

# MA 27/MA 27e Operating Manual







# MA 27/MA 27e Operating Manual

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# MA 27/MA 27e Operating Manual

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## Title: MA 27/MA 27e Operating Manual

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### Compliance

MAICO Diagnostics is an ISO 13485 certified corporation.



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## 1. Introduction

Thank you for selecting one of our quality products from the MAICO family range. The MA 27/MA 27e is designed and manufactured to meet all quality and safety requirements.

Particular attention has been taken during the designing phase of the MA 27/MA 27e to ensure its user-friendliness, meaning that its operation is simple, easy to learn and to understand. As all the functions are software-controlled, upgrading the software and/or adding additional functions at a later date will be simple and cost-effective. By purchasing the MAICO MA 27/MA 27e, you have made a decision towards long-term investment.

This operating manual aims to make learning and understanding the different MAICO MA 27/MA 27e functions as quick and as easy as possible. Should you encounter any problems or have ideas for any further improvements, we are only a phone call away. Please do not hesitate to contact us.

Your MAICO-Team



# MA 27/MA 27e Operating Manual

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## 1.1. Intended Use

The MA 27/MA 27e audiometer is intended to be used by an audiologist, hearing healthcare professional, or trained technician in a quiet environment for the purpose of hearing screening.

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

The instrument is intended for professional use in clinics and hospitals.

## 1.2. Description

The MA 27/MA 27e screening audiometer is designed to be a device for screening for hearing loss. Output and specificity of this type of device are based on the test characteristics defined by the user, and may vary depending on environmental and operating conditions. The screening for hearing loss using this kind of audiometer depends on the interaction with the patient. As with any type of hearing screening, a "pass" result should not overrule any additional concerns regarding hearing ability. A full audiologic evaluation should be administered if concerns about hearing sensitivity persist.

## 1.3. Extended Function

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

- The MA 27e can communicate with a computer.
- In addition to traditional manual testing, the MA 27e 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 MA 27e.
- Talk Forward function that makes the MA 27e easy to work with particularly in sound booth installations.

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## 1.4. Important Safety Note

The MA 27/MA 27e should always be operated in a quiet room with minimal magnetic influence, to ensure that examinations are not disturbed by external noise.

Electro-medical instruments that emit strong electromagnetic fields (e.g. microwaves, radiotherapy devices) can affect the operation of the MA 27/MA 27e.

Therefore, the operation of these instruments in close proximity to the MA 27/MA 27e should be avoided at all times.

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

The separable mains plug is used to safely disconnect mains from the device. Do not position the power supply in a position so that it is difficult to disconnect the device.

### Attention



PLEASE READ THE ENTIRE MANUAL CAREFULLY BEFORE OPERATING THIS INSTRUMENT.

Please only use this instrument as described in the manual.

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

Should defects or damages be suspected, please do not, under any circumstances, use or attempt to fix the instrument yourself. Unauthorized modifications can result in electrical hazards

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

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**NOTE:** Uncalibrated instruments may lead to faulty measurements.

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

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



Within the European Union it is illegal to dispose electric and electronic waste as unsorted municipal waste. Electric and electronic waste may contain hazardous substances and therefore has to be collected separately. Such products will be marked with the crossed-out wheeled bin shown

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below. The cooperation of the user is important in order to ensure a high level of reuse and recycling of electric and electronic waste. Failing to recycle such waste products in an appropriate way may endanger the environment and consequently the health of human beings.

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

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

If the instrument is connect 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

## 1.5. Unpacking and Checking the MA 27

Checking for packaging and content damage

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

**PLEASE KEEP ALL ORIGINAL PACKAGING FOR FUTURE USE!**

The MA 27 is packaged in a specially-designed box. Please keep the box as it will be useful for sending the instrument for the annual instrument check-up.

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

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## 1.6. Standard Accessories

- DD 45 Audiometric Headset with HB7 Headband\*
- Operation Manual
- Quick Guide
- AC Power Adapter, USE ONLY UE24WCP Type
- Audiogram Pad

## 1.7. Optional Accessories

- Patient Response Switch\*
- Audiocup Headset

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

## 1.8. Connecting the Accessories

All the connection jacks can be found on the inside compartment of the MA 27/ MA 27e. All the cables and accessories have to be connected before the instrument is switched on.

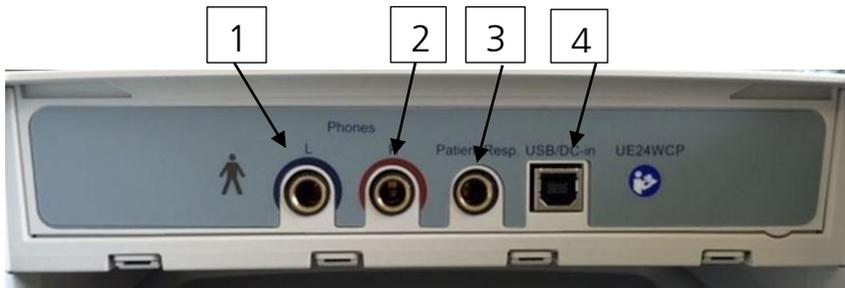


Figure 1 Jack panel located inside compartment of MA 27/ MA 27e

| Position: | Symbol:       | Function:                             |
|-----------|---------------|---------------------------------------|
| 1         | Phones L      | Socket for left headphone jack (Blue) |
| 2         | Phones R      | Socket for right headphone jack (Red) |
| 3         | Patient Resp. | Socket for patient response switch    |
| 4         | USB/DC-in     | Socket for external power supply      |

# MAICO

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### 2. Function of Buttons and Display

#### 2.1. Power On and Power Off



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**NOTE:** Power on is only possible if headphones are plugged-in!

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**Power On:** To turn on the audiometer press the "Tone Switch" button.

**Power Off:** To power off the audiometer press and hold the "Hearing Level" dialer and "Frequency" dialer for a few seconds or unplug the device.

#### 2.2. Pure Tone Presentation

**Frequency:** Turn the "Frequency Hz" dialer to select another frequency.

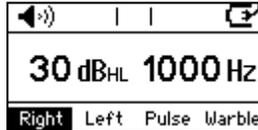
**Level:** Rotate the "Hearing Level dB" dialer to increase or decrease the level.

**Present tone:** Press the "Tone Switch."

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## 2.3. Display



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

 : No signal is being presented.

 : Signal is being presented.

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

 : Patient response switch is being activated (pressed).

 : Patient response switch is not being activated (not pressed).

**Device is powered:**

 : The device is plugged in to a power source.

**Intensity:**

**30 dBHL** : Intensity displayed on the screen reflects the intensity/volume presented to patient. To change, rotate the left rotary wheel.

**Frequency:**

**1000 Hz** : Frequency displayed on the screen reflects the frequency presented to the patient. To change, rotate the right rotary wheel.



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## 2.4. Function Buttons

Function Buttons are those buttons labeled with F1, F2, etc. The function of the button is displayed on the bottom of the display screen.

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

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**F1:** MA 27 : Select the Right ear.

MA 27e : Toggle between right and left.

**F2:** MA 27 : Select the Left ear.

MA 27e : 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.

## 2.5. MA 27e Special Functions

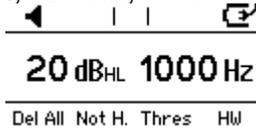
**Talk Forward:** On the MA 27e, Talk Forward is activated by holding down the "Hearing Level dB" rotary wheel. Rotating the dial while in the talk-forward mode will adjust the level of the talk-forward to the patient.



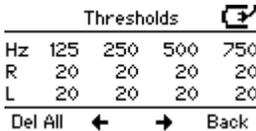
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**F-Key Functions:** The following F-key functionalities can be accessed by pressing the "Frequency Hz" rotary wheel:



- F1:** Delete all thresholds stored in the internal memory of the MA 27e.
- F2:** Store a Not Heard threshold point.
- F3:** Display the L/R thresholds stored in the internal memory of the MA 27e.



|    | Thresholds |     |     |     |
|----|------------|-----|-----|-----|
| Hz | 125        | 250 | 500 | 750 |
| R  | 20         | 20  | 20  | 20  |
| L  | 20         | 20  | 20  | 20  |

Del All ← → Back

**F4:** Start the Hughson-Westlake (HW) automatic test procedure. Please refer to the next chapter for instructions about how to setup the HW test.

## 3. Performing Tone Audiometric Tests

### 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 abnormality in the conductive mechanism and sensorineural mechanism.

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

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

Ensure that the headphones are positioned correctly: red side on the right ear, blue side 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).

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 left or right hand when you hear the tone in the left or right ear".



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## 3.2. Threshold Determination:

The test normally starts at 1000 Hz on the patient's better ear with the L/R switch adjusted accordingly. A procedure of "down 10 dB, up 5 dB" is typically utilized to establish a threshold at each frequency.

## 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, 1000, 2000, and 4000 HZ in each ear. If a patient hears all the tones in each ear, the result would be considered a "pass." Failure to hear any of the tones in either ear would result in a "refer". This is an example of one screening protocol. Each state may have their own screening protocol. Please contact your state health department for guidelines in your area.

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**NOTE:** Background noise can produce false test results, especially at lower frequencies. It is important to test in a quiet environment.

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For hygienic reasons, it is important to clean the headphone ear cushions after testing.

## 3.4. Auto Threshold (Hughson-Westlake):

In addition to traditional manual testing, the MA 27e 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 MA 27e.

Hughson-Westlake is a procedure used to determine pure tone thresholds. The MA 27e 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 patient should sit at a distance of at least 1 m from the device.

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

Ensure that the headphones are positioned correctly: red side on the right ear, blue side 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).

Prior to hearing threshold level measurements, 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."

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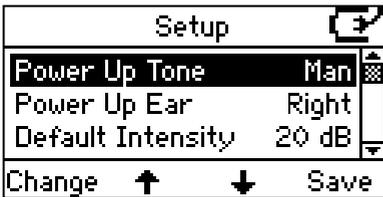
## 4. Setup Menu

To access the MA 27/MA 27e Setup menu press F1 and F4 simultaneously for 2-3 seconds. Once in the Menu, the following function keys will direct you through the setup process.

|    |        |   |
|----|--------|---|
| F1 | Change | Change setting that is highlighted  |
| F2 | ↑      | Browse up in the setup menu   |
| F3 | ↓      | Browse down in the setup menu   |
| F4 | Save   | Save settings and Back to previous screen display – see below for details |

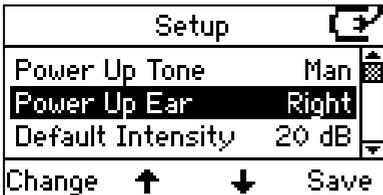
### 4.1. Standard Menu Setup

Power Up Tone:



Press Change to toggle between Manual and 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 ear as the default ear for Power Up.

Default Intensity:



The default intensity when changing ear side is 20 dB.

Choose between: Off, -10 dB, -5 dB, 0 dB, 5 dB, 10 dB, 15 dB, 20 dB, 25 dB, 30 dB, 35 dB, 40 dB, 45 dB, and 50 dB.

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## Intensity Steps:

|                        |   |   |
|------------------------|---|---|
| Setup                  |   |  |
| Default Intensity      | 20 dB   |  |
| <b>Intensity Steps</b> | <b>5 dB</b>   |  |
| Power Off              | 5 Min   |  |
| Change                 |   | Save  |

Choose between 1 dB, and 5 dB.

## Power Off Settings:

|                  |   |   |
|------------------|---|---|
| Setup            |   |  |
| Power Up Ear     | Right   |  |
| <b>Power Off</b> | <b>Never</b>  |  |
| Pulse Length     | 250mS   |  |
| Change           |   | Save  |

The MA 27/MA 27e requires an electrical outlet and will not power off on its own.

## Pulse Length:

|                     |   |   |
|---------------------|---|---|
| Setup               |   |  |
| Power Off           | Never   |  |
| <b>Pulse Length</b> | <b>250mS</b>  |  |
| Language            | Eng.  |  |
| Change              |   | Save  |

Press Change to toggle between 250 msec and 500 msec.

## Language:

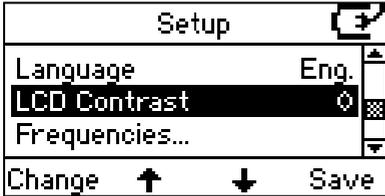
|                 |   |   |
|-----------------|---|---|
| Setup           |   |  |
| Pulse Length    | 500mS   |  |
| <b>Language</b> | <b>Eng.</b>   |  |
| LCD Contrast    | ◊   |  |
| Change          |   | Save  |

Press Change to toggle between English, German, Spanish, and French.

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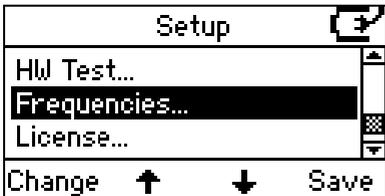
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## LCD Contrast:

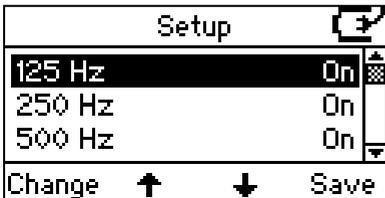


Press Change to toggle between settings ranging from 0 (very bright) to 6 (very dark).

## Frequencies:



Press Change to access the default frequency range from 125 Hz to 8 kHz for daily operation.



10 frequencies are available to change: 125; 250; 500; 750; 1,500; 2,000; 3,000; 4,000; 6,000; and 8,000.

Press Change to toggle between On or Off.

Press Save to return to the main Setup menu.

## License:



Press Change to access the license key of the MA 27/MA 27e.

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Press Change to enter and modify the license key. Use the Hearing Level dB dialer to change the letter and Frequency Hz dialer to move the cursor. Press Save to return to the main Setup menu.

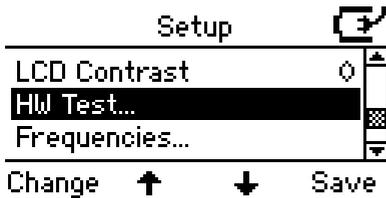
About:



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

## 4.2. Hughson Westlake (HW) Test Setup (only on MA 27e)

MA 27e incorporates the Hughson Westlake test. The automation of this test is configured in the Setup Menu.



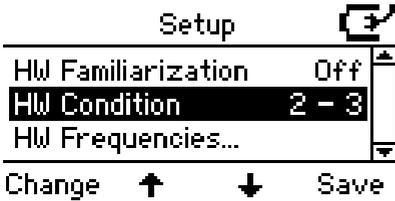
Press Change to go to the HW automatic test procedure setup.



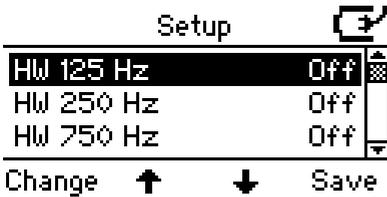
Press Change to toggle between Familiarization On/Off. Familiarization is used to train the patient.

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Press Change to toggle between "2 correct out of 3 answers" and "3 correct out of 5 answers". The conditions used before going to the next frequency.



Select the frequencies to include in the HW test. Press Change to toggle between frequencies On/Off.

Press Save to return to the main setup menu.



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## 5. Warranty and Disclaimer

### Warranty, Maintenance and After-Sales Service Hardware

The MA 27/MA 27e audiometer is guaranteed for 1 year. This warranty is extended to the original purchaser of the instrument by MAICO through the Distributor from whom it was purchased and covers defects in material and workmanship for a period of one year from date of delivery of the instrument to the original purchaser.

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

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

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

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

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



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## 6. Care and Maintenance

### **Disconnect the unit's energy source before cleaning!**

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

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

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



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## 7. Safety Regulations

### 7.1. Electrical Safety:

The MA 27/MA 27e is in compliance with Class B of EN 60601-1. The instrument is not to be used in environments dealing with explosive material or equipment.

### 7.2. Measurement Safety:

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

### 7.3. Instrument Handling:

The instrument should be checked once a week.

### 7.4. Operation:

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

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## 8. Technical Data

### Standards:

Audiometer : EN 60645-1/ANSI S3.6, Type 4  
Safety : EN 60601-1 Class II, Type B applied parts  
EMC : EN 60601-1-2

Frequencies and Maximum Intensities:

| Freq. Hz. | AC (Air Condition) dB <sub>HL</sub> |
|-----------|-------------------------------------|
| 125       | 70                                  |
| 250       | 90                                  |
| 500       | 100                                 |
| 750       | 100                                 |
| 1000      | 100                                 |
| 1500      | 100                                 |
| 2000      | 100                                 |
| 3000      | 100                                 |
| 4000      | 100                                 |
| 6000      | 100                                 |
| 8000      | 90                                  |

Inputs: Patient response switch (MA 27e),  
USB-Power-Supply

Outputs: Left AC, Right AC 10 ohm impedance

Attenuator: -10 to 100 dBHL in 5 or 1 dB steps (chosen  
in set-up menu).

Tone Presentation: Manual or reverse (chosen in Setup Menu);  
Multiple pulses 250 or 500 msec (chosen in  
Setup Menu); On/Off; pure tone or warble  
tone

Talk Forward (MA 27e): Built in talk forward microphone. 60-100  
dBHL. Continuously adjustable on  
operation panel.

Auto Threshold: Patient controlled Hughson-Westlake  
procedure according to ISO 8253-1



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|                            |   |
|----------------------------|---|
| Store Function:            | Soft key (F-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<br>1% maximum at full intensity  |
| Rise/fall Times:           | ~35 msec.   |
| Display Header Indicators: | Tone On<br>Patient Response<br>Power Status   |
| Modulation:                | Warble +/- 5% 5 Hz sinusoidal   |
| Calibration:               |   |
| Air Conduction:            | ISO 389-1/ANSI S3.6   |
| Warm Up Time:              | None  |
| Dimensions:<br>W x D x H:  | 25.5 x 37 x 15 cm / 10 x 14.5 x 6 inches  |
| Weight:                    | 2.4 kg/5.28 lbs – including power supply, headset and audiogram pad.  |
| Operation (environment)    | Temperature: 15°C to 35°C (59-95°F)<br>Relative humidity: 30% to 90% (non cond.)<br>Ambient pressure: 98 kPa to 104 kPa                               |
| Storage (environment)      | Temp: 0°C to 50°C (32-122°F) (Storage)<br>Temp: -20°C to 50°C (-4-122°F) (Transport)<br>Relative humidity: 10% to 95% (non cond.)                     |
| Power:                     | Use Only UE24WCP Type 100-240 VAC<br><br>USB Power from IT-equipment in accordance with IEC 60950-1 - See also safety notice<br>5V DC ±5%, min 150 mA |



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|                        |  |
|------------------------|--|
| Operating Environment: | Temperature 15-35°C/59-95°F<br>Relative Humidity 30-90 %<br>The instrument is not intended to be used above 2000 meter from sea-level  |
| Construction:          | Plastic cabinet  |
| PC-connection          | The audiometer can be connected to any type of IT-equipment fulfilling the requirements of IEC 60950-1 by USB. Please also refer to power specifications and safety issues in section 3.2. There are no further requirements for the IT equipment except that the whole system shall comply to safety regulations in IEC 60601 |

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## 9. Regulatory Symbols

| Label or International Symbol  | Reference                                       | Placement   |
|--|---|---|
|   | Serial Number                                   | Registration Label  |
|   | Date of Manufacture<br>yyyy                     | Registration Label  |
|   | Address of Manufacturer                         | Registration Label<br>Package Label<br>IFU                    |
|   | Return to Authorized Representative             | Registration Label  |
|   | B Patient Applied Part according to IEC60601-1. | Registration Label  |
|   | Consult Operating Instructions                  | On device where appropriate                                   |
|  | Product Name                                    | Rating Label<br>IFU<br>Package Label                          |
|   | SKU   | Rating Label<br>Package Label                                 |
|   | Logo  | Front Label   |
| <br>Maico<br>Sickingenstr. 70-71<br>10553 Berlin<br>Germany | EU Authorized Representative                    | Package Label<br>IFU  |
|   | CE Mark –                                       | <b>EU Only</b><br>Directly on Product<br>Package Label<br>IFU |

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## Appendix A: EMC Compatibility

Portable and Mobile RF communications equipment can affect the MAICO MA 27/MA 27e. Install and operate the MAICO MA 27/MA 27e according to the EMC information presented on this page and the next 5 pages.

The MAICO MA 27/MA 27e has been tested for EMC emissions and immunity as a standalone instrument. Do not use the MAICO MA 27/MA 27e 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.

### EUT Support Equipment and Cables\*

| Item                    | Manufacturer   | Model             | Cable          |                | SIP/SOP        |                | Serial no. |
|-------------------------|----------------|-------------------|----------------|----------------|----------------|----------------|------------|
|                         |                |                   | Length [meter] | Screened [Y/N] | Socket ID      | Type           |            |
| Audiometric Headset     | Radioear       | DD45              | 2.0            | Y              | Phones L and R | Headset output | -          |
| Patient response switch | Interacoustics | APS3              | 2.9            | Y              | Patient Resp.  | DC level       | -          |
| Power Supply            | Fuhua          | UE24WCP-050250SPA | 1.5            | N              | USB/DC-in      | DC level       | -          |

*\*To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the follow*

### Essential Performance

To generate and present stimulus signals in the audio range as specified in the applicable IEC 60645 series in normal conditions.

Absence of these performance features can lead to failure in diagnosis which is considered as an unacceptable risk to the patient. Temporary loss of essential performance is not considered an acceptable risk as long as the loss of performance is detectable. This could be the loss of power, fuse blow of system halt with error message.

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## Electromagnetic Compatibility

Although the instrument fulfils the relevant EMC requirements precautions should be taken to 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.

## Electrical Safety, EMC and Associated Standards

1. UL 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety
2. IEC/EN 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety
3. CAN/CSA-C22.2 No. 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety Electrical Equipment for Laboratory Use
4. IEC/EN 60601-1-2: Medical Electrical Equipment, Part 1 - Electromagnetic Compatibility - Requirements and Tests
5. Essential Requirements of the current European Union Medical Device Directive 93/42/EEC
6. RoHS (Restriction of the use of certain Hazardous Substance)
7. WEEE (Waste Electrical & Electronic Equipment) Legislation



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## 9.1. Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The MAICO MA 27/ MA 27e is intended for use in the electromagnetic environment specified below. The customer or the user of the MAICO MA 27/MA 27e should assure that it is used in such an environment.

| Emissions Test   | Compliance       | Electromagnetic environment - Guidance   |
|--|------------------|--|
| RF Emissions<br>CISPR 11                                     | Group 1          | The MAICO MA 27/ MA 27e 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 Limits   |  |
| Harmonic Emissions<br>IEC 61000-3-2                          | Class A Category |  |
| Voltage Fluctuations /<br>Flicker Emissions<br>IEC 61000-3-3 | Complies         | The MAICO MA 27/ MA 27e is suitable for use in all commercial, industrial, business, hospital, and residential environments.   |

## Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the MA 27/MA 27e

The MAICO MA 27/ MA 27e is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MAICO MA 27/ MA 27e can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MA 27/ MA 27e as recommended below, according to the maximum output power of the communications equipment.

| Rated Maximum<br>Output Power of<br>Transmitter<br>W | Separation distance according to frequency of transmitter<br>m |   |   |
|--|--|---|---|
|  | 150 kHz to 80 MHz<br>$d = 1.17\sqrt{P}$                        | 80 MHz to 800 MHz<br>$d = 1.17\sqrt{P}$ | 800 MHz to 2.5<br>GHz<br>$d = 2.23\sqrt{P}$ |
| 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 transmitters, 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.

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| <b>Guidance and Manufacturer's Declaration - Electromagnetic Immunity</b>   |   |   |   |
|---|---|---|---|
| The MAICO MA 27/ MA 27e is intended for use in the electromagnetic environment specified below. The customer or the user of the MA 27/ MA 27e should assure that it is used in such an environment. |   |   |   |
| <b>Immunity Test</b>  | <b>IEC 60601 Test Level</b>   | <b>Compliance</b>   | <b>Electromagnetic Environment-Guidance</b>   |
| <b>Electrostatic Discharge (ESD)</b><br><br>IEC 61000-4-2   | $\pm 6$ kV contact<br><br>$\pm 8$ kV air  | $\pm 6$ kV contact<br><br>$\pm 8$ kV air  | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be greater than 30%.  |
| <b>Electrical Fast Transient/Burst</b><br><br>IEC 61000-4-4   | $\pm 2$ kV for power supply lines<br>$\pm 1$ kV for input/output lines  | $\pm 2$ kV for power supply lines<br>$\pm 1$ kV for input/output lines  | Mains power quality should be that of a typical commercial, hospital, or residential environment.   |
| <b>Surge</b><br><br>IEC 61000-4-5   | $\pm 1$ kV differential mode<br><br>$\pm 2$ kV common mode  | $\pm 1$ kV differential mode<br><br>$\pm 2$ kV common mode  | Mains power quality should be that of a typical commercial, hospital, or residential environment.   |
| <b>Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Lines</b><br><br>IEC 61000-4-11   | <b>&lt;5% UT</b> (>95% dip in UT) for 0.5 cycle<br><b>40% UT</b> (60% dip in UT) for 5 cycles<br><b>70% UT</b> (30% dip in UT) for 25 cycles<br><b>5% UT</b> (>95% dip in UT) for 5 sec | <b>&lt;5% UT</b> (>95% dip in UT) for 0.5 cycle<br><b>40% UT</b> (60% dip in UT) for 5 cycles<br><b>70% UT</b> (30% dip in UT) for 25 cycles<br><b>5% UT</b> (>95% dip in UT) for 5 sec | Mains power quality should be that of a typical commercial, hospital, or residential environment. If the user of the MAICO MA 27/ MA 27e requires continued operation during power mains interruptions, it is recommended that the MA 27/ MA 27e be powered from an uninterrupted power supply. |
| <b>Power Frequency (50/60 Hz)</b><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 hospital environment.   |
| <b>Note:</b> UT is the a.c. mains voltage prior to application of the test level.   |   |   |   |

# MA 27/MA 27e Operating Manual

## Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The MAICO MA 27/ MA 27e is intended for use in the electromagnetic environment specified below. The customer or the user of the MA 27/ MA 27e should assure that it is used in such an environment.

| Immunity Test  | IEC 60601 Test Level   | Compliance                 | Electromagnetic Environment-Guidance  |
|--|--|----------------------------|---|
| <p>Conducted RF<br/>IEC 61000-4-6</p> <p>Radiated RF<br/>IEC 61000-4-3</p>   | <p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p> | <p>3 Vrms</p> <p>3 V/m</p> | <p>Portable and mobile RF communications equipment should be used no closer to any part of the MA 27/ MA 27e, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 1.17\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m).</p> <p>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*).</p> <p>Interference may occur in the vicinity of equipment marked:</p>  |
| <p><b>Note 1:</b> At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p><b>Note 2:</b> These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> |  |                            |   |

(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 27/ MA 27e is used exceeds the applicable RF compliance level above, the MA 27/ MA 27e should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MA 27/ MA 27e.

(b\*) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.





Specifications are subject to change without notice.

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