Operation Manual

MA 1

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Title: Operation Manual MA 1
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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**
- **features and benefits**
- **a description of the device**

1.1 Intended Use

The MA 1 is a device designed to perform a hearing screening. The instrument is intended for all patient populations over 3 years old and able to respond to test signals in a rational way

1.2 Indications for Use Statement

The MA 1 is a portable or hand-held device intended to be used for the identification of hearing loss and the factors that contribute to the occurrence of hearing loss. 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, or healthcare facility.

1.3 Contraindications of Use

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

1.4 Features and Benefits

The MA 1 gives you the benefit of

- Compact handheld portable device
- Multiple transducer options
- Air Conduction
- Battery operation

1.5 Description

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

2 For Your Safety

This section offers you important information about:

- **how to read the operation manual**
- **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 OPERATION MANUAL BEFORE ATTEMPTING TO USE THIS SYSTEM!

Use this device only as described in this operation manual.

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

WARNING

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

CAUTION

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

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

2.2 Customer Responsibility

All safety precautions given in this operation manual must be 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 1 gives an explanation of the symbols used on the device itself, on the packaging and the accompanying documents including the Operation Manual.

Table 1 Regulatory Symbols

REGULATORY SYMBOLS SYMBOL	DESCRIPTION
SN	Serial number
	Date of manufacture
	Manufacturer
	Caution, consult accompanying documents
	Warning, consult accompanying documents
	Return to authorized representative, special disposal required
REF	Reference number
MD	Medical Device
GTIN	Global Trade Item Number
	Patient applied part type B according to IEC 60601-1
	Refer to instruction manual (mandatory)
	Keep away from rain
	Transport and storage temperature range
	Transport and storage humidity limitations
	Transport and storage atmospheric pressure limitations
	Do not reuse
CE	Conforms to Medical Device Regulation (EU) 2017/745
	Non-ionizing electromagnetic radiation
MAICO	Logo

2.5 General Precautions

WARNING

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

Use and store the device indoors only. For operation, storage and transport conditions see table in section 6.1.

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

WARNING

No modification of this equipment is allowed.

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

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

WARNING

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

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

2.6 Electrical and Electrostatic Safety

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

WARNING

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

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

WARNING

The device is not intended for operation in areas with an explosion hazard. Do NOT use the device in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc.

WARNING

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

2.7 Device Control

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

For annual calibration see section 2.5 and 3.2.

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.

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 device, 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**
- **handling disposables**
- **recycling and disposal of the device**

3.1 Warranty

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

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

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

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

3.2 Maintenance

In order to ensure that the device works properly, it has to be checked and calibrated at least every twelve months.

The service and calibration must be performed by your dealer or to 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 like headphones, ear cushions) which come in direct contact with the patient be subjected to standard cleaning and disinfecting procedure between patients.

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

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

- For cleaning use a lightly dampened cloth with soap water solution.
- Disinfect the plastic housing of the MA 1 and its accessories by wiping the surfaces with disinfectant wipes or a comparable product. Follow the instructions on the specific disinfection product.
    - Wipe before and after each patient
    - After contamination
    - After infectious patients

CAUTION

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

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

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

CAUTION

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

Use 70 % isopropyl alcohol only on hard cover surfaces.

3.4 Disposables

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

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

WARNING

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

3.5 Components/Replacement Parts

Some reusable components are subject to wear with use over time. MAICO recommends that you keep these replacement parts available (as appropriate for your MA 1 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 Installation

This section provides information on:

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

4.1 Unpacking the System

Check Box and Contents for Damage

- It is recommended that you unpack your MA 1 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 insure 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 1 comes with different components (see the following tables). The availability of configurations with the following components is country and version specific. Contact your local distributor for more information.

Table 2 Available Components

Components
MA 1 Base Unit
MA 1 Stand
DD45 Audiometric Headset*
DD65 v2 Audiometric Headset*
2x AA Batteries
Carrying Case
Operation Manual**
Quick Guide**
Audiogram Pad

*Applied parts according to IEC 60601-1
**As download from the download center - see accompanying leaflet.

Table 3 Replacement Parts and Disposables

Replacement Parts and Disposables
Ear Cushion Cover
Audiogram Pad

4.2 Hardware Orientation – Connection for Headphones

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

Socket for headphone

Figure 1

4.3 Battery Compartment

Figure 2

To install batteries:

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

4.4 Battery Life

NOTE: MAICO recommends using AA Alkaline Batteries

Batteries will last approximately 30,000 tone presentations. The MA 1 has an auto shut-off to conserve battery life. The device will power off after 90 s of inactivity.

When batteries get too low to produce the proper signal (remaining battery power of 2.1 V or lower), the device will shut off and will not turn back on until batteries are replaced.

4.5 Storage

When the MA 1 is not in use, store 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.

CAUTION

Leaking batteries can cause damage to the device.

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

5 Operating the Device

This section offers you information about:

- **how to get started with the MA 1**
- **preparing the patient for testing**
- **performing a hearing screening**

5.1 Getting Started with the MA 1

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 Switching the Device On and Off

Switch on the device by pressing the black right/left button to turn on the MA 1.

An automatic power shutoff occurs after 90 s of inactivity to conserve battery life.

5.2 Front Panel Controls

Figure 3

Table 4 Explanation of Front Panel

No.	Function
1	Power button and R/L Ear Selector
2	LED Ear Indicator, R = right, L = Left
3	LED Level Indicator
4	dB Level selector buttons
5	Frequency selector buttons/stimulus presentation buttons

5.3 Preparing for Testing

5.3.1 Preparing the Patient

The patient should sit with back to device and examiner so they do not see any pressing of the buttons.

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 as soon as you hear the tone in either ear".*

5.3.2 Placement of Headphones

Figure 4

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 4) 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).

5.3.3 Test Environment

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

5.4 Performing Tone Tests with MA 1 (Air Conduction Testing)

5.4.1 Screening

A hearing screening utilizes a ***Pass*** or ***Refer*** result and is used to determine if further testing is required as a hearing problem may exist. Patients are typically screened at a level of ***20 dB HL*** at ***500 Hz***, ***1000 Hz***, ***2000 Hz***, and ***4000Hz*** in ***each ear***. If a patient hears all the tones in each ear, the result would be considered a ***Pass***. Failure to hear even one of the tones in either ear would result in a ***Refer***.

NOTE: This is an example of one screening protocol. Each state may have their own screening protocol. Contact your state health department for guidelines in your area.

5.5 Conducting a Hearing Screening

5.5.1 Familiarize the patient with the test procedure

1. Press the black right/left button to turn on the MA 1.
2. Use this same button to select the right ear (red LED).
3. Press the up or down arrow keys to select 50 dB HL.
4. Press the 1000 Hz button 1-2 seconds to present the tone to the patient. The tone will be presented as long as the corresponding frequency key is held down. (This level is loud enough that a normal hearing patient should hear the tone clearly in a quiet setting.)
5. The patient should raise their hand when the tone is played. Play the tone a second time to make sure they understand the task. If not, re-instruct and try again. If no response is obtained, change to the left ear to confirm unresponsiveness.

5.5.2 Perform the Hearing Screening

Once the patient understands the task, continue to the screening process.

1. Change the hearing level to 20 dB HL and press the 1000 Hz button 1-2 seconds to present the tone to the patient.
2. Record whether the patient responded by raising their hand. Present again to confirm response at 20 dB HL.
3. Continue the same procedure for the other frequencies. Record all results on the audiogram card provided.
4. Patients are typically screened at a level of ***20 dB HL*** at ***500 Hz***, ***1000 Hz***, ***2000 Hz***, and ***4000Hz*** in ***each ear***. If a patient hears all the tones in each ear, the result would be considered a ***Pass***. Failure to hear even one of the tones in either ear would result in a ***Refer***.

Note: When presenting tones, be sure to vary the timing of the tone presentation. This is to prevent the patient from routinely raising his/her hand instead of responding to the actual tone presentation.

- Best practice is to confirm each frequencies response before moving to the next frequency. Limit testing to no more than 4 presentations to reduce false positive responses.
- When no response is given at one or more frequencies, reinstruct the patient, reposition headphones and, when possible, change examiners. Continue rescreen within the same screening period.

5.5.3 Results

PASS: The screening is considered a pass result if the child responds to all screening frequencies in both ears.

REFER: The child does NOT pass the screening and should be referred for further testing if:

- child misses any of the frequencies in either ear, even if it is just one, OR
- cannot complete the screening process.

6 Technical Data

This section offers you important information about

- **the MA 1 hardware specifications**
- **connections**
- **the pin assignment**
- **calibration values and maximum levels**
- **electromagnetic compatibility (EMC)**
- **electrical safety, EMC and associated Standards**

6.1 MA 1 Hardware

CE 0123

The MA 1 is an active, diagnostic medical product according to the class IIa of the Medical Device Regulation (EU) 2017/745.

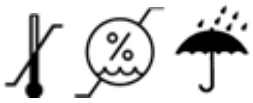
General Information About Specifications

The performance and specifications of the device can only be guaranteed if it is subject to technical maintenance at least once every 12 months.

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

STANDARDS	
Safety Standards	IEC 60601-1:2005 + Cor. :2006 + Cor. :2007 + A1:2012 Internally powered, Type B Applied Parts
EMC Standard	IEC 60601-1-2:2014

The MA 1 is not classified according to the standard EN 60645-1 and is not in conformity with this standard.

DEVICE SPECIFICATIONS		
Mode of Operation	Continuous	
Batteries		
Battery Type	2 x AA Battery power required for operation: > 2.1 V	
Battery operation	Automatic battery on/off switching	
Battery Life	Standby: 6 months, depending on the battery self-discharge, Tone presentations: 30,000	
Environmental conditions 	**Operation:**	+15 °C to +35 °C / + 59 °F to +95 °F
		Relative humidity 30 % to 90 % (non-condensing)
		Air pressure 98 kPa to 104 kPa Maximum altitude: 2000 m / 6561 ft above sea level
	Storage:	0 °C to + 50 °C / 32 °F to +122 °F Humidity 10 to 95 % (non-condensing)
	Transport:	-20 °C to + 50 °C / -4 °F to +122 °F Humidity 10 % to 95 % (non-condensing)

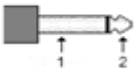
Calibration	Calibration information and instructions are located in the MA 1 Service Manual.	
Transducers		
Air Conduction	DD45:	RadioEar Standard Values
	DD65 v2:	RadioEar Standard Values
Transducers – Headband tension	DD45:	Headband Static Force: 4.5 N ± 0.5 N
	DD65 v2:	Headband Static Force: 10.0 N ± 0.7 N
Inputs	Tone	
Accuracy	Level ± 4 dB	
Precision	5 dB level steps	
Outputs	Left, Right	
Stimuli		
Presentation	Manual, continuous	
Intensity	AC: 15 dB HL to 50 dB HL	
Frequency range	500 Hz to 4000 Hz	
Weight	952,5 g/2.1 lbs with accessories and carry case.	
Dimensions	6.35 x 15.24 x 2.22 cm / 2.5 x 6 x 7/8 inches	
Warm Up Time	None	
Distortion:	<3 %	

6.2 Connections

Figure 5

CONNECTIONS		
No	**Connection-socket**	**Specification**
1	**Phone**	ZA =10 Ω, UA = 7 Veff

6.3 Pin Assignment

SOCKET	CONNECTOR	PIN 1	PIN 2
Phone	 3.5 mm Mono	Ground	Signal

6.4 Calibration Values and Maximum Levels

Table 5 Coupler Types

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

Table 6 Sound attenuation values

SOUND ATTENUATION		
Frequency [Hz]	Reference equivalent threshold sound pressure level [RETSPL, dB re. 20µPa]	
	DD45	DD65 v2
500	7.0	26.1
1000	15.0	32.4
2000	26.0	43.6
4000	32.0	43.8

Table 7 Reference Values for Stimulus Calibration

REFERENCE VALUES FOR STIMULUS CALIBRATION		
Fre-quency [Hz]	Reference equivalent threshold sound pressure level [RETSPL, dB re. 20 µPa] according to:	
	PTB Report 2009, DTU Report 2010 Coupler IEC 60318-3	PTB Report 2018, DTU Report 2018 Coupler IEC 60318-1
	DD45	DD65 v2
500	13.0	8.0
1000	6.0	4.5
2000	8.0	2.5
4000	9.0	9.5

Table 8 Frequencies and Maximum Intensities: AC (Air Condition) dB HL

TRANSDUCER MAXIMUM HEARING LEVELS		
Frequency [Hz]	Intensities [dB HL]	
	DD45	DD65 v2
	Tone	Tone
500	50	50
1000	50	50
2000	50	50
4000	50	50

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.

Guidance and manufacturer's declaration - electromagnetic emissions		
The *MA 1* is intended for use in the electromagnetic environment specified below. The customer or the user of the *MA 1* should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ***MA 1*** 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 1*** is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Recommended separation distances between portable and mobile RF communications equipment and the *MA 1*.			
The ***MA 1*** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ***MA 1*** can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ***MA 1*** 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 1*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***MA 1*** 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	Not applicable +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	Not applicable	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	Not applicable	Mains power quality should be that of a typical commercial or residential environment. If the user of the ***MA 1*** requires continued operation during power mains interruptions, it is recommended that the ***MA 1*** be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The ***MA 1*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***MA 1*** should assure that it is used in such an environment,			
Immunity test	**IEC / EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC / EN 61000-4-6 Radiated RF IEC / EN 61000-4-3	3 Vrms 150kHz to 80 MHz 3 V/m 80 MHz to 2,7 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any parts of the ***MA 1,*** 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: 
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ***MA 1*** is used exceeds the applicable RF compliance level above, the ***MA 1*** should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ***MA 1.*** **b)** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

6.6 Electrical Safety, EMC and Associated Standards

1. IEC 60601-1:2012/ ANSI/AAMI ES 60601-1: 2005 / A2:2010: Medical Electrical Equipment, Part 1 General Requirements for Safety
2. 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
3. DIN/EN/ISO 14971:2012 - Application of risk management to medical devices
4. General Safety and Performance Requirements of the current REGULATION (EU) 2017/745
5. DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2)
6. Directive 2002/96/EC on waste electrical and electronic equipment (WEEE)

6.7 Checklist for Subjective Device Check

- 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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