

Operating Instructions MA 25





Operating Manual MA 25 / MA 25e

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1 Introduction

Thank you for selecting one of our quality products from the MAICO family range. The MA 25 is designed and manufactured to meet all quality and safety requirements, and has been certified with the CE-symbol according to Medical Directive.

Particular attention has been taken during the designing phase of the MA 25 to ensure its user-friendliness, meaning that its operation is simple, easy to learn and to understand. As all the functions are software-controlled, upgrading the software and/or adding additional functions at a later date will be simple and cost-effective. By purchasing the MAICO MA 25, you have made a decision towards long-term investment.

This operating manual aims to make learning and understanding the different MAICO MA 25 functions as quick and as easy as possible. Should you encounter any problems or have ideas for any further improvements, we are only a phone call away. Please do not hesitate to contact us.

Your MAICO-Team



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2. Description

The MA 25 / MA 25e screening audiometer is designed to be a device for screening for hearing loss. Output and specificity of this type of device are based on the test characteristics defined by the user, and may vary depending on environmental and operating conditions. The screening for hearing loss using this kind of audiometer depends on the interaction with the patient. "Normal hearing" result should not allow for ignoring other contra indications. A full audiologic evaluation should be administered if concerns about hearing sensitivity persist.

The MA 25/MA 25e audiometer is intended to be used by an audiologist, hearing healthcare professionals, or trained technicians in a quiet environment.

Extended Functions

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

In addition to traditional manual testing, the MA 25e incorporates a Hughson Westlake patient controlled automatic threshold test complying with ISO 8253. When the test is completed the results are easily recalled from the internal memory of the MA 25.

Talk Forward function that makes the MA 25e easy to work with particularly in sound booth installations.



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2.1 Important safety note

The MA 25 should always be operated in a quiet room with minimal magnetic influence, to ensure that examinations are not disturbed by external noise.

Electro-medical instruments that emit strong electromagnetic fields (e.g. microwaves, radiotherapy devices) can affect the operation of the MA 25.

Therefore, the operation of these instruments in close proximity to the MA 25 should be avoided at all times.

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

MAICO MA 25 is specified according to EN 60 601-1.



Attention

PLEASE READ THE ENTIRE MANUAL CAREFULLY BEFORE OPERATING THIS INSTRUMENT.

Please only use this instrument as described in the manual.

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

Should defects or damages be suspected, please do not, under any circumstances, use or attempt to fix the instrument yourself.

Calibration of the instrument: The audiometer and the headphone complement each other and share the same serial number (i.e. 7663252). Therefore, the instrument shall not be used with any other headphone prior to recalibration. Recalibration also needs to be conducted, when a defected headphone is replaced.

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

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

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



In accordance with the Electronic Equipment Act for disposal of electronic equipment, the customer is obliged to dispose of the used consumables, according to appropriate regulation at own cost.



To observe the CE-mark with an external power supply, the power supply must be CE-medical approved according to EN 60601-1.

2.2 Unpacking and checking the MA 25

Checking for packaging and content damage

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

PLEASE KEEP ALL ORIGINAL PACKAGING FOR FUTURE USE!

The MA 25 is packaged in a specially-designed box. Please keep the box as it will be useful for sending the instrument for the instrument check-up, as required by law.

Please contact your nearest responsible dealer when the check-up is needed.

2.3 Accessories

- **Audiometer MA 25**
- DD 45 Audiometric Headset.
- 1 Pad with 50 audiogram charts
- Operation Manual.
- 3 batteries inside the device

MA 25 e - same like MA 25

- Patient response switch
- Test Hughson-Westlake

Optional

- Carrying bag

2.5 Connecting the accessories

All the connection jacks can be found on the rear side of the MA 25. All the cables and accessories have to be connected before the instrument is switched on.

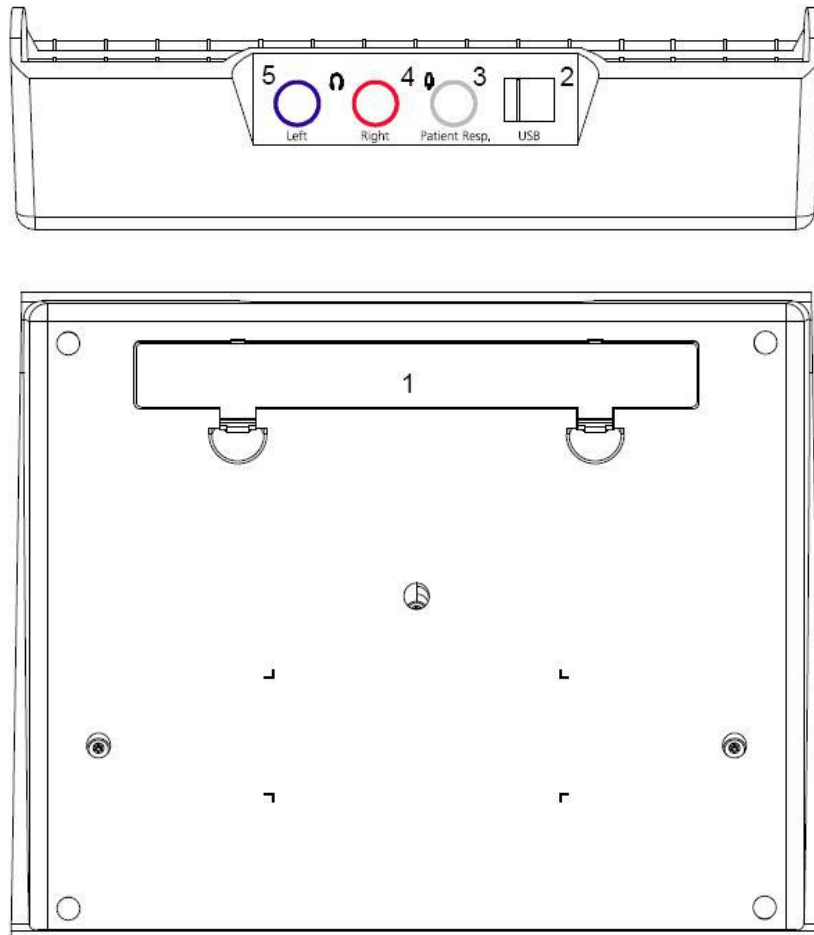


Figure 1 Rear and bottom of the MA 25

Position:	Symbol:	Function:
1	Battery	Compartment for three batteries AA/LR6
2	Power / USB	Socket for external power supply
3	Patient Resp.	Socket for patient response switch
4	Right	Socket for right headphone DD 45
5	Left	Socket for left headphone DD 45



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3 Function of buttons and display



Power On and Power Off

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

To turn on the audiometer press the Tone Switch button.

To power off the audiometer press the level dialer and frequency dialer for a few seconds. The audiometer will also automatically power off after 3, 4, 5 minutes (or not) depending on the settings.

Pure Tone Presentation

Frequency: Turn the Frequency Hz dialer to select another frequency

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

Present tone: Touch the Tone Switch

3.1 Function buttons

F1 - MA 25 - Select the Right ear. **MA 25e:** Toggle between Right and Left.

F2 - MA 25 - Select the Left ear. **MA 25e:** Store threshold.

F3 – Pulse – Pulse Off: Manual tone presentation; **Pulse On:** Pulsing Tone will be presented.

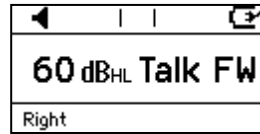
F4 – Warble - Warble off: Pure tones will be presented. **Warble on:** Warble tones will be presented.



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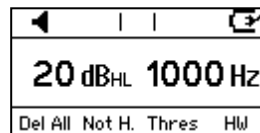
3.2 Special functions of MA 25e

Talk Forward: Talk Forward is activated by holding down the Hearing Level db dialer.



While holding down the Tone Switch the talk forward level can be adjusted.

Hughson-Westlake: The following MA 25e F-key functionalities can be accessed by pressing the frequency dialer.



F1 - Delete all thresholds stored in the internal memory of the MA 25e.

F2 - Store a Not Heard threshold point.

F3 - Display the L/R thresholds stored in the internal memory of the MA 25e.

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

Del All ← → Back

F4 - Start the Hughson Westlake (HW) automatic test procedure. Please refer to the chapter 5 for instructions about how to setup the HW test.

3.3 Display

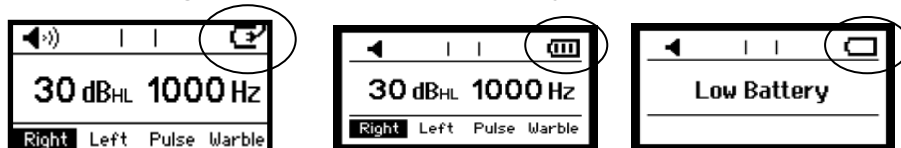
Tone: A tone presentation indicator is provided in the top left corner of the display header.



Response: When using the patient response switch, a response is indicated in the middle of display header.



Power On or Battery status: The power status of the MA 25/MA 25e is indicated in the top right corner of the display header.



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

When powered by batteries, the battery icon will change depending on the battery power level. When batteries are running low the display will read Low Battery and flash.

The Power Off settings of the instrument can be adjusted at different time intervals or set to never power off – please see Setup section for details.



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4 Performing tone audiometric tests

Hearing threshold levels can be determined by presenting test signals to the test subject with the included earphones (air conduction – AC). The purpose of AC audiometry is to establish the hearing sensitivity at various frequencies. The test can specify the AC loss but cannot distinguish between abnormality in the conductive mechanism and sensor neural mechanism.

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

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

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

Prior to hearing threshold level measurements, the following instructions should be given. "You will now hear a variety of pitches with various loudness levels. Please push the response switch when you hear a tone and release the button when you no longer hear it. If not using the response switch, ask the patient to "raise their left or right hand when you hear the tone in the left or right ear".

Threshold Determination: The test normally starts at 1000 Hz on the patient's better ear with the L/R switch adjusted accordingly.

Attention: Background noise can produce false test results, especially at lower frequencies.

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

4.1 Performing automatic tone audiometric test (MA 25e)

Another form of threshold search is using the Hughson Westlake automatic tests procedure, also known as the "10 down, 5 up" method.

Prepare and instruct the test person as described above.

Press the Frequency Hz dialer and F4 to start the automatic Hughson Westlake test. If Familiarization is activated the HW tests starts with 1000 Hz at 40 dB and proceeds in 10 dB steps in a familiarization phase before the Hughson Westlake test itself starts.

If the hearing level is confirmed the value will be stored and the next frequency is selected automatically. The level decreases for 10 dB.



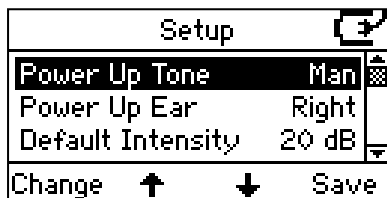
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5 Setup menu

To access the MA 25/MA 25e setup menu press F1 and F4 simultaneously for 2-3 seconds.

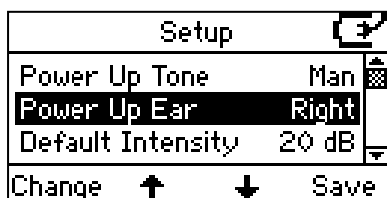
F1	Change setting
F2	Browse up in the setup menu
F3	Browse down in the setup menu
F4	Save settings and Back to previous screen display – see below for details

Power Up Tone



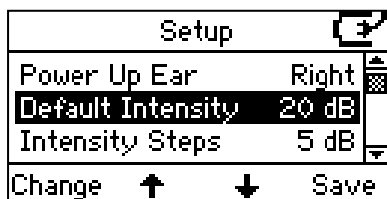
Press Change to toggle between Manual and Reverse. **Man**: Tone is presented as long as the Tone Switch is activated. **Rev**: Tone will be interrupted if Tone Switch is activated.

Power Up Ear



Press Change to toggle between Right and Left ear as the default ear for Power Up

Default Intensity



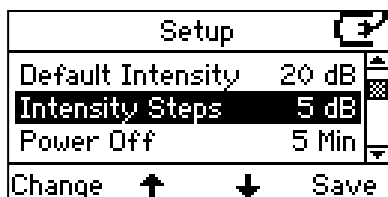
The default intensity when changing ear side is 20 dB.

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



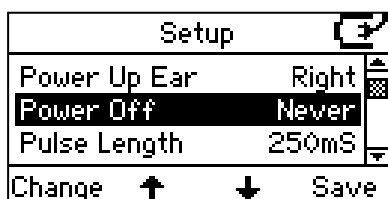
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Intensity Steps



Choose between 1 dB and 5 dB.

Power Off Settings



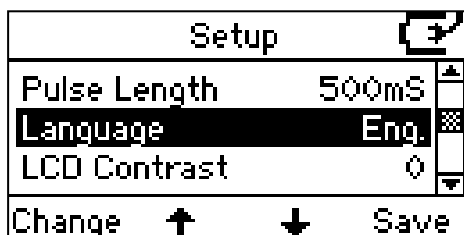
Press Change to toggle between Never, 1, 2, 3, 4 or 5 minutes.

Pulse Length



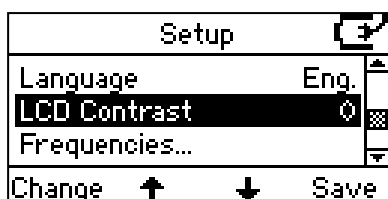
Press change to toggle between 250 msec and 500 msec.

Language



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

LCD Contrast

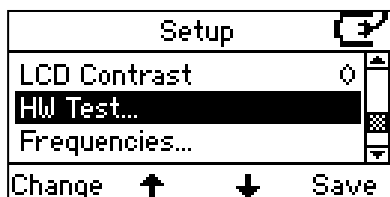


Press Change to toggle between settings ranging from 0 (very bright) to 6 (very dark).

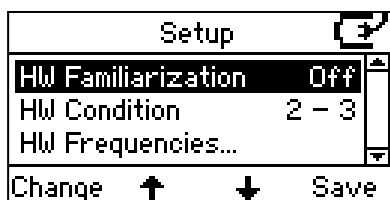


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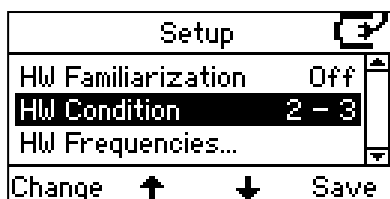
HW Test (only MA 25e)



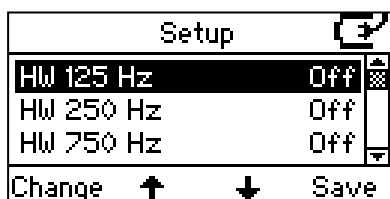
Press Change to go to the Hughson Westlake (HW) automatic test procedure setup.



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



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

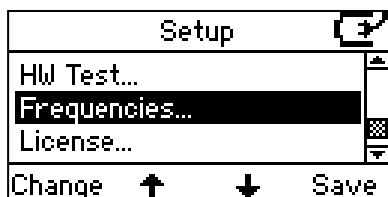


Select the frequencies to include in the HW test. Press Change to toggle between frequencies On/Off. Press Save to return to the main HW setup menu.



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Frequencies



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



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

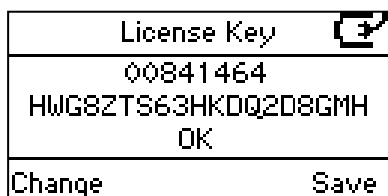
Press Change to toggle between On or Off.

Press Save to return to the main setup menu

License



Press Change to access the license key of the MA 25/MA 25e.



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

About



Press Change to access the information in the About section.



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6 Warranty and disclaimer

Warranty, Maintenance and After-Sales Service Hardware

The MA 25 audiometer is guaranteed for 1 year. This warranty is extended to the original purchaser of the instrument by MAICO through the Distributor from whom it was purchased and covers defects in material and workmanship for a period of one year from date of delivery of the instrument to the original purchaser.

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

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

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

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



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7 Care and maintenance

Disconnect the power plug before cleaning!

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

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

Always disconnect the mains conductor during the cleaning process, and be careful that no fluid is entering the inside of the instrument or the accessories; no alcohol or spirits should be used.

8 Disinfection

It is recommended that parts which are in direct contact with the patient (e.g. earphone cushions or patient response switch) are subjected to standard disinfecting procedure between patients. This includes physically cleaning and use of a recognized disinfectant. Individual manufacturer's instruction should be followed for use of this disinfecting agent to provide an appropriated level of cleanliness. If ear cushions are contaminated, it is strongly recommended to remove them from the transducer before they are cleaned



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9 Safety regulations

8.1 Electrical safety: The MA 25 / MA 25e is in compliance with Class B of EN 60601-1.



The instrument is not to be used in environments dealing with explosive material or equipment.

8.2 Measurement safety: In order to ensure safety and quality of the measurement, an annual inspection and calibration should be performed. The annual check-ups can be performed by one of MAICO's authorized service centers. MAICO will not be liable for any failure to comply with the specified inspection date, according to the Medical Product Law. The use of uncalibrated and uninspected audiometer is strictly prohibited.

8.3 Instrument handling: The instrument should be checked once a week.

8.4 Operation: The instrument should only be handled and operated by trained personnel (audiologists, ENT doctors or personnel with similar qualifications).



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10 Technical data

Standards

Audiometer : EN 60645-1/ANSI S3.6, Type 4

Safety : EN 60601-1

EMC : EN 60601-1-2



Frequencies and Maximum Intensities:

Freq. Hz.	AC (Air Condition) dB _{HL}
125	70
250	90
500	100
750	100
1000	100
1500	100
2000	100
3000	100
4000	100
6000	100
8000	90

Inputs: Patient response switch, USB-Power-Supply

Outputs: Left AC, Right AC

Attenuator: -10 to 100 dB HL in 5 dB steps.

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

Talk Forward (MA 25e): Built in talk forward microphone
0-100 dB_{SPL} adjustable.

Auto Threshold (MA 25e): Patient controlled Hughson Westlake procedure according to ISO 8253-1.

Store Function (MA 25e): Soft key (F2-key) store button and internal memory for AC L/R. Stored measurements can be viewed on the build in display.



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Modulation: Warble +/- 5% 5 Hz.

Calibration

Air Conduction: ISO 389-1/ANSI S3.6 (DD 45).

Calibration values: AC-Headphone DD 45 Force 4-5 N

Frequency [Hz]	Reference equivalent threshold according to ISO 389-1 with coupler IEC 60 318-3 [dB] (re 20 μ Pa)
125	47.5
250	27.0
500	13.0
750	6.5
1000	6.0
1500	8.0
2000	8.0
3000	8.0
4000	9.0
6000	20.5
8000	12.0

Calibration values: Optional AC headphone Holmco 8103 B 26 Force 13...16 N

Frequency [Hz]	Equivalent Reference Threshold Level according to ISO 389 - 2 Measured with Coupler IEC 60 318-3 [dB] (re 20 μ Pa)	Sound Masking [dB]
125	39.5	12.5
250	25	14.5
500	18.5	18.5
750	13.5	-
1000	12.0	25
1500	10.0	-
2000	9.5	36.5
3000	9.0	-
4000	9.0	44
6000	19.5	-
8000	20.0	35



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Calibration values: AC-Headphone TDH 39 Force 4-5 N

Frequency [Hz]	Reference equivalent threshold according to ISO 389-1 with coupler IEC 60 318-3 [dB] (re 20 μ Pa)
125	45
250	25.5
500	11.5
750	7.5
1000	7
1500	6.5
2000	9
3000	10
4000	9,5
6000	15.5
8000	13
Speech*	4,5

*Sound pressure level of 70 dB

Dimensions

W x D x H: 22.5 x 18 x 5.5 cm / 8.9 x 7.1 x 2.2 inches
Weight: 1.0 kg/2.2 lbs – including batteries and headset.
(1.6 kg/3.5 lbs – including carrying bag headset, audiogram charts etc.)

Power

Batteries 3 type AA batteries / External Power supply
Automatic battery on/off switching
Automatic battery status indication
External Power Supply 5V DC 100, 110 – 120V AC 10%, 50 – 60 Hz.
220 - 240 V AC 10%, 50 – 60 Hz.
USB-Connector 5VDC minimum 150 mA
The power supply must fulfill the medical device standard EN 60601-1
Battery life: Standby: 6 months
Tone presentations: 70.000

Construction: Plastic cabinet

Additional parts: Response switch 705270
Carrying case 705270
Medical Power supply 50002401



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Checklist for Subjective Audiometer Testing

<ul style="list-style-type: none"> - 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:.....
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Quality of test signals

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

kHz	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	
AC									30dB HL									
									50dB HL									
									70dB HL									

- * When noise "B", "G", "V" or "S" has been checked, please inform your service center!
- * If conduction test signals are also audible in the non-test ear, please inform your service center!

Air Conduction Audiogram with test person

kHz	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	
									Target dBHL*									
Left Earpiece									Actual dBHL**									Left Earpiece
Right Earpiece									IS dBHL**									Right Earpiece

- * Target value is the value measured in the last audiogram of the test person
 - **Repeat the measurement with headphones the wrong way around
- If the difference between target and actual value at a particular frequency or between right and left headphones is more than 10 dB, please inform your service center!

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



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Specifications are subject to change



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