Operation Manual
MA 28

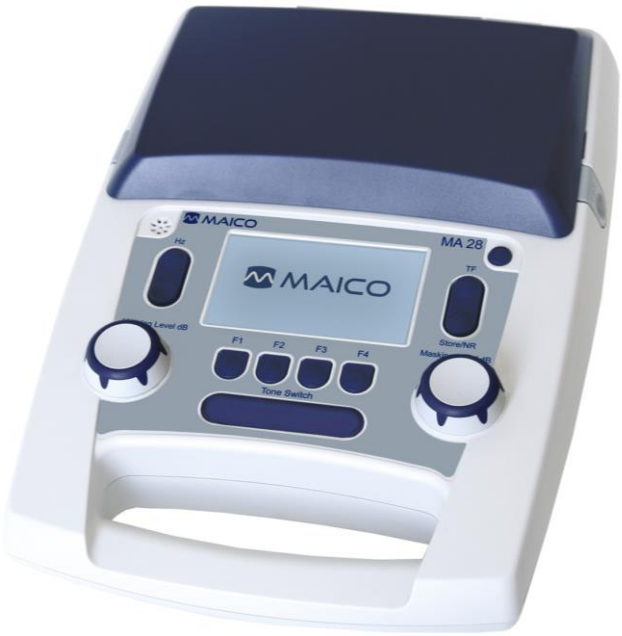

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Table of Contents

Title: Operation Manual MA 28

Date of issue/last revision: 05/05/2021

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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 GmbH is an ISO 13485 certified corporation.

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

1 Introduction

This section offers you important information about:

- **the intended use of the device**
- **indications and contraindications of use**
- **essential performance**
- **features and benefits**
- **a description of the device**

1.1 Intended Use Statement

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

Indications for Use:

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

1.2 Contraindications of Use

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

1.3 Description

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

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

2 For Your Safety

This section offers you important information about:

- **how to read the operation manual**
- **where to spend special attention**
- **the customer responsibility**
- **the explanation of all regulatory symbols used**
- **important cautions and warnings that have to be considered during the whole time handling and operating your device**

2.1 How to Read this Operation Manual

This Operation Manual contains information pertinent to the use of the MAICO device system including safety information as well as maintenance and cleaning recommendations.

READ THIS ENTIRE MANUAL BEFORE ATTEMPTING TO USE THIS SYSTEM!

Use this device only as described in this manual.

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

In this manual, the following two labels identify potentially dangerous or destructive conditions and procedures:

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

The CAUTION label identifies conditions or practices that could result in damage to the equipment

NOTE: Notes help you identify areas of possible confusion and avoid potential problems during system operation.

2.2 Customer Responsibility

All safety precautions given in this operation manual must be observed at all times. Failure to observe these precautions could result in damage to the equipment and injury to the operator or subject.

The employer should instruct each employee in the recognition and avoidance of unsafe conditions and the regulations applicable to his or her work environment to control or eliminate any hazards or other exposure to illness or injury.

It is understood that safety rules within individual organizations vary. If a conflict exists between the material contained in this manual and the rules of the organization using this device, the more stringent rules should take precedence.

This product and its components will perform reliably only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and/or inserts. A defective product should not be used. Make sure all connections to external accessories are snug and secured properly. Parts which may be broken or missing or are visibly worn, distorted, or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from MAICO.

NOTE: Customer responsibility includes proper maintenance and cleaning of the device (see sections 3.2 and 3.3). Breach of the customer responsibility can lead to limitations of Manufacturer's Liability and Warranty (see sections 2.3 and 3.1).

NOTE: In the unlikely case of a serious incident, inform MAICO as well as the competent authority in the country where the user is established.

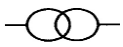
2.3 Manufacturer's Liability

Usage of the device in a way deviant from the intended use will lead to a limitation or termination of the manufacturer's liability in case of damage. Improper use includes disregarding the operation manual, the operation of the device by underqualified personnel as well as making unauthorized alterations on the device.

2.4 Regulatory Symbols

The following Table 11 gives an explanation of the symbols used on the device itself, on the packaging and the accompanying documents including the Operation Manual.

Table 1 Regulatory Symbols

REGULATORY SYMBOLS SYMBOL	DESCRIPTION
SN	Serial number
	Date of manufacture
	Manufacturer
	Caution, consult accompanying documents
	Warning, consult accompanying documents
	Return to authorized representative, special disposal required
REF	Reference number
MD	Medical Device
	Patient applied part type B according to IEC 60601-1
	Refer to operation manual (mandatory)
	Keep away from rain
	Transport and storage temperature range
	Transport and storage humidity limitations
	Voltage transformer
	Electrostatic sensitive devices
	Do not reuse
CE	Conforms to Medical Device Regulation (EU) 2017/745
ETL CLASSIFIED c ETL us Intertek	ETL listed mark
MAICO	Logo

2.5 General Precautions

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

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

No modification of this equipment is allowed.

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

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

Calibration of the device: The audiometer and the transducers complement each other and share the same serial number (i.e. MA1234567). Therefore, the device shall not be used with any other transducer prior to recalibration. Recalibration also needs to be conducted, when a defected headphone is replaced.

Uncalibrated devices may lead to faulty measurements and sometimes even damage the hearing of the examinee.

2.6 Electrical Safety and Measuring Security

This icon indicates that patient applied parts of the device conform to IEC 60601-1 Type B requirements.

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 and/or the plug is damaged.

To transfer data to a PC, establishing a PC-connection via USB is required. See section 4.2.4 on how to safely establish a connection with a power supplied PC or laptop (medical device/non-medical device) or to a battery-driven laptop.

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

If the device is connected to a PC (IT equipment forming a system) assembly and modifications shall be evaluated by qualified medical technician according to safety regulations in IEC 60601-series.

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

Do not touch the contacts of the device and the patient at the same time. When connected to computer equipment do not simultaneously touch the computer equipment and the patient at the same time. The consequence 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 MA 28 in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc. If the device is not used switch it off and disconnect it from the power supply.

Never short-circuit the terminals.

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

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

2.7 Device Control

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

For annual calibration please see sections 2.5 and 3.1

2.8 Electromagnetic Compatibility (EMC)

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 the section 6.5 of this instruction.

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 28, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result in improper operation.

3 Warranty, Maintenance and After-Sales Service

This section offers you important information about:

- **warranty conditions**
- **maintenance**
- **cleaning and disinfection recommendations**
- **accessory and replacement parts**
- **handling disposables**
- **troubleshooting**
- **recycling and disposal of the device**

3.1 Warranty

The MAICO device is guaranteed for at least one year. Ask your authorized local distributor for more information.

This warranty is extended to the original purchaser of the device by MAICO through the distributor from whom it was purchased and covers defects in material and workmanship for a period of at least one year from date of delivery of the device to the original purchaser.

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

WARNING

No modification of this equipment is allowed.

In the event of repair during the guarantee period, please enclose evidence of purchase with the device.

3.2 Maintenance

In order to ensure that the device works properly, it has to be checked and calibrated at least once a year.

The service and calibration must be performed by your dealer or by a service center authorized by MAICO.

When returning the device for repairs or calibration it is essential to send the acoustic transducers with the device. Please include a detailed description of faults. In order to prevent damage in transit, please use the original packing when returning the device.

3.3 Cleaning and Disinfection Recommendations

It is recommended that parts (device and accessories like headphones, ear cushions) which come in direct contact with the patient be subjected to standard cleaning and disinfecting procedure after each patient.

Recommendations for cleaning and disinfection of MAICO device presented in this document are not intended to replace or contradict policies in effect or procedures required for infection control at the facility.

If there is not a high infection potential, MAICO recommends:

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

To avoid damage of the device and its accessories, please mind the following:

- Do not autoclave or sterilize.
- Do not use the device in the presence of fluid that can come into contact with any of the electronic components or wiring.

Should the user suspect fluids have contacted the system components or accessories, the unit should not be used until deemed safe by a MAICO certified service technician.

Do not use hard or pointed objects on the device or its accessories.

3.4 Disposables

Use only the Sanibel Supply disposable supplies that are supplied with your MA 28 system.

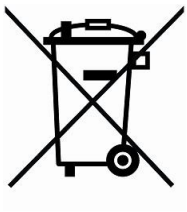
Foam eartips are intended for single-use only. These should be discarded after use. They cannot be cleaned.

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

3.5 Accessories/Replacement Parts

Some reusable components are subject to wear with use over time. MAICO recommends that you keep these replacement parts available (as appropriate for your MA 28 device configuration). Ask your authorized local distributor when accessories need to be replaced.

3.6 Recycling and Disposal



Within the European Union it is illegal to dispose of electric and electronic waste as unsorted municipal waste. According to this, all MAICO products sold after August 13, 2005, are marked with a crossed-out wheeled bin. Within the limits of Article (9) of DIRECTIVE 2002/96/EC on waste electrical and electronic equipment (WEEE), MAICO has changed their sales policy. To avoid additional distribution costs we assign the responsibility for the proper collection and treatment according to legal regulations to our customers.

Non-European countries

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

4 Unpacking and Hardware Orientation

This section provides information on:

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

4.1 Unpacking the System

Check Box and Contents for Damage

- It is recommended that you unpack your MA 28 carefully making sure that all components are removed from the packing materials.
- Verify that all components are included as shown on the packing slip included with your shipment.
- If any component is missing, contact your distributor immediately to report the shortage.
- If any component appears to be damaged in shipment, contact your distributor immediately to report it. Do not attempt to use any component or device that appears to be damaged.

Reporting Imperfections

Notify the carrier immediately if any mechanical damage is noted. This will ensure that a proper claim is made. Save all packaging material so the claim adjuster can inspect it as well.

Report Immediately any Faults

Any missing part or malfunction should be reported immediately to the supplier of the device together with the invoice, serial number, and a detailed report of the problem.

Keep Packaging for Future Shipment

Save all the original packing material and the shipping container so the device can be properly packed if it needs to be returned for service or calibration (see section 3.2).

The MA 28 comes with different components (see Table 22). The availability of configurations with the following components are country specific. Contact your local distributor for more information. See also Table 33 for replacement parts and disposables.

Table 2 List of Components

Available Components
Base Unit
Power Supply UES18LCPU-050200SPA
USB Cable
DD45 Audiometric Headphones*
DD65 v2 Audiometric Headphones*
DD450 High Frequency Headphones*
IP30 Insert Phones*
B71 Bone Conduction Headphones*
B81 Bone Conductor Headphones*
Patient Response Switch*
Thermal Printer HM-E300 Kit (Optional Accessory)
MAICO Sessions Kit (USB)
Operation Manual
Quick Guide
Audiogram Pad

*Applied part according to IEC 60601-1.

Table 3 Replacement Parts and Disposables

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

**Only for use with Insert Phones.

4.2 Hardware Orientation

4.2.1 MA 28 Device

Figure 11 shows the MA 28 device. The device has a main device layout, a case to store headsets and cables and a handle to easily carry the device (Figure 22). The connections are located in the case (Figure 33).

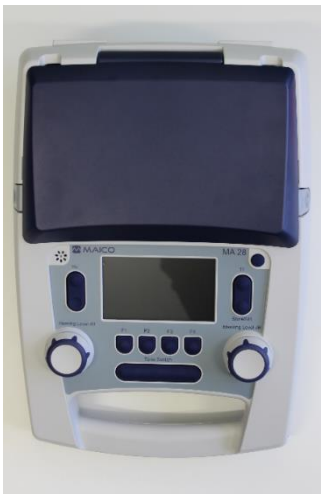


Figure 1

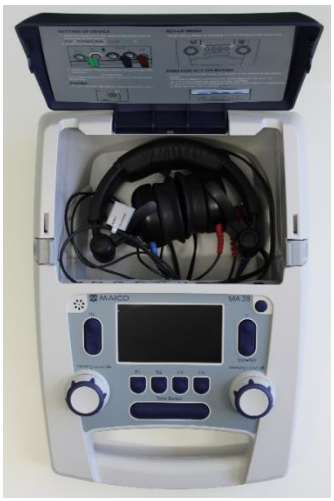


Figure 2

Figure 3

NOTE: See section 5.4 detailed information about the device layout.

Adjusting feet height

Figure 4

To adjust the height, turn the device over. Adjust the two feet by turning them in a counterclockwise to increase height, or in a clockwise direction to decrease height (Figure 44.)

4.2.2 Connections for Headphones, Power Supply and USB Devices

Figure 55 shows the connections on the inside panel of the device. The connections are explained in Table 44. Insert the plugs before turning on the device.

CAUTION

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

Figure 5

Table 4 Connections on Inside Panel of Device

CONNECTIONS	
1	Power Supply UES18LCPU-050200SPA
2	USB Host (Printer or Keyboard)
3	USB Connection for PC Communication
4	Patient Response Switch
5	Bone Conduction
6	No Function
7	Left Phone or Left Insert
8	Right Phone or Right Insert
9	No Function

4.2.3 Thermal Printer (Optional Accessory)

Connect the included USB cord to the printer and to the MA 28 device. Push the printer power button for three seconds to power ON or OFF. Three short beeps will be heard at power ON and OFF. Inactivity of the printer does turn printer OFF.

In order to change paper rolls:

- Push the marker on the right side of the thermal printer to open the printer cover (Figure 66).
- Insert a paper roll in the compartment with its loose end to the front of the printer.
- Hold the end of the printing paper and close the printer cover (Figure 77).

Figure 6

Figure 7

NOTE: Use of the printer requires the device to be connected to the AC power supply. Printer is only charged when the MA 28 device is plugged in and on.

4.2.4 Establishing a PC-Connection

WARNING

Infection of the device or the software used with the device can lead to system failure and data misuse.

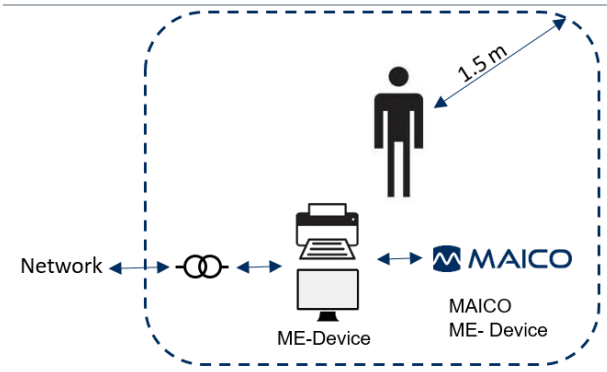
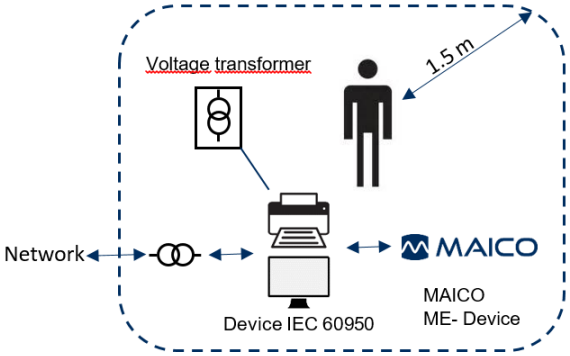
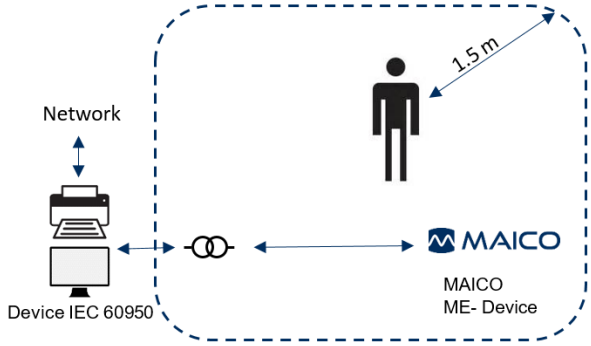
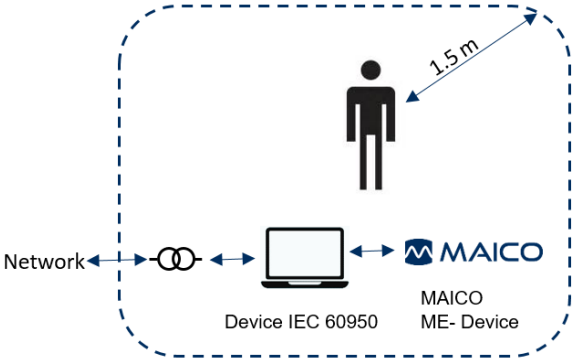
Ensure that your PC is adequately protected against cyber-attacks.

To transfer data to a PC, establishing a PC-connection via USB is required. If the MA 28 is used with office equipment that is not a medical device itself (see Table 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 a medical device itself or meets the requirements of IEC 60950. If a non-medical device is used within the patient environment (1.5 m from patient as defined in IEC 60601-series) a voltage transformer must be used (exception: a battery driven laptop is used).

Table 5 PC Connections

PC CONNECTIONS	
PC Connection 1 Medical device – Medical Device	PC Connection 2 Medical device – Non Medical Device
	
PC Connection 3 Medical device – Non Medical Device	PC Connection 4 Medical device –Laptop (battery driven)
	

4.2.5 PC-Interface

Please refer to the MAICO Sessions operation manual for complete installation instruction and transferring of results to the PC.

4.2.6 Storage

When the MA 28 is not in use, store it in a location where it will be safe from damage to sensitive components such as the acoustic transducers and cables. Store according to the recommended temperature conditions described in section 6.1.

5 Operating the Device

This section offers you information about:

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

5.1 Getting started with the MA 28

Place the MA 28 on a stable counter or table. Plug the power cord into the power socket. Connect all accessories with the appropriate sockets as shown in section 4.2.2.

5.1.1 Use of Equipment After Transport and Storage

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

5.1.2 Where to Setup

The MA 28 should be operated in a quiet room, so that the audiometric examinations are not influenced by outside noises. Ambient sound pressure levels in an audiometric test room shall not exceed the values specified in ISO 8253 series or ANSI S3.1.

Electronic devices, which emit strong electromagnetic fields (e.g. microwaves or radiotherapy devices), can influence the function of the audiometer. Therefore, it is not recommended to use these devices in close proximity to the audiometer as it may lead to incorrect test results.

The test room must be at a normal temperature, usually from 15° C/59 °F to 35° C/ 95 °F, and the device should be switched on approximately 10 minutes before the first measurement. If the device has been cooled down (e.g. during transport), please wait until it has warmed to room temperature before using.

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

5.2 Switching On the Device

Figure 8

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

Briefly press the Power key on the MA 28 to turn on the device (Figure 88).

5.3 Switching Off the Device

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

5.4 Device Layout

Figure 99 shows the device layout. Table 66 gives further explanation.

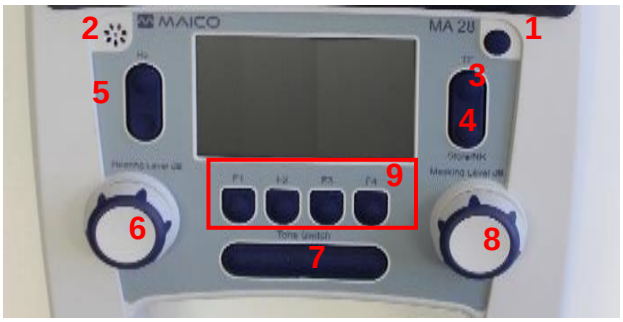
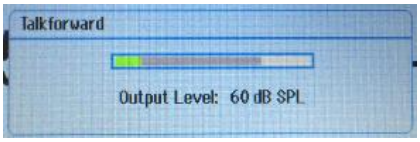


Figure 9

Table 6 Explanation of Device Layout

#	Name(s) / Function (s)	Description
1	**Power On/Off**	Turning the device on/off.
2	**Microphone**	To use the Talk Forward function.
3	**TF (Talk Forward)**	Press and release to activate talk forward function. Increase/decrease the volume by rotating one of the ***level dials*** (6 or 8). See Figure 1010. To turn off talk forward, press and release TF.  **Figure 10**
4	**Store** **NR (No Response)**	Press and release to store result. Press and hold to display a No Response (***NR***) result.
5	**Hz (+/-)**	Press + to increase the frequency (Hz). Press – to decrease the frequency (Hz).
6	**Hearing Level dB**	Turns the volume of the tone up/down.
7	**Tone Switch**	***Presenter mode:*** Press to present the signal. A tone presentation signal (i.e. ) will display on the screen. ***Interrupter mode***: Press to stop the signal being presented.
8	**Masking Level dB**	Turns on the masking/noise signal by rotating the wheel to the right. Once on, turns the masking/noise signal up/down. Turn off the noise by rotating the wheel to the left until the display on the right side no longer displays a number.
9	**Function Keys**	These keys (***F1*** to ***F4***) are dependent upon the label displayed on the display screen. See Table 7 for more details.

5.5 Display

Figure 1111 shows the main display. See the explanation of the screen areas below.

NOTE: 2 Audiogram view is the default setting for the MA 28. See section 5.10 for review of different setting options for the display.

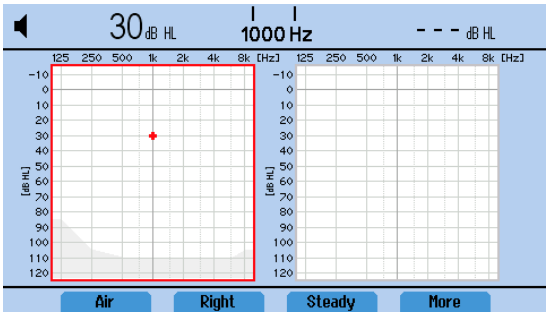


Figure 11

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

Tone is presented (turned on).

Tone is not presented (turned off).

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

Patient response switch is being activated (pressed).

Patient response switch is not activated (not pressed).

Level:

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

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

Frequency:

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

Result Display:

Results are stored on the device for later saving to the database, printing or transferring to the PC. The display can be configured to ***1 audiogram, 1 audiogram and masking table, 2 audiograms, 2 audiograms and masking table***, ***Table*** or ***None*** from the ***Settings***. See section 5.10 for more information.

NOTE: ***None***-display does not allow storing of results.

5.6 Function Keys

Function keys are the buttons below the screen. A label above the button displays the function of that key. These buttons are labeled ***F1***, ***F2***, ***F3*** and ***F4***. See Figure 1212 and Table 77 for the selections available for each function key in the testing mode.

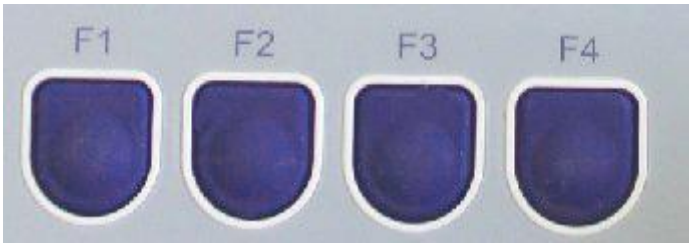


Figure 12

Table 7 Explanation of Function Buttons

Menu Screen	Function button	Label	Description
1st menu screen	**F1**	**Air Bone**	Selection between ***Air*** or ***Bone*** conduction transducer.
	F2	**Right Left**	Selection between ***Right*** or ***Left*** ear.
	F3	**Steady Pulse Warble P&W**	Type of signal presented. Options include ***Steady***, ***Pulse***, ***Warble***, Pulse and Warble (***P&W***).
	F4	**More**	To move to the ***2nd menu screen.***
2nd menu screen	**F1**	**Delete**	To delete single stored measurement. Set device with the ear, test type and frequency to delete the measurement.
	F2	**New**	To delete all stored results.
	F3	**Print**	To print test results.
	F4	**More**	To move to the ***3rd menu screen***.
3rd menu screen	**F1**	**HW**	Activates ***Hughson-Westlake*** automatic air conduction threshold test.
	F2	**Save DB**	To save results to the internal database.
	F3	**View DB**	To view results saved to the internal database.
	F4	**More**	To move to the **4th *menu screen.***
4th menu screen	**F1**		No function
	F2		No function
	F3	**Menu**	To access the **Setup menu**.
	F4	**Back**	Returns the function key selection to the **1st menu screen.**

5.7 Preparing for Testing

5.7.1 Preparing the Patient

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

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

5.7.2 Placement of Headphones (for Testing with Headphones)

Figure 13

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

5.7.3 Placement of Foam Eartips (for Testing with Insert Phones Only)

WARNING

The insertion of the insert phones into the ear canal without an earplug can scratch the ear canal.

Always apply a foam eartip before inserting the insert phones into the ear canal.

Figure 14

First, place the eartip securely on the adapter at the end of the insert earphone tubing. To prepare the foam eartip for insertion in the ear canal, you must compress the foam by rolling it in your fingers to narrow its diameter (Figure 1413). Check to be sure that the foam does not obstruct the opening of the black sound tube.

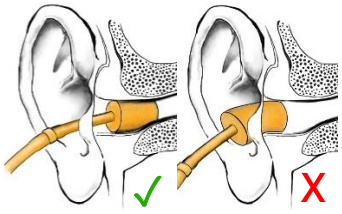


Figure 15

Quickly, while the foam is still compressed, grasp the patient's ear and gently pull it up and back to open and straighten the ear canal. While holding the canal open, slide the compressed foam ear tip into the ear canal. The foam should be completely surrounded by the canal with virtually none of the foam sticking out of the canal (Figure 1514).

Placement of Bone Conductor (for Bone Conduction Testing)

Figure 16

Place the bone conduction oscillator on the patient's head. The flat, circular side of the transducer is place on the mastoid, at the noticeable ledge of the cranial bone behind, but not touching the pinna. The other side of the headband is placed inly front of the opposite ear (Figure 16).

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

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 abnormality.

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 Bone Conduction Testing

Place the bone conduction oscillator on the patient's head so that the flat, circular side of the transducer is placed on the mastoid, at the noticeable ledge of the cranial bone behind, but not touching the pinna. The other side of the headband is placed in front of the opposite ear. Set the ***F1*** key to ***Bone*** and select the test ear.

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

5.8.3 Masking

Masking is required if there is a notable threshold difference between the left and right ears. It is possible for sound to be transmitted to both ears via bone conduction while testing the poorer ear. This is called "***crossover***".

Crossover occurs often while testing bone conduction, but it can also occur during air conduction testing. Relevant to crossover is the sound level received by the opposite ear. The difference between the original test signal in the test ear and the received signal in the opposite ear is called "***interaural attenuation***".

For bone conduction measurements the interaural attenuation is 0 dB to 15 dB. Bone conduction crossover is therefore possible even with a slight difference in hearing loss between ears.

To ensure that the patient will not experience crossover, mask the opposite ear. Masking may increase the hearing threshold of the test ear. For bone conduction the masking signal is automatically routed to the opposite output of the phones or inserts, based on the test ear selected.

The masking is turned on by rotating the ***Masking Level dB*** level control dial to the right. The masking sound should be continuously presented for effective masking. The masking is done with a noise signal which is transmitted by the headphone. For pure tone audiometry a narrowband noise is used. This noise changes its center frequency according to the frequency of the test signal.

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

5.8.4 Auto Threshold (Hughson-Westlake) – Air Only

In addition to traditional manual testing, the MA 28 incorporates a Hughson-Westlake patient controlled automatic threshold test complying with ISO 8253 for air conduction thresholds only.

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

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 is accessed through the function keys in the 3rd menu selection. From the main test screen Press ***F4*** (**More**) until ***HW*** is displayed at ***F1***. The HW Test results are captured in an audiogram or table, identified by the Display type setting. See section 5.10.

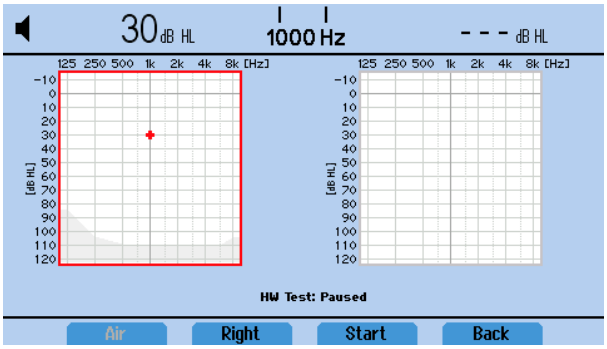


Figure 17

The function keys for test operation are defined in Table 88

Table 8 Explanation of Function Keys for HW Test

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

NOTE: To delete the HW test, select ***New*** from the second function key menu in the Tone test screen. This will delete all results stored within the Tone and HW test screens.

An optional familiarization portion can be incorporated into the test process. See section 5.10 for more information on this setting.

5.9 Managing Test Results

5.9.1 General

There are different options to manage the results stored on the device.

1. Save the result to the internal database
2. Print the result (optional printer required)
3. Transfer the result to PC software (optional MAICO Sessions software required)

5.9.2 Completed Results

With the first stored response, the function keys, ***Print*** and ***Save DB***, are active for selection as described in section 5.6

5.9.3 Saving to the Database

Test results can be saved to the internal database for later review or printing. Once the first result is stored, the ***Save DB*** Function key becomes active. The ***Save DB*** is within the third Function Key Menu, see section 5.6

Once ***Save DB*** is selected the ***Save to database*** screen is entered. The results can be saved to a default name (1) created by the device (i.e. ☐New Patient 3) or enter in patient details by selecting the ***Edit*** button (2). See section 5.9.7 for review of the Edit patient details screen.

Figure 18

The ***Storage*** counter (3) displays the number or patients created in the database. Up to 500 patients can be saved with up to seven sessions per patient. The function keys for the ***Save to Database*** screen are defined in Table 99.

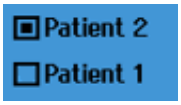
Table 9 Explanation of Function Keys for Save to Database

Function key	Label	Description
F1	**Back**	Return to test screen without saving.
F2	**Edit**	To save record with patient demographic information.
F3		No function
F4	**Save**	Saves test to selected patient and returns to the test screen.

5.9.4 View Database

Saved test results can be viewed from the internal database by selecting ***View DB*** within the third Function Key Menu, see section 5.6. This selection will enter the list of patients/sessions saved to the device.

The box beside the patient list identifies when there is a saved session:



- **Closed box:** Session is saved to patient record.
- **Open box:** Patient record was created but all sessions were deleted.

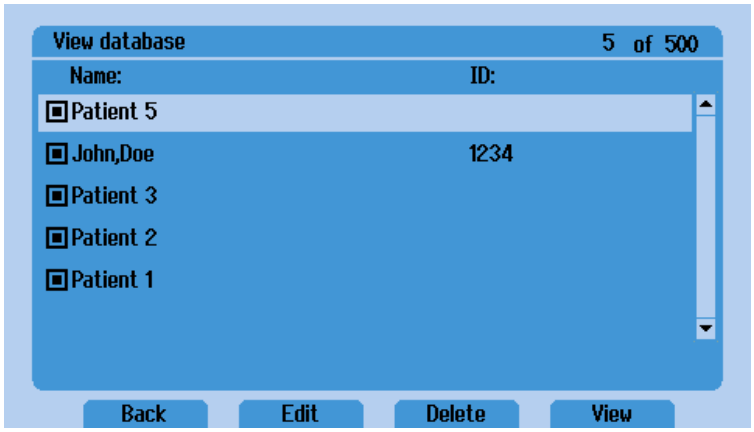


Figure 19

Table 10 Explanation of Function Keys for View Database

Function key	Label	Description
F1	**Back**	Return to test screen.
F2	**Edit**	To update record with patient demographic information.
F3	**Delete**	Deletes selected patient and all stored sessions.
F4	**View**	Opens Session list to select record to view results. See section 5.9.5.

NOTE: The entire database can be deleted by selecting the buttons ***Delete*** and ***Store/NR*** at the same time. A message appears that this can take up to 10 minutes. This is dependent upon the number or patients and sessions stored within the database.

5.9.5 View Session

Once you have entered the ***View Database*** screen, highlight a patient and select ***View (F4).*** This will take you to the session list for that patient.

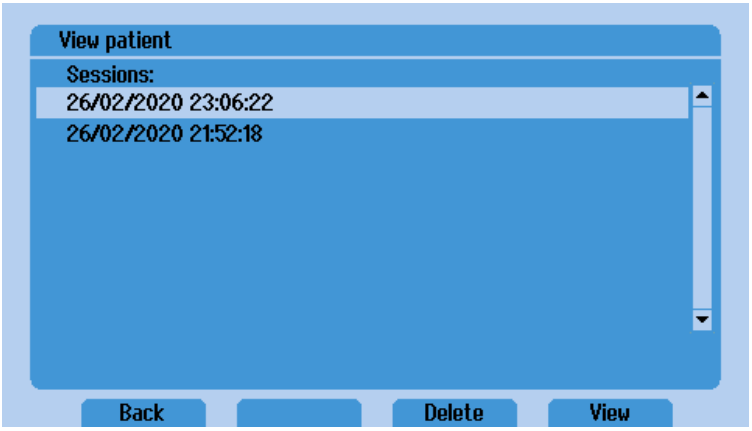


Figure 20

Table 11 Explanation of Function Keys for View Database

Function key	Label	Description
F1	**Back**	Return to ***View database*** screen.
F2		No function
F3	**Delete**	Deletes selected session.
F4	**View**	Opens session to view results. See section 5.9.6.

NOTE: The entire session list can be deleted by selecting the buttons ***Delete*** and ***Store/NR*** at the same time. A message appears to confirm deleting of all sessions.

5.9.6 View Results

Once you select ***View*** (F4) from the session list screen, the stored results are displayed.

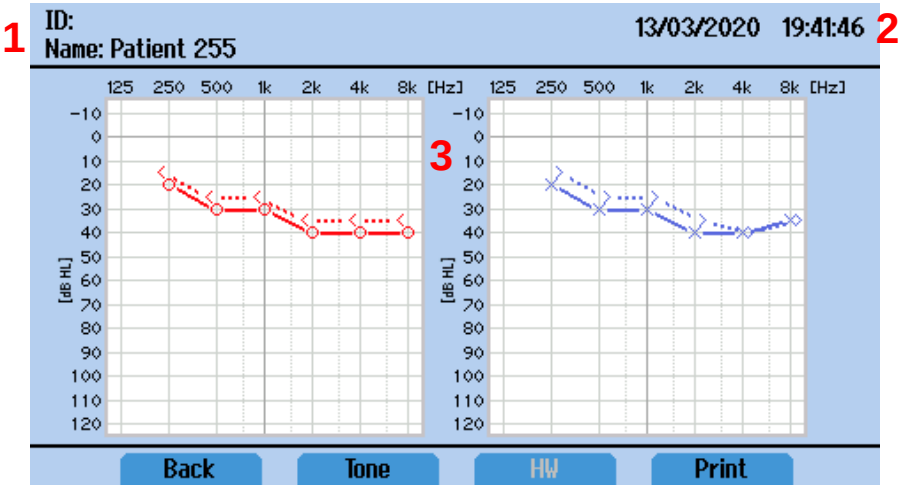


Figure 21

1. ID and Name are displayed as enterd in the Edit Screen.
2. Sessions date and time of test.
3. Test results

Table 12 Explanation of Function Keys for View Results

Function key	Label	Description
F1	**Back**	Return to ***View database*** screen.
F2	**Tone**	Displays Tone test results
F3	**HW**	Displays HW test results
F4	**Print**	Print saved results for this session.

NOTE: Function key F2 and F3 will be grey/inactive if no results were stored for the test type.

5.9.7 Edit Patient Record

To input patient information, select ***Edit*** from the function key list of the ***Save to database*** or ***View database*** screens.

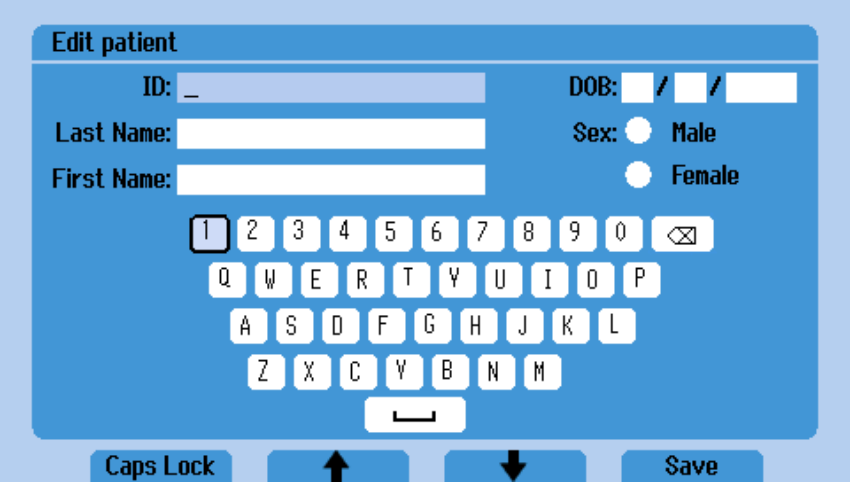


Figure 22

Once the Edit screen is entered, the fields to input include:

- ID
- Last name
- First name
- Date of Birth (DOB)
- Sex

Table 13 Explanation of Function Keys for View Database

Function key	Label	Description
F1	**Caps Lock**	Activates Caps Lock for internal keyboard.
F2	⬆	Navigate to previous field
F3	⬇	Navigate to next field
F4	**Save**	Saves patient details to database record and returns to the patient list screen.

To make selection with the on-screen keyboard, scroll through the keyboard using the ***Hearing Level dB*** (movement right/left) and ***Masking Level dB*** (movement up/down) dials and make your selection by pressing the ***Tone switch***.

NOTE: Entry of patient fields can be completed by an external keyboard connected to the USB port or the on-screen keyboard. Internal or connected keyboard only allows QWERTY keyboard entry.

5.9.8 Deleting Test Results

Results are deleted by using the function keys of the device. The delete options are found within the 2nd menu screen of the Function Key list. Select ***More*** to access these functions. See section 5.6.

Table 14 Deleting Test Results

Function key	Description
F1: Delete	To delete a specific stored result. Set the device to the Ear, transducer and frequency before selecting ***Delete*** (F1).
F2: New	To clear all stored results and start a new test.

NOTE: If you select ***New*** for deleting all test results, a message box appears asking if you want to create a new session and discard data.

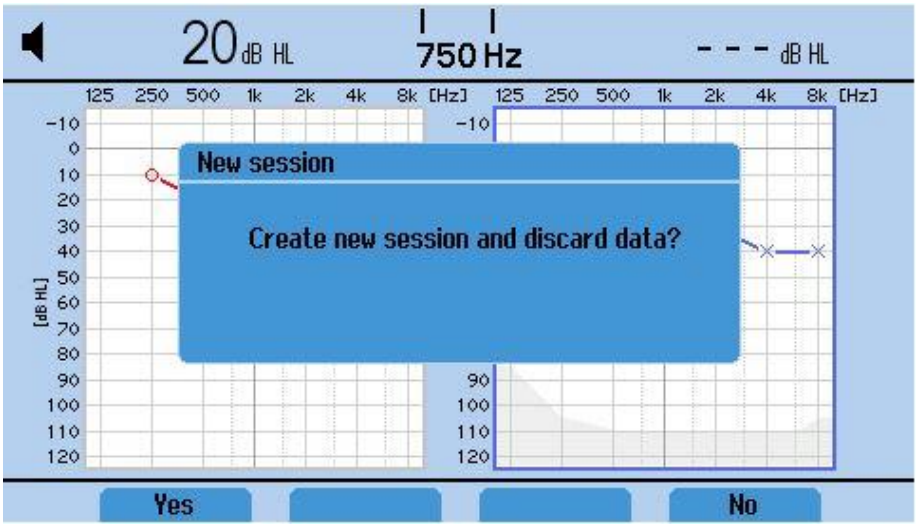


Figure 23

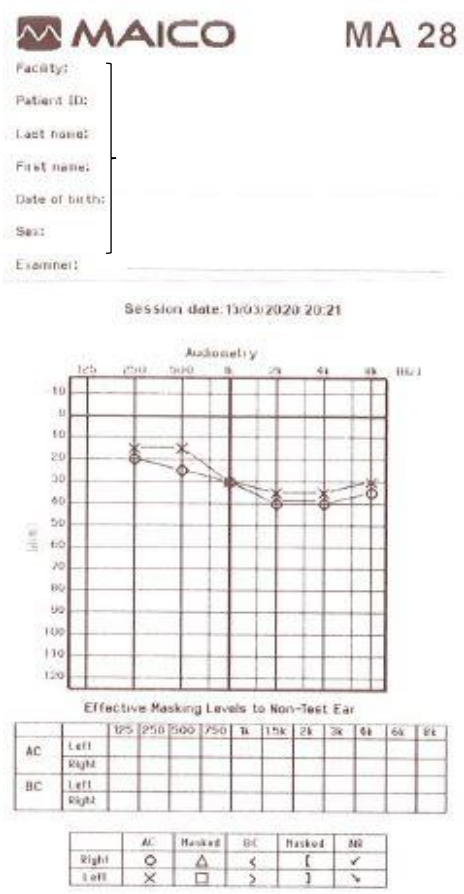
5.9.9 Printing Test Results (Optional Printer)

Test results can be printed with the optional printer. Once the first result is stored, the ***Print*** Function key becomes active (see section 5.6, Function key menu). Printing will print all current stored test results (i.e. Pure Tone Audiometry and Automatic Hughson-Westlake).

- Device must be connected to Power Unit Supply (not USB) for power to be supplied to printer.

5.9.10 Understanding the Print-Out

The print-out displays the following information:



1 ***MAICO logo and name of device***

2 ***Facility:*** provides field name to write in facility information after printout.

3 ***Patient data*:** provides the field names **Patient ID**, **Last name**, **First name**, **Date of birth** and **Sex**, to manually enter.

4 ***Examiner*:** empty line for examiner‘s signature.

5 ***Session date and time*:** shows the date and time of the session as defined in the device.

6 ***Test result:*** graphical display as defined in the settings for Display type.

7 ***Test result masking table:*** prints masking table defined in the settings for Display type.

8 ***Symbol key:*** prints when an audiogram is the display type as defined in the Settings.

Figure 24

NOTE: A customizable image can be displayed in place of the Facility label on the printout.

Figure 25

See section 5.10.3 for details on creation and importing an image for the printout.

5.9.11 Transferring Test Results to PC (Extra License)

PC connection requires a specific license for connectivity. Review section 5.10.4 to verify your device has this license. Before transferring data to a PC make sure that you have installed the ***MAICO Sessions*** software properly according to the separately delivered operation manual. Before establishing the PC connection you will have to consider the recommendations given in section 4.2.4 in case the MA 28 is connected to a non-medical device.

To transfer the data, make sure the device is connected to the PC via USB connection and the ***MAICO Sessions*** is open. When connected, the ***Get Measurement*** (Figure 2624) button appears. Click on ***Get Measurement*** and the tone audiometry values are transferred and displayed on the PC screen.

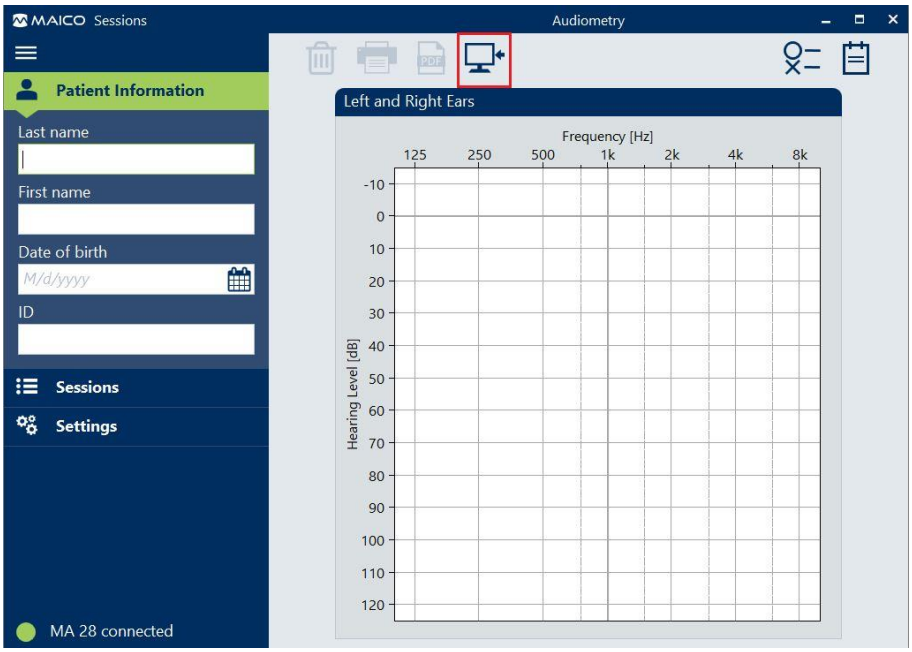


Figure 26

NOTE:

- Upon results transferred to MAICO Sessions, the results are deleted from the device.
- Transferring results from the internal database requires the use of MAICO Sessions and OtoAccess® Database. Contact your distributor for further details.

5.10 Setup Menu

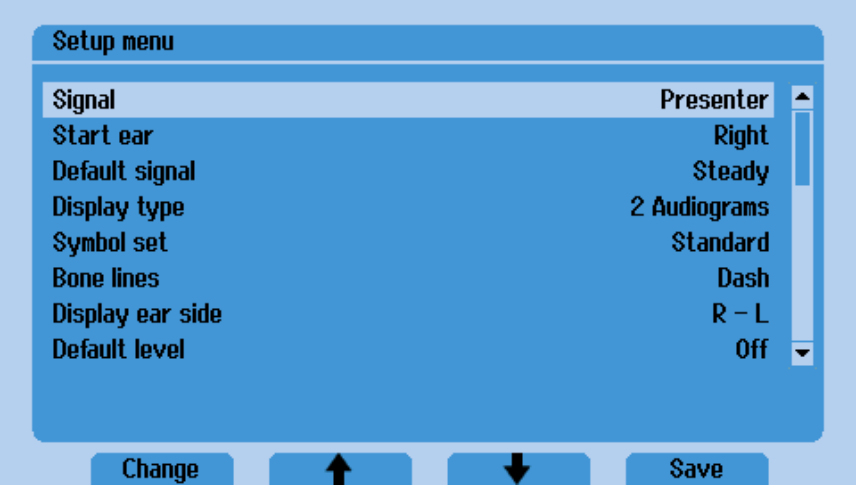


Figure 27

Accessing the ***MA 28 Setup menu*** can be completed in 2 ways:

1. Select F4 from the function keys until ***Menu*** is seen (F3).

2. Press F1 and F4 for 2-3 seconds simultaneously from the First menu function key list.
3. Once in the Menu (Figure 2725), the different Setup options are listed and can be entered using the function keys. See Table 1515 for further explanation.

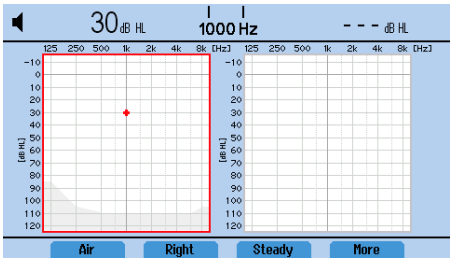
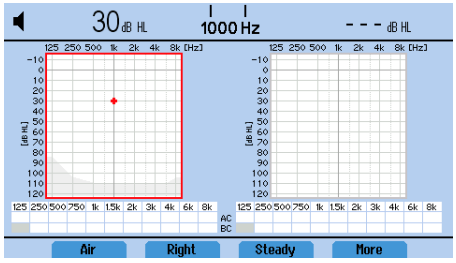
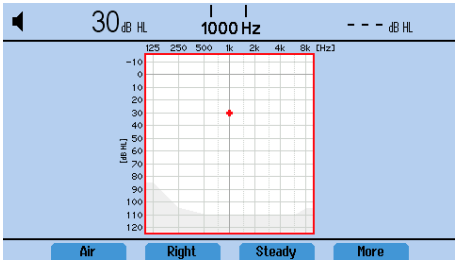
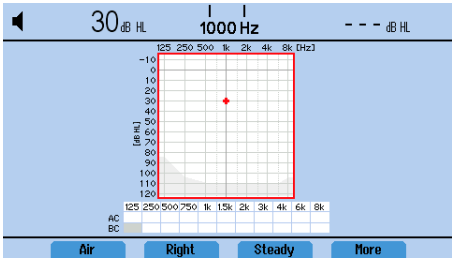
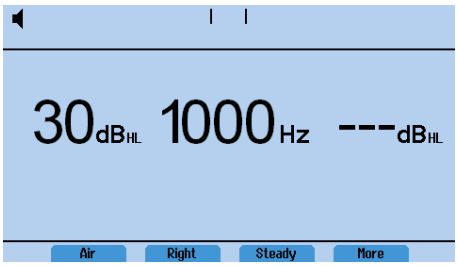
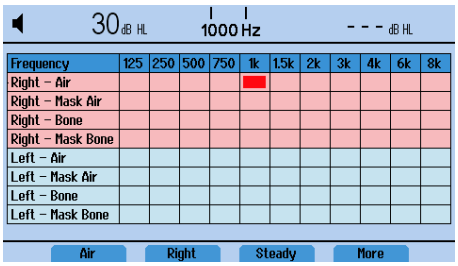
Table 15 Explanation of Function Keys in Setup Menu

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

NOTE: A secondary way to manage the setting options is use the ***Masking Level*** control to scroll through the menu list and the ***Hearing Level*** control to change the options. For the ease of reading the manual, only the function keys selection is used.

Table 16 Explanation of Options in the Setup Menu

Setup Menu	Description
Signal	To select the operation mode of the audiometer: • ***Presenter:*** Tone is presented when the Tone Switch is activated. • ***Interrupter*****:** Tone is interrupted/stopped when the Tone Switch is activated.
Start ear	To select ***Right*** or ***Left*** ear as the default ear when device powered on.
Default signal	To select the default signal type (i.e. ***Steady***, ***Pulse***, ***Warble***, or Pulse & Warble – ***P & W***).

Setup Menu	Description
Display type	The display of the test screen. Options include: ***2 audiogram, 2 audiogram/mask, 1 audiogram, 1 audiogram/mask, None, Table***. 2 audiogram (default):  2 audiogram/mask:  1 audiogram:  1 audiogram/mask:  None:  Table: 
Symbol set	To select the country specific symbols to be plotted on the audiogram displays. Choose between: ***Standard, UK, Australia, Hong Kong.***
Bone lines	To select the type of lines displayed for bone conduction results on the audiogram. Choose between: ***Dash, Solid, No line.***
Display ear side	To select the ear side for 2 audiogram displays. Choose between: ***L – R, R – L***.
Default level	To set the default intensity when changing transducer and ear side. Choose between: ***Off***, ***-10 dB*** to ***50 dB***.
Level step	To change the intensity/volume level that changes with each rotation of the attenuator dial. Choose between ***1 dB*** and ***5 dB***.
Noise start level	To select the default intensity when the noise is turned on using the ***Masking Level dB*** level control dial. Choose between ***0 dB*** to ***50 dB***.
Masking type	To select between Narrowband (**NB**) and White noise (**WB**).

Setup Menu	Description
Frequency roll	To define the movement to the next frequency. Selections include: • ***None:*** Frequency roll is off. To change the frequency during testing, use the ***+/-*** buttons. Frequency stops when minimum or maximum levels are reached. • ***Wrap:*** When using the frequency buttons ***+/-*** or ***Store*** the frequency selection will cycle through all active frequencies. • ***Back:*** Frequency returns to 1000 Hz when minimum and maximum has been reached. Occurs when selecting ***Store*** or the frequency buttons ***+/-***.
Pulse length	To select the length of each tone when ***Pulse*** is selected. Choose between ***250 ms*** and ***500 ms***.
Language	To select the display language. Choose between: ***Deutsch, English, Español, Français, Italiano, Nederlands, Polski, Русский, 中文.***
Backlight	To select the intensity of the Backlight. Choose a value between ***30 %*** (very dark) to ***100 %*** (very bright).
Air frequencies	To select the frequencies to be active during the air conduction test. Press ***Change*** to toggle between the 10 frequencies that can be set to ***On*** or ***Off***: ***125 Hz, 250 Hz, 500 Hz, 750 Hz, 1500 Hz, 2000 Hz, 3000 Hz, 4000 Hz, 6000 Hz, and 8000 Hz***.
Bone frequencies	To select the frequencies to be active during the bone conduction test. Press ***Change*** to toggle between the 9 frequencies that can be set to ***On*** or ***Off***: ***250 Hz, 500 Hz, 750 Hz, 1500 Hz, 2000 Hz, 3000 Hz, 4000 Hz, 6000 Hz, 8000 Hz***.
Hughson-Westlake (HW) test…	See section 5.10.1
Date/time setup…	See section 5.10.2
Facility info…	See section 5.10.3
License key…	See section 5.10.4
About	To view relevant information to the device (i.e. Serial number, firmware version, etc.). Press ***Change*** to access the license information of the MA 28.
Database password…	See section 5.10.5

5.10.1 Hughson-Westlake Test (HW)…

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

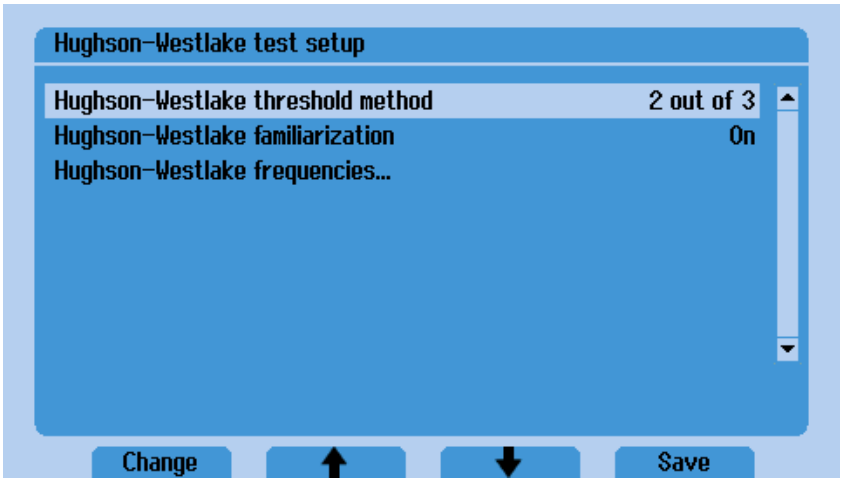


Figure 28

Table 17 Hughson/Westlake Test

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

Press ***Save*** to return to the main ***Hughson-Westlake tests setup*** menu.

5.10.2 Date/time setup…

Once ***Date/time setup…*** is selected, a new screen appears as in Figure 2927:

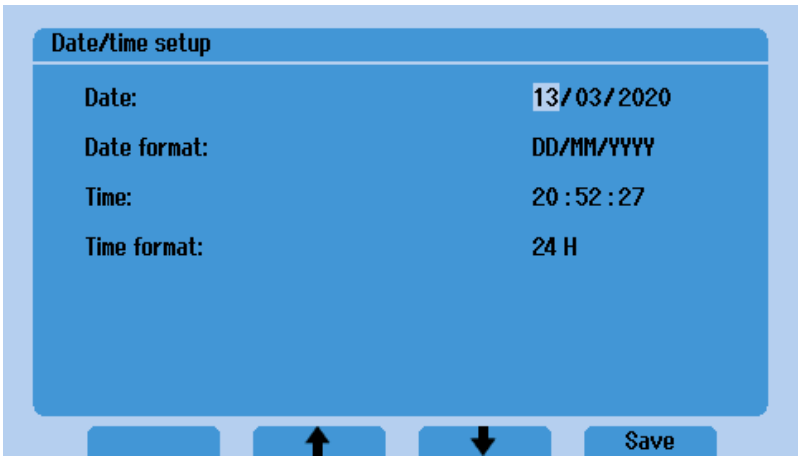


Figure 29

Table 18 Date/time setup

Date/time setup	Description
Date:	Set the current date using the left dial (***Masking Level dB***) to cycle through the fields. The right dial (***Hearing Level dB***) to make the field selection. The ***Date format:*** is applied to the date selection.
Date format:	Select the preferred date format to be displayed. Choose between: ***DD/MM/YYYY, DD.MM.YYYY, MM/DD/YYY***.
Time:	Set the hour and minute by using the time control. If time format 12 H is chosen a further setting is available for selection of AM/PM.
Time format:	Select the preferred clock, using the 12 or 24 hour time format.

5.10.3 Facility info…

Facility info… allows loading of an image for display on the printout (optional thermal printer).

Figure 30

Once ***Facility info…*** is selected, a new screen appears as follows:

Figure 31

To load an image to the device, follow the instruction below for configuring the image correctly.

To create an image for use on the MA 28 printout:

1. Requires a minimum 32 MB USB flash drive.
2. Insert USB into PC and go to My Computer. Right click on the USB flash drive and select “Format”

NOTE: This will erase everything on your USB thumb drive

3. Ensure **FAT32** is selected as your **File System**, all other settings leave as listed.

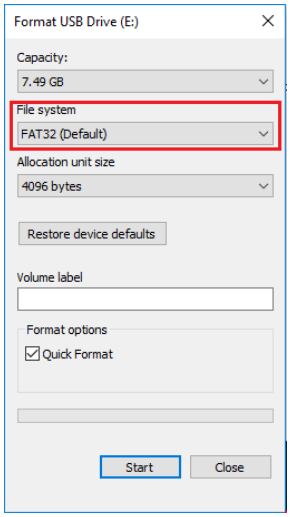


Figure 32

4. Open Paint
5. Press Ctrl + e and change **Width: 560, Height: 144** and select '**OK**'

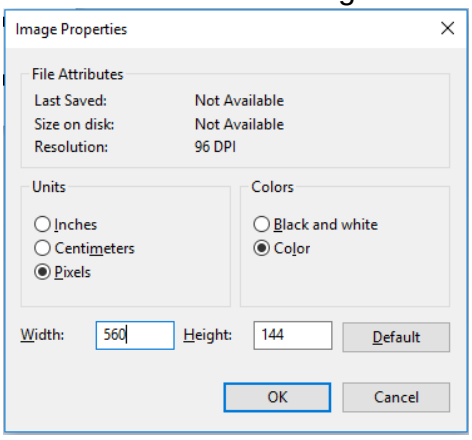


Figure 33

6. Enter facility information into window size.

Note: The MA 28 printout uses: arial narrow, bold, and font size 14. Anything placed in this window can be printed (i.e. text, logo), but printer only supports monochrome. For best quality, only use black font/images.

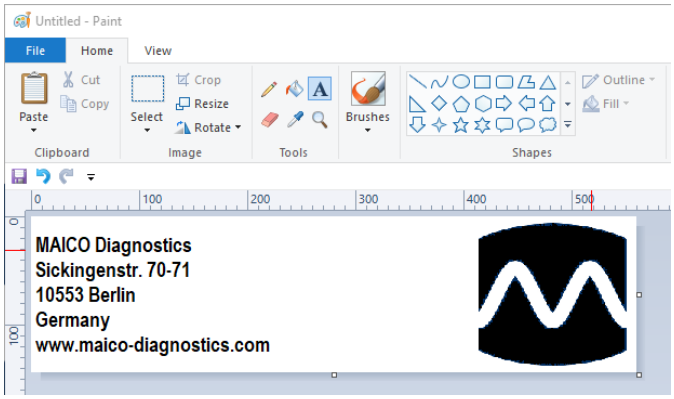


Figure 34

7. Select **Save as** and select **BMP picture**

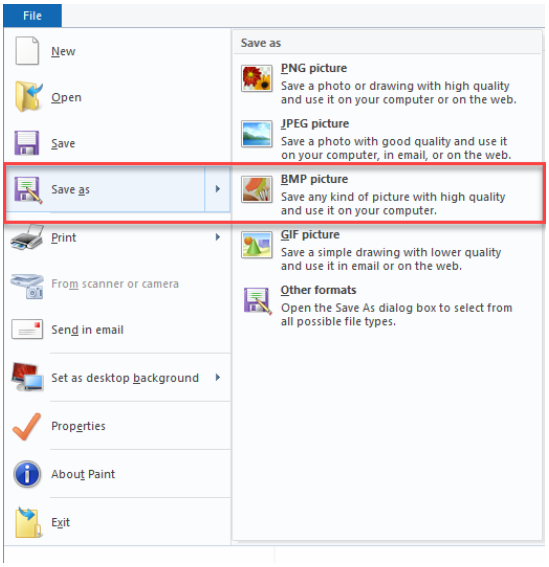


Figure 35

8. Save to a USB flash drive. Save the created file as follows:
   - **File name: FCI.bmp**
   - **Save as type: Monochrome Bitmap (*.bmp;*.dib)**

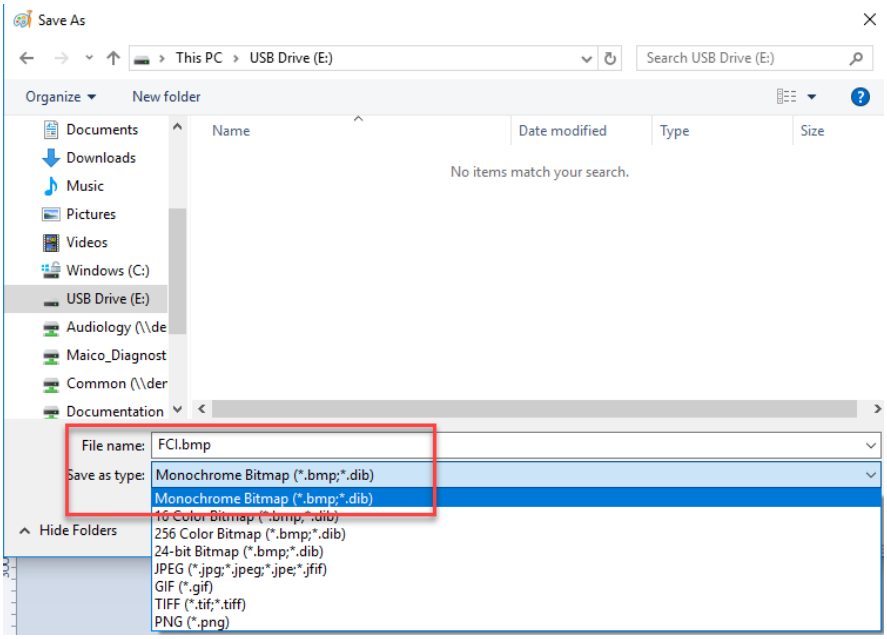


Figure 36

9. A confirming message on color quality appears, select **OK**

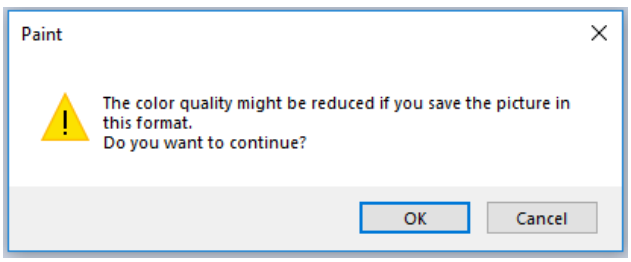


Figure 37

10. Insert the USB flash drive into the USB port

Figure 38

11. Go to the **Setup menu** and select **Facility info…**

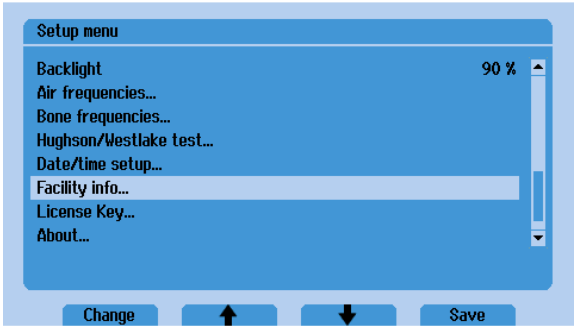


Figure 39

12. Select **Load**.
    The image is loaded correctly, a pop-up message displays **"Image successfully loaded".** Re-entry into the Facility information screen reads **"Image loaded to thermal printout."**

To change a loaded image, first ***Delete*** loaded image. This will allow the ***Load*** button to become active.

5.10.4 License key…

The **License key** screen allows licensed functions to be added to the device. Contact MAICO or your local distributor for more information.

Highlight ***License key…*** and select ***Change*** to enter License key screen (See Figure 4038). Use the ***Hearing Level dB*** and ***Masking Level dB*** dials to navigate the internal keyboard.

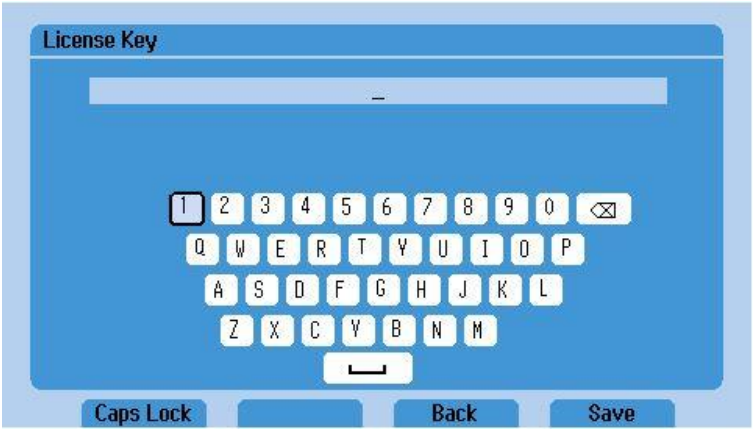


Figure 40

Once entered and verified, press ***Save*** to return to the main Setup menu. Return to the Setup menu without saving the license key, select ***Back***.

NOTE: Connecting an external keyboard to the USB port can also be used to enter the license key.

If the license key entered is invalid a message box will display to verify the license key (Figure 4139). Contact your local distributor if any problems occur.

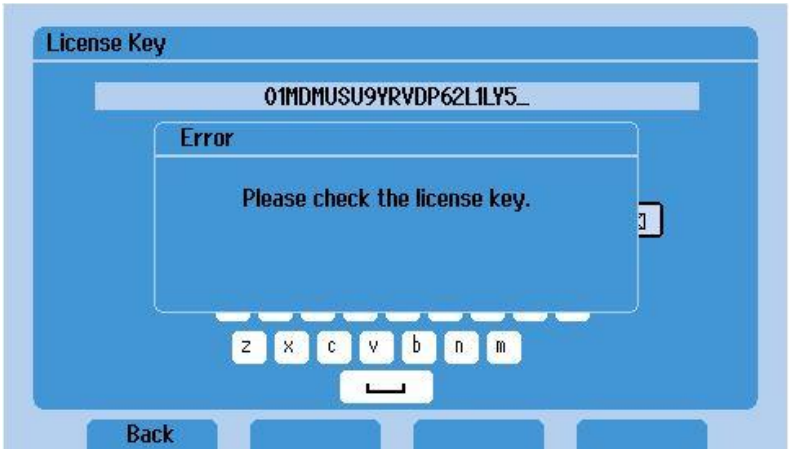


Figure 41

Verification of added licenses is shown in the ***About*** screen (Figure 4240).

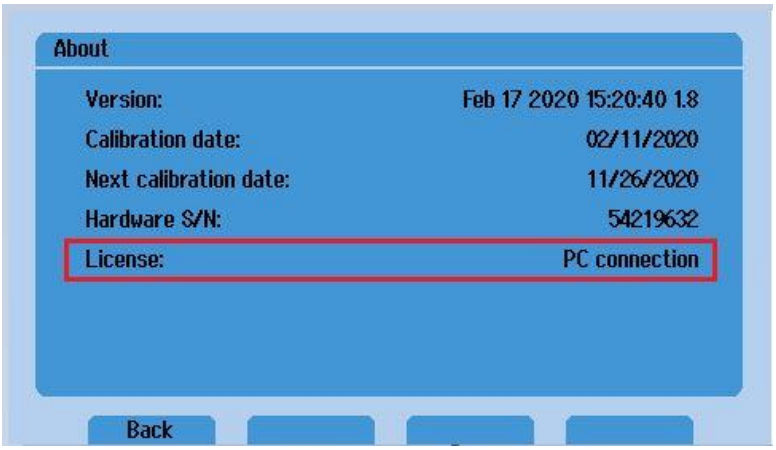


Figure 42

5.10.5 Database password. . .

The ***Database password. . .*** setting requires a 4-digit number to allow access to the database.

Highlight ***Database password…*** and select ***Change*** to enter the screen (See Figure 4341). A confirming message appears as once a password is turned ***'On'*** it cannot be turned ***'Off'*** without a MAICO service technician and possession of the device.

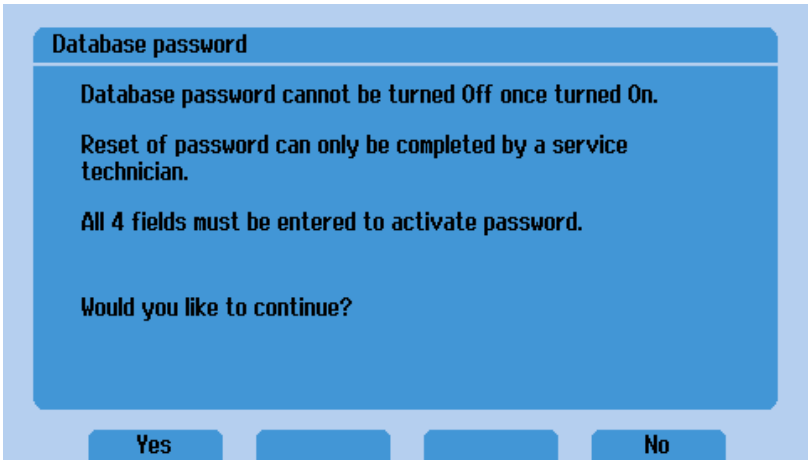


Figure 43

Enter the password, use the ***Hearing Level dB*** and ***Masking Level dB*** dials to navigate password fields. Press ***Save*** to continue setting up the database password. Press ***Back*** to return to the ***Setup menu*** without saving the ***Database password***.

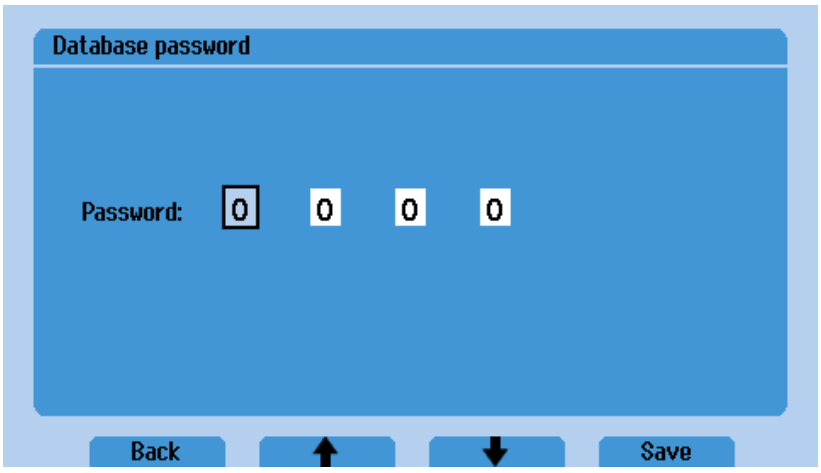


Figure 44

Once ***Save*** is selected, a message appears to confirm saving of password (See Figure 4543). Keep this password in a safe location as entry into the database will require it.

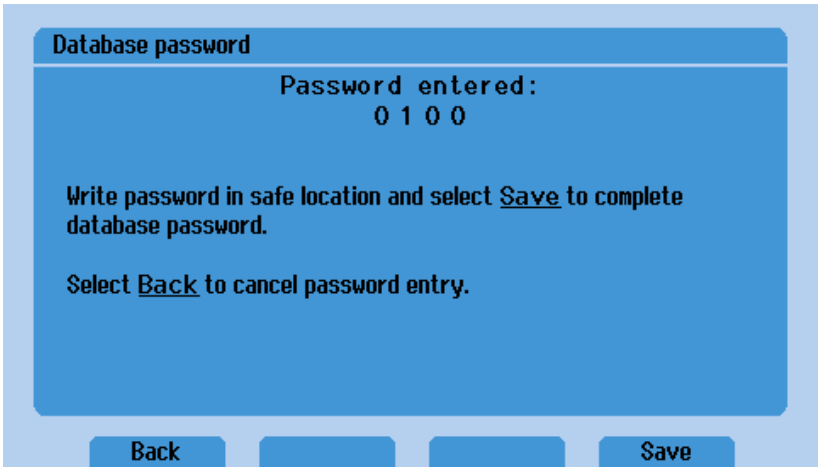


Figure 45

6 Technical Data

This section offers you important information about

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

6.1 MA 28 Hardware

CE 0123

The MA 28 audiometer is an active, diagnostic medical product according to the class IIa of the Medical Device Regulation (EU) 2017/745.

General Information About Specifications

The performance and specifications of the device can only be guaranteed if it is subject to technical maintenance at least once per year.

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

STANDARDS		
Safety Standards	IEC 60601-1:2012 ANSI/AAMI ES60601-1:2005 / A2:2010 CAN/CSA-C22.2 No. 60601-1:08 Class II, Type B Applied Parts	
EMC Standard	IEC 60601-1-2:2014	
Audiometer Standards	Tone: EN 60645-1:2012/ANSI S3.6:2010 Type 3	
DEVICE SPECIFICATIONS		
Power supply	Type Input Output Safety	UES18LCPU-050200SPA 100 to 240 V AC, 50/60 Hz, 0.5 A 5.0V DC, 2.0A MAX IEC 60601-1, Class II
Mode of Operation	Continuous	
Environmental conditions: 	**Operation:**	+15 °C to +35 °C / + 59 °F to +95 °F Relative humidity 30 % to 90 % (non-condensing)
	Storage:	0 °C to + 50 °C / 32 °F to +122 °F Humidity 10 % to 95 % (non-condensing)
	Transport:	-20 °C to + 50 °C / -4 °F to +122 °F Humidity 10 % to 95 % (non-condensing)

Calibration	Calibration information and instructions are located in the MA 28 Service Manual.	
Air Conduction	DD45	MAICO Standard Values
	IP30	ISO 389-2, ANSI S3.6
	DD450	MAICO Standard Values
	DD65 v2	MAICO Standard Values
Bone Conduction	B71	ISO 389-3, ANSI S3.6
	B81	ISO 389-3, ANSI S3.6
	Placement:	Mastoid
Effective masking	ISO 389-4, ANSI S3.6	
Transducers – Headband tension	DD45	Headband Static Force 4.5 N ± 0.5 N
	DD450/DD65 v2	Headband Static Force 10.0 N ± 0.5 N
	B71/B81 Bone	Headband Static Force 5.4 N ± 0.5 N
Patient Response switch	One push button	
Patient communication	Talk Forward (TF)	
Special tests/test battery	Auto threshold:Hughson Westlake: Time window for patient response: 2 s	
Inputs	Tone, Warble Tone +5 %, 5 Hz (true sine wave frequency modulation)	
Outputs	Left, Right, Bone	
Accuracy	Frequency ± 2 %	
Precision	1 dB or 5 dB	
Stimuli		
Tone	125 Hz - 8000 Hz	
Warble Tone	5 Hz sine +/- 5 % modulation	
Pulse Tone	Pulse Length: 250 ms or 500 ms	
Masking	Narrow band noise: IEC 60645-1, 5/12 Octave filter with the same center frequency resolution as pure tone. Synchronous masking: Locks channel 2 attenuator to channel 1 attenuator Alternative: White noise	
Presentation	Presenter or Interrupter. Single, Pulse or Warble.	
Level	AC: -10 dB HL to 110 dB HL, BC: -10 dB HL to 80 dB HL Available Extended range function: Warning displayed when 100 dB HL reached. Extended range is accessed automatically. Extended range only available when mains powered and not with USB-Cable connection.	
Frequency range	125 Hz to 8000 Hz. Frequencies can be freely deselected (except 1000 Hz)	
Weight MA 28:	1.9 kg / 4.1 lbs	
Dimensions MA 28:	380 mm x 270 mm x 140 mm 14.96 in x 10.62 in x 5.51 in	
Display:	4.3 in in in full color display with normally white LED back-light	
Language Settings:	Deutsch, English, Español, Français, Italiano, Nederlands, Polski, Русский, 中文.	
PC Connection:	1 x USB B for PC Connection (comparable with USB 1.1 and later)	
Warm-up time:	Approx. 1 minute (incl. bootup-time)	

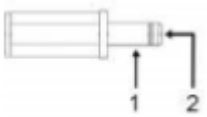
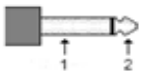
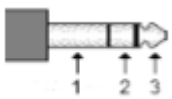
6.2 Connections

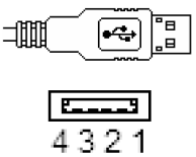
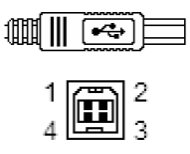
Figure 46

Table 19 Connections on Backside

CONNECTIONS No	Connection-socket	Specification
1	**DC**	5.0 V, 0,4 A Part No. Power Supply UES18LCPU-050200SPA
2	**USB out**	USB 2.0
3	**USB in**	USB 2.0
4	**Response**	RI = 330R
5	**Bone**	ZA= 10 Ω, UA= 3 Veff
6	**Insert Masking**	Not applicable in actual version
7	**Phone L**	ZA =10 Ω, UA = 3 Veff
8	**Phone R**	ZA =10 Ω, UA = 3 Veff
9	**AUX input**	Not applicable in actual version

6.3 Pin Assignment

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

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

6.4 Calibration Values and Maximum Levels

Calibration values and Max Levels: Headphone DD45

Coupler IEC 60318-3

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

Table provides max levels for PSE power only. USB power results in reduced max levels.

Calibration values: Insert phones IP30

Coupler IEC 60318-4

FRE-QUENCY [HZ]	TONE IEC 60318-5 RETSPL DB RE 20µPA	NBN IEC 60318-5 RETSPL DB RE 20µPA	TONE MAX LEVEL [DB HL]	NBN MAX LEVEL [DB HL]	SOUND ATTENUA-TION [DB] ISO 8253-1
125	26.0	30.0	90	85	33
250	14.0	18.0	105	100	36
500	5.5	9.5	110	105	38
750	2.0	7.0	110	110	-
1000	0.0	6.0	110	110	37
1500	2.0	8.0	110	110	-
2000	3.0	9.0	110	110	33
3000	3.5	9.5	110	110	-
4000	5.5	10.5	110	105	40
6000	2.0	7.0	100	95	-
8000	0.0	5.0	90	90	43
White Noise	-	0.0	-	110	-

Table provides max levels for PSE power only. USB power results in reduced max levels.

Calibration values: High Frequency Headphone DD450

Coupler IEC 60318-1

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

Table provides max levels for PSE power only. USB power results in reduced max levels.

Calibration values: Bone conductor Radioear B71 / B81

Coupler IEC 60318-6, mastoid placement

FREQUENCY [HZ]	REFERENCE EQUIVALENT THRESHOLD FORCE LEVEL FOR TONE	AIR RADIATION	MAX LEVEL
	ISO 389 – 3 / ANSI S3.6 [DB] (RE 1µN)	MIN/MAX [DB]	TONE [DB HL]
250	67.0	-	45
500	58.0	-	65
750	48.5	-	70
1000	42.5	-	70
1500	36.5	-	70
2000	31.0	-	75
3000	30.0	80	80
4000	35.5	-	80
6000	40.0	50	50
8000	40.0	-	40

Table provides max levels for PSE power only. USB power results in reduced max levels.

Calibration values: AC-Headphone Radioear DD65 v2

Coupler IEC 60318-1

FREQUENCY [HZ]	TONE IEC 60318-1 RETSPL DB RE 20µPA	NBN IEC 60318-1 RETSPL DB RE 20µPA	TONE MAX LEVEL [DB HL]	NBN MAX LEVEL [DB HL]	SOUND ATTENUA-TION [DB] ISO 4869-1
125	30.5	34.5	85	70	8.3
250	17.0	21.0	100	85	15.5
500	8.0	12.0	110	95	26.1
750	5.5	10.5	110	100	-
1000	4.5	10.5	110	100	32.4
1500	2.5	8.5	110	100	-
2000	2.5	8.5	110	95	43.6
3000	2.0	8.0	110	100	-
4000	9.5	14.5	110	95	43.8
6000	21.0	26.0	100	85	-
8000	21.0	26.0	95	80	45.6
White Noise	-	0.0	-	110	-

Table provides max levels for PSE power only. USB power results in reduced max levels.

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.

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

ITEM	MANUFACTURER	MODEL	CABLE	
			LENGTH [M]	SCREENED (YES/NO)
Audiometric Headphones	Radioear	DD45	2.0	Yes
Audiometric Headphones	Radioear	DD65 v2	2.0	Yes
High Frequency Headphones	Radioear	DD450	2.0	Yes
Insert Earphone	Radioear	IP30	2.0	Yes
Bone conductor	Radioear	B71	2.0	No
Bone conductor	Radioear	B81	2.0	No
Patient response switch	Radioear	APS3	2.0	Yes
Power Supply (Wall plug)	UE / Fuhua	UES18LCPU-050200SPA		No
USB cable		8507326	1.5	
USB cable for printer (A/micro)	Sanibel	8105182	1.0	Yes

Electromagnetic Compatibility (EMC)

Portable and mobile RF communications equipment can affect the MA 28. Install and operate the MA 28 according to the EMC information presented in this section.
The MA 28 has been tested for EMC emissions and immunity as a standalone device. Do not use the MA 28 adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.
The use of accessories, transducers and cables other than those specified, with the exception of servicing parts sold by MAICO as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device.
Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard
.

Guidance and manufacturer's declaration - electromagnetic emissions		
The *MA 28* is intended for use in the electromagnetic environment specified below. The customer or the user of the *MA 28* should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ***MA 28*** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ***MA 28*** is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Complies Class A Category	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the *MA 28*.			
The ***MA 28*** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ***MA 28*** can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ***MA 28*** as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	**800 MHz to 2.7 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 28*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***MA 28*** should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test level**	**Compliance**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	+8 kV contact +15 kV air	+8 kV contact +15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	+2 kV for power supply lines +1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	+1 kV differential mode +2 kV common mode	+1 kV differential mode +2 kV common mode	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% *U*T (>95% dip in *U*T) for 0.5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T (>95% dip in *U*T) for 5 sec	< 5% *U*T (>95% dip in *U*T) for 0.5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T for 5 sec	Mains power quality should be that of a typical commercial or residential environment. If the user of the ***MA 28*** requires continued operation during power mains interruptions, it is recommended that the ***MA 28*** be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration — electromagnetic immunity</th></tr>
<tr><td colspan="4">The MA 28 is intended for use in the electromagnetic environment specified below. The customer or the user of the MA 28 should assure that it is used in such an environment,</td></tr>
<tr><th>Immunity test</th><th>IEC / EN 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Conducted RF
IEC / EN 61000-4-6</td><td>3 Vrms
150kHz to 80 MHz</td><td>3 Vrms</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any parts of the MA 28, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance:

$d = 1{,}2\sqrt{P}$

$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz

$d = 2{,}3\sqrt{P}$ 800 MHz to 2,7 GHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF
IEC / EN 61000-4-3</td><td>3 V/m
80 MHz to 2,7 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MA 28 is used exceeds the applicable RF compliance level above, the MA 28 should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MA 28.
b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

6.6 Electrical Safety, EMC and Associated Standards

1. IEC 60601-1:2012/ ANSI/AAMI ES 60601-1: 2005 / A2:2010: Medical Electrical Equipment, Part 1 General Requirements for Safety
2. CAN/CSA-C22.2 No. 60601-1:2008: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
3. UL/IEC/EN 60950-1:2005: Information Technology Equipment - Safety - Part 1: General Requirements
4. IEC 60601-1-1:2000: General requirements for safety; Collateral standard: Safety requirements for medical electrical systems
5. IEC 60601-1-2:2014: Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and tests
6. DIN/EN/ISO 14971:2012 - Application of risk management to medical devices
7. General Safety and Performance Requirements of the current REGULATION (EU) 2017/745
8. DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2)
9. Directive 2002/96/EC on waste electrical and electronic equipment (WEEE)

6.7 Checklist for subjective Audiometer Testing

- Clean the ear and head cushion! - Untangle all lines when necessary! - Are the headphone cushions in good condition? If not → replace. - Are plugs and leads in good condition/ undamaged? - Are all controls working properly? - Is the Patient Response Key working properly (if available)? - Check batteries and renew if necessary!	Instrument:..... Manufacturer:..... Serial No.:..... Examiner:.....

Test Signal Quality

All the test frequencies in the below table indicate typical hearing level and can be changed when necessary:
Masking: "B" for Buzz tone, "G" for Noise, "V" for signal distortion, "S" for switching masking noise.

	Right Ear								Level	Left Ear								
kHz	0.25	0.5	1	2	3	4	6	8		0.25	0.5	1	2	3	4	6	8	kHz
AC									30 dB_{HL}									
									50 dB_{HL}									
									70 dB_{HL}									
BC									30 dB_{HL}									
									50 dB_{HL}									

* When noise "B", "G", "V" or "S" is blocked, inform the service center!
* When the test tone is heard at the masking ear, contact the service center!

Air Conduction Audiogram

	Right Ear								Level	Left Ear								
kHz	0.25	0.5	1	2	3	4	6	8		0.25	0.5	1	2	3	4	6	8	kHz
									Should dB_{HL*}									
Left Earpiece									Is dB_{HL}									Left Earpiece
Right Earpiece **									Is dB_{HL}									Right Earpiece **

* Should is the last measurement of the patient
** For inverted measurement please reattach the headphone
If the frequency difference between „Should" and „Is" for one ear averages more than 10 dB, contact the SERVICE CENTER!

Bone Conduction Audiogram

	Right Ear								Level	Left Ear								
kHz	0.25	0.5	1	2	3	4	6	8		0.25	0.5	1	2	3	4	6	8	kHz
									Should dB_{HL*}									
									Is dB_{HL}									

If the frequency difference between „Should" and „Is" for one ear averages more than 10 dB, contact the SERVICE CENTER!

Tested.....
Date:.....

Specifications are subject to change without notice.

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