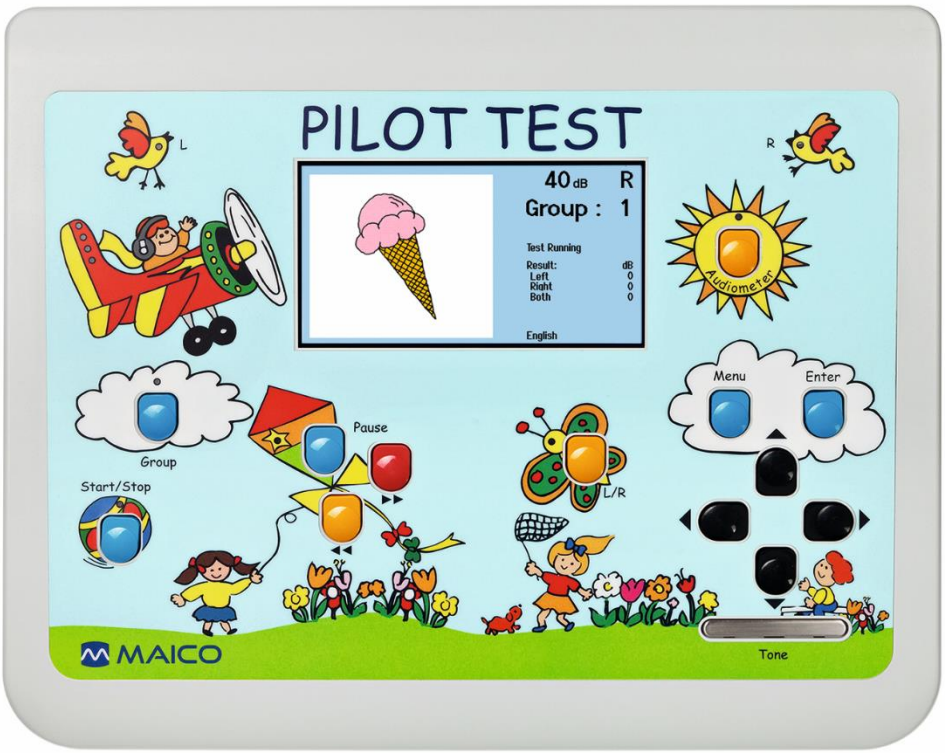
Operation Manual
PILOT TEST



MAICO Diagnostics GmbH, Sickingenstr. 70-71 , D-10553 Berlin, Tel. +49 30 / 70 71 46-50, Fax -99

Table of Contents **Page**

Title: **Operation Manual PILOT TEST**

For FW Release 1.33 and later versions

MAICO Diagnostics GmbH
Sickingenstr. 70-71
10553 Berlin
Germany
Tel.: + 49 30 / 70 71 46-50
Fax: + 49 30 / 70 71 46-99
E-mail: sales@maico.biz
Internet: www.maico.biz

Compliance

MAICO Diagnostics is an ISO 13485 certified corporation.

Caution for USA

Federal Law restricts this device to sale by or on the order of a licensed medical professional.

Trademark Notice

OtoAccess is a trademark of OtoAccess A/S registered in the USA and Europe.

1 Introduction

This Section offers you important information about:

- **the intended use and indications for use of the device**
- **contraindications for use**
- **features and benefits**
- **a description of the device and its functions**

1.1 General

Thank you for purchasing a quality product from the MAICO product family.

The PILOT TEST is designed and manufactured to meet all quality and safety requirements. When designing the PILOT TEST, MAICO placed particular importance on making it a user-friendly device. The intent was to make its operation easy-to-learn, thus making the device simple and easy to operate.s

This operation manual is meant to make it as easy as possible for the operator to become familiar with the operation and functions of the PILOT TEST. If you have questions or suggestions for further improvements, please, do not hesitate to contact MAICO.

1.2 Intended Use and Indications for Use

Screening audiometers are designed to determine hearing thresholds levels. The device is intended for all patient populations over 2 years age and able to response to test signal in a rational way.

Audiometers are intended to be used by an audiologist, hearing healthcare professional, or trained technician.

1.3 Contraindications of Use Statement

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

1.4 Features and Benefits

1.4.1 General Information About the PILOT TEST

The PILOT TEST gives the benefit of:

- Child-friendly control panel
- Air Conduction Pure Tone Audiometry
- Select Picture Audiometry in multiple of languages
- Multiple transducers selectable at purchase
- Transfer results to PC for database storage or printing
- Print directly from device via USB-connected thermal printer

1.4.2 Language Pack

The PILOT TEST comes with the following languages:

- Arabic, Chinese, Croatian, English, French, German, Greek, Italian, Polish, Russian, Serbian, Spanish, Swiss German, Turkish, Vietnamese

Further languages available are:

- Afrikaans, Basque, Catalan, Czech, Danish, Dutch, Finnish, Galician, Hungarian, Japanese, Korean, Norwegian, Polish Audifon, Portuguese, Romanian, Slovakian, South Sotho, Swedish, Xhosa, and Zulu.

1.4.3 Printing Options

Printing test results from the PILOT TEST can be accomplished as follows:

- Transfer test data into the PC-software and print results on your PC-printer (Audiometry only).
- Use the thermal printer to directly print results.

1.5 Description

1.5.1 General

The PILOT TEST is a portable dual functioning audiometer offering pure tone air conduction audiometry and simple screening speech audiometric test. The device was designed to offer a child-friendly appearance by placing technical controls “hidden" behind nice illustrations such as butterfly or sun.

1.5.2 Pure Tone Audiometry

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

1.5.3 Select Picture Audiometry

Select Picture Audiometry incorporates the child listening to a series of “spondee” words at different decibel levels and point to the picture. The purpose is to establish an ear specific hearing level when standard pure tone testing cannot be performed. The level at which a patient can understand spoken language can be a valuable screening tool, especially with young children. This speech recognition level can be determined easily by the PILOT TEST.

2 For your Safety

This Section offers you important information about:

- **how to read the operation manual**
- **the explanation of all regulatory symbols used**
- **the customer responsibility and manufacturer's liability**
- **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 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
	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
	Voltage transformer
CE	Conforms to European Medical Device Directive 93/42/EEC
ETL CLASSIFIED Intertek	ETL listed mark
MAICO	Logo

2.3 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.

WARNING

This product and its components performs 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 2.4 and 3.1).

NOTE: In the unlikely case of a serious incident, inform MAICO as well as your local distributor.

2.4 Manufacturer's Liability

Usage of the device in a way deviant from the intended use leads 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.

2.5 Device Control

The user of the device should perform a subjective device check once a week according ISO 8253-1. See Section 6.6 for a checklist.

For annual calibration please see Sections 2.6 and 3.2.

2.6 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.

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 audiometer and the headphone complement each other and share the same serial number (i.e. MA7663252). Therefore, the device shall not be used with any other headphone 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.

2.7 Electrical Safety and Measuring Security

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

WARNING

In Case of Emergency

In case of emergency, disconnect the device from the computer.

WARNING

In Case of Emergency

In case of emergency, disconnect the device from power supply.

Do not position the device in a way that it is difficult to operate the disconnection device. The supply mains and the power socket shall be accessible at all times.

Do not use the device if the mains cable and/or the outlet is damaged.

WARNING

To transfer data to a PC, establishing a PC-connection via USB is required. See Section 4.2.2 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.

WARNING

This equipment is intended to be connected to other equipment thus forming a Medical Electrical System. External equipment intended for connection to signal input, signal output or other connectors shall comply with the relevant product standard e.g. IEC 60950-1 for IT equipment and the IEC 60601-series for medical electrical equipment.

In addition, all such combinations – Medical Electrical Systems – shall comply with the safety requirements stated the general standard IEC 60601-1, edition 3, clause 16.

Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support or shall be supplied via a separation transformer to reduce the leakage currents.

Any person who connects external equipment to signal input, signal output or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements. If in doubt, contact qualified medical technician or your local representative.

If the device is connected to a PC (IT equipment forming a system) ensure not to touch the patient while operating the PC.

Do not touch the patient while touching the connections of the device or printer.

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.

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. If the device is not used switch it off and disconnect it from the power supply.

Never short-circuit the terminals.

CAUTION

In order to maintain a high level of safety and to ensure the device works properly, it is necessary to have the device and its power supply checked according to the medical electrical safety standard IEC 60601-1 by a qualified service technician at least once a year. For more information see Section 3.2.

The use of non-calibrated devices can lead to incorrect test results and is not advisable.

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

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.

WARNING

Electrostatic discharge (ESD) according to IEC 61000-4-2. Use the device only in an electrostatic controlled environment.

The device fulfills the relevant EMC requirements.

Avoid unnecessary exposure to electromagnetic fields, e.g. from mobile phones etc.

WARNING

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.

Please also refer to EMC consideration in Section 6.5.

WARNING

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

The list of accessories, transducers and cables can be found in section 6.5 of this instruction.

WARNING

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 PILOT TEST, 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**
- **component and replacement parts**
- **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 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 Do not modify this equipment without authorization of the manufacturer.

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 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

3.3.1 General

It is recommended that parts (device and components 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:

- Before cleaning always switch off and disconnect the device from power supply.
- For cleaning use a lightly dampened cloth with soap water solution.
- Disinfect the plastic housing of the PILOT TEST 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 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.

For more detailed cleaning recommendations see the following Section 3.3.2.

3.3.2 Cleaning the Case and Cables

CAUTION

Use caution while cleaning.

Use a damp cloth to clean the plastic parts of the PILOT TEST.

If disinfection is required, use a disinfectant wipe rather than a spray product. Make sure that excess liquid from the wipe does not seep into any sensitive areas such as connectors and seams where plastic pieces connect.

Follow the instructions on the disinfection product.

3.4 Components and 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 PILOT TEST device configuration). Ask your authorized local distributor when accessories need to be replaced.

3.5 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 establish a PC connection**
- **how to store the device**
- **getting to know the thermal printer**

4.1 Unpacking the System

Check Box and Contents for Damage

- It is recommended that you unpack your PILOT TEST 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 PILOT TEST 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 General Components

Components
General Components
PILOT TEST Device
Power Cord
Thermal Printer HM-E300 Kit
External Loudspeaker ***
Soft-side Carrying Case
Patient Response Switch*
Monitor Phone
Operation Manual
Quick Guide
Set of training pictures
Picture chart 1160
Headphones**
DD45 with HB7 Headband*
DD65 V2*
Software
OtoAccess® Database
Noah 4
MAICO Sessions Bundle incl. USB cord

*Applied parts according to IEC 60601-1
**Selection of one transducer at time of purchase
*** Loudspeaker uncalibrated, only to be used for conditioning of test procedure

Table 3 Speech Test Languages

Standard Speech Test Languages
Standard Languages
Arabic, Chinese, Croatian, English, French, German, Greek, Italian, Polish, Russian, Serbian, Spanish, Swiss German, Turkish, Vietnamese
Extra Languages
Afrikaans, Basque, Catalan, Czech, Danish, Dutch, Finnish, Galician, Hungarian, Japanese, Korean, Norwegian, Polish Audifon, Portuguese, Romanian, Slovakian, South Sotho, Swedish, Xhosa, Zulu

Table 4 Replacement Parts and Disposables

Replacement Parts and Disposables
Audiogram chart multilingual
Roll of Stickers „Pilot License“ (500 Pieces)

4.2 Hardware and Components

4.2.1 Connections for Headphones, Power Supply and USB Devices

Figure 1 shows the connections on the backside of the device. The connections are explained in Table 5.

CAUTION

Insert plugs with care into the appropriate connection. Do not wiggle the plug or pull with force while connected. Disconnect plugs cautiously. A device should always be off when inserting or removing an accessory from the rear panel connectors.

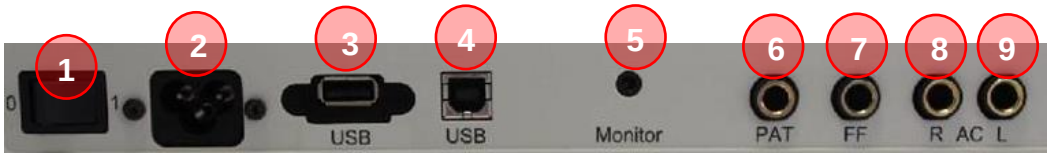


Figure 1

Table 5 Connections on Backside of Device

CONNECTIONS	
1	Power switch (0 = Off, 1 = On)
2	Power socket for power supply
3	USB out for thermal printer
4	USB in/out
5	Connection for monitor phone
6	Connection for patient response switch
7	Connection for free-field loudspeaker
8	Connection for Headphones (R - Right/Red)
9	Connection for Headphones (L - Left/Blue)

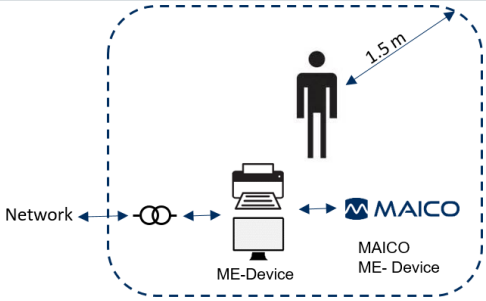
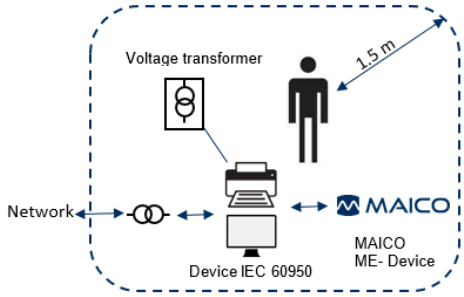
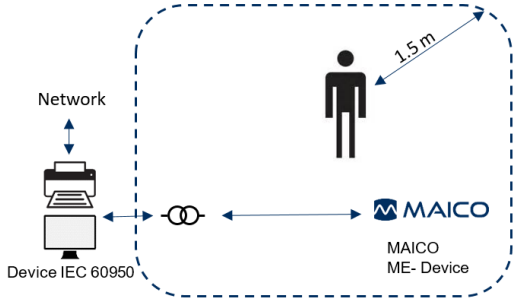
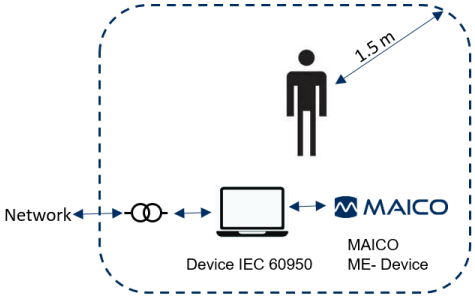
4.2.2 Establishing a PC-Connection

To transfer data to a PC, establishing a PC-connection via USB is required. If the PILOT TEST is used with office equipment that is not a medical device itself (see Table 6), make sure to establish the PC-connection in one of the following ways (see Table 6, 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) a voltage transformer must be used (exception: a battery driven laptop is used).

Table 6 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)
	

4.2.3 Storage

When the PILOT TEST is not in use, store in a location where it will be safe from damage to the display, acoustic transducers and cables. Store according to the recommended temperature conditions described in section 6.

4.2.4 Thermal Printer

Connect the included USB cord to the printer and to the PILOT TEST device. Push the 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 2).
- 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 3).

Figure 2

Figure 3

5 Operating the Device

This Section offers you information about:

- **how to get started with the PILOT TEST device**
- **the display and control panel**
- **performing PILOT TEST and audiometry testing**
- **managing the test results**
- **settings to be made**

5.1 Getting Started with the PILOT TEST

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 PILOT TEST 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 the norm ISO 8253-1:2010 or ANSI S3.1-1999. For use in noisier environments, headphones with optional sound insulation muffs are available.

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.

NOTE: The warm up time for the device including boot up process takes approx. 1 minute. If the device has not been used for a while (e.g. overnight), wait for the recommended period of time before operating the device.

5.1.3 Switching the Device On and Off

Switch the PILOT TEST on and off by using the power switch on the rear panel of the device: ***1 = On, 0 = Off***.

5.1.4 Display and Control Panel

Figure 4 shows the Display and the Control Panel of the PILOT TEST.

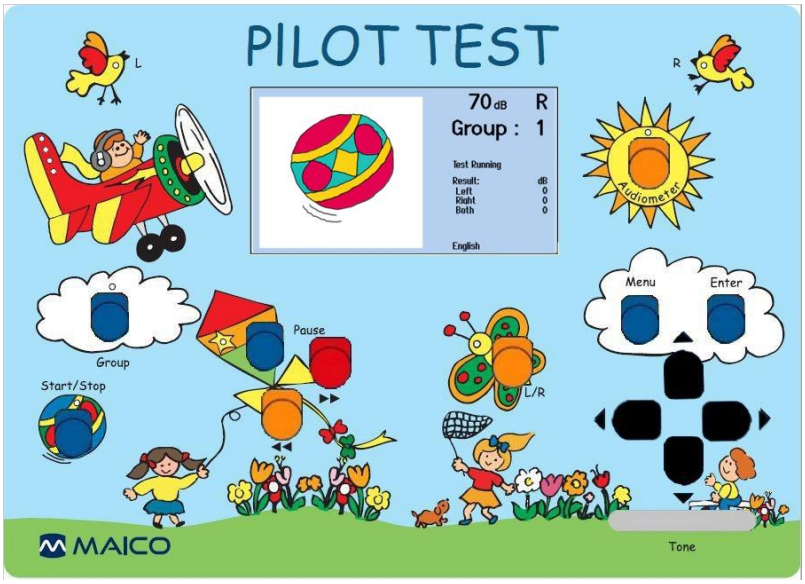
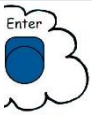


Figure 4

Table 7 Explanation of Keys

KEY	EXPLANATION	KEY	EXPLANATION
	**Group** Selection of the word list for PILOT TEST (Group 1-4)		**Menu** Set up Menu (see Section 7 of Operating Instructions)
	**Start / Stop** Start / Stop of PILOT TEST		**Enter** Store response during test
	**Pause** Temporily stop PILOT TEST		**Audiometer** Starts Tone Audiometry
	**Forward** PILOT TEST: Next word Audiometry: Pulse tone on		**Loudness** Decrease or increase of intensity level (dB) in Tone Audiometry mode
	**Backwards** PILOT TEST: Repeat last word Audiometry: Pulse tone off		**Frequency** Decrease or increase of frequency (Hz) in audiometry mode
	**L / R Ear** Change ear selection		**Tone** Signal presentation in Tone Audiometry test (adjustable in the User menu)

5.2 Performing the PILOT TEST

5.2.1 General – PILOT TEST

The following Sections 5.2.2 to 5.2.8 offer information about the PILOT TEST.

5.2.2 PILOT TEST Display

Once the test is started the display provides the progression and/or status of the test. The following provide descriptions of those items shown on the display.

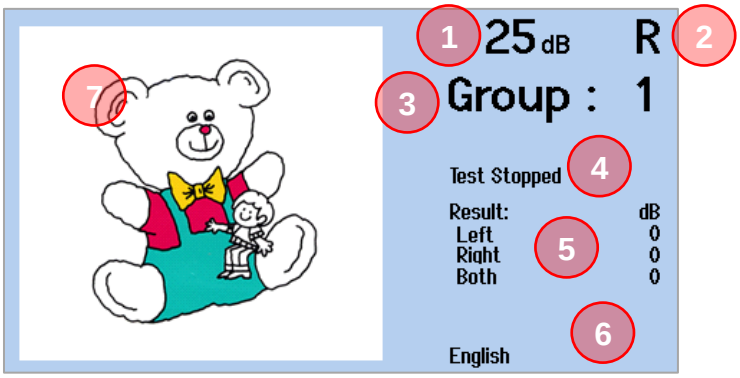


Figure 5

Table 8 Test Screen

#	ITEM	EXPLANATION
1	25 dB	**Hearing Level**: Level of test sentence presented to the child.
2	L R	**Ear:** Test ear selected (***R*** = Right Ear, ***L*** = Left Ear, ***B*** = Both Ears). **NOTE**: Both is only selected if activated in the ***PILOT TEST menu*** (see Section 5.5.3).
3	Group : 1	**Word Group:** The prerecorded list of test words that are played. There are 4 test groups available for selection.
4	Test Stopped	**Status** of the test being performed. Options include: • ***Test Stopped***: No Group is being played.7 • ***Test Running*:** Test is started and words are being presented. • ***Test Paused***: Examiner has temporarily stopped the test.
5	Result:	**Table of stored results**, including ***Left***, ***Right*** and/or ***Both*** ears.
6	English	**PILOT TEST Language**: Language of words being presented.
7		**Picture:** As test progresses, the test word that is being presented is displayed on the screen.

5.2.3 Preparing for Testing

The child will first need to learn the correct names for the pictures. This can often be accomplished by having a parent help the child in the waiting room while they are waiting for the health care professional to administer the test. To be sure the child understands, ask the child to identify the pictures in the same manner as the screening test, i.e., ***"Point to the toothbrush; show me the airplane, etc.".*** Do not start the test until you are confident that the child understands and knows the pictures.

The test can be less intimidating if the child is to pretend that he/she is going to play the "***Pilot Game***". This will reduce the anxiety associated with screening. Tell the child that when the test starts, the pilot needs his/her help and will ask them some questions. Introduce the headphones and explain that they are needed to help the pilot; he/she must put on the headphones – just like pilots wear – so that they can hear each other. Make this instruction fun and entertaining for the child.

Explain that the pilot will ask where a picture is and he/she should point to it on the picture board. The child should be told that the voice will start out loud and get softer, so he/she must listen very carefully.

The child should sit in a way that the screen of the device is not visible. Place the pictures in front of the child for selection. Place the headphones on: red side on the right ear, blue side on the left ear and make sure that they are secure. Adjust the headband of the headphones so that the transducers are at the correct angle (i.e. the sound output grid exactly facing the ear canal). The headphones needs to fit snuggly (make sure the child's hair and/or glasses are away from the ear).

Put the monitor phone on your ear to hear the presentation of the word during the test.

You are ready to begin!

5.2.4 PILOT TEST Process

Figure 6

Figure 6 shows the PILOT TEST display. See Section 5.2.2 for more information.

The PILOT TEST process is described below.

1. Press the ***L/R*** key, located in the butterfly. ***R*** (Right) or ***L*** (Left) will display on the screen.

   B (Binaural) is selectable if ***Binaural presentation*** is activated in the PILOT TEST menu (see Sections 5.2.6 and 5.5.3)

2. Press the ***Group*** key in the left cloud to change the test group. There are four test groups to select. The ***Group*** that is selected is displayed on the screen as well as indicated by the green LED located on the airplane.

3. Press the ***Start/Stop*** key in the ball, to start the test. Once started, "***Test Running***" shows on the display.

5. **NOTE**: The left side of the screen provides a white line to indicate the time left before the next word is presented.

6. The child should respond by pointing to the correct word on the picture board and the tester marks the response. See Section 5.2.5 on scoring results.

   The test will automatically go to the next sentence and the volume level decreases to 60 dB HL. Continue to mark the answers. Each successive sentence decreases in volume as shown in Table 9.

When the test set has completed for one ear and passed, select the other ear by pressing the **L/R** key and confirm a new ***Group*** is selected.

Table 9 Group Lists

GROUP 1		GROUP 2		GROUP 3		GROUP 4	
Picture = Test word	Level (dB HL)	Picture = Test word	Level (dB HL)	Picture = Test word		Picture =	Level (dB HL)
	70		70		70		70
	60		60		60		60
	50		50		50		50
	40		40		40		40
	40		40		40		40
	35		35		35		35
	35		35		35		35
	30		30		30		30
	30		30		30		30
	25		25		25		25
	25		25		25		25

Pausing the Test

You can interrupt the test at any time by pressing the blue ***Pause*** key (located on the kite). The green ***Pause LED*** will light up and "***Test Paused***" is shown on the display.

To restart the test, press the Pause key again. The green Pause LED turns off and the test will continue.

NOTE: If the test is paused during the presentation of a sentence, repeat the sentence.

You can skip or repeat test sentences by pressing the ***Forward arrow*** ►► or the ***Backward arrow*** ◄ ◄ keys. This only functions while the test is running.

Ending the Test Early

If the child does not understand two successive test sentences, press the ***Start/Stop*** key to end the test. The next training group will automatically be entered. Repeat the test with this next group.

Completion of Test

The test is complete when all 11 words have been presented and recorded for both ears. A passing result is when 25 dB has been identified correctly. If the child does not pass, repeat the screening or refer the child for further audiometric examination.

The child has passed when both ears have been tested and pass criteria met.

Protocol recommendation

The above is an example screening protocol. Users are therefore recommended to refer to State or Country guidelines.

5.2.5 Scoring results

There are two options for scoring responses:

- **Audiogram Pad:** Mark the corresponding column/field on the audiogram pad with a checkmark ✓ for the ear tested. That means the answer was correct. If the answer was wrong, mark the field with a cross ☒.
- **Save to device**: Score the response for immediate printing to the thermal printer upon test completion. Record the test results by pressing the ***Enter*** key when the child signals his/her understanding and points to the corresponding picture on the picture board. The level is saved under results beside the respective ear. The result is then shown on the display. While the level decreases, the displayed test results will remain the same unless the response is confirmed by pressing the ***Enter*** key again. The test results change according to this confirmation. The level at which the patient correctly understood the sentence is shown beside the respective ear on the display.

  NOTE: ***Save to device*** requires the optional thermal printer.

5.2.6 Testing Both Ears (Binaural)

To test both ears at once, press the ***L/R*** key until the letter ***B*** appears on the screen. Complete the test in the same manner as the right ear. Mark the test results in the ***B*** column of the evaluation pad.

NOTE: The test results of a binaural test are typically a little better than the test results of a single ear. Binaural testing must first be enabled in the ***PILOT TEST Menu*** (see Section 5.5.3).

5.2.7 Changing the Test Language

To change the language the child hears during the test, press ***Menu***. Select the ***arrow*** ▼ key until ***PILOT TEST speech language*** is highlighted and press ***Enter***. The next screen will show you the language options that are programmed into the device. Press the ***arrow*** ▼ key until the language you wish to select is highlighted and press ***Enter***. Select the ***Menu*** key to exit and return to the test screen.

5.2.8 Adjusting Volume of Monitor Phone

Press the ▲ or the ▼ keys to increase and decrease the volume through the monitor phone while the PILOT TEST is in progress. The monitor phone is only active for the PILOT TEST.

5.3 Audiometry Testing

The Audiometry test investigates the hearing threshold of the patient and offers a frequency-specific test result.

5.3.1 Audiometry Control Keys and Display

Figure 7

Audiometry uses the arrows and silver bar on the right side of the device for test operation (Figure 7). To enter the audiometry screen press the ***Audiometer*** key.

NOTE: The Audiometry display has two options, graph view (Figure 8) or table view (Figure 9). See Section 5.5.4 on ***Display type***.

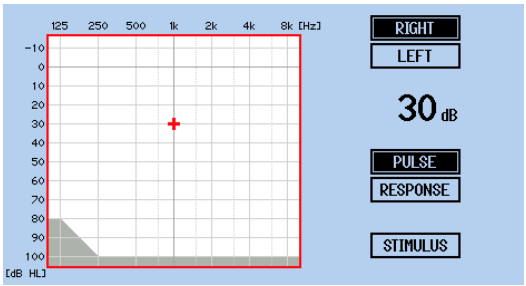


Figure 8

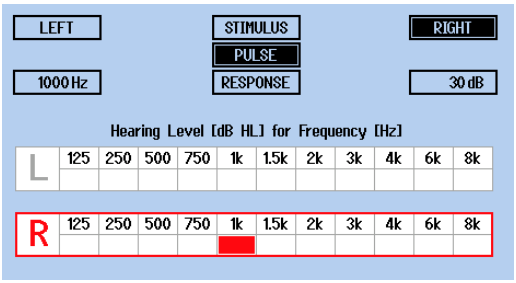


Figure 9

Table 10 Explanation of Audiometry Control Keys

#	ITEM	EXPLANATION
1	◄ ►	**Frequency:** Press ◄ key to decrease the frequency or ► key to increase the frequency. **Graph:** Frequency is displayed on the screen with the red (right ear) or blue (left ear) cursor. **Table:** Frequency is displayed in the left lower box 1000 Hz and highlighted frequency box for the selected ear. **NOTE**: Frequencies that have been turned off in the settings will be greyed out in the ***Table*** view. See Section 5.5.4 for more information.
2	▲ ▼	**Hearing Level**: Change level of the tone by pressing ▲ key to increase the level and ▼ key to decrease. **NOTE**: The arrow to increase the loudness can change in the ***User menu***. See Section 5.5.4 for more information. **Graph:** Hearing level is displayed in the middle of the screen (e.g. 30 dB). **Table:** Hearing level is displayed within the right lower box 30 dB.
3	**Tone**	Touch the Tone bar to present the signal. When a signal is presented to the child the Stimulus box is in black. **Signal on:** STIMULUS **Signal off:** STIMULUS **NOTE**: When ***User menu*** is set to interrupter, pressing the Tone bar will stop the signal from presenting.
4		**Ear:** Press key to change the test ear. The selected ear is in black. RIGHT LEFT
5	PULSE	**Pulse:** when ***Pulse*** is highlighted in black, the pure tone presented to the child will quickly turn on/off (pulse). The Stimulus box will show the pulsing of the signal. Pulse tone can be defaulted upon startup. See Section 5.5.4 for more information. To temporarily turn on pulse, use the ***Forward*** ►► key. To turn off pulse select the ***Backwards*** ◄◄ key. Upon exiting the Audiometry test, the pulse returns to default setup.
6	RESPONSE	Response box is highlighted in black when the patient response button is pushed. **NOTE**: This is an optional accessory and only used when child is old enough to respond with the push of a button.

5.3.2 Preparing for Testing

5.3.2.1 Preparing the Patient

Select a quiet environment and away from distractions.

The child should sit at a distance of at least 1 m from the device and at an angle with his/her back to the audiometer. This will insure the child is unable to see the examiners hand movements or facial expressions during the test.

Put the child at ease and provide instruction of the test procedure*: "I am going to place these headphones on your ears. You will hear some beeping sounds at different tones and levels, raise your hand as soon as you hear a beep in either ear, even if it is very soft."*

Place the headphones on the patient: red side on the right ear, blue side on the left ear and make sure that they are secure. Adjust the headband of the headphones so that the transducers are at the correct angle (i.e. the sound output grid exactly facing the ear canal). The headset needs to fit snuggly (make sure the child's hair and/or glasses are away from the ear).

5.3.3 Audiometry Screening Process

The device can be used for air conduction threshold or screening tests.

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 better ear. A procedure of **"*down 10 dB when heard, up 5 dB when not heard*"** is typically utilized to establish a threshold at each frequency. Vary the length of the tone and intervals between tone presentations to ensure the child is responding to the tone and not just repeating the behavior.

Screening

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

The following is a sample of a screening protocol. Please refer to your state or facility guidelines for specific test procedures for your location.

1. Press the **Audiometry** key to perform a pure tone hearing test.
   Press the ***L/R*** key until the preferred test ear (***LEFT/RIGHT***) is highlighted in black. Test usually starts in the ***Right*** ear.
2. Set the frequency (keys ◄ ►) and hearing level (keys ▲ ▼).

NOTE: Starting at a higher level then the screening guideline specifies allows you to train or condition very young children in understanding your instruction. This would not count as part of the screening. Once you start at the screening level (i.e. 20 dB HL), the test has begun.

3. Press the ***Tone*** key to present a tone for 1-2 seconds. As soon as the bar is pressed, the STIMULUS field on the display is highlighted. If the field is already highlighted when starting the test, the Interrupter Mode is selected within ***User menu*** settings.

   The child should respond by raising their hand when a tone is heard. For younger children, making it a "*listening game*" where they stack blocks or drop a block in a bucket as they hear the tone, might put the child at ease, make it more fun, and keep their attention longer.

   Observe the child's response or non-response to the tone. Vary the length of the tone and intervals between tone presentations to ensure the child is responding to the sound and not just repeating the behavior. When the child makes two correct responses, record ***Pass*** and move on to the next frequency.

   NOTE: More than one but no more than four presentations should be made at one frequency. This provides a reliability check to the response. If child does not meet this criteria, record ***Refer*** and continue testing.

   When one ear is completed, select the other ear ***L/R*** key and start the screening process over.

Completion of Test

The test is complete when all protocol test frequencies have been presented and recorded for both ears. If the child does not pass, repeat the screening or refer the child for further audiometric examination.

The child has passed when both ears have been tested and pass criteria met.

Protocol recommendation

The above is an example screening protocol. Users are therefore recommended to refer to State or Country guidelines.

5.3.4 Scoring Results

There are two options for saving responses:

1. **Audiogram Pad**: The included audiogram pad offers you a way to document the responses on either a table or graph.
2. **Save to device**: Save the response within the device for printing to the thermal printer or transfer to the PC. When the patient's hearing threshold is established, or screening protocol has been met, press the ***Enter*** key to store the result and move to the next frequency.

   NOTE: ***Save to device*** requires the Thermal Printer or PC software (optional accessories) for result storage.

5.4 Managing Test Results

5.4.1 Delete/Print Test Results

It is best practice to delete any results stored in the device from one child to the next.

To access the menu, press and hold the ***Group*** key or ***Audiometer*** key for two seconds to delete, print, or print/delete the results (Figure 10). Confirm your choice by pressing the appropriate key as defined on the screen.

If a printer is not connected and powered on at time of accessing the ***Delete/Print*** screen, the ***Print*** and ***Print/Delete*** will not be shown (Figure 11).

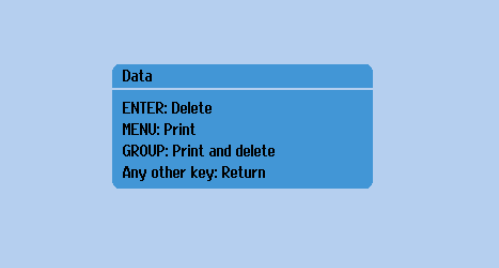


Figure 10

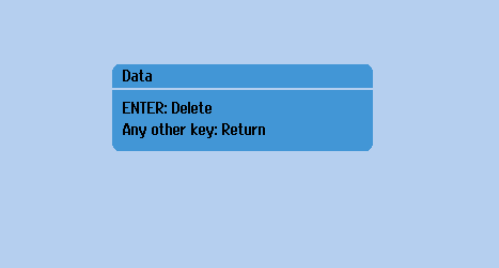


Figure 11

5.4.2 Understanding the Printout

Printouts can contain up to three parts:

- Header
- Audiometry test results and
- PILOT TEST results.

Figure 12

The header shows the date and time of the session (time of printing) as well as the logo and name of device (Figure 12, **1**).

Furthermore, it is possible to fill in the following fields manually (**2**):

- ***ID No.***
- ***Name*** (of the patient)
- ***Examiner*** (signature of examiner)
- ***Remarks***

Test results for ***Audiometry*** are shown in audiogram (Figure 13) or table format (Figure 14) dependent on the settings made.

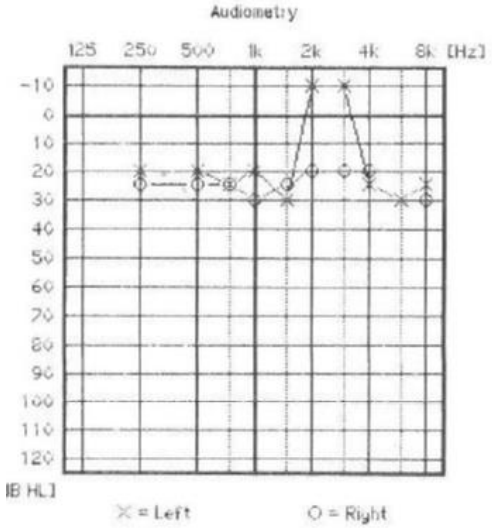


Figure 13

Audiometry
Hearing Level [dB HL]

Hz	125	250	500	750	1k	1.5k	2k	3k	4k	6k	8k
Left		20	20	25	20	30	-10	-10	25	30	25
Right		25	25	25	30	25	20	20	20		30

Figure 14

PILOT TEST results are shown in ***short*** table view (Figure 15) or a table ***with Pictures*** (Figure 16) dependent on the settings made in the ***PILOT TEST menu*** (submenu ***Print size***, see Section 5.5.3).

PILOT TEST
Hearing Level [dB HL]

	Left	Right	Both
Group 1	25	25	25
Group 2	25	25	25
Group 3	35	35	35
Group 4	35	25	35

Air Conduction: English

Figure 15

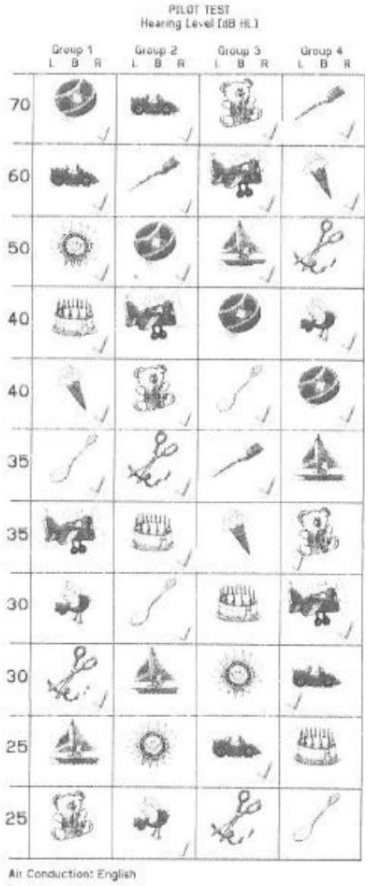


Figure 16

5.4.3 Transferring Test Results to PC

Before transferring data to a PC make sure that you have installed MAICO Sessions according to the separately delivered operation manual.

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

5.5 User Menu

5.5.1 General

The PILOT TEST is pre-configured, but allows customization with the ***User Menu***. After having set the changes they are saved in the device. The settings remain unchanged even if the device has been switched off.

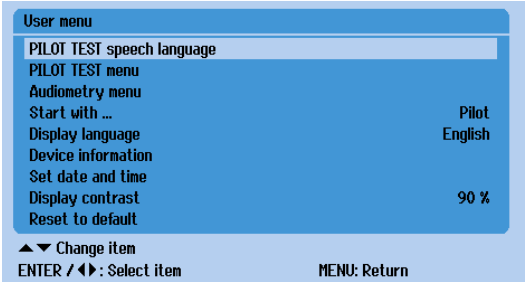


Figure 17

Press the ***Menu*** key to enter the ***User menu*** (Figure 17). By pressing the ▲ or ▼ keys, the different menu options are highlighted for selection. Press the ***Enter*** key to choose a submenu or to select a new setting.

Press the ***Menu*** key again to exit the (sub)menu and save the new settings. After leaving the ***User menu*** you will return to the test you last selected.

See Sections 5.5.2 to 5.5.9 for more information on the menu items and submenus.

5.5.2 PILOT TEST Speech Language

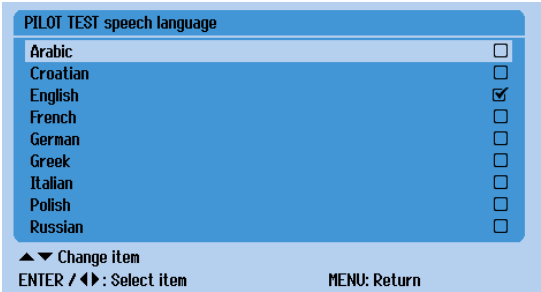


Figure 18

Select a speech language for the PILOT TEST by selecting a language with the ▲ or ▼ keys and confirming with the ***Enter*** key (Figure 18).

5.5.3 PILOT TEST Menu

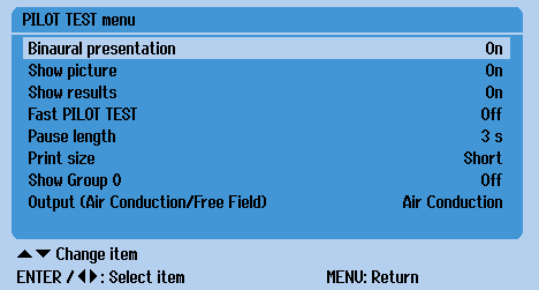


Figure 19

The ***PILOT TEST menu*** offers various options for adjusting test settings (Figure 19). The options are explained in Table 11.

Table 11 PILOT TEST menu

ITEM	EXPLANATION
Binaural presentation	The option to present the words to both ears at the same time. When menu option is ***On***, ***B*** (i.e. binaural) is a selection option with the ***L/R*** key. When menu option ***Off*** is selected, binaural selection is not available from ***L/R*** key selection.
Show picture	Set ***On/Off*** to show/hide picture of the test word on the display. **NOTE:** When this setting is ***On*** verify the child is unable to see the display screen.
Show results	Results table displays within the ***PILOT TEST*** screen when this setting is ***On***.
Fast PILOT TEST	Set ***On*** to start the test at 40 dB rather than at 70 dB.
Pause length	Pause length between the test sentences can be set between ***1 s*** and ***20 s***. Default length is ***3 s***.
Print Size	Selection is between ***Short*** where only numerical data will print or ***with Pictures*** where the test word picture is shown. A checkmark ✓ is displayed if the examiner scored a correct response. See Section 5.4.2 for more information.
Show Group 0	When set ***On***, an additional ***Group 0*** is available. This is a conditioning group where all words are presented at 70 dB.
Output (Air Conduction/ Free Field)	Output selection with headphones or Free Field. Free field allows a speaker (optional accessory) to be connected and is useful during the conditioning of the test process. This allows the child to hear the signal along with the examiner during training. Once testing starts, free field should not be used for presentation.

5.5.4 Audiometry menu

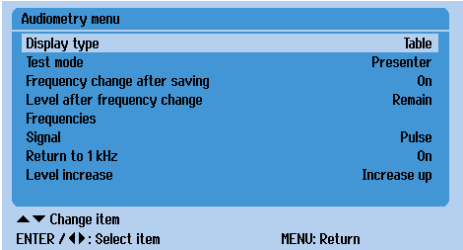
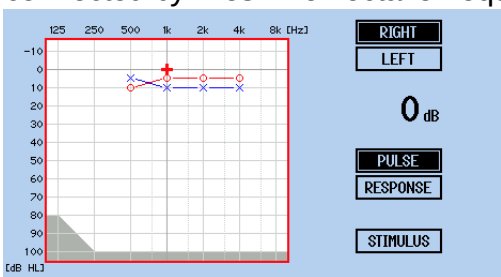
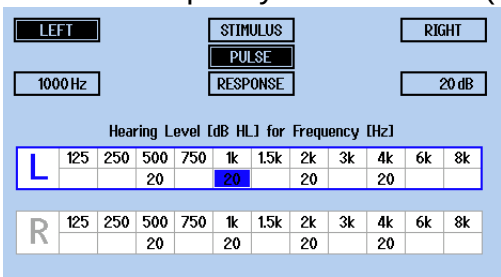
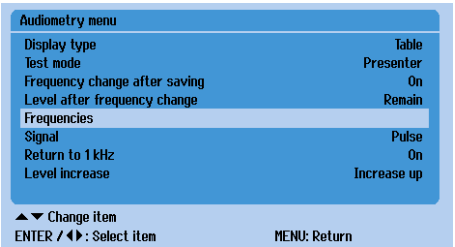
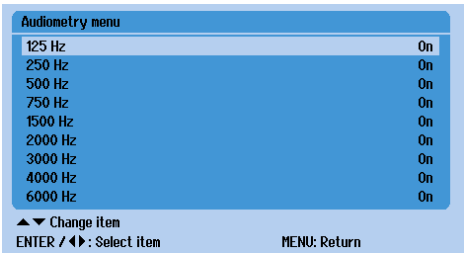


Figure 20

The ***Audiometry menu*** (Figure 20) covers all settings for performing audiometry tests. The options are explained in Table 12.

Table 12 Audiometry menu

ITEM	EXPLANATION
Display type	Results are displayed with: • **Graph:** The level and frequency of the response is highlighted by a red **O** for the right ear and blue **X** for the left ear. The results are connected by lines when octave frequencies are tested (Figure 21).  Figure 21 • **Table:** The response in the table view is stored as a numerical value under the frequency and ear tested (Figure 22).  Figure 22
Test mode	Selection of the operation mode: • ***Presenter***: Tone is presented when the ***Tone*** key is touched. • ***Interrupter***: Tone is interrupted/stopped when the ***Tone*** key is touched.
Frequency change after saving	When ***On***, the next frequency is selected upon storing the result. If this function is switched ***Off***, the next frequency must be selected by pressing the ***arrow*** ◀ ▶ keys.

ITEM	EXPLANATION
Level after frequency change	Change to hearing level when frequency is changed. • ***Remain***: The hearing level does not change with the frequency change. • ***Return to minimal level:*** The hearing level at the next frequency is -10 dB. • ***Decrease by 30 dB***: The hearing level at the next frequency is decreased by 30 dB. • ***Return to 30 dB:*** The hearing level at the next frequency is 30 dB. **NOTE**: This setting also defines the start level with a new test. ***Remain*** and ***Return to 30 dB*** start level is 30 dB HL. ***Return to minimal level*** and ***Decrease by 30 dB*** start level is -10 dB HL.
Frequencies	Press ***Enter*** to access this submenu. Select/deselect the frequencies that are active and selectable during the test (Figure 23 and Figure 24).  **Figure 23**  **Figure 24** **NOTE**: 1000 Hz cannot be turned off and is therefore excluded from the list.
Signal	Select the default tone type of ***Steady*** or ***Pulse***. Steady presents the signal continuously during the tone presentation. ***Pulse*** turns signal on and off every 250 ms during tone presentation.
Return to 1 kHz	After having reached the highest (i.e. 8 kHz) or lowest (125 Hz) test frequency device returns to 1 kHz automatically. When set to ***Off***, it will continue to next highest/lowest frequency.
Level increase	This function sets the direction of the ***arrow*** ▲ ▼ keys to increase the hearing level. Choose between: • ***Increase up***: Pressing ▲ will increase the hearing level (ie. 35 dB to 40 dB). Recommended to use with ***Display type Table***. • ***Increase down***: Pressing the ▼ will increase the hearing level (ie. 35 to 40 dB). Recommended to use with ***Display type Graph***.

5.5.5 Start with…

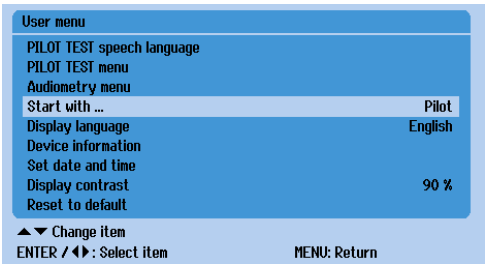


Figure 25

Select the test selected upon turning on the device: **PILOT TEST** or **Audiometry** (Figure 25).

5.5.6 Display Language

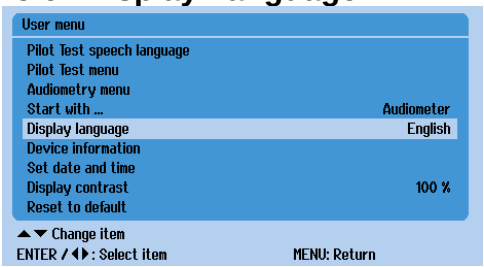


Figure 26

Select the operating language of the device (**Figure** 26). Display languages include: ***Deutsch, English, Español*** and ***Français***.

5.5.7 Device Information

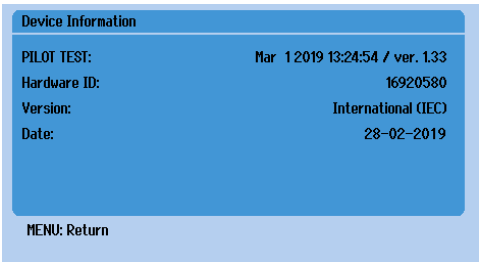


Figure 27

General information can be found here (Figure 27).

- **PILOT TEST:** The firmware release date and version installed on the device.
- **Hardware ID:** Internal serial number of the device.
- **Version:** Calibration standard selected.
- **Date:** Date device was calibrated.

5.5.8 Set date and time

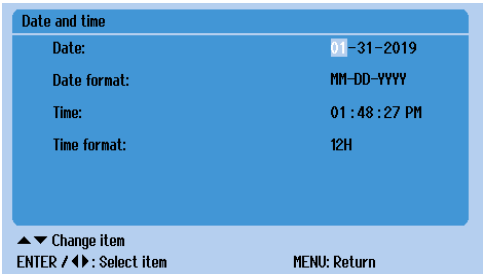


Figure 28

Set the correct date and time of the device for printing and transferring of tests (Figure 28).

Move to the available field with the ***arrow*** ◀ ▶ keys. To make a change, use the ***arrow*** ▲ ▼ keys.

- **Date**: Set the current date.
- **Date format**: Select the preferred date format to be displayed on the printout and transferred to the PC.
- **Time**: Set the current time. Hour and minute are selectable for change. If time format ***12H*** is chosen ***AM***/***PM*** will be displayed.
- **Time format**: Select the preferred clock, using the ***12H*** or ***24H*** time format.

5.5.9 Display Contrast

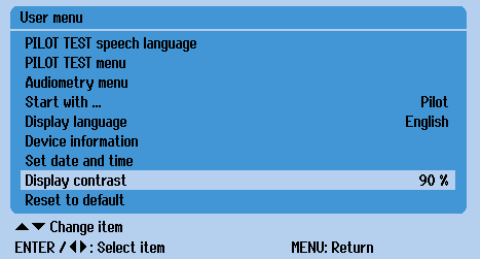


Figure 29

By pressing the ◀ (light) or ▶ (dark) key the display can be adapted to your preference (Figure 29).

5.5.10 Reset to Default

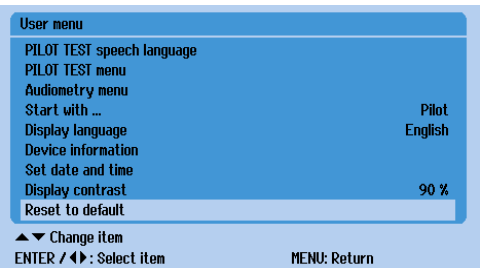


Figure 30

Returns device settings to factory defaults by pressing the ***Enter*** key (Figure 30). Press any other key to return. Once entered a secondary menu is displayed to confirm selection (Figure 31).

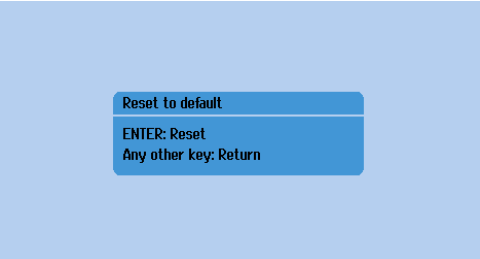


Figure 31

5.6 Troubleshooting

If your device is no longer working properly, see Table 13.

Table 13 Troubleshooting

PROBLEM	REASON	SUGGESTION
Lamps do not light up	Lack of power supply	• Is the power switch on? • Is the power cord plugged in correctly in the power connector? • Is the wall outlet working?
No sound from headphone	Disturbed connection	• Is the headphone cable plugged in correctly to the socket? • Is the lead loose or defective? • Is the cord cracked or bent?
No sound from monitor phone	Disturbed connection	• Is the cable plugged in correctly to the socket? • Is the lead loose or defective? **NOTE**: Monitor is only available for PILOT TEST, not Audiometry.
Printing is not possible	Disturbed connection, lack of paper	• Is the printer cable connected to the device and printer? • Is the printer on? • Is there paper in the printer?
Transfer to PC is not possible	Disturbed connection	• Is the USB plugged in correctly to the device and PC? • Is the USB plugged into a version 2.0 USB port on the PC? • Is the PC software showing a connection to the PILOT device?

NOTE: If there are any problems that you cannot solve yourself, please contact your local distributor.

6 Technical Data

This Section offers you important information about

- the PILOT TEST hardware specifications
- connections
- the pin assignment
- audiometry calibration values
- electromagnetic compatibility (EMC)
- electrical safety, EMC and associated standards

6.1 PILOT TEST Hardware

CE 0123

The PILOT TEST is an active, diagnostic medical product according to class IIa of the EU Medical Directive 93/42/EEC.

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	
Medical CE-mark	Yes
Safety Standards	IEC 60601-1:2005/EN 60601-1:2006 + A1: 2012 ANSI/AAMI ES60601-1:2005/(R)2012 CAN/CSA-C22.2 NO. 60601-1:14 Class I, Type B applied parts
EMC Standards	IEC 60601-1-2:2014
Audiometer Standards	Tone: IEC 60645-1:2017/ANSI S3.6:2010, Type 4

DEVICE SPECIFICATIONS	
Mains voltage	100-240 V~ ±10 %, 50/60 Hz
Power consumption	Max. 15 VA
Mode of operation	Continuous

DEVICE SPECIFICATIONS

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[1] Maximum altitude: 2000 m / 6561 ft above sea level
		Warm up time: approx. 1 minute (incl. boot up time)
	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)
Weight:	1.3 kg / 2.9 lbs	
Dimensions:	305 mm x 260 mm x 65 mm (12.01 in x 10.24 in x 2.56 in)	
Display:	TFT LCD Panel 5.0 in Active size: 110.88 mm x 62.83 mm (4.37 in x 2.30 in)	
User interface:	Push button	
Language Settings	English, French, German, Spanish	

[1] Environmental conditions during operating according IEC 60645-1.
NOTE: Reference equivalent threshold sound pressure levels may differ significantly with ambient pressures outside the above range. Therefore recalibration around the normal ambient pressure at the site of the user should be undertaken in those circumstances where the calibration site and the user site do not share similar ambient conditions.

AUDIOMETRY

Patient Response switch (optional):	One push button	
Air conduction:	DD45 with HB7	MAICO Standard Values
	DD65 V2	MAICO Standard Values
Transducers – Headband tension:	DD45 with HB7:	Headband Static Force 4.5 N ± 0.5 N
	DD65 V2:	Headband Static Force 10.0 N ± 0.5 N

Tone Audiometry	
Inputs:	Pure tone
Outputs:	Left, Right, Free Field (only for conditioning)
Accuracy:	Frequency ± 2 %, Level ± 3 dB
Tone Stimuli	
Headphone intensity:	-10 dB HL to 100 dB HL (with exception of 125 Hz); 5 dB intensity steps
Frequency range:	125; 250; 500, 750 Hz; 1;1.5; 2; 3; 4; 6; 8 kHz
Presentation:	Presenter or interrupter (single/pulse)
Pulse tone:	Pulse length: 250 ms
PILOT TEST	
Intensity	70 dB HL to 25 dB HL; 5 dB intensity steps
Speech signal source:	WAVE files
PILOT TEST languages:	Arabic, Chinese, Croatian, English, French, German, Greek, Italian, Polish, Russian, Serbian, Spanish, Swiss German, Turkish, Vietnamese Further languages available: Afrikaans, Basque, Catalan, Czech, Danish, Dutch, Finnish, Galician, Hungarian, Japanese, Korean, Norwegian, Polish Audifon, Portuguese, Romanian, Slovakian, South Sotho, Swedish, Xhosa, and Zulu.

THERMAL PRINTER	
Type	HM-E300
Display	OLED display
Accessories	USB Cable, Paper (2 rolls), Quick Guide
Connection	USB
Battery	2300 mAh/7.4 V rechargeable Li-ion battery 5 days stand-by
Charger	Output: DC 5 V/1A Battery: 2300 mAh/7.4 V rechargeable Li-ion battery
Dimension	38.8 mm x 106.3 mm x 61.2 mm (1.52 in x 4.19 in x 2.41 in)
Weight	475.8 g / 17.8 oz (without paper roll)
Paper	Continuous paper Paper Width: 80 mm Paper Thickness: 0.053 mm to 0.100 mm Paper Roller Diameter: ≤ 50 mm To be printed on paper roll:
Printing time	<5 seconds per test result

6.2 Connections

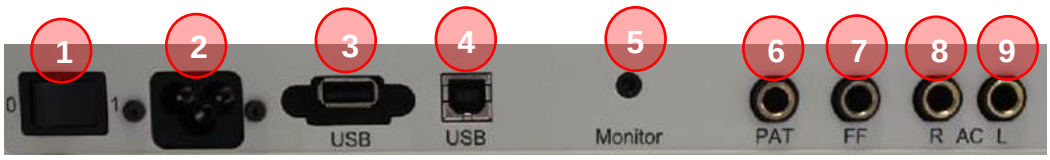
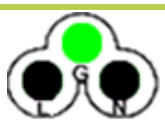
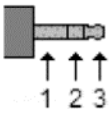
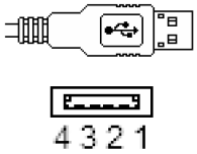
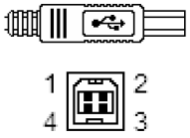


Figure 32

#	CONNECTION SOCKET	SPECIFICATION
1	0/1 (On/Off)	Power
2	Mains	100...240 V~, 50/60 Hz middle = protection earth
3	USB in	USB 1.1
4	USB out	USB 1.1
5	Monitor	ZA= 10 Ω, UA= 35 mV_{eff}
6	Patient Response Switch	RI= 500 Ω
7	Speaker	ZA= 8 Ω, UA= 3,5 V_{eff}
8	Phone R (red)	ZA= 8 Ω, UA= 3,5 V_{eff}
9	Phone L (blue)	ZA= 8 Ω, UA= 3,5 V_{eff}

6.3 Pin assignment

SOCKET	CONNECTOR	PIN 1	PIN 2	PIN 3
Mains	 DC socket Rated current international: 250 V/2,5 A	L (Live)	G (Ground)	N (Neutral)
Phone L	 6.3 mm Mono	Ground	Signal	-
Phone R				
Free Field				
Patient Response				-
Monitor	 3.5 mm Stereo	Ground	Signal	-

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, PTB Report 2009, DTU Report 2010

Calibration values and Max Levels: Headphone DD65 V2
Coupler IEC 60318-1, PTB Report 2018, AAU Report 2018

Frequency [Hz]	DD45			DD65 V2		
	Tone RETSPL dB re 20µPa	Tone Max Level	Sound Attenua-tion [dB] ISO 4869-1	Tone RETSPL dB re 20µPa	Tone Max Level [dB HL]	Sound Attenua-tion [dB] ISO 4869-1
125	47.5	80	3	30.5	75	8.3
250	27.0	100	5	17.0	90	15.5
500	13.0	100	7	8.0	100	26.1
750	6.5	100	-	5.5	100	-
1000	6.0	100	15	4.5	100	32.4
1500	8.0	100	-	2.5	100	-
2000	8.0	100	26	2.5	100	43.6
3000	8.0	100	-	2.0	100	-
4000	9.0	100	32	9.5	100	43.8
6000	20.5	100	-	21.0	90	-
8000	12.0	100	24	21.0	85	45.4

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

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 following accessories:

Item	Manufacturer	Model
Audiometric Headset	Radioear	DD45
Audiometric Headset	Radioear	DD65 V2
Patient response switch	Radioear	APS3

Conformance to the EMC requirements as specified in IEC 60601-1-2 is ensured if the cable types and cable lengths are as specified below:

Description	Length (m)	Screened (Yes/No)
Audiometric Headset	2.0	Yes
Patient response switch	2.0	Yes

Electromagnetic Compatibility (EMC)

Portable and mobile RF communications equipment can affect the PILOT TEST. Install and operate the PILOT TEST according to the EMC information presented in this Section.
The PILOT TEST has been tested for EMC emissions and immunity as a standalone device. Do not use the PILOT TEST 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 PILOT TEST is intended for use in the electromagnetic environment specified below. The customer or the user of the PILOT TEST should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The PILOT TEST 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 PILOT TEST 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 PILOT TEST.			
The PILOT TEST is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PILOT TEST can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PILOT TEST 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 PILOT TEST is intended for use in the electromagnetic environment specified below. The customer or the user of the PILOT TEST 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 100 kHz repetition frequency ± 1 kV Line-to-line 100 kHz repetition frequency	± 2 kV ± 1 kV	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	± 1 kV Line-to-line ± 2 kV Line-to-ground	± 1 kV ± 2 kV	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	0% *U*T for 0.5 cycle 0 % UT for 1 cycle and 70% *U*T for 25/30 cycles Single phase: at 0°	0% *U*T for 0.5 cycle 0 % UT for 1 cycle and 70% *U*T for 25/30 cycles Single phase: at 0°	Mains power quality should be that of a typical commercial or residential environment. If the user of the PILOT TEST requires continued operation during power mains interruptions, it is recommended that the PILOT TEST 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 ***PILOT TEST*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***PILOT TEST*** should assure that it is used in such an environment,			
Immunity test	**IEC / EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any parts of the ***PILOT TEST,*** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC / EN 61000-4-6	3 Vrms 150kHz to 80 MHz 6 Vrms in ISM bands 150kHz to 80 MHz 80 % AM at 1 kHz	3 Vrms 6 Vrms	$d = 1{,}2\sqrt{P}$
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kHz	3 V/m	$d = 1{,}2\sqrt{P}$ 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 ***PILOT TEST*** is used exceeds the applicable RF compliance level above, the ***PILOT TEST*** should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ***PILOT TEST.*** [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

6.6

6.6 Checklists

6.6.1 Checklist for Subjective Device Check

Model:	
Serial #:	
Test person:	

- All keys can be pressed easily ☐
- All the cords are disentangled ☐
- Connectors and cables are intact ☐
- Cushions of the headphone are cleaned ☐
- Cushions of the headphone are undamaged ☐

Test subject:

PILOT TEST carried out with test person:

(T) correct answer; (x) wrong answer; (na) no answer

Level (dB HL)	Word from Group 1	Test person's answer(s)			
		today RIGHT EAR	today LEFT EAR	last session RIGHT EAR	last session LEFT EAR
70					
60					
50					
40					
40					
35					
35					
30					
30					
25					
25					

If the difference between today's and last answer of the test person is 10 dB or more on the same ear, perhaps the PILOT TEST needs service!

Tested:

Date:

6.6.2 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.

MAICO Diagnostics GmbH
Sickingenstr. 70-71
10553 Berlin
Germany
Tel.: + 49 30 / 70 71 46-50
Fax: + 49 30 / 70 71 46-99
E-mail: sales@maico.biz
Internet: www.maico.biz