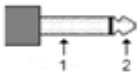

Figure 12

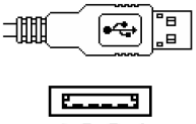
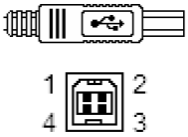
**Table 12 Connections on Backside**

| CONNECTIONS | | |
|---|---|---|
| **No** | **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

**Table 13 Pin Assignment**

| SOCKET | CONNECTOR | PIN 1 | PIN 2 |
|---|---|---|---|
| Left |  | Ground | Signal |
| Right | | | |
| Pat. Resp. | 6.3 mm Mono |  | |

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

## 6.4 Calibration Values and Maximum Levels

**Table 14 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: 10 Ω |
| **DD65 v2:** | Calibrated using a IEC 60318-1 acoustic coupler. Tested in accordance with ANSI S3.6:2010 / ISO 389-1:1998, Impedance: 10 Ω |

**Table 15 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 16 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 17 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 device is in compliance with IEC 60601-1-2:2014, emission class B group 1.

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

*NOTICE:* 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.

Portable and mobile RF communications equipment can affect the MA 25/MA 25e. Install and operate the MA 25/MA 25e according to the EMC information presented in this section.
The MA 25/MA 25e has been tested for EMC emissions and immunity as a standalone MA 25/MA 25e. Do not use the MA 25/MA 25e 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.

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 | |
| Audiometric Headphones | Radioear | DD65 v2 | 2.0 | No |
| Patient Response Switch | Radioear | APS3 | 2.0 | Yes |
| Power Supply (Power Connector) | UE / Fuhua | UES18LCPU-050200SPA | 1.5 | No |
| USB Cable Type A/B | Sanibel | 8011241 | 2.0 | Yes |

| **Guidance and manufacturer's declaration - electromagnetic emissions** | | |
|---|---|---|
| The *MA 25/MA 25e* is intended for use in the electromagnetic environment specified below. The customer or the user of the *MA 25/MA 25e* should assure that it is used in such an environment. | | |
| **Emissions Test** | **Compliance** | **Electromagnetic environment - guidance** |
| RF emissions<br>CISPR 11 | Group 1 | The ***MA 25/MA 25e*** 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<br>CISPR 11 | Class B | The ***MA 25/MA 25e*** is suitable for use in all commercial, industrial, business, and residential environments. |
| Harmonic emissions<br>IEC 61000-3-2 | Complies<br>Class A Category | |
| Voltage fluctuations / flicker emissions<br>IEC 61000-3-3 | Complies | |

**Recommended separation distances between portable and mobile RF communications equipment and the *MA 25/MA 25e*.**

The ***MA 25/MA 25e*** 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 25e*** can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ***MA 25/MA 25e*** 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 25e*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***MA 25/MA 25e*** should assure that it is used in such an environment.

| Immunity Test | IEC 60601 Test level | Compliance | Electromagnetic environment - guidance |
|---|---|---|---|
| Electrostatic Discharge (ESD)<br><br>IEC 61000-4-2 | +8 kV contact<br><br>+15 kV air | +8 kV contact<br><br>+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<br><br>IEC61000-4-4 | +2 kV for power supply lines<br><br>+1 kV for input/output lines | +2 kV for power supply lines<br><br>+1 kV for input/output lines | Mains power quality should be that of a typical commercial or residential environment. |
| Surge<br><br>IEC 61000-4-5 | +1 kV differential mode<br><br>+2 kV common mode | +1 kV differential mode<br><br>+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<br><br>IEC 61000-4-11 | < 5% *U*T (>95% dip in *U*T) for 0.5 cycle<br><br>40% *U*T (60% dip in *U*T) for 5 cycles<br><br>70% *U*T (30% dip in *U*T) for 25 cycles<br><br><5% *U*T (>95% dip in *U*T) for 5 sec | < 5% *U*T (>95% dip in *U*T) for 0.5 cycle<br><br>40% *U*T (60% dip in *U*T) for 5 cycles<br><br>70% *U*T (30% dip in *U*T) for 25 cycles<br><br><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 25e*** requires continued operation during power mains interruptions, it is recommended that the ***MA 25/MA 25e*** be powered from an uninterruptable power supply or its battery. |
| Power frequency (50/60 Hz)<br><br>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 25e*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***MA 25/MA 25e*** should assure that it is used in such an environment, | | | |
| **Immunity test** | **IEC / EN 60601 test level** | **Compliance level** | **Electromagnetic environment – guidance** |
| Conducted RF<br>IEC / EN 61000-4-6 | 3 Vrms<br>150kHz to 80 MHz | 3 Vrms | Portable and mobile RF communications equipment should be used no closer to any parts of the ***MA 25/MA 25e,*** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>**Recommended separation distance:**<br><br>$d = 1{,}2\sqrt{P}$ |
| Radiated RF<br>IEC / EN 61000-4-3 | 3 V/m<br>80 MHz to 2,7 GHz | 3 V/m | $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz<br><br>$d = 2{,}3\sqrt{P}$ 800 MHz to 2,7 GHz<br><br>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).<br><br>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]<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>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 25e*** is used exceeds the applicable RF compliance level above, the ***MA 25/MA 25e*** 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 25e.***<br>[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

- IEC 60601-1:2012: Medical Electrical Equipment, Part 1 General Requirements for Safety and Essential Performance
- AAMI ES60601-1:2005+A2+A1: Medical Electrical Equipment, Part 1 General Requirements for Safety and Essential Performance
- CAN/CSA-C22.2 No. 60601-1:14: Medical Electrical Equipment, Part 1 General Requirements for Basic Safety and Essential Performance
- IEC/EN 60601-1-1 General requirements for safety; Collateral standard: Safety requirements for medical electrical systems
- 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
- General Safety and Performance Requirements of the current REGULATION (EU) 2017/745
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2)
- DIRECTIVE 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)

## 6.7 Checklist for Subjective Audiometer Testing

| | |
|---|---|
| - Clean the ear and head cushion!<br>- Untangle all lines when necessary!<br>- Are the headphone cushions in good condition?<br>If not → replace.<br>- Are plugs and leads in good condition/ undamaged?<br>- Are all controls working properly?<br>- Is the Patient Response Key working properly (if available)?<br>- Check batteries and renew if necessary! | Instrument:.....<br>Manufacturer:.....<br>Serial No.:.....<br>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 | | | | | | | | | Left Earpiece |
| | | | | | | | | | $dB_{HL}$ | | | | | | | | | |
| Right Earpiece ** | | | | | | | | | Is | | | | | | | | | Right Earpiece ** |
| | | | | | | | | | $dB_{HL}$ | | | | | | | | | |

* 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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