Operation Manual
MA 33

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Title: **MA 33** – Operation Manual

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All available operation manuals can be found in the download center on the MAICO homepage:

Download | MAICO Diagnostics
https://www.maico-diagnostics.com/ support/download/

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

Windows is a registered trademark of Microsoft Corp.

1 Introduction

This section offers you important information about:

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

1.1 Intended Purpose

The MA 33 tone audiometer is designed to quantitatively measure and monitor an individual's hearing threshold across different frequencies. It also provides speech audiometry functionality for assessing speech recognition ability.

1.2 Indications for UseStatement

There are no indications for use for this device. It is used as a measuring tool for screening purposes to quantify the hearing acuity of patients by determining their hearing thresholds.

1.3 Target Population

The target population is children from 3 years to adults.

1.4 Contraindications

A discharging ear, acute external auditory canal trauma, discomfort (e.g., severe otitis externa) or occlusion of the external auditory canal, or if the patient is sick or uncooperative to perform the tasks.

1.5 Intended Operator

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

1.6 Features and Benefits

1.6.1 General

NOTE: Operation of the MA 33 requires knowledge of the Windows operating system.

The MA 33 is available in 3 versions:

- MA 33 AC
- MA 33 BC
- MA 33 Speech

The MA 33 gives the benefit of:

- PC-controlled audiometer for Air Conduction
- Bone Conduction (MA 33 BC only)
- Pulse and Warble Tone
- Masking
- Individual test configurations
- Compatibility with MAICO Database, Noah 4, EssiConnect, or your existing practice management software via BDT/GDT
- Power supply via USB
- Keyboard and/or mouse operation
- SISI (MA 33 BC and MA 33 Speech only)
- German, English, French, Italian, Spanish, Netherlands, Polish

Additionally available tests for each version are:

- Module Pilot Test (Select Picture Audiometry for children)
- Module Hughson-Westlake (automatic test according to Hughson-Westlake)

1.6.2 Language Pack for Module Pilot Test

The MA 33 with the Module Pilot Test comes with the following languages

- International configuration: Afrikaans, Arabic, Basque, Catalan, Croatian, Czech, Danish, Dutch, English, Finnish, French, Galician, German, Greek, Hungarian, Italian, Japanese, Korean, Norwegian, Polish/Polish (Audifon), Portuguese, Romanian, Russian, Serbian, Slovakian, South Sotho, Spanish, Swedish, Swiss German, Turkish, Vietnamese, Xhosa, Zulu
- US configuration: English (US) and Spanish (US)

1.7 Description

1.7.1 General

1.7.2 AC Audiometry

Hearing threshold levels can be determined by presenting test signals to the test subject with the included headphones (Air Conduction – AC). The purpose of AC audiometry is to establish the hearing sensitivity at various frequencies. The test can specify the AC loss but cannot distinguish between a conductive versus a sensorineural abnormality.

1.7.3 BC Audiometry

Hearing threshold levels can be determined by presenting test signals to the test subject with the included bone conduction headphone (Bone Conduction – BC). The purpose of BC audiometry is to establish the hearing sensitivity at various frequencies. The test can specify the BC loss in combination with AC loss. It can distinguish between conductive versus a sensorineural abnormality.

1.7.4 Speech Audiometry

The Speech functionality provides various speech tests.

Together with pure tone audiometry, it can help to determine the degree and type of hearing loss. The Speech functionality is used to determine the speech reception threshold and provides word recognition ability.

1.7.5 Select Picture Audiometry (Pilot Test)

Select Picture Audiometry incorporates the child listening to a series of two syllable “spondee” words at different decibel levels and point to the picture. The purpose is to establish an ear specific hearing level when standard tone audioemetry 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 MA 33.

1.7.6 Masking

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

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

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

1.8 PC-System Requirements

PC connection: 1 available USB port

Operating system: Windows® 11 64-bit

Processor: Intel Core i5, i7

Memory: 8 GB RAM

Graphic display: 1280 x 1024 (optimal), min. 1024 x 768

Silent PC for use in audiometric room

Optional use of a touch screen for certain functions.

2 For your Safety

This section offers you important information about:

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

2.1 How to Read this Operation Manual

This operation manual contains information pertinent to the use of the MAICO MA 33 system including safety information as well as maintenance and cleaning recommendations.

READ THIS ENTIRE OPERATION MANUAL BEFORE ATTEMPTING TO USE THIS SYSTEM!

Use this device only as described in this manual.

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

In this operation 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.

2.3 Customer Responsibility

All safety precautions given in this operation manual must be always observed. 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 operation manual and the rules of the organization using this device, the more stringent rules should take precedence.

This product and its components will perform reliably only when operated and maintained in accordance with the instructions contained in this operation manual, accompanying labels, and/or inserts. Defective products 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 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 the competent authority in the country where the user is established.

2.4 Manufacturer's Liability

Using 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 failure to follow the operation manual, operation by unqualified personnel, and unauthorized modifications to the equipment.

2.5 Regulatory Symbols

The following Table 1 gives an explanation of the symbols used on the device itself, on the packaging and the accompanying documents including the Operation Manual.

Table 1 Regulatory Symbols

REGULATORY SYMBOLS SYMBOL	DESCRIPTION
SN	Serial number
	Date of manufacture
	Manufacturer
	Caution, consult accompanying documents
	Warning, consult accompanying documents
	Return to authorized representative, special disposal required
REF	Reference number
MD	Medical Device
(01)04260176127444 (11)201020 (21)MA0123456	UDI information (example): (01) GTIN (Global Trade Item Number), (11) Date, (21) Serial number
	Applied part type B according to IEC 60601-1
	Refer to operation manual (mandatory)
	Keep away from rain
	Transport and storage temperature range
	Transport and storage humidity limitations
	Transport and storage atmospheric pressure limitations
CE 0123	CE marking with notified body ID
	Non-ionizing electromagnetic radiation
	Direct Current (DC)
ETL CLASSIFIED Intertek	ETL listed mark
MAICO	Logo

2.6 General Precautions

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

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

For operation in certain places, recalibration may be necessary.

Do not open the case of the MA 33. Refer servicing to qualified personnel.

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.

Do not modify this equipment without authorization of the manufacturer.

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.

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

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

The device is not intended to be used in environments exposed to fluid spills. Ingress of any fluids is considered a single fault condition. No means specified for fluid protection (not IP classed).

Connect only accessories purchased from MAICO to the MA 33. Only accessories which have been stated by MAICO as being compatible are allowed to be connected to the device.

2.7 Electrical Safety and Measuring Security

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

In Case of Emergency

In case of emergency, disconnect the device from the USB cable. A laptop should not be connected to power supply during testing.

Position the device in such a way that it can be easily disconnected from the USB cable at any time.

Do not use the device if the USB cable is damaged.

The device is not intended for operation in areas with an explosion hazard. Do NOT use the device in a highly oxygen rich 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.

Prevent cable breakage: cables must not be bent 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.

The device fulfills the relevant EMC requirements.

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

Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally.

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

The list of accessories, transducers and cables can be found in Section 6.5 of this operation manual.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the MA 33, including cables specified by the manufacturer.

Otherwise, degradation of the performance of this equipment could result in improper operation.

2.9 Cyber Security and Data Protection

Connecting the MA 42 to a PC or other IT equipment implies connecting the device to an IT network. The connection to an IT network may result in previously unidentified risks to patients, operators or third parties.

Security risks must be identified, analyzed, evaluated, and controlled by the responsible Health Care Provider.

Changes to the IT network could introduce new risks that require additional analysis. Changes include:

- changes in network configuration
- connection of additional items
- disconnection of items
- update of equipment
- upgrade of equipment.

As a part of data protection, ensure to be compliant with all the following points:

- Use only the operating systems specified for the MAICO software in this operation manual. Ensure these operating systems have continued software and security support.
- Ensure operating systems are security patched.
- Install only apps and software from trusted sources and keep them up to date.
- Ensure secure physical and network access to computers. Change any default administration passcodes immediately and use individual user accounts with strong passcodes for PC logins.
- Install antivirus protection, anti-malware software and a firewall from a trusted vendor and keep them up to date.
- Implement appropriate backup and log retention policies.
- Do not use public WiFi.
- Learn about phishing scams: Be very suspicious of e-mails and calls.

2.10 Device Control

The user of the device should perform a subjective device check once a week (ISO 8253-1). See Section 6.5 for a checklist.

For annual calibration see Sections 2.6 and 3.2.

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

3.1.1 General

The MAICO device is guaranteed for at least 1 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 1 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.

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

3.1.2 Ownership, Warranty and Disclaimer (Software)

Ownership

The MA 33 Software (hereinafter the “SOFTWARE”) is solely owned by MAICO Diagnostics GmbH, Sickingenstr. 70-71, D-10553 Berlin, Germany. By purchasing the SOFTWARE the buyer is entitled the right of usage, but not ownership of the SOFTWARE. The SOFTWARE is to be used in accordance to the agreed terms of usage provisioned by MAICO.

Copyrights

MAICO’s ownership of the SOFTWARE covers worldwide and is therefore, protected against any unauthorized copying of the SOFTWARE. Non conformity of use of the SOFTWARE is strictly prohibited.

Restrictions

You may not:

Reverse engineer or attempt in any manner to discover the source code of the SOFTWARE.

Attempt to defeat any mechanisms in the SOFTWARE, including those mechanisms responsible for password protection of data and limiting the number of concurrent users.

Rent, lease, sublicense or in any manner, copy or transfer (except as permitted above) the SOFTWARE.

Obscure or obliterate any MAICO copyright or trademark notices which appear on the SOFTWARE, the documentation, the screen-display, or otherwise in connection with the SOFTWARE.

MAICO specifically calls your attention to the fact that, any violation or infringement of above restrictions will result in legal action.

The SOFTWARE can be used by any number of users, on any number of computers, and in any place, provided but not on more than one display screen at the same time.

Limited Warranty

MAICO warrants that any physical media and physical documentation provided by MAICO are free of defects in materials and workmanship. This limited warranty is effective for a period of ninety (90) days from the original purchase date.

If MAICO receives notification within the warranty period of defects in materials or workmanship and determines that such notifications are correct, MAICO will replace defective media or documentation.

Do not return any product until you have obtained authorization to do so from your supplier. The entire and exclusive liability and remedy for breach of this limited warranty shall be limited to replacement of defective media or documentation supplied by MAICO, and shall not include or extend to any claim for or right to recover any other damages, including but not limited to, loss of profit, data, or use of the SOFTWARE, or special, incidental or consequential damages, or other similar claims, even if MAICO has been specifically advised of possibility of such damages. In no event will MAICO's liability for any damages to you or any other person ever exceed the lowest list price or the actual price paid for the license to use the SOFTWARE, regardless of the form of the claim.

Disclaimer

MAICO covers; including but not limited to; all warranties, representations and terms and conditions, either expressed or implied; under specified terms of use ans application of the SOFTWARE for its specific purpose. All other terms and conditions shall not apply.

Furthermore, MAICO does not guarantee that the SOFTWARE or Documentation is free of bugs, or fulfill the relevant standards, requirement or needs of a user. In this case, all the warranties, guarantees and terms and conditions on all MAICO delivered physical disk and documentation shall be limited to the 90 days warranty period.

MAICO is not liable for any third party's product, disks, SOFTWARE or documentation that is used in conjunction with MAICO's SOFTWARE or programs, but is not directly manufactured or supplied by MAICO.

General Terms and Conditions

Any change made to this Agreement shall be notified in writing, agreed and signed between both parties, namely the purchaser of the SOFTWARE and a representative of MAICO.

In the event that the essential purpose of the above remedy (limited warranty) is not fulfilled, all other limited liability including the liability limits and exclusions of damage claims shall continue to apply.

This SOFTWARE License Agreement shall be interpreted and construed according to, and governed by, the laws of Jurisdiction of Federal Republic of Germany.

In the event that any legal or commercial dispute or controversy arising out of, or relating to this agreement; provided MAICO is in all case violated of the rights, to the SOFTWARE or other intellectual property protection right related to the SOFTWARE; shall be presented under the Jurisdiction of Federal Republic of Germany in the court of Berlin.

The SOFTWARE is protected under both Copyright Law and the International Copyright Treaties. Copying of the SOFTWARE is strictly prohibited except for copies made of the SOFTWARE for backup purposes to protect data loss.

3.2 Maintenance

To ensure that the device works properly, it must be checked and calibrated at least every 12 months.

The service and calibration must be performed by your distributor, 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. Include a detailed description of faults. To prevent damage in transit, use the original packaging 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 turn off and disconnect the device from power supply (USB).
- For cleaning use a lightly dampened cloth with soap water solution.
- Disinfect the plastic housing of the MA 33 and its accessories by wiping the surfaces with wet disinfection wipes. Follow the instructions on the specific disinfection product.
    - Wipe before and after each patient
    - After contamination
- Disinfect computer, keyboard, etc. with wet disinfection wipes:
    - once a week
    - after contamination
    - when polluted

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 entered the system components or accessories, the device should not be used until deemed safe by a MAICO certified service technician.

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

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 MA 33.

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 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 2012/19/EU of the European Parliament and of the Council of 4 July 2012 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**
- **MA 33 Software Installation**
- **how to establish a PC connection**
- **how to store the device**

4.1 Unpacking the System

Check Box and Contents for Damage

- It is recommended that you unpack your MA 33 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.

The MA 33 comes with different components (see Table 2 and Table 3). The availability of configurations with the following components is country and version specific. Contact your local distributor for more information.

Table 2 MA 33 Available Components

Available components
Base Unit
MAICO USB Flash Drive Kit with MAICO Database and MA 33 Software
AC Headphones DD65 v2*
AC Headphones DD45*
AC Headphones DD45 with HB-7 Headband*
BC Headphones B71W*
Patient Response Switch APS3*
USB Cable
Carry Case
Living Speech Microphone
Operation Manual
Quick Guide
Software Modules
Module Pilot Test
Module Hughson-Westlake

*Applied parts according to IEC 60601-1

Table 3 Accessories for Software Pilot Test

Accessories for Software Pilot Test
Picture Board
Roll of Stickers

4.2 Hardware and Components

4.2.1 Connections for Accessories and USB Connection

All the connection jacks can be found on the rear side of the MA 33 (Figure 1 and Table 4). All the cables and accessories should be connected before the device is turned on.

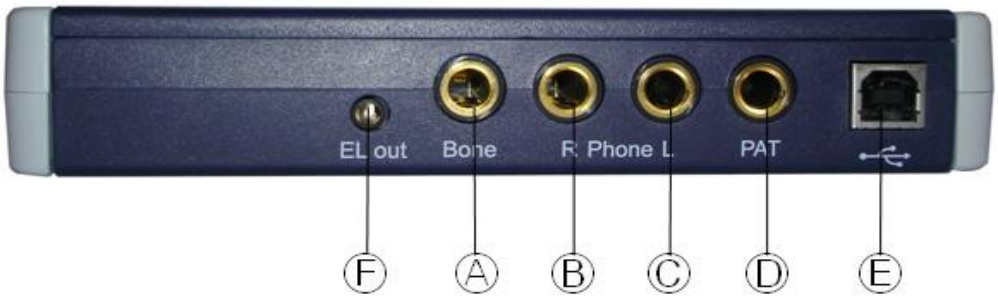


Figure 1

Table 4 Connections on Backside of Device

Letter	MA 33 AC
A	Bone Conduction Headphone
B	Air Conduction Headphone (Red Plug)
C	Air Conduction Headphone (Blue Plug)
D	Patient Response Switch
E	USB Connector
F	No function

4.2.2 Light Indicator

The green light indicator on the front side of the device light up as soon as the device is successfully connected to a PC (Figure 2).

Figure 2

4.3 MA 33 Software Installation

4.3.1 General

NOTE: Make sure that the device is not connected with your computer while installing.

In case you already use an older MAICO Database version and want to use it with the MA 33 Software, the MAICO Database will automatically be updated. It is recommended to make a backup of the patient data prior to initiating the installation process.

Close all open or running programs. Insert the USB flash drive into the USB port. The InstallShield Wizard will appear. If the InstallShield Wizard does not appear automatically, double-click ***Setup.exe*** from the USB flash drive. It is possible to stop installation at any time by pressing ***Cancel***.

The User Account Control asks if you want to allow this app to make changes to your PC. Press ***Yes*** to proceed (Figure 3).

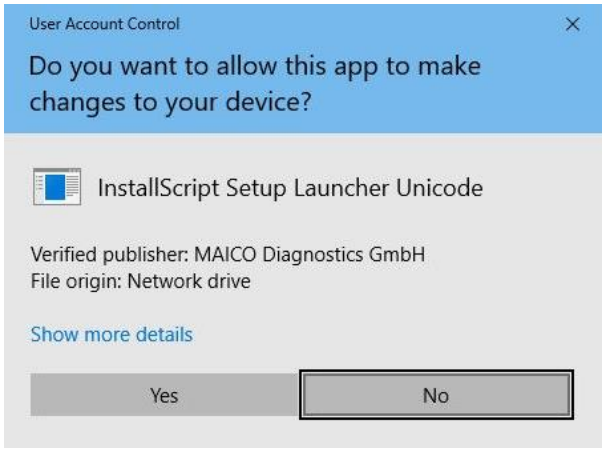


Figure 3

The InstallShield Wizard prepares the setup. Wait to proceed (Figure 4).

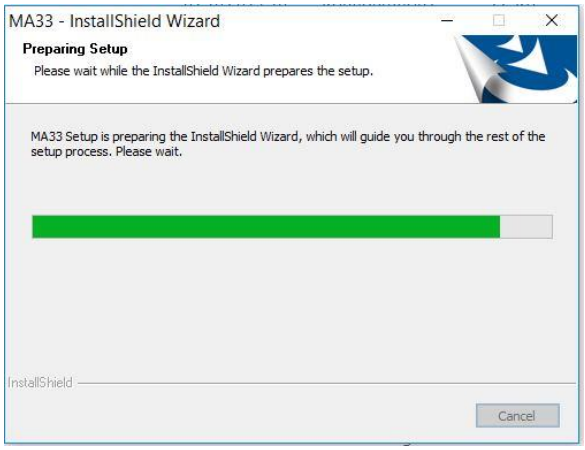


Figure 4

Press ***Next>*** to proceed (Figure 5).

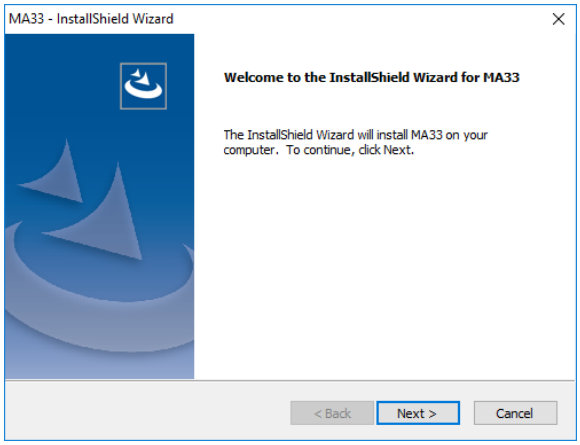


Figure 5

Press ***Browse*** to choose another Destination Location and/or press ***Next>*** to proceed (Figure 6).

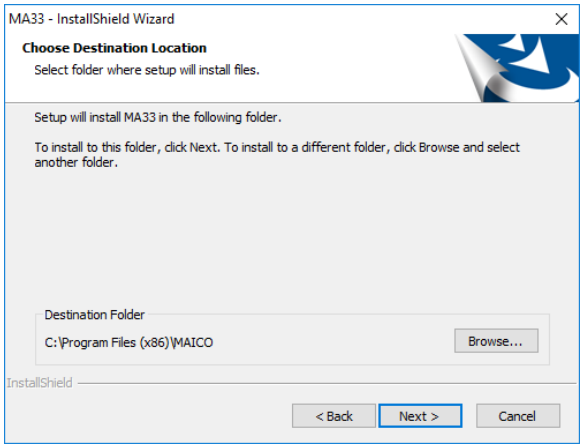


Figure 6

4.3.2 Choose Program Options

Choose the data connection, the program settings and program language (Figure 7):

- ***Choose Data Connection:***
  - ***MAICO Database:*** starts the parallel setup of the MA 33 Software and the MAICO Database. In case the MAICO Database is already installed deinstallation of the program will be requested prior to installation (Figure 13).
  - ***Noah:*** connects the MA 33 Software to Noah.
  - ***BDT/GDT:*** allows the connection of the MA 33 Software to your existing practice management software.
  - ***EssiConnect:*** connects the MA 33 Software to EssiConnect.

- ***Choose Program Settings***
  - ***International:*** Default settings for International version preselected. English language is selected by default and can be changed.
  - ***Americas:*** Default settings for Americas version preselected. English language is selected by default and can be changed.
  - ***Essilor:*** Default settings for Essilor version preselected. French language (Français) is selected by default and can be changed.
  - ***Audiofon:*** Default settings for Audiofon version preselected. Polish language (Polski) is selected by default and can be changed.
  - ***Audioprotesi:*** Default settings for Audioprotesi version preselected. Italian language (Italiano) is selected by default and can be changed.

- ***Choose Program Language***: sets the language for operating the MA 33 Software. This setting can be changed again later on while running the MA 33 Software.

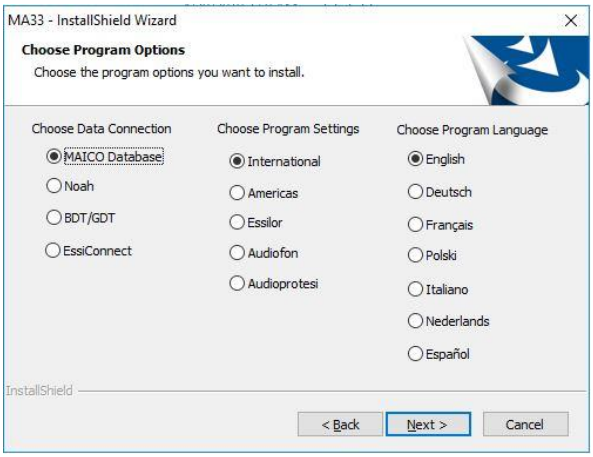


Figure 7

NOTE: In case MAICO database is selected the installation process for the MAICO database will be initiated parallel to the installation of the MA 33 Software and show the same steps.

Press ***<Back*** if a review or change of the settings is wanted. Press ***Next>*** to proceed (Figure 8).

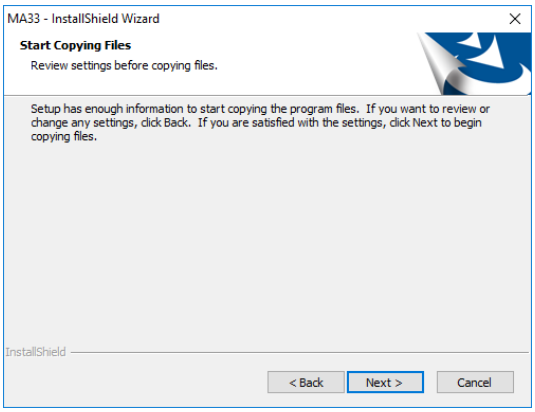


Figure 8

Please wait during the installation of MA 33 Software is configurating (Figure 9).

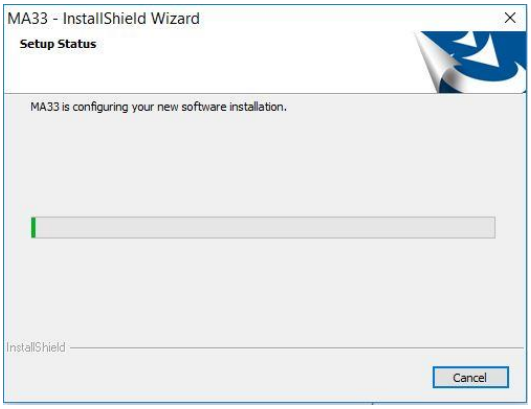


Figure 9

The Device Driver Installation Wizard appears in order to install the software drivers that some computers may need. Press ***Next*** to continue (Figure 10).

Figure 10

The device drivers are successfully installed. Press ***Finish*** to complete the setup process (Figure 11).

Figure 11

Setup of the MA 33 Software is complete. Press ***Finish*** to complete the installation (Figure 12).

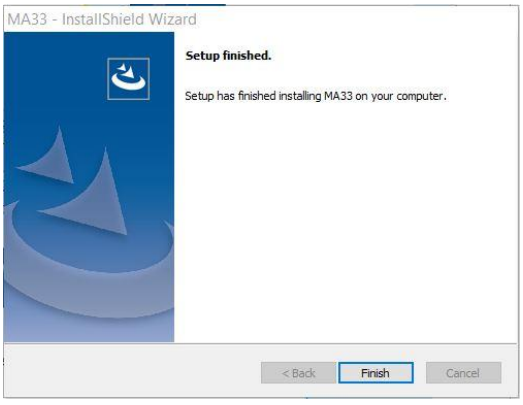


Figure 12

4.3.3 Reinstallation

NOTE: In case the MA 33 Software and/or MAICO Database shall be reinstalled it is recommended to use Windows functionality to remove the programs prior to restarting the installation process. Otherwise, proceed as follows.

In case a reinstallation of the MA 33 Software via InstallShield Wizard is required, start the process with setup.exe. The InstallShield Wizard will ask you if you want to completely remove the selected application and all of its features (Figure 13). Select one of the options to proceed.

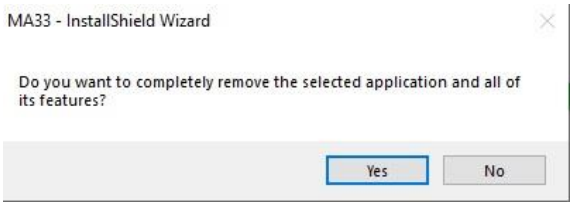


Figure 13

Press ***Yes*** to remove the MA 33 Software (Figure 14). Choose if you want to restart your computer now or later. Start the installation process again after restart.

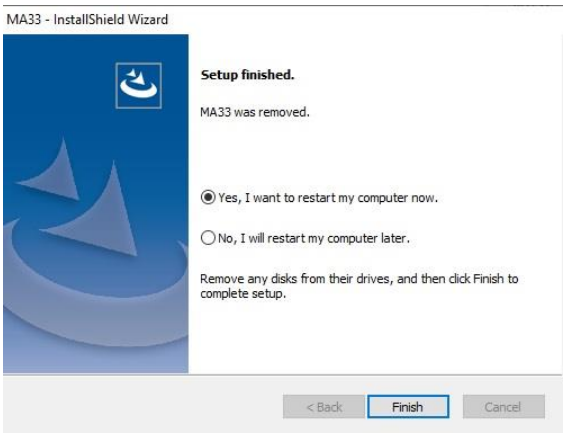


Figure 14

Press ***No*** to cancel the setup (Figure 15).

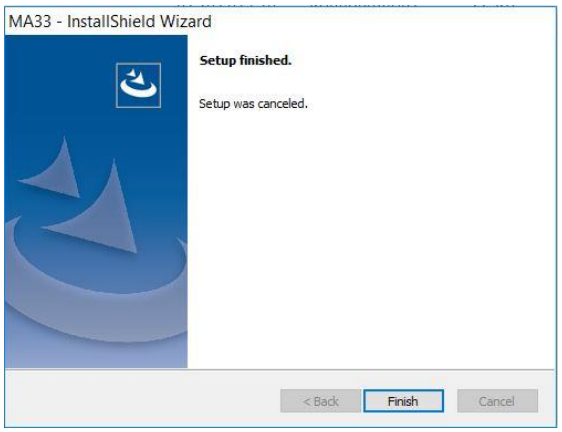


Figure 15

4.4 Storage

When the MA 33 is not in use, store in a location where it will be safe from damage to the acoustic transducers and cables. Store according to the recommended temperature conditions described in section 6.1.

5 Operating the Device

This section offers you information about:

- **how to get started with the MA 33**
- **using the MA 33 software**
- **performing the tests**
- **preparing the patient for testing**
- **settings to be made**

5.1 Getting Started with the MA 33

5.1.1 Use of Equipment After Transport and Storage

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

5.1.2 Where to Setup

The MA 33 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 ISO 8253 series or ANSI S3.1.

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

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

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

5.2 Starting the MA 33 Software

5.2.1 General

The MA 33 Software is started from the connected database (MAICO Database, Noah, BDT/GDT or EssiConnect). See the instructions in section 5.2.2 (for MAICO Database), section 5.2.3 (for Noah), section 5.2.4 (for BDT/GDT) or section 5.2.5 (for EssiConnect).

5.2.2 Starting the MA 33 Software from the MAICO Database

5.2.2.1 General

Certain MAICO software can be run as a module within the MAICO Database (as an alternative to Noah). This allows for patient storage, re-call of results, and comparison of audiograms.

NOTE: The MAICO Database cannot be accessed while working with the MA 33 Software. Close the MA 33 Software to access the MAICO Database.

5.2.2.2 Starting the MAICO Database

Click on the icon to open the MAICO database. The main screen of the database will be displayed (Figure 16).

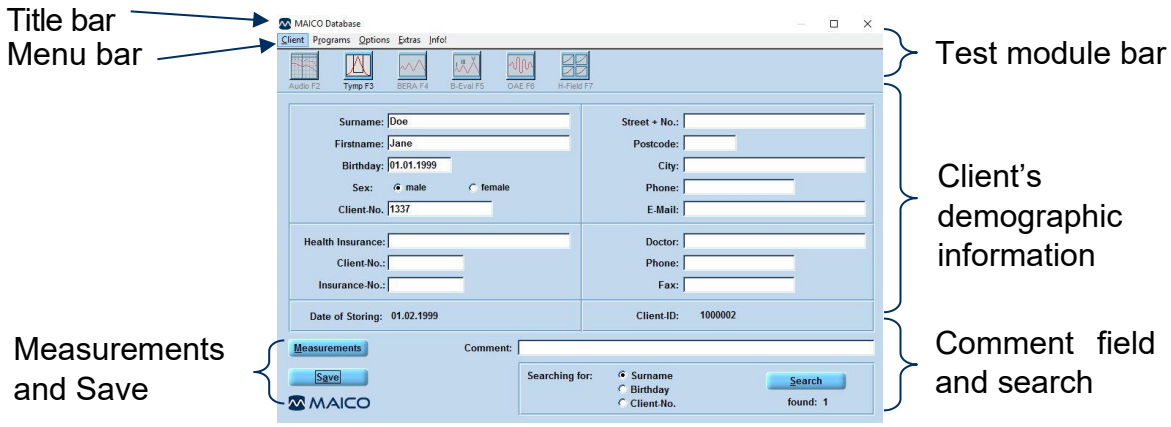
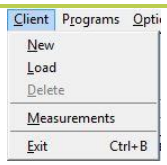


Figure 16

5.2.2.3 Making Your Selection in the MAICO Database

The MAICO Database offers multiple ways to make a selection. These include using the mouse or using shortcut keys. The shortcut keys are accessed by pressing ***Alt+shortcut***. The shortcut is displayed by a letter being underlined (i.e. Search or Client).

NOTE:



When accessing the Menu bar by using shortcuts, shortcuts are still available within the menu selection (Figure 17). Press the shortcut within the menu selection without pressing ***Alt***.

Figure 17

5.2.2.4 Menu Items and Buttons

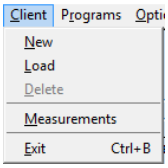
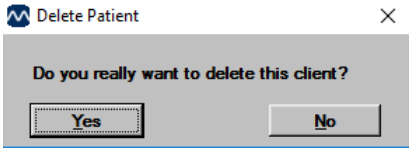
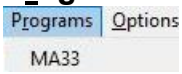
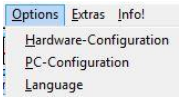
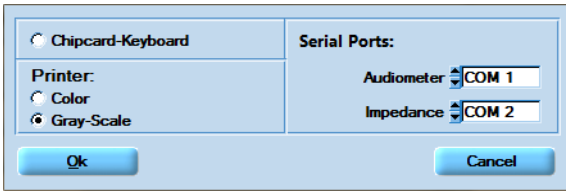
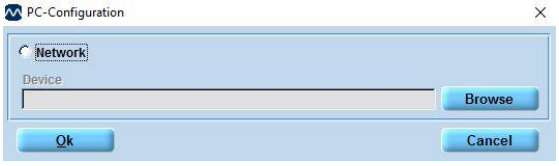
The buttons on the screen are described in Table 5.

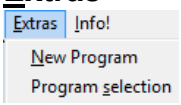
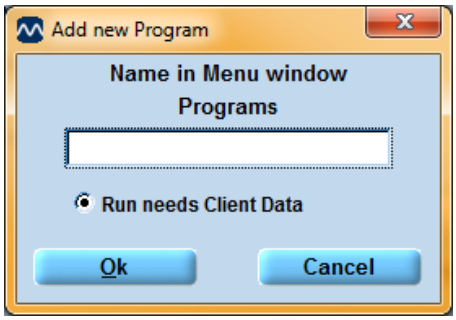
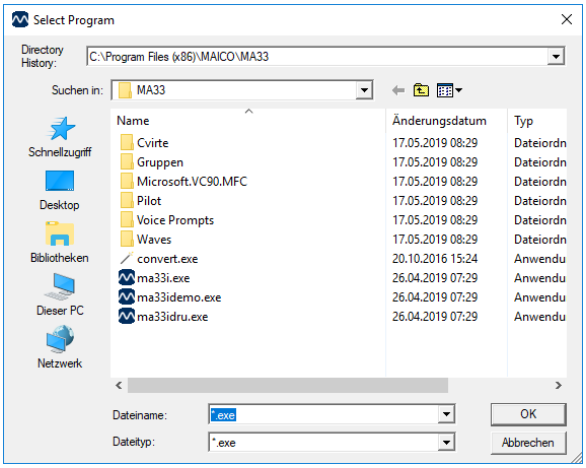
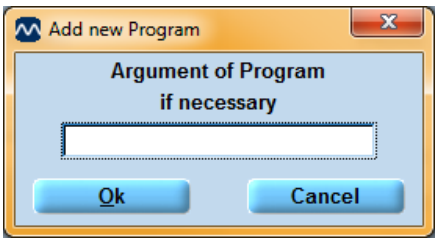
Table 5 MAICO Database – Buttons

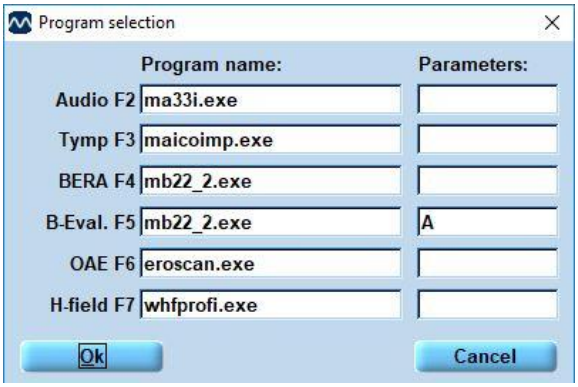
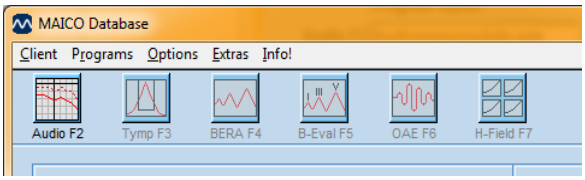
BUTTON SELECTION	
Button	**INFORMATION**
Search	Displays list of patients saved within the Database.
Measurements	Displays list of saved test for the selected patient.
Save	Saves patient demographic information entered.

The items offered in the Menu bar are described in Table 6.

Table 6 MAICO Database – Menu Bar

MENU BAR		
Menu	**Item**	**INFORMATION**
Client 	**New**	Clears the demographic fields to enter a new client into the database.
	Load	Loads an existing client from the database.
	Delete	Deletes a client from the database. A message box appears asking if you really want to delete this client (Figure 18).  **Figure 18**
	Measurements	Displays saved sessions for a particular client. Same function as ***Measurements*** button described in Section 5.2.2.5.
	Exit	Closes the database application.
Programs 	**MA 33**	Opens the MA 33 Software.
Options 	**Hardware-Configuration**	Select communication/comports between PC and MAICO audiometry and impedance hardware. Select printer type (color/grey scale) (Figure 19).  **Figure 19**
	PC-Configuration	To network the database. If so, enter the pathway for the database in the ***Device*** field and click ***Ok*** (Figure 20).  **Figure 20**
	Language	Select the display language: ***English***, ***Français***, ***Italiano***, ***Español***, ***Nederlands***, ***Polski*** or ***Deutsch***. Also select the date format: ***DDMMYYYY*** or ***MMDDYYYY*** (Figure 21).  **Figure 21**

MENU BAR		
Menu	**Item**	**INFORMATION**
Extras 	**New Program**	Select to add a module into the database. 1. The following window will appear (Figure 22):  **Figure 22** 2. Type name of program as it should appear in the ***Programs*** menu and click ***OK.*** 3. The following window will appear. Open the ***MA 33*** folder and select the ***MA33i.exe*** file for the program that is being added to the database. Click ***OK*** (Figure 23).  **Figure 23** 4. The following window will appear. If an argument for the program is required, enter the code here and click ***OK*** (Figure 24).  **Figure 24**

MENU BAR		
Menu	**Item**	**INFORMATION**
	Program selection	This will display which programs are activated by the program icons lo cated at the top of the database screen. A program file (i.e.: .exe file) may be typed into a field to activate the appropriate icon (Figure 25).  **Figure 25** The program can then be selected by pressing the icon at the top of the screen instead of going to the ***Programs*** menu (Figure 26).  **Figure 26**
	Info! Info!	Shows the MAICO Database version and the MAICO contact information (Figure 27).  **Figure 27**

5.2.2.5 Selecting a Client in the MAICO Database

Enter a new client or select an existing client prior to starting the MA 33 Software.

NOTE: The client ID is created by the database with a consecutive numbering. For patients created via the GDT or XML interface, the ID of the practice management software is adopted. It is not possible to change the client ID later.

Enter a New Client

Select ***Client – New*** to clear the demographic fields to enter a new client into the database. Enter the client's demographic information and click ***Save***. The following fields have to be entered: ***Surname***, ***First name***, ***Birthday,*** and ***Sex***. Otherwise it is not possible to save the data or proceed to the MA 33 Software. If any of those data are missing a message box will request the data input.

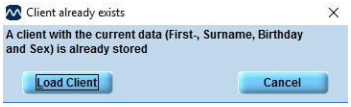


Figure 28

If a client with the current data already exists, a message box will appear asking if the client shall be loaded (Figure 28). Press ***Load Client*** to load the data set or ***Cancel***.

Select an Existing Client

Use the ***Search*** button to choose an existing client. This will display a list of clients which are already in the database. Narrow the search by typing information into one of the demographic fields (1) and then selecting a search category (2): ***Surname***, ***Birthday***, or ***Client-No.*** (Figure 29).

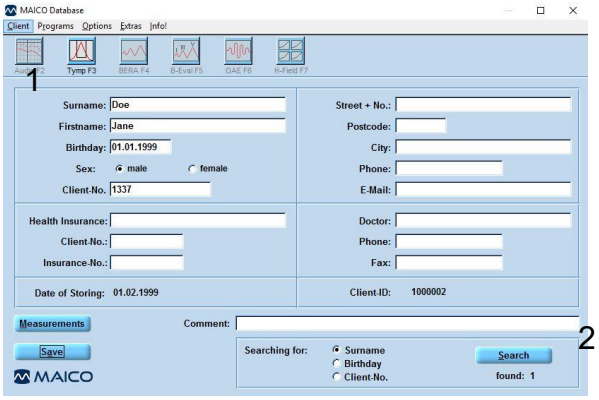


Figure 29

Select a client from the list by double-clicking the line or selecting and pressing ***Load*** (Figure 30). The client's information will then be displayed in the fields on the main database screen.

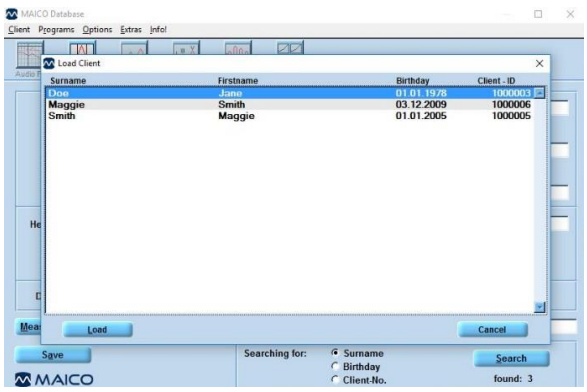


Figure 30

Click the ***Measurements*** button to view past tests for the selected client. A list of stored tests is displayed. Press ***Close*** to leave the measurement view again (Figure 31).

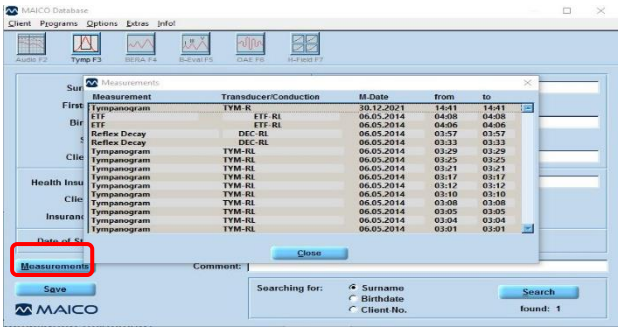


Figure 31

If no measurements are available a message box will be shown (Figure 32).

Figure 32

Changing a client

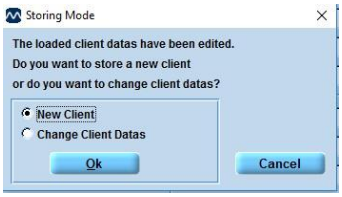


Figure 33

For changing a client data enter the new data in the fields and press ***Save***. A message box will appear asking if a new client shall be saved or the client data shall be changed. Select ***New client*** to save a new client or ***Change Client Datas*** to change the current client data. Press ***Cancel*** to go back to the main screen (Figure 33).

5.2.2.6 Starting the MA 33 Software

After having selected a client open the MA 33 Software using the menu (***Programs*** – **MA 33**), the shortcut ***F2*** or via mouse-click on the ***Audio***  button.

5.2.3 Starting the MA 33 Software from Noah

Choose the MAICO icon  from the Noah Menu bar. Under ***Measurements*** an overview of the installed Measurement modules will appear (Figure 34).

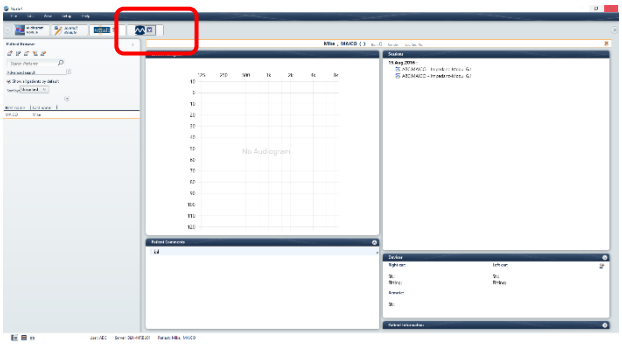


Figure 34

5.2.4 Starting the MA 33 Software from BDT/GDT

The program can be started directly from the BDT/GDT. Follow the instructions given in the Operation Manual of the manufacturer.

5.2.5 Starting the MA 33 Software from EssiConnect

The program can be started directly from the EssiConnect. Follow the instructions given in the Operation Manual of the manufacturer.

5.3 Turning Off the MA 33

WARNING

In Case of Emergency

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

Figure 35

Press ***Save & exit*** or ***Exit*** to end the MA 33 Software (Figure 35). Pull out the USB cable to end the connection between the MA 33 Hardware and the PC.

5.4 Using the MA 33 Software

Start the patient database, load the patient to be tested, and then start the MA 33 software.

The program´s start screen is displayed below (Figure 36). Slight differences in settings and functionality will be apparent depending on the specific version.

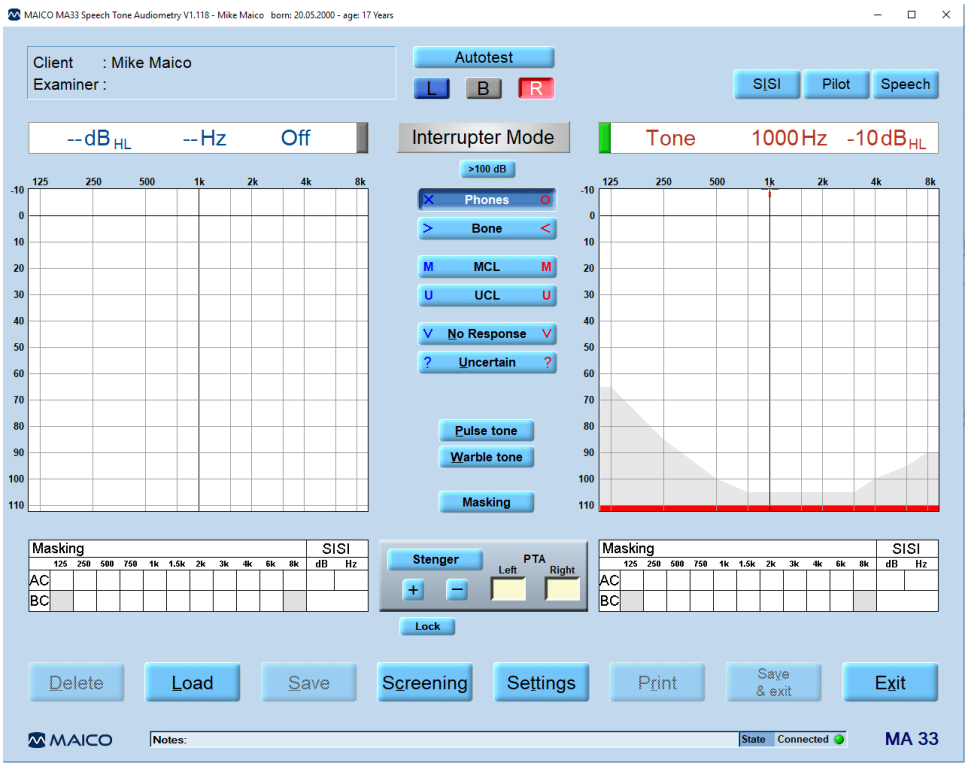


Figure 36

5.4.1 Operation with Mouse and Keyboard

The MA 33 is easily operated with the mouse by simply pointing and clicking on the required button or input field on the screen.

5.4.2 Shortcuts

The following is a list of different key combinations which allow for quick operation (i.e. key shortcuts, Table 7). Some shortcuts are only available for German and English language.

Table 7 Explanation of Shortcuts

Key	Function
TAB	Switching between left/right ears
Ctrl (right)	Activates Interrupter/Presenter for active channel
Ctrl (left)	Activates Interrupter/Presenter for active channel
Spacebar	Interrupter/Presenter adjustment for the active ear
Alt+D	Delete measurement
Alt+L	Load available measurement
Alt+N	New (NOAH)
Alt+S	Save measurement
Alt+X	Exit program
Alt+U	Marking of uncertain hearing
B	Binaural
Alt+T	Settings
Alt+E	Edit
Alt+C	Screening
L	Left ear
R	Right ear
Alt+R	Print
?	Marking of unclear curves
↑↓	Volume control for the testing ear
Home	Return to 1 kHz
Page↑↓	Volume control for the opposite ear
Del	Delete last measured value
SISI Test	
S	Start/Stop (Player)
E	Exit SISI Test
Alt+W	Warble tone
Alt+P	Pulse tone

5.5 Tone Audiometry

5.5.1 General

The following settings are displayed after opening the tone screen (Figure 37).

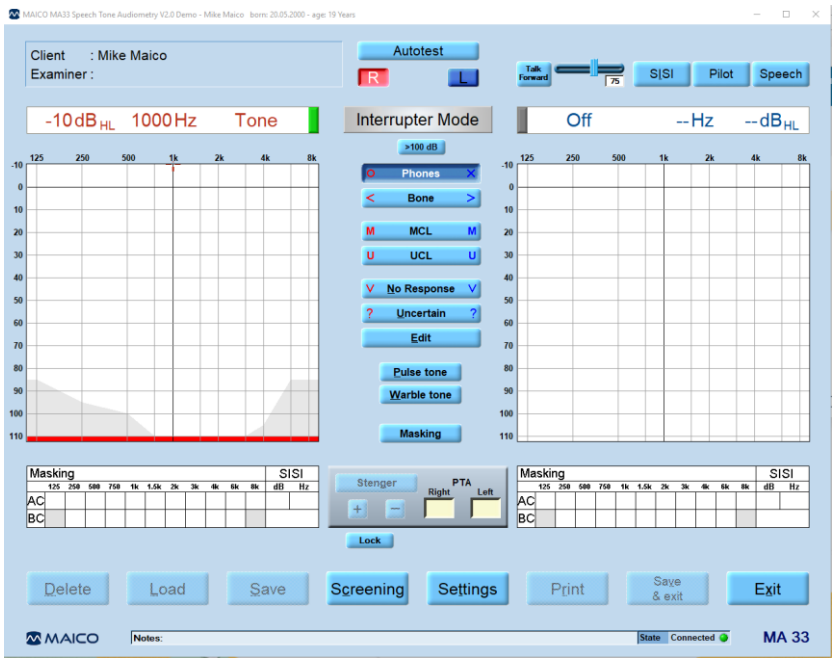


Figure 37

Note: Figure 37 shows the ***Audiogram View***. The ***Table View*** (Figure 38) can be activated in the ***Tone Audiometry Settings***. It is activated per default for ***Americas***. Explanation of the buttons are the same as the ones for the ***Audiogram View***.

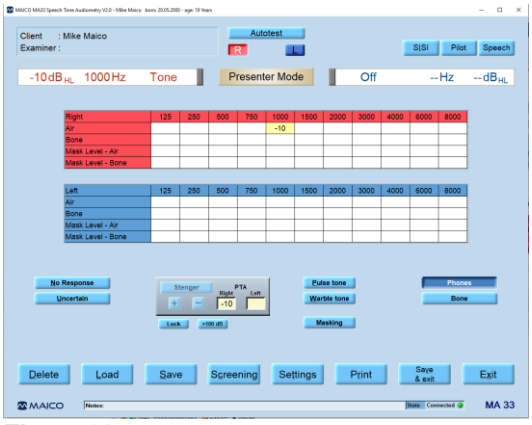


Figure 38

Default setting: right channel is set to air conduction pure tone and the left channel is inactive (i.e. ***OFF*** is displayed until the channel is turned on). The frequency is automatically set to 1 kHz. (Any of these settings may be changed by using the mouse or keyboard shortcuts.)

The start screen displayed above, is an example of the tone audiometry screen. The grey shadows in the lower area of the audiogram, mark the level limits of the selected transducer. The MA 33 tone audiometry software supports (depending on the device version) the main tone audiometry methods. The following testing methods can be started from the tone audiometry screen and documented in the software (Table 8).

Table 8 Test Methods

Method	Version
Air conduction	All
Hughson-Westlake Test	Optional for all versions
Bone conduction	BC, Speech
Most Comfortable Level (MCL)	Speech
Uncomfortable Level(UCL)	Speech
Stenger Test	All
SISI Test	Speech, optional for other versions

Table 9 gives an overview over the different button functions of the ***Tone Audiometry*** screen.

Table 9 Tone Audiometry Screen – Buttons

Button	Function
Client	Name selected from the patient database is displayed here
Examiner	Name chosen at start of module is displayed here and on printout
Autotest	Hughson-Westlake patient controlled automatic threshold test
Talk Forward	Allows examiner to provide instruction to the patient while the headphones are in place (only available if Speech functionality is activated). It is possible to change the level for the Talk Forward function using the slider.
L / B / R	Select left, both or right ear
SISI	Speech. Opens the SISI Test start screen
Speech	Selects speech audiometric screen
Status bar	The status bars show signal (i.e. tone or noise), frequency and level for each side
Interrupter mode	Click here to switch between presenter and interrupter mode
>100 dB	Allows stimulus presentation above 100 dB HL
Phones	Stimuli will be presented through headphones
Bone	Stimuli will be presented through bone conduction headphone
MCL	Tests Most Comfortable Level, displays stored score as MCL in data table
UCL	Tests Uncomfortable Level, displays stored score as UCL in data Table
No Response	Stimulus not heard by patient — Stores threshold with a ***No Response*** symbol
Uncertain	Uncertainty if stimulus was heard by patient - Stores threshold with a ***Uncertain*** symbol.
Edit	Allows to edit an audiogram (only available if activated in ***Settings***). See section 5.5.2.5 for more details.
Pulse tone	If required, the test can also be performed with a pulsed tone.

Warble tone	If required, the test can also be performed with a warble tone.
Masking	Activates Masking
Stenger/PTA	***Stenger***: Activates binaural mode to conduct and score Stenger test. ***PTA***: Displays Pure Tone Average from tone screen (Figure 39).

Figure 39

Track	Activates the masking noise to automatically increase and decrease the level in relation to the signal. It also increases and decreases the other ear (only in binaural mode).
Lock	Locks presentation of the signal in both channels together, so they will both be presented at the same time using only one presentation key.

Level and frequency of masking and level and frequency of SISI test (i.e. right side see below) will be stored and displayed in the table below the audiogram (Figure 40):

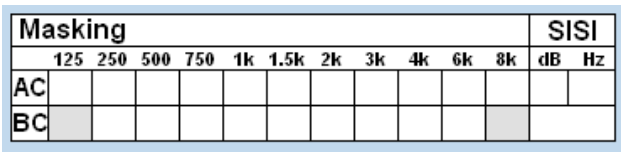


Figure 40

To start further processing of your measurement press the appropriate button (Figure 41). See Table 10 for an explanation of the buttons.

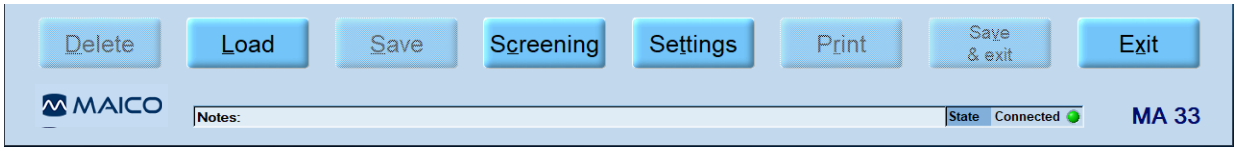


Figure 41

Table 10 Explanation of Buttons

Button	Function
Delete	Delete the previous measurement.
Load	Load a previously stored measurement. The stored result will be displayed in different color.
Save	Save current measurement.
Screening	Screening test with 20 dB, or as defined in the Settings.
Settings	Different setting options are available.
Print	Prints directly.
Save & Exit	Save current measurement and end the program.
Exit	End the Program.
Notes	Comments and additional remarks can be added here.
Connection Status	Indicates if the device is properly connected to the PC.

5.5.2 Performing Tone Audiometric Tests

5.5.2.1 General

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).

Explain to the patient that he/she needs to press the patient response switch as soon as he/she just hears the test tone. The patient will be presented with a series of soft tones; hence it is important to pay attention.

As soon as a tone is heard, even a very soft tone, the patient should respond by pressing the patient response switch.

5.5.2.2 Air Conduction Threshold Measurement

The hearing threshold of the patient is measured in comparison to the normal hearing threshold for air conduction (Figure 42). The test starts on the ear with better hearing ability.

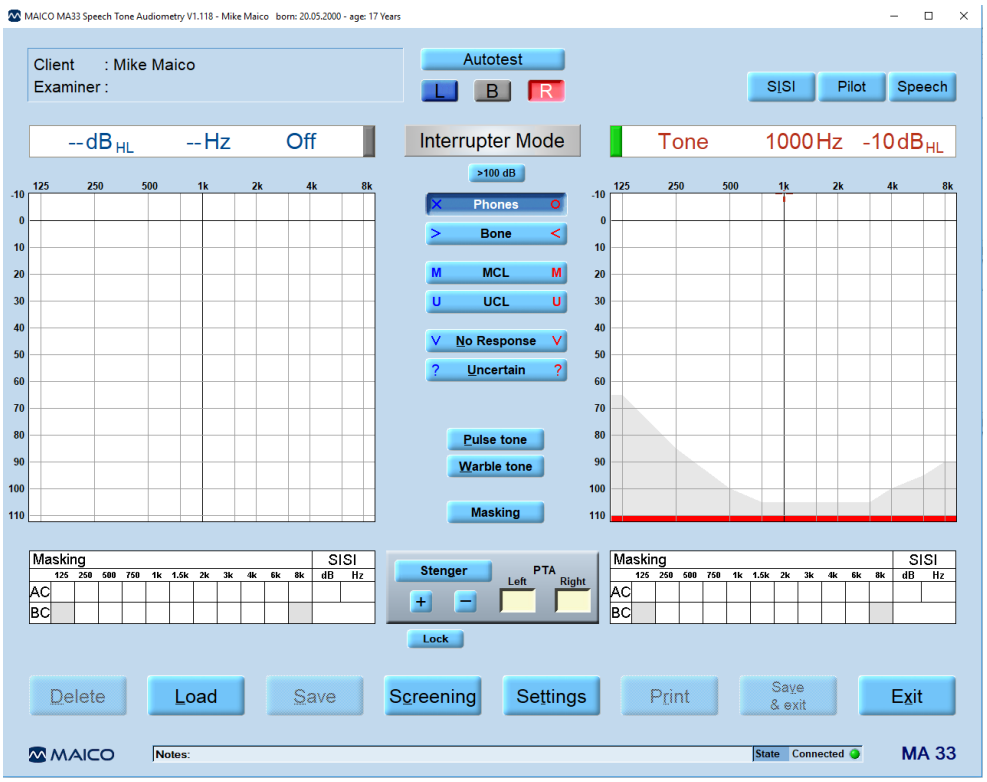


Figure 42

Default setting: right channel is set to air conduction pure tone and the left channel is inactive (i.e. ***OFF*** is displayed until the channel is turned on). The frequency is automatically set to 1 kHz. (Any of these settings may be changed by using the mouse or keyboard shortcuts.)

Select the ear to be tested either by mouse click or by pressing R (right ear) / L (left ear) on the keyboard.

The volume can be changed using the ↑↓ cursor or with the mouse.

The volume is displayed as markers in the audiogram, as well as numerical values above and on the outer sides of the audiograms.

The measuring frequency can be adjusted using the ← → cursor or per mouse click.

The left click lowers the frequency, while the right increases it.

Test through the frequencies: start at 1 kHz; set the higher frequencies first then the lower frequencies.

Select the next frequency, increase the level again and proceed with presenting the test signal as described above.

Once a threshold value has been established, record the measured value by pressing the (***Enter*** key) or use the centre mouse button. The appropriate symbol will be plotted on the audiogram.

Once all frequencies have been tested, choose the less capable ear and repeat the hearing threshold test. After the patient presses the patient response switch (the audiogram for the left channel highlights blue, and the audiogram for right channel highlights red), confirm the response by either pressing the ***Enter*** key or the center mouse button.

As soon as the patient responds to the tone and presses the patient response switch, press the ***Enter*** key or the center mouse button to confirm the response. This is displayed in the audiogram as a red marking **O** for the right ear and as a blue marking **X** for the left ear.

The hearing threshold can be measured several times, and each new measurement overwrites the previous one. The measured values are automatically incorporated into the threshold curve, if only one intermediate frequency is sampled.

Pulse Tone

If required, the test can also be performed with a pulsed tone. Click on the ***Pulse tone*** button and the pure tone will change to a pulsing tone.

Warble Tone

If required, the test can also be performed with a warble tone. Click on the ***Warble tone*** button and the pure tone will modulate. The warble tone can also be pulsed as described above.

5.5.2.3 Automatic Threshold Test (Hughson-Westlake)

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

To open the automatic test screen click the ***Autotest*** button (Figure 43).

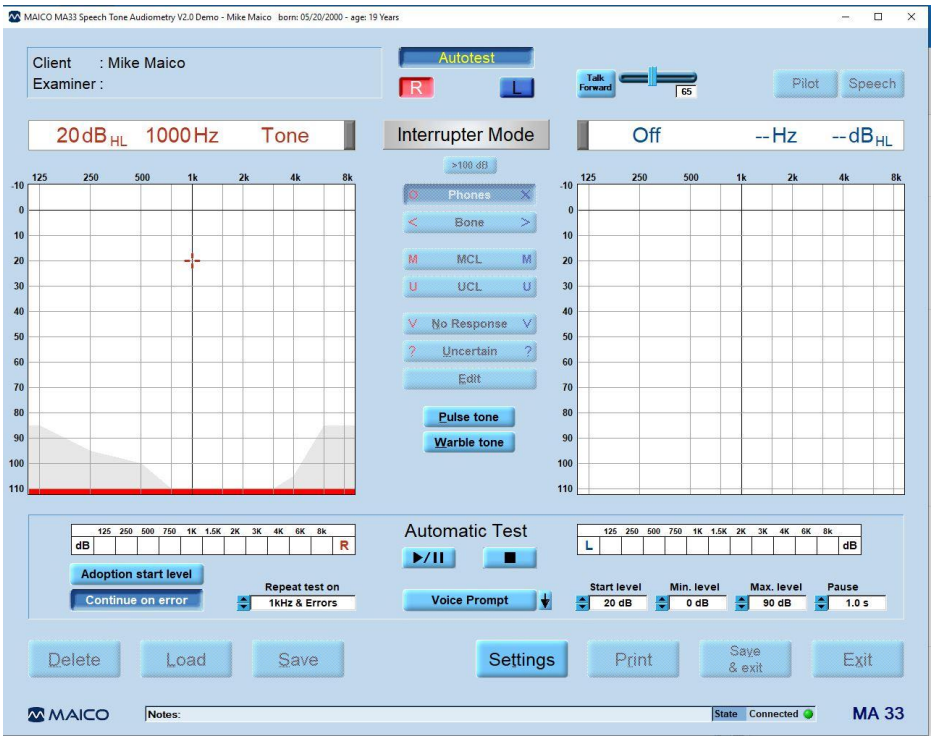


Figure 43

Before starting the test it is useful to explain following directions regarding the hearing test to the test person: The test person will hear a series of soft "beeps" and should listen

very carefully. The test person should press and release the response button as soon as he/she hears the sound, even if it is very soft. The test person will hear directions given through the earphones, and should listen to those carefully when they are presented.

Testing will begin in the right ear at 1000 Hz. The red bar of the right ear audiogram will be highlighted and the cursor will indicate the level and frequency where the test will start.

Press the ***Start/Pause*** ▶/II button in order to start the automatic Hughson-Westlake test. If voice prompt is activated, the test person will hear an initial set of instructions in his/her headphones. Following these instructions, the test will immediately begin by presenting the first tone.

If the test person does not respond by pressing the patient response switch, the tone intensity will increase for 5 dB. This will continue until the test person responds to the tone. When the test person presses the patient response switch in response to the tone, the level will decrease by 10 dB and then ascend in 5 dB steps until the patient responds again. This pattern of increasing by 5 dB and decreasing by 10 dB will continue until the patient has two out of three responses at a particular level.

After this threshold is established, it is displayed in the corresponding audiogram and stored as a numerical value in a table for the appropriate ear. The test will continue until all frequencies have been tested for both the right and the left ear.

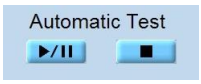


Figure 44

Start/Pause ▶/II and ***Stop*** ■ the test (Figure 44).

Figure 45

Activate ***Adoption start level*** to start with the previously recorded hearing threshold. Deactivate to start with the start level at next frequency (Figure 45).

Figure 46

Activate ***Continue on error*** to continue to test the next frequency after an error is recorded without stopping the test. Deactivate to pause the test after an error is recorded to allow the operator to intervene (Figure 46).

Possible errors: Multiple responses to a tone; continuously holding down the response button without releasing it; not responding at all to the tones even at the loudest level.

Figure 47

Repeat test on (Figure 47):

Off: All frequencies will be tested only once for each ear regardless of errors.

Only 1 Khz: 1000 Hz will be retested in order to make sure that the patient's responses are valid.

All Errors: Frequencies that have errors recorded instead of a threshold value will be retested at the end of the test.

1 Khz & Errors: 1000 Hz will be retested as well as all frequencies containing recorded errors.

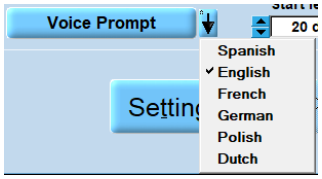


Figure 48

Voice Prompt (Figure 48):

Activate this option to allow voice prompts to be presented to the patients during testing. These include instructions at the beginning and the ending of the test and error messages if the test person is answering not correctly.

Deactivate this option to conduct testing without any voice prompts to instruct the patient.

To change the language of the instructions the test person hears during the test, click on the ***arrow*** button next to the ***Voice Prompt*** button (Figure 49) to open the dropdown menu with the available voice prompt languages.

Start Level: Level at which the automatic test will be initiated. This level can only be as low as the Minimal Level. (Choose from 0 dB to 90 dB in 5 dB steps.)

Minimal Level: This is the lowest level that will be tested in the automatic mode. (Choose from 0 dB to 90 dB in 5 dB steps.

Maximal Level: This is the highest level that will be tested in the automatic mode. (Choose from 0 dB to 90 dB in 5 dB steps.)

Pause: Pause duration between tone presentations in addition to the randomized time variable (choose from 1 to 99 seconds) (Figure 49).

Figure 49

5.5.2.4 Masking

When measuring a pure tone audiogram, you need to assume that the measured hearing threshold is correct. But if you recognize that sound is also transmitted through bone conduction over the entire skull, it is probable that the opposite ear also receives sound. This is called "*crossover*".

Crossover can also occur when measuring air conduction because a small amount of air conducted sound is received by the skull and transmitted by bone. Whether the crossover signal can be heard by the opposite ear, depends on its inner ear function.

Relevant to crossover, is the sound level which is received by the opposite ear. The difference between the original test signal with the test ear and the received signal at the opposite ear is called "*interaural attenuation*".

NOTE: Please advise the patient to inform you with which ear he/she hears the test signal. In doing so, it will be easier to detect crossover.

To ensure that the patient does not experience crossover, you must mask the opposite ear. Masking increases the hearing threshold of the opposite ear.

Masking is done with a noise signal which is transmitted by the headphone. For pure tone audiometry, a narrowband noise is used. This noise changes its center frequency according to the frequency of the test signal.

Adjust the required masking level.

NOTE: For effective masking the masking sound is presented continuously. You can interrupt the masking signal by pressing the corresponding ***Ctrl*** key.

5.5.2.5 Edit Mode: Tone Screen

To enter ***Edit*** mode, click on ***Settings / Function Key / Edit*** and save the changes. The ***Edit*** button is displayed in the middle part of the tone screen (center of screen). Click on this button to activate the edit function. Once in ***Edit*** mode, the functions described below may be performed:

Deleting the last stored value

The last value stored can normally be quickly and simply deleted by pressing the ***Delete*** key on the keyboard. The user then needs to confirm with ***Yes*** to delete this last stored value, or ***No*** to not delete it and continue testing.

However, in order to delete additional values, the user must enter ***Edit*** mode. This is a precautionary measure, so that data may not be unintentionally deleted from the main test screen.

Changing hearing thresholds on the audiogram

During a current test session, hearing threshold levels can normally be changed by simply moving the cursor to the place on the audiogram where the correct level needs to be and then by pressing ***Enter*** key or center mouse click. The stored symbol will move to this new level.

However, if thresholds need to be completely deleted, and not just changed, then the user must enter the ***Edit*** mode.

Deleting Values in Tone Screen

To delete a threshold completely, select the transducer used and place mouse over the threshold. Right-click on the mouse and make the appropriate selection: ***Delete Value*** or ***Delete curve***. Selecting ***Delete Value*** will permanently remove only that one particular threshold point.

Adding Values in Tone Screen

Threshold values can also be added while in ***Edit*** mode. Select the transducer and if appropriate the type of testing (i.e. MCL, UCL, aided, etc.). This will ensure that the appropriate symbol is plotted. Left click on the audiogram with the mouse to plot a threshold value. To plot thresholds for the right ear, click on the right- channel audiogram. To plot thresholds for the left ear, click on the left-channel audiogram. There is no need to change ear selections while in ***Edit*** mode.

5.5.2.6 Air Conduction Screening

Select ***Screening*** in the lower-middle part of the start screen (Figure 50).

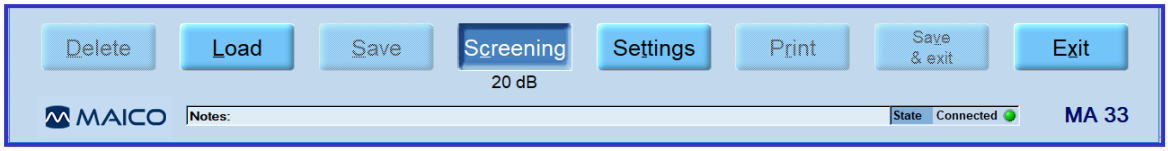


Figure 50

Default setting: Intensity 20 dB (changeable under ***Settings***/***Function Key***/***Screening 20 dB***), Frequency 1 kHz, pulse tone. The measurement will start with the right ear.

Test the frequency: begin at 1 kHz, then increase the frequency, confirm the patient´s response by pressing ***Enter*** or the center mouse button and then continue with the next frequency.

The right l cursor increases the frequency while the left j cursor decreases the frequency.

The test tone can be interrupted by pressing the ***Spacebar***.

After the patient has pressed the patient response switch, record the measured value by pressing the ***Enter*** key or use the centre mouse button.

The red marking **O** in the audiogram is for the right ear and the blue marking **X** is for the left ear.

5.5.2.7 Speech Therapy Mode (BPTA) (optional)

Using the ***Binaural Pure Tone Audiometry*** (BPTA) you check at 20 dB and/or the hearing threshold, if the child hears the tone on the left, right or both sides. Activate BPTA-Mode by clicking ***Binaural*** in ***Setting/View***.

Transfer test results per mouse click to the according table. The index will automatically be calculated (Figure 51).

Figure 51

Utilization of BPTA mode (Figure 52):

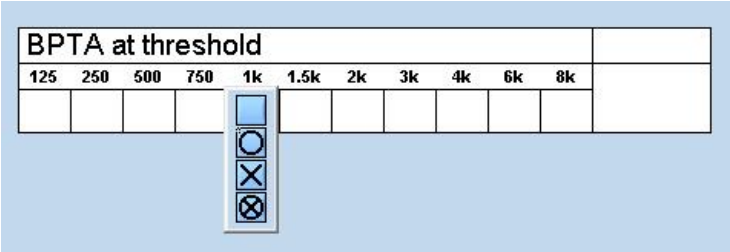


Figure 52

Click on the white area and choose red circle (meaning right), cross (meaning left) or circle with cross (for both).

The average results of the sum of the whole selection.

5.5.2.8 Bone Conduction Threshold (MA 33 BC, Speech)

Bone conduction, which involves the transmission of sound waves through the skull directly to the inner ear, provides information regarding the function of the inner ear. For a neural hearing loss, the values of air conduction and bone conduction are the same. In this case, a hearing loss of the middle ear can be eliminated.

Place the bone conduction transducer so that the flat, circular side of the transducer is positioned on the mastoid, on the noticeable ledge of the cranial bone behind the pinna. The other side of the headband is placed in front of the opposite ear.

Set the transducer selector to ***Bone*** (Figure 53).

Perform the test in the same way as for air conduction.

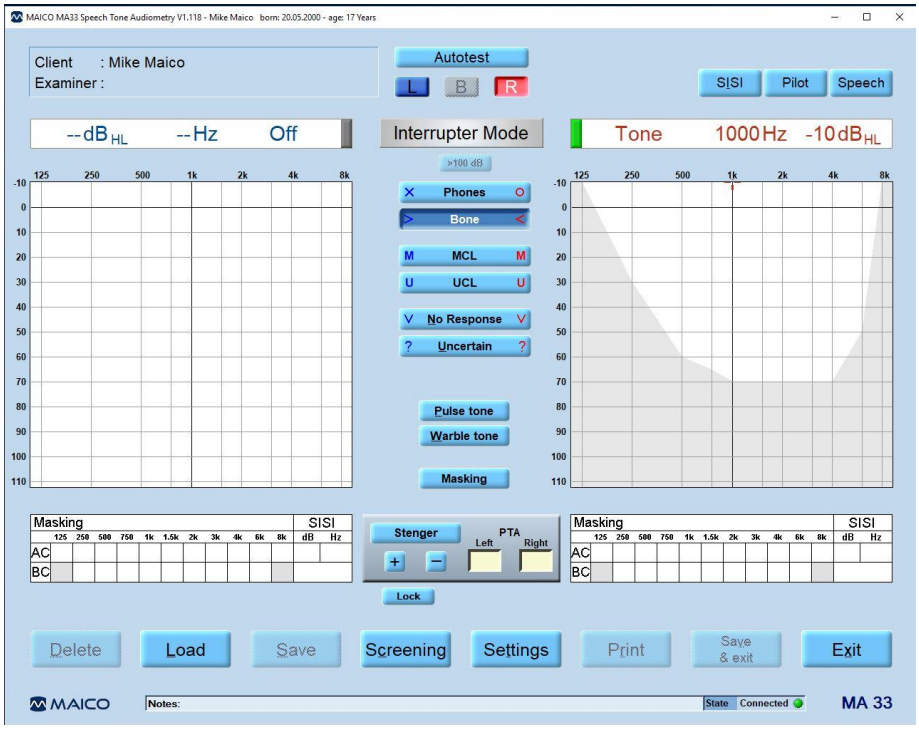


Figure 53

Masking

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

NOTE: Please advise the patient to inform you as to which ear he/she hears the test signal. In doing so, it will be easier to detect crossover.

Adjust the required masking level.

NOTE: For effective masking the masking sound is presented continuously. You can interrupt the masking signal by pressing the corresponding ***Ctrl*** key.

To mask when performing bone conduction testing: place the headphone on the opposite ear so that the earphone sits at the correct height (i.e. the sound output grid exactly faces the ear canal). Adjust the headband of the headphones, if necessary. Then place the transducer of the bone conduction headphone on the mastoid of the test ear (i.e. on the noticeable flat area of the cranial bone behind the auricle).

5.5.2.9 Most Comfortable Level (MCL)

Testing of MCL can be measured using pure tone stimuli or speech. The purpose is to determine the most comfortable listening level for the patient for a given stimulus. The dB level at which the stimulus is the most comfortable is determined. This level might be described as, the level at which the patient would be comfortable listening for an extended period of time. Select MCL in order to test and store the Most Comfortable Level.

5.5.2.10 Uncomfortable Level (UCL) Testing

Testing of UCL can be measured using pure tone stimuli or speech. The purpose is to determine the dB level at which the stimuli becomes uncomfortable for the patient. The UCL is described as the level between very loud and loud perception of the test signal. This information is valuable in determining the patient's upper dynamic range limit.

Because this test uses high sound pressure levels, it is extremely important to perform this test using the utmost caution so as to avoid damaging the ear.

To prevent the possibility of extreme discomfort for the patient, it is important to start the test with levels near the patients MCL (Most Comfortable Level).

Click UCL. The ***>100 dB HL*** field will be highlighted. Start testing with a test level of 60 dB HL. Present the tone briefly (max. 1s). If the signal was recognized by the patient as “not uncomfortable”, increase the level and proceed as described above. If the signal was uncomfortable for the patient, store the value. Proceed accordingly with other test frequencies.

5.5.2.11 SISI Test

The SISI (Short Increment Sensitivity Index) is guided by the principle that patients with cochlear impairment are hypersensitive to small intensity increments. The continuous test tone is increased by 1 dB for a period of 0.2 seconds every 4.8 seconds. Whenever the patient hears the increment, he/she needs to press the patient response switch. The SISI

test information and the test score are shown on the screen. The test will end automatically after 20 presented increments. The score is expressed as a percentage of ratio of the increments heard to the delivered increments (all increments heard = 100 %, no increments heard = 0 %). A high score indicates a cochlear impairment. A low score is related to normal hearing or conductive or retrocochlear disorder.

Preparation of the SISI Test

To start the test, click the ***SISI*** button on the top of the screen. The SISI Test start screen opens (Figure 54).

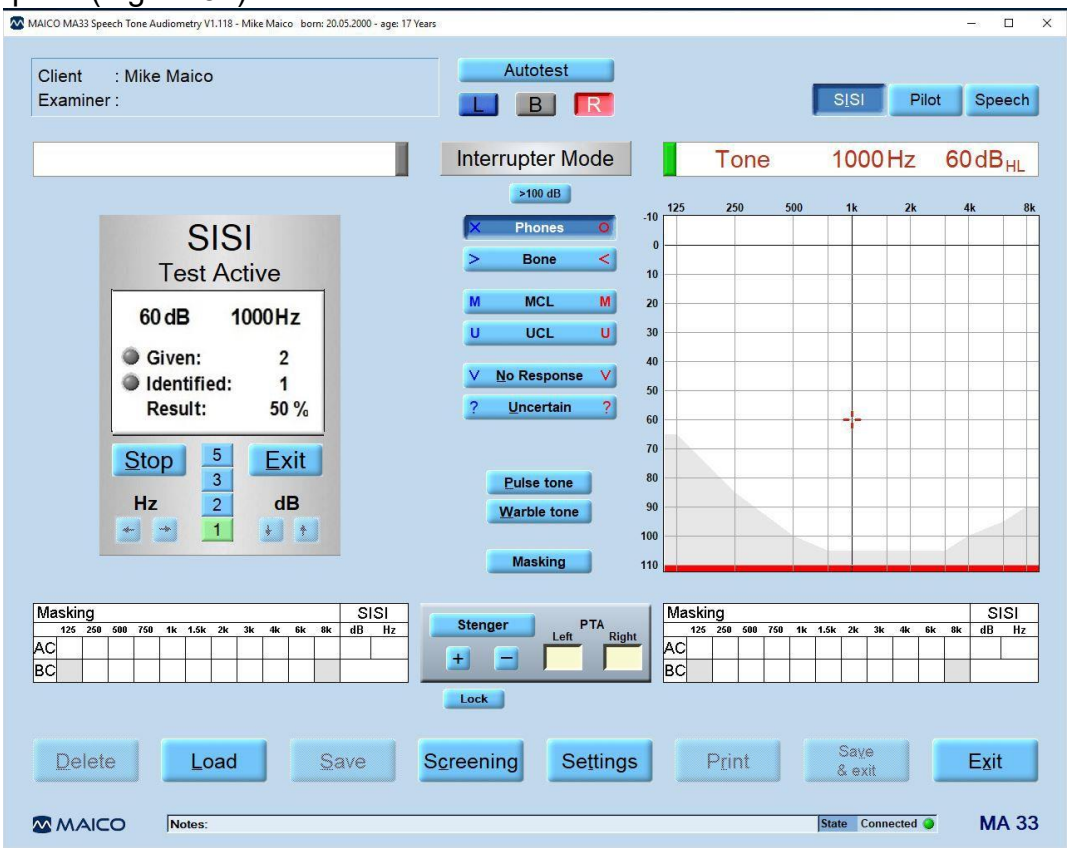


Figure 54

Click ***R*** or ***L*** to select the ear for testing:

Select the test frequency with the ← → cursor.

For the test, you should choose the frequency at which the maximum bone conduction hearing loss was measured, as described in section 5.2.4.

Select the level with the ↑↓ cursor.

The level should be set to a value 20 dB above the individual hearing threshold (which was attained during measurement as described in section 5.2.2). It must reach at least 60 dB HL .

Take note, that in the SISI mode, the tone for the test is presented continuously. You can interrupt the test by pressing ***S*** or by clicking on ***Stop***. Press ***S*** or click ***Start*** to continue the test.

The patient must be instructed: *"You will now hear a continuous tone. Every time it becomes louder, immediately push the switch".*

Training of the Patient

Only with careful training during the following conditioning phase, can a valid test result be achieved.

Press the start button or ***S*** key to start the SISI Test.

The intensity starts automatically 20 dB above measured threshold and can either be adjusted by clicking the ↑↓ arrows in the SISI box on the screen or the ↑↓ cursor keys.

For training purposes, the intensity increases by 5 dB every 5 seconds. For example, 60 dB HL to 65 dB HL .

Increment presentation is identified when the grey dot lights up and turns yellow on the screen (i.e. when tone is presented, the ***Given*** dot lights up).

The dot indicates the time frame, within which the patient is allowed to respond to the increment (about 1.5 seconds). Any response that falls outside this time frame will not be registered, so as to exclude false responses.

When the patient presses the patient response switch and thereby identifies that he/she has registered the tone, the ***Identified*** dot lights up and turns green.

The number of detected (***Identified***) increments is counted and shown on the screen. Furthermore, the number of presented (***Given***) increments is also shown.

When the patient has understood the procedure of the test, reduce the level to increase the increments to 3 dB, and subsequently to 2 dB, for further training and familiarization.

Performing the SISI Test

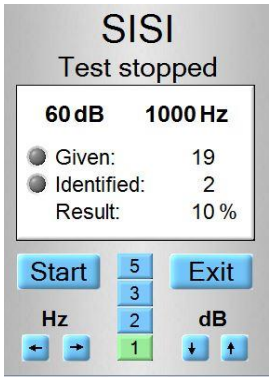


Figure 55

Increase the intensity to 1 dB.

If the patient is responding correctly, start the SISI test with increments of 1 dB by clicking the ***Start*** button. The following 20 signals will be presented with incremental intensity and the examiner can track the progress on test screen. The intensity increase can be prolonged by pressing the ***Spacebar***.

Once twenty increments have been presented, the test stops automatically and the result will be displayed on the screen (Figure 55). The percentage of correctly-identified increments, together with the total number of presented increments will be presented on the screen.

If the test result has reached a satisfactory level before twenty increments have been presented, the test can be terminated by pressing the ***Stop*** button.

The SISI test can be ended and the result saved after ten increments have been presented, by clicking the ***Exit*** button. The result will be shown automatically in the SISI table in the measuring screen. The total incremental ratio of SISI test is expressed as a percentage value. A 25 % value indicates neural (auditory nerve) impairment, and sensory (inner ear) hearing impairment is indicated by a value greater than 70 %.

5.5.3 Settings – Tone Audiometry

5.5.3.1 General

The ***Settings*** menu allows the following different setting options to be modified: ***View***, ***Masking***, ***Operation***, ***Function Key***, ***Frequencies*** and ***Settings*** (Figure 56).

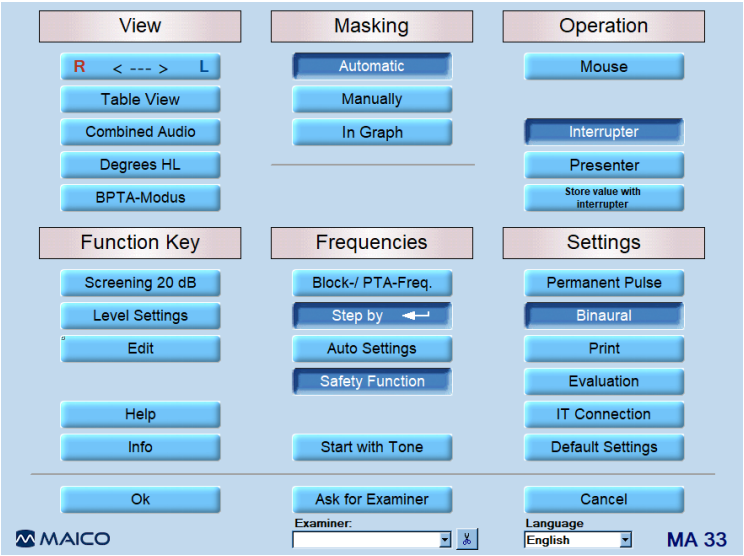


Figure 56

The settings can be changed by clicking on the different setting options. Click ***OK*** to apply the new setting.

5.5.3.2 View

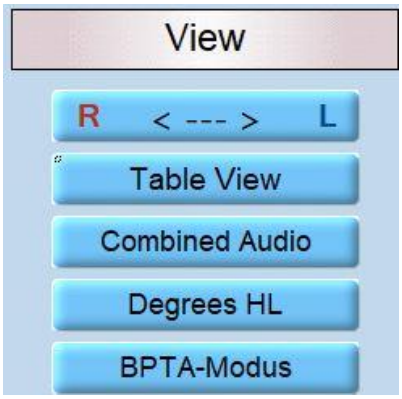


Figure 57

R < --- > L: Choose the side of the screen on which the right and left channel are to appear.

Table View: activates the Table view instead of the Audiogram view (default for ***Americas***).

Combined Audio: Changes display. The combined audiogram displays both ears, together on one audiogram.

Degrees HL: Displays sample categories for different degrees of hearing loss on the audiogram.

BPTA-Modus: Activates the Speech Therapy Mode (Figure 57).

5.5.3.3 Masking

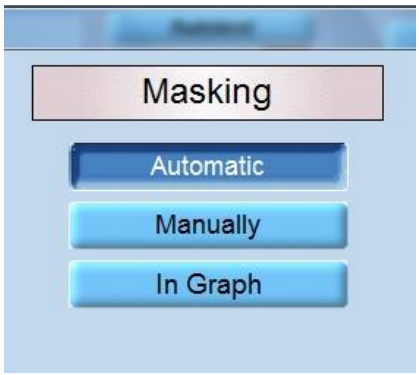


Figure 58

The masking function is by default ***Automatic*** .

Different intensities of masking can be entered directly, when ***Automatic*** masking is activated.

Manually: Enables masking level to be adjusted manually during testing.

In Graph: To view the masking setting graphically, click ***In Graph*** (Figure 58).

5.5.3.4 Operation

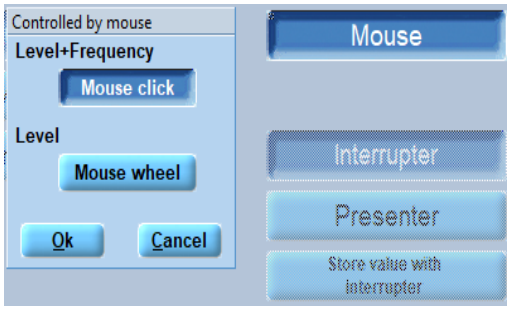


Figure 59

Mouse: once ***Mouse click*** is activated, enables the user to control volume setting by using the mouse. ***Level+Frequency*** is adjusted per mouse by clicking on the level in the left or right audiogram, depending on the channel being tested. If ***Mouse wheel*** is activated, level changes are changed by using the mouse wheel.

Interrupter: Switch to interrupter mode.

Presenter: Switch to presenter mode.

Store value with interrupter: value is automatically stored when the sound is paused (pressing the ***Enter*** key is not necessary) (Figure 59).

5.5.3.5 Function Key

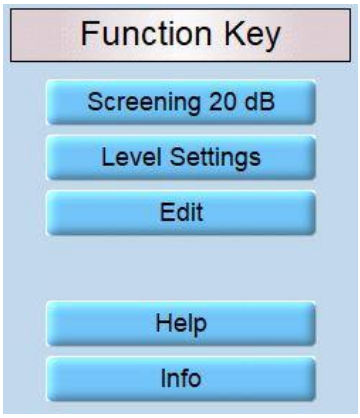


Figure 60

Screening 20 dB: By clicking this button, a screen opens and enables the user to conduct screening tests at different decibel levels. Moving the decibel bar increases or decreases the tone intensity used for screening. ***Default*** is set at ***20 dB***.

Level Settings: See explanation of below.

Edit: Activates the ***Edit*** button on the screen.

Help: Opens the operation manual.

Info: Shows information such as serial number and software version (Figure 60).

Pressing the ***Level Settings*** button opens a screen to make the following settings (Figure 61):

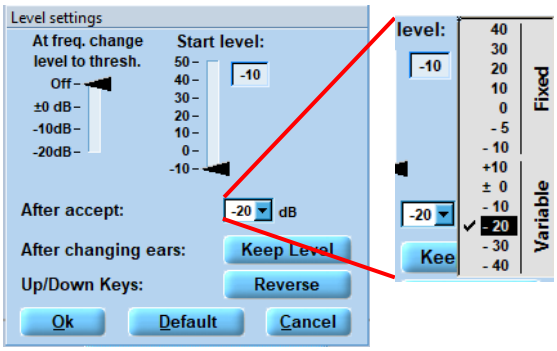


Figure 61

At freq. change level to thresh.: If a frequency with an existing threshold value is selected in the audiogram, the cursor automatically jumps to the threshold value plus/minus the value set in this option. Choose a value between ***±0 dB*** and ***-20 dB*** or set the option ***Off***.

Start level: Set the level at which a new measurement shall start between ***-10*** and ***50*** (dB).

After accept: Set the next level after acception by choosing fixed values (***Fixed***) or level steps between ***+10*** and ***-40*** (dB) (***Variable***).

After changing ears: Activate the ***Keep Level*** option to proceed with the last measured level when changing the ears.

Up/Down Keys: Activate the ***Reverse*** option to change the assignement of the up and down arrow keys on your keyboard for choosing the frequencies.

5.5.3.6 Frequencies

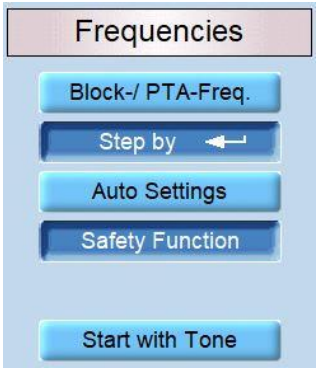


Figure 62

The following settings are available (Figure 62):

Block-/PTA-Freq: Certain frequencies can be blocked and hence will be skipped during audiometric testing (this does not apply when a mouse is used).

Step by ↵: If you use the ***Enter*** key to confirm the data, the cursor "steps" to the next frequency (i.e. either to the left or to the right in the audiogram) depending on whether you decide to test the lower frequencies (i.e. < 1 kHz) first or the higher frequencies (i.e. > 1 kHz) first.

Auto Settings:
There are 3 ways of activating the option ***Return to 1 kHz***. ***Change of transducer***, ***Change of Right/left***, or ***End of frequency change***. When ***Wrapping*** is activated, instead of returning to 1 kHz at the end of the frequency range, the cursor will return to the start of the frequency range, as if circulating the frequency range (Figure 63).

Figure 63

Safety Function: The safety function prevents an immediate increase in the frequency level to exceed 70 dB, during frequency change.

If the ***Safety Function*** is disabled a message box appears. Press ***Yes*** if you really want to disable the function or ***No*** if you want to keep the function enabled (Figure 64).

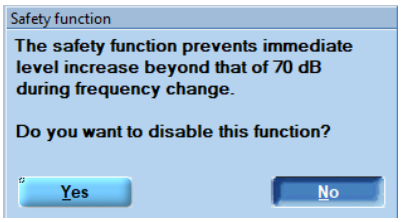


Figure 64

Start with Tone: Pressing the ***Start with Tone*** button opens a message box that allows for the selection of the test the programm shall start with (Figure 65).

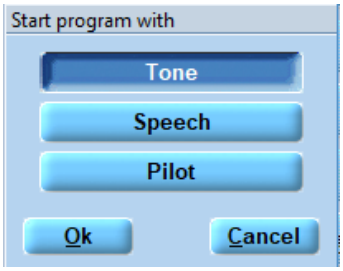


Figure 65

5.5.3.7 Settings

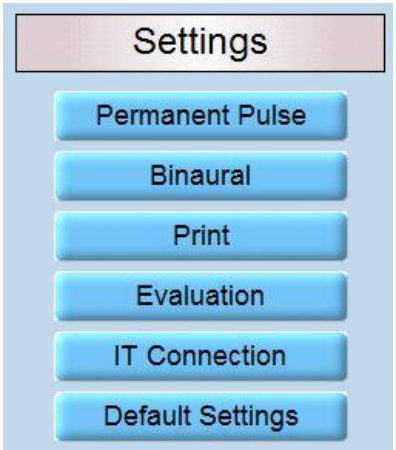


Figure 66

The following settings are available (Figure 66).

Permanent Pulse: Permanent pulse can be activating by clicking the button.

Binaural: Binaural measurement can be performed in addition to single left or right ear measurement. Select ***Individual*** to change the levels for the right and left ear individually. Select ***Simultaneous*** if you want the left and right ear levels to match (Figure 67).

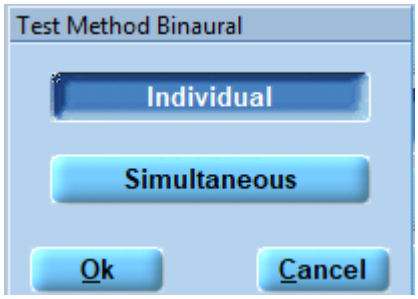


Figure 67

Print: Offers different print settings such as ***Color*** Print (standard setting B/W), ***DIN A5*** (Standard A4) and other print options.

Pressing ***Address/Phone*** opens a window, in which you can enter the data as well as the address and telephone number of the examiner. Note that these are not two separate lines. So first fill in the first line completely and then write on the second line. You can also select an image for the print head from your drive. Activate the ***Header bitmap*** function and load an image for the print head by pressing the ***Load*** button (Figure 68).

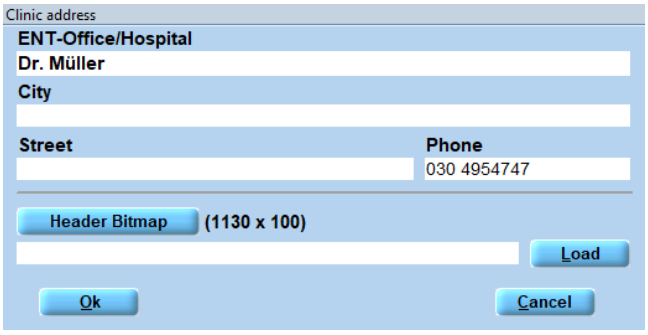


Figure 68

Evaluation: Setting for a pure evaluation workstation (no device check).

IT Connection: IT Connection: Browse in the fields ***Import path and file OAS --->MAICO*** and ***Export path and file MAICO ---> OAS*** to select the exchange data for the data based communication Database. Changes will be activated after restart of the program.

Activate the Save to PDF function by pressing the ***PDF-File*** button and then the ***Browse*** button. Choose a folder and enter a file name ***XXX.pdf*** and press ***OK***. This way a PDF is going to created as soon as you have saved and exited a session.

The database file is stored locally on the PC per default. To use a database file stored in a network use the field ***Data base path network*** (Figure 69)

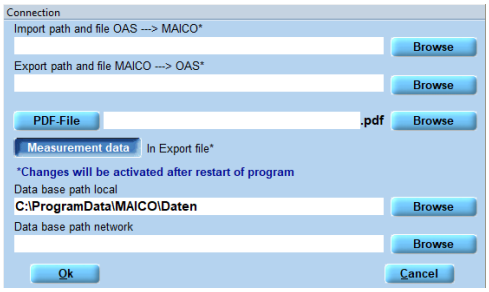


Figure 69

Default Settings: following options are available (Figure 70):

***Reset*:** All individual settings will be removed. Return to default settings.

***Save*:** The individual settings can be saved.

***Load*:** The individual settings, that have been saved, can be loaded for using.

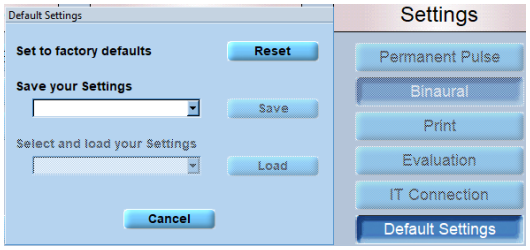


Figure 70

5.5.3.8 General Function Keys

Figure 71 shows the general function keys. See Table 11 for explanation.

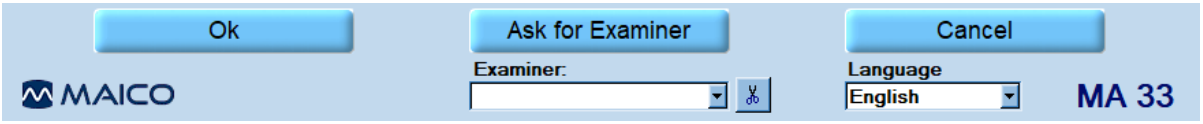


Figure 71

Table 11 Explanation of Function Keys

Button	Function
Ok	By clicking ***Ok***, changes will be applied and the program returns to the start screen.
Ask for Examiner	In the event that more than one examiner is using the program, each examiner can save his/her customized settings for future use and reference. When the program starts, enter the examiner´s name.
Cancel	Returns to start screen without saving the changed settings.
Examiner	Several different settings can be customized and saved for different examiners, should more than one examiner be using the MA 33 program.
Language	Displays current language

5.6 Speech Functionality (MA 33 Speech)

5.6.1 General

As part of the MA 33 Speech software you are able to enter the speech functionality by pressing ***F2*** on the keyboard or by clicking on the ***Speech*** button in the top, right-hand corner of the tone audiometric screen (Figure 72). See Table 12 for an explanation of the buttons.

To conduct a test using speech functionality you can use a microphone, WAVE files or CD-ROM.

Use of unrecognized speech material can lead to faulty results and therefore wrong diagnosis.

Only recognized speech material can be used (i.e. material with known relation to the calibration signal).

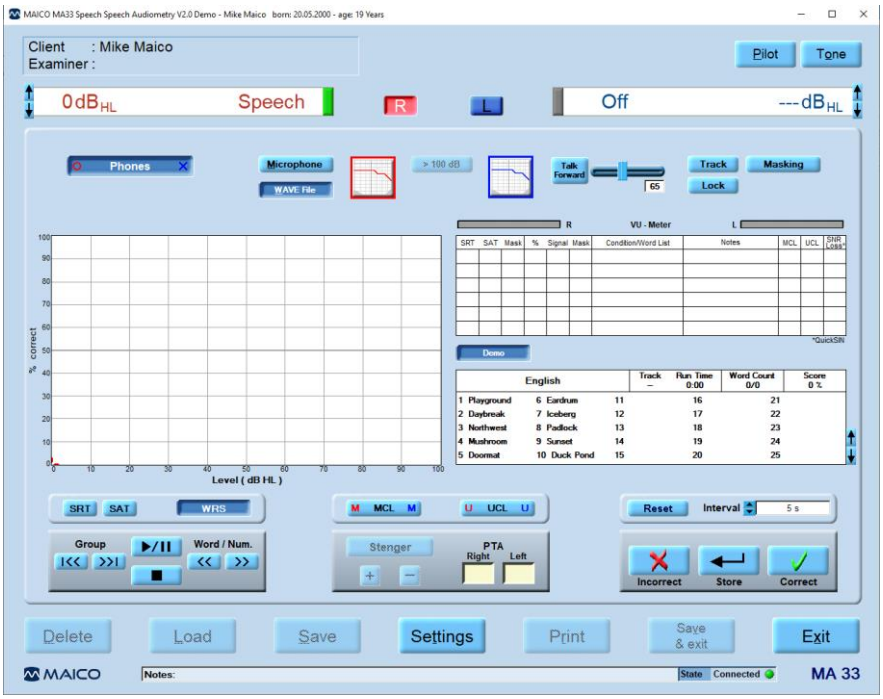


Figure 72

Table 12 Speech Audiometry Screen – Explanation

Button	Function
L / B / R	Select left, both or right ear
Phones	Stimuli will be presented through headphones
WAVE File	To conduct test using speech functionality by wave file
CD-ROM	To conduct test using speech functionality by CD-ROM
>100 dB	Allows presentation above 100 dB HL

Button	Function
Talk Forward	Allows examiner to provide instruction to the patient while the headphones are in place (only available if Speech functionality is activated). It is possible to change the level for the Talk Forward function using the slider.
Track	Activates the masking noise to automatically increase and decrease level in relation to the signal
Lock	Locks presentation of the signal in both channels together so they will both be presented at the same time using only one presentation key.
Masking	Activates Masking
SRT	Speech Recognition Threshold, displays stored score as SRT in data table
SAT	Speech Awareness Threshold, displays stored score as SAT in data table
WRS	Word Recognition Score, displays the stored score in the table
MCL	Tests Most Comfortable Level, displays stored score as MCL in data table
UCL	Tests Uncomfortable Level, displays stored score as UCL in data Table
Reset	Resets the word table
Interval	Select the amount of time (in seconds) between word presentations, when using the WAVE files included in the software.

Figure 73

Player for Speech functionality: Choose word group, start/pause test, go to previous / next word, stop test (Figure 73).

Figure 74

Stenger: Activates binaural mode to conduct and store result of Stenger Test.

PTA: Displays Pure-Tone Average from tone screen (Figure 74).

Figure 75

Click the corresponding buttons to record the response and to allow test results to be displayed in the ***Speech Audiometry*** table (Figure 75).

Columns shown in ***Speech Audiometry*** table (Figure 76 and Table 13):

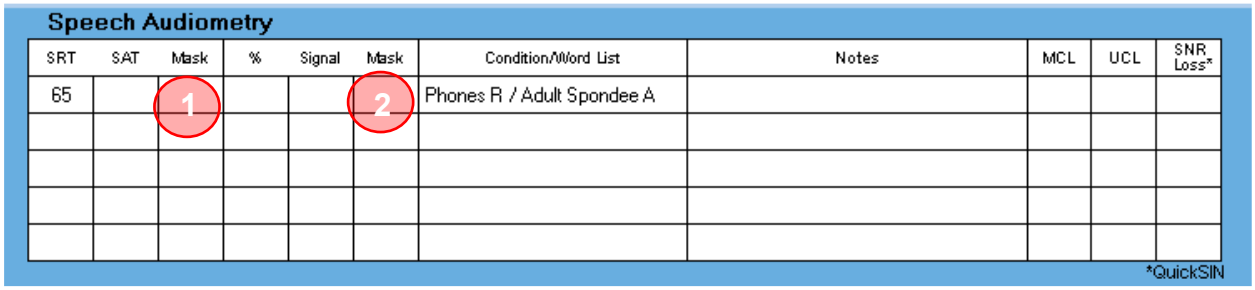


Figure 76

Table 13 Explanation of Screen Text

Display text	Information
SRT	dB HL, level at which speech reception threshold is obtained
SAT	dB HL, level at which speech awareness threshold is obtained test ear during an SRT/SAT test
Mask (**1**)	dB HL, level of masking noise presented
%	percent correct score obtained for a Word Recognition Score test.
Signal	dB HL, level at which a word list was presented to the test ear for a word recognition (discrimination) task
Mask (**2**)	dB HL, level of masking noise presented to the non-test ear during a word recognition (discrimination) task
Condition/Word List	lists transducer, ear, and lists what was presented
Notes	the user may type comments into this field
MCL	dB HL, value obtained for Most Comfortable Level to Speech
UCL	dB HL, value obtained for Uncomfortable Levellevel to Speech
SNR loss	Value calculated from the results of the QuickSIN test.

If WAVE file is selected, a speech list is displayed on the screen (Figure 77).

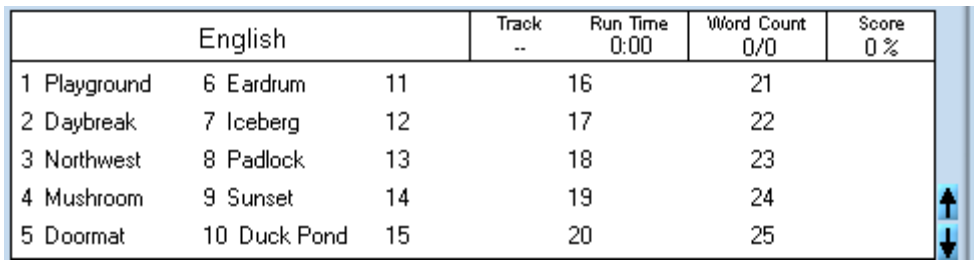


Figure 77

Figure 78 shows the General Function Keys of the Speech screen. See Table 14 for an explanation of the buttons.

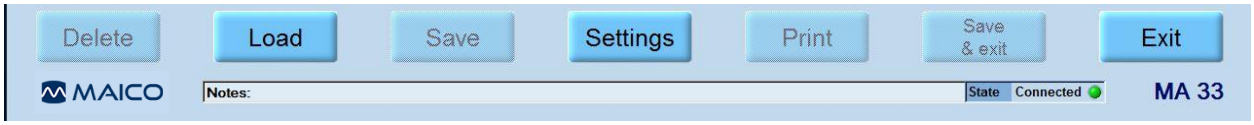


Figure 78

Table 14 Speech Screen – Explanation of Buttons

Button	Information
Delete	Deletes the previous measurement.
Load	Loads a previously stored measurement (i.e. test result). The loaded wave will be displayed in different color.
Save	Saves current measurement.
Settings	Different setting options are available.
Print	Prints directly.
Exit	Ends the Program.
Notes	Comments and additional remarks can be added here.
State	Indicates if the device is properly connected to PC.

5.6.2 Performing a Test Using Speech Functionality

5.6.2.1 General

The Speech Recognition Threshold (SRT) is the hearing threshold for speech. It is the lowest level at which the patient correctly recognizes the stimuli 50 % of the time. Usually, recognition is indicated by repetition of the speech-stimulus item. Speech functionality can be used with recorded speech test material from CD-ROM or WAVE file or with the microphone and live voice using standardized word lists.

After entering the Speech screen, select the source and method of speech generation (Microphone, WAVE File, CD-ROM). Also choose what type of measurement you would like to store (SRT, WRS, MCL, etc.)

Explain to the patient that he should repeat each word he hears. 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 the headphones are put on correctly: Red side on the right, blue side on the left. Adjust the headband of the headphones so that the receivers are at the correct height (the sound output grid exactly facing the ear canal).

Perform the test words.

Figure 79

Score the patient´s response for each word using the ***Correct*** and ***Incorrect*** buttons located at the right-hand, bottom corner of the Speech screen (Figure 79). If ***WAVE File*** is selected a correct

response will be highlighted in green and an incorrect response will be highlighted in red. At the end of the test, the test finishes automatically. Save the test score by clicking on the ***Store*** key in the control panel. Information about the test will then be stored in the data table on the right side of the screen.

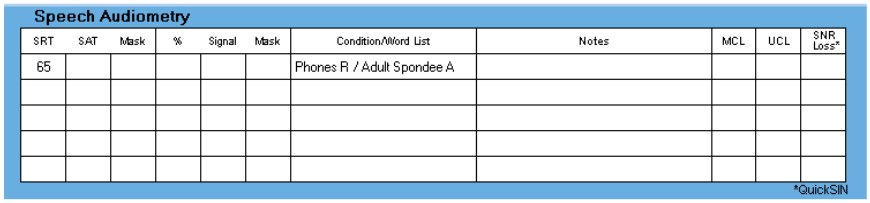


Figure 80

The scored word lists are saved as part of the patient's record and can be viewed by clicking on the appropriate list stored in the data table (Figure 80). If you use ***WAVE File*** this full list will then be displayed in the Word list and the list can be reviewed.

To change the level of the currently active signal, use the ↑↓ keys.

To change the level of the currently active signal in binaural mode:

Right ear: right mouse click in the audiogram or use the ↑↓ keys.

Left ear: left mouse click in the audiogram or use the ***Page Up/Page Down*** cursors.

5.6.2.2 Speech Functionality with WAVE File

After preparing the test person select a speech list to be displayed on the screen using the buttons on the left side of the speech test player control panel.

Start anywhere in the word list by clicking on the word with which to start (It will highlight grey).

Arrows displayed in the lower right corner of the word list box, can be used to scroll to another part of the list.

Start the presentation by clicking the ***Play/Pause*** button on the test player control panel for speech functionality (Figure 81).

Figure 81

5.6.2.3 Conducting a Test Using Speech Functionality with CD-ROM

Put your CD with the recorded test material into the CD-ROM drive and click on the ***CD-ROM*** button.

The MA 33 must be calibrated to the particular test material in use to ensure valid test levels. That means every time you change the CD you must recalibrate the device. Click on ***Calibration*** next to the ***CD-ROM*** button and the calibration panel opens (Figure 82).

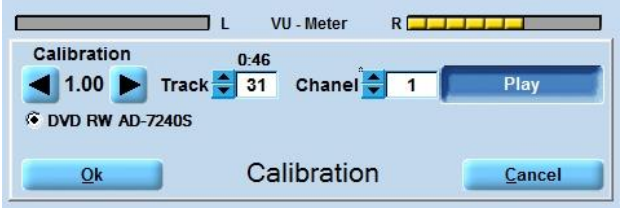


Figure 82

On every CD with test material should be a calibration track with a calibration noise.

Choose calibration track, select the channel and click on play.

Change the Amplitude with the left and right arrow buttons until the yellow and one green light of the VU meter lights up (Figure 83). If one or more red lights are on, reduce the amplitude. Store the calibration by clicking ***OK***.

Figure 83

After preparing the test person start the test and proceed as described above.

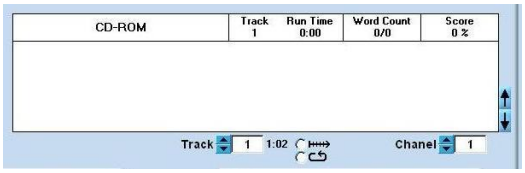
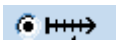


Figure 84

You can choose any track directly by clicking on ***Track*** underneath the CD-ROM list (Figure 84). The length of the track is displayed next to the number.

 Next tracks will be played automatically.

 The chosen track will be repeated automatically.

5.6.3 Edit Mode: Speech Screen

5.6.3.1 General

To enter ***Edit Mode*** click on ***Settings*** / ***View*** / ***Edit*** and save the changes. The ***Edit*** button is displayed in the upper part of the speech screen (Figure 85). Click on the button to activate. Once in ***Edit Mode***, the functions described below may be performed.

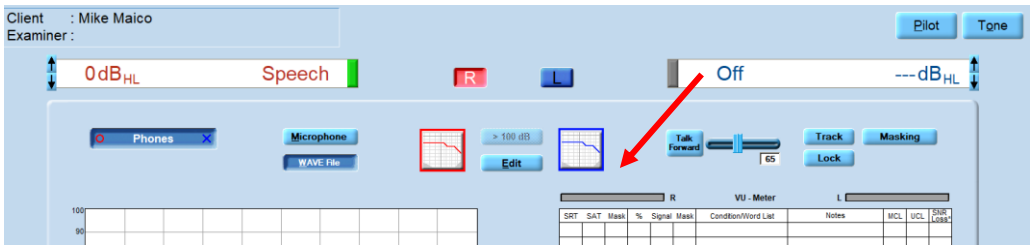


Figure 85

5.6.3.2 Deleting Values in Speech screen

To completely remove a stored value from the speech table, select the row in the table to be deleted by clicking in the “condition/word list” cell of that row. The entire row will highlight blue. Right-click on the mouse on the blue-highlighted cell “condition/word list.” A prompt box will appear asking if the value should be deleted. Click yes or no. Selecting ***Yes***, will permanently remove the data in the blue-highlighted row. Selecting ***No*** will cancel the delete function, but will remain in ***Edit Mode***.

5.6.3.3 Changing Stored Values in the Speech Screen

To change a stored value in the speech table, select the row in the table to be changed by clicking in the “condition/word list” cell of that row. The entire row will highlight blue. Then edit a response answer in the word list and reselect the appropriate word with left mouse click, so as to display the changed response (i.e. highlight from green to red, or from red to green). This amendment will affect a change in the Speech Audiometric Table.

Use the ↑↓cursor keys to change the level of the signal (WRS, MCL, UCL).

Activate the masking button (top right-hand corner of the screen) and use ***Page Up/Page Down*** cursor on the keyboard, to change the level of the masker (SRT or WRS).

5.6.4 Settings – Speech

5.6.4.1 General

The ***Settings*** option allows different settings to be modified for the following: ***View***, ***Counter***, ***Operation***, ***Information***, ***Functionality*** and ***Settings*** (Figure 86).

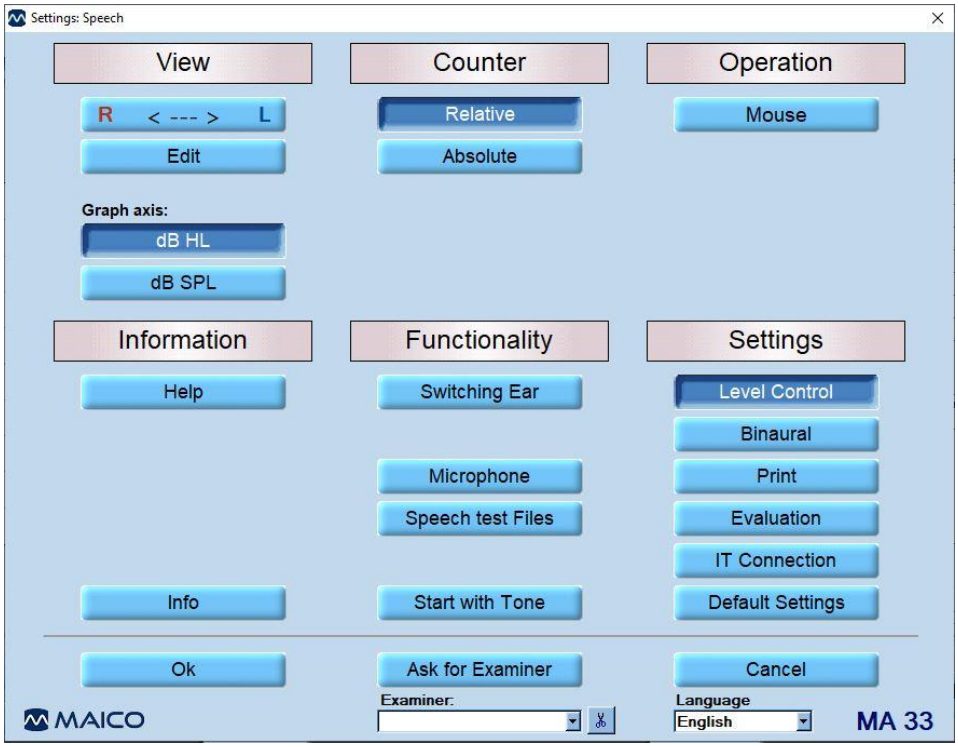


Figure 86

The setting can be changed by clicking on the different setting options. Click ***Ok*** to apply the new setting.

5.6.4.2 View

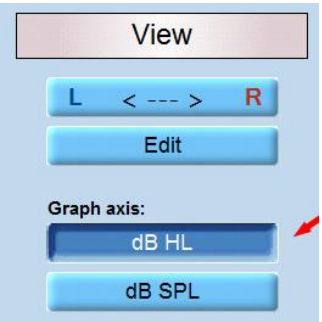


Figure 87

R <---> L: Choose on which side of the screen the right and left channel are to be displayed.

Edit: Activates the ***Edit*** button on the display.

Graph Axis: Choose between ***dB HL*** and ***dB SPL*** (Figure 87). See also Figure 88 and Figure 89.

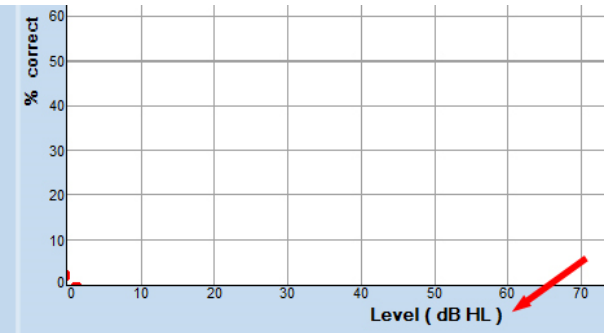


Figure 88

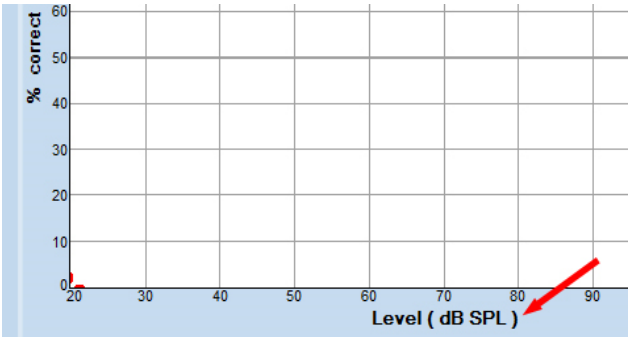


Figure 89

5.6.4.3 Counter

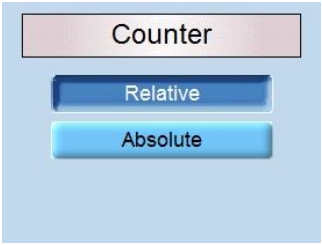


Figure 90

Relative: Displays the correct score result of a word list as a percentage, relative to the number of words presented to the patient.

Absolute: Displays the correct score result of a word list as a percentage, in reference to the absolute (i.e. total) number of words (Figure 90).

5.6.4.4 Operation

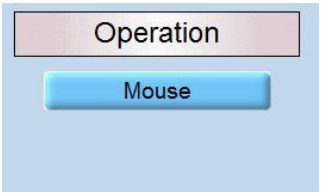


Figure 91

Mouse: once activated, enables the user to control volume setting by using the mouse. Volume is adjusted per mouse by either: clicking on the level in the corresponding audiogram or by pressing the ↕ arrows in the top left-hand corner or top right-hand corner of the screen, depending on the channel (Figure 91).

5.6.4.5 Information

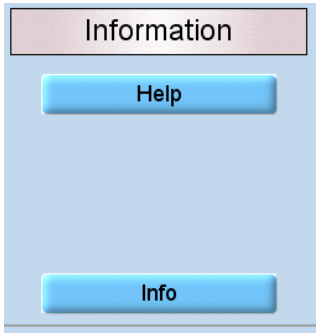


Figure 92

Help: Opens the Operation manual.

Info: Shows information such as serial number and software version (Figure 92).

5.6.4.6 Functionality

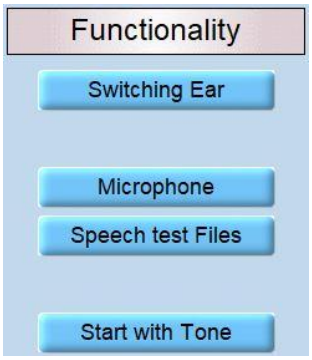


Figure 93

Switching Ear: Activate to ***Keep Level + Noise*** or deactivate to ***Reset Level – Switch Off Noise*** (default) when switching ears (Figure 93).

Microphone: Select a ***Sound device*** and ***Input*** via the drop-down menu and adjust the ***Level*** (Figure 94).

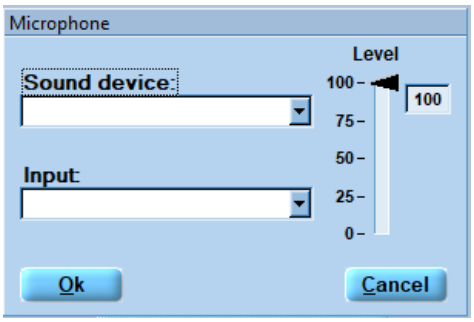


Figure 94

Speech test Files: Opens ***C:\Program Files (x86)\MAICO\MA33*** for selection of a speech test.

Start with Tone: Pressing the ***Start with Tone*** button opens a message box that allows for the selection of the test the programm shall start with (Figure 95).

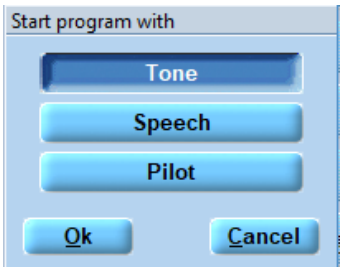


Figure 95

5.6.4.7 Settings

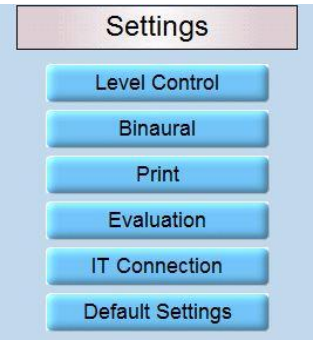


Figure 96

Level Control: (default) when the level control is activated and the examiner changes the level during the speech test, a warning dialog box appears.

Binaural: Binaural measurement can be performed individually or simultaneously.

Print: Offers different print settings such as ***Color*** Print (Standard Setting B/W), ***DIN A5*** (Standard A4) and other print options.

Pressing ***Address/Phone*** opens a window, in which you can enter the data as well as the address and telephone number of the examiner. Note that these are not two separate lines. So first fill in the first line completely and then write on the second line. You can also select an image for the print head from your drive. Activate the ***Header bitmap*** function and load an image for the print head by pressing the ***Load*** button (Figure 97).

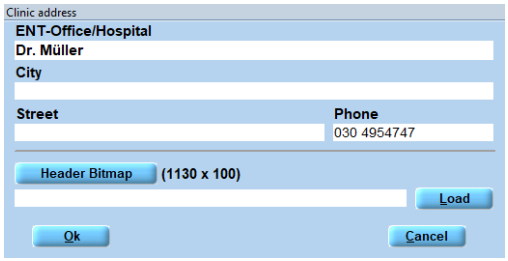


Figure 97

Evaluation: Setting for a pure evaluation workstation (no device check).

IT Connection: Changes the IT Connection. For more details see section 5.5.3.7.

Default Settings: following options are available.

Reset: All individual settings will be removed. Return to default settings (Figure 98).

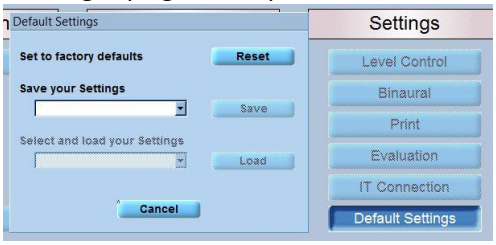


Figure 98

Save: The individual settings can be saved.

Load: The individual settings, that have been saved, can be loaded for using (Figure 98).

5.6.4.8 General Function Keys

shows the General Function Keys of the ***Speech Audiometry*** screen. See Table 15 for an explanation of the buttons.

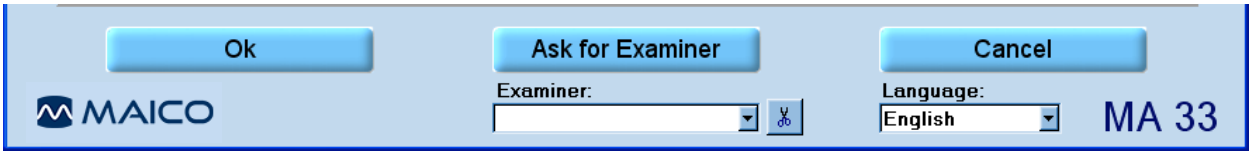


Figure 99

Table 15 Speech Audiometry Screen – Explanation of General Function Keys

Button	Information
OK	By clicking ***OK***, changes will be applied and the program returns to start screen.
Ask for Examiner	In the event that more than one examiner is using the program, each examiner can save his/her customized settings for future use and reference. When the program starts, enter the examiner´s name
Save	Saves current measurement.
Cancel	Returns to start screen without saving the changed settings.
Examiner	Several different settings can be customized and saved for different examiners, should more than one examiner be using the MA 33 program.
Language	Displays current language.

5.7 Pilot Test

5.7.1 General

The Pilot Test is a fast and funny hearing test for children from the age of 2 years on. After a short training the children will play the Pilot game to get the *"Pilot license".* A hearing test of speech recognition is included in the game. Severe hearing impairments can be detected at an early stage.

The child is asked, via headphones, to point to different pictures on the picture board: *„Point to the ball"*! During the following test the degree of difficulty will be increased step by step, as the test level decreases from 70 dB HL to finally 25 dB HL .

The Pilot Test enables to test foreign-language children, as it is available in 26 different languages.

5.7.2 Preparing the Pilot Test

Start the test by clicking the ***Pilot*** button on the start screen. The ***Pilot Test*** screen appears on the display.

Figure 100 shows the test screen for ***International*** program settings (see Section 4.3.2). Test screens for ***Americas***, ***Essilor***, ***Audiofon*** and ***Audioprotesi*** show different test pictures and levels.

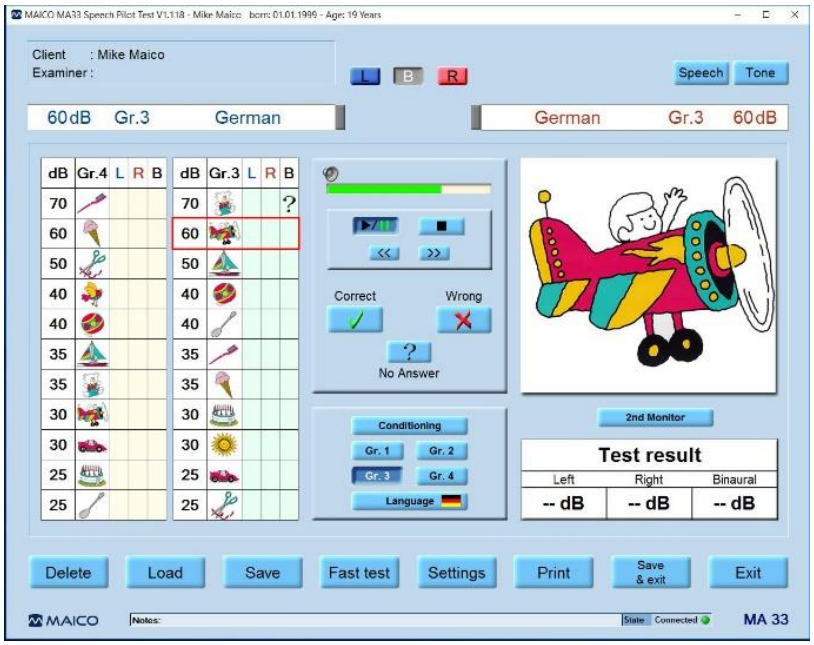


Figure 100

5.7.3 Preparing/motivating the child

Explain the test procedure, e.g. as follows: *„Today you will make the Pilot test and when you participate well, you will get the Pilot license (sticker). The Pilot will ask you to show him a certain picture on this picture board. You will then point to the picture, so that I know you understood him. The Pilot will start out loud and get softer, so you must listen very carefully.“*

The child will first need to learn the correct names for the pictures on the picture board; e.g. *„teddybear“* instead of *“bear“*. For this purpose, you can use the function *„Conditioning“*.

Figure 101 shows the conditioning screen for ***International*** program settings (see Section 4.3.2). Test screens for ***Americas***, ***Essilor***, ***Audiofon*** and ***Audioprotesi*** show different test pictures and levels.

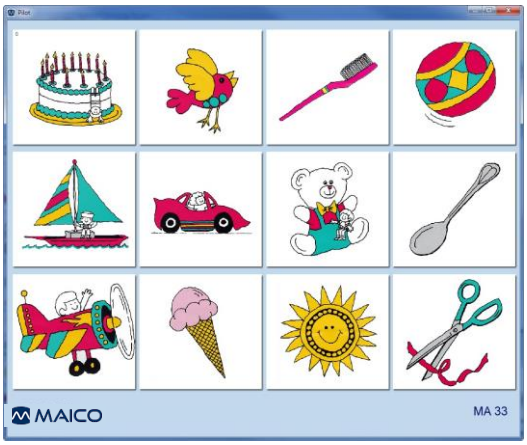


Figure 101

Press the Pilot test ***Start/Pause*** button  to start the training with Group 0. The Pilot test language is displayed as small flag on the language button.

The child will hear the 11 following questions at a constant level of 70 dB. The corresponding pictures will be displayed for approval at the left side of the screen:

- Point to the scissors.
- Where is the teddybear?
- Point to the cake.
- Where is the sun?
- Point to the bird.
- Where is the airplane?
- Point to the toothbrush.
- Where is the sailboat?
- Point to the spoon.
- Where is the ice-cream?
- Point to the ball.

If you are not sure the child knows the words, point to the pictures and call them as they are called on the audiogram cards; e.g. „*teddybear*“ and not „*bear*“. To be sure that the child understands the questions, ask the child to identify the pictures in the same manner as the screening test, i.e. *“Where is the teddybear?“*.

Once you are confident that the child understands the test before all the 11 training words were spoken, you can finish the training by clicking the pilot test ***Start***/***Pause*** button.

After a successful training you can start the pilot hearing test.

5.7.4 Performing the Pilot Test

Please click on the ***Pilot*** button in the start screen to open the pilot test screen. Select a Group of words, e.g. ***Gr. 3***, in order to display the first group of words (Figure 102).

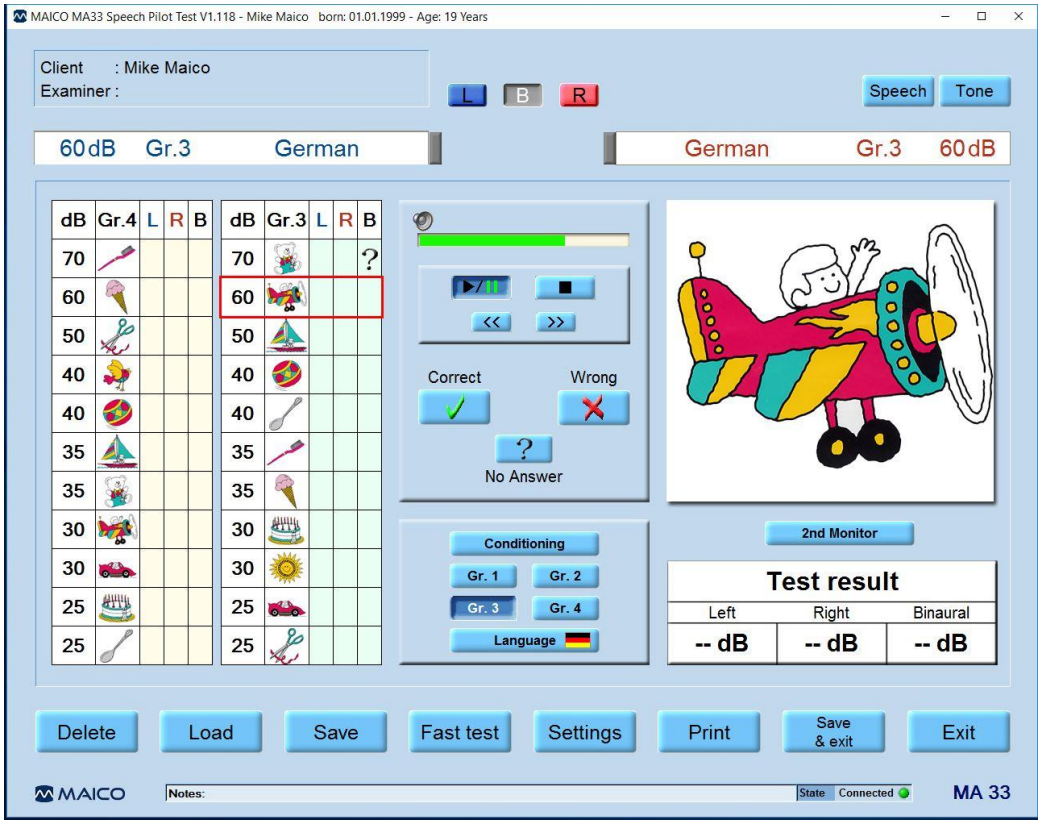


Figure 102

Before beginning the test, select the left, the right or both ears using the buttons R B L.

If you do not preselect one ear, the test starts on the right ear.

Please click the ***Start-/Pause*** ▶/II, in order to start the pilot hearing test. At the right hand side of the screen, the current word is displayed as picture. At the left hand side of the table, the level is displayed beside the small pictures of the current word. The current word is marked with a red frame.

You can interrupt the test at any time by clicking the ***Start-/Pause*** ▶/II button. To restart the test, click the ***Start/Pause*** ▶/II button again.

While the test is running, it is possible to repeat or to skip test sentences by clicking the Forward/Backward-buttons << >>.

The test can be finished at any time by clicking the ***Stop*** ■ button.

The first sentence "*Point to the ball*" will play at a level of 70 dB HL .

If the child points to the picture on the picture board that corresponds to the sentence, the examiner confirms the answer by clicking the ***Correct*** ✓ button. This can be done by a mouse click or by the ***C*** key on the keyboard.

If the answer was wrong, the examiner has to click the ***Wrong*** ✗ button. This can be done by a mouse click or by pressing the ***W*** key on the keyboard.

If there was no response at all, a question mark appears automatically in the table. This question mark appears also, when the examiner clicks the No-answer-button or the ***?***-key on the keyboard.

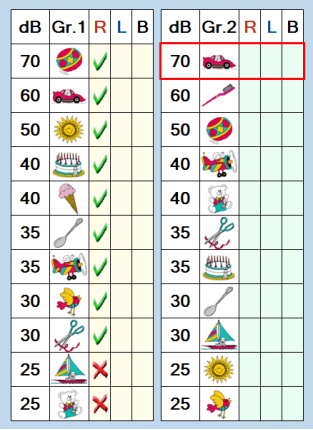


Figure 103

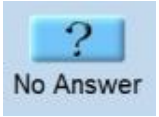
The test will go on to the next sentence *„Where is the car?“* and the volume level decreases to 60 dB HL. The next picture is displayed on the screen. The test will continue with the next words of the Group 1 and decreasing levels.

The results are shown in the table (Figure 103).

The level at which the patient correctly understood the sentence is shown on the display. This level is saved under ***Test result*** beside the respective ear and is displayed on the screen (Figure 77). Instead of the picture board you can also use a touch screen. You can get to the touch screen by clicking on the button ***2nd Monitor*** (Figure 76). It allows answering the test questions by touching the right picture on the screen.

If the little patient touches the correct picture, a green check mark appears in the table.

If the patient touches the wrong picture, a red cross is displayed.



If the child does not touch a picture at all, a question mark is displayed in the table.

Figure 104

Choose a different test group for the second ear, so that the patient does not get too familiar with the test. Do this by clicking on the correspondent ***Group*** button (Figure 104).

There are four different groups of test words/sentences at your d

+isposal.

The test continues after the confirmation of the examiner (correct/incorrect).

The ***interval*** between the sentences can be changed in the Pilot Test settings (see Section 5.7.6.4).

The ***Fast test*** button allows performing a short hearing test, beginning at 40 dB HL (Figure 105).

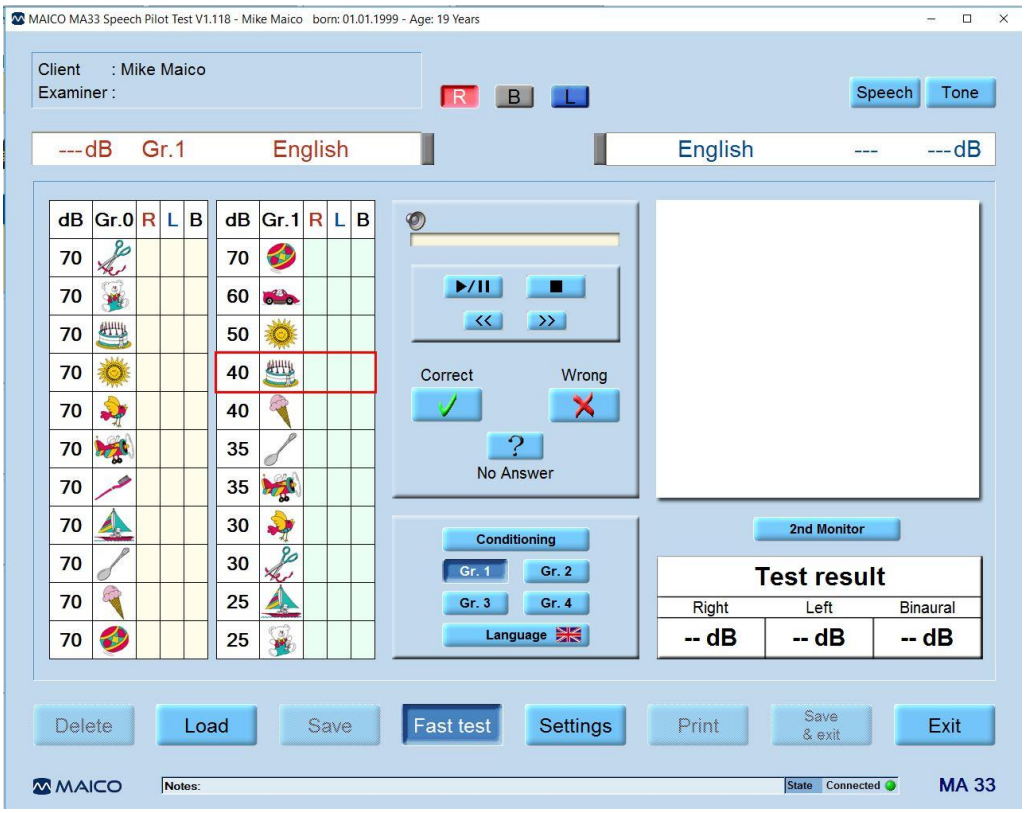


Figure 105

Click on the ***Save*** button in order to save the test results. When you click on the ***Exit*** button, you are asked if you want to save the test results (Figure 106).

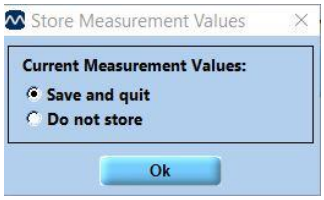


Figure 106

Saved test results can be recalled by clicking the ***Load*** button.

5.7.5 Testing Both Ears (Binaural)

The binaural presentation allows testing both ears at once (binaural). For this purpose, please click on the ***Settings*** button. Select ***Binaural*** in the opening menu. Afterwards, please click on ***OK*** (Figure 107).

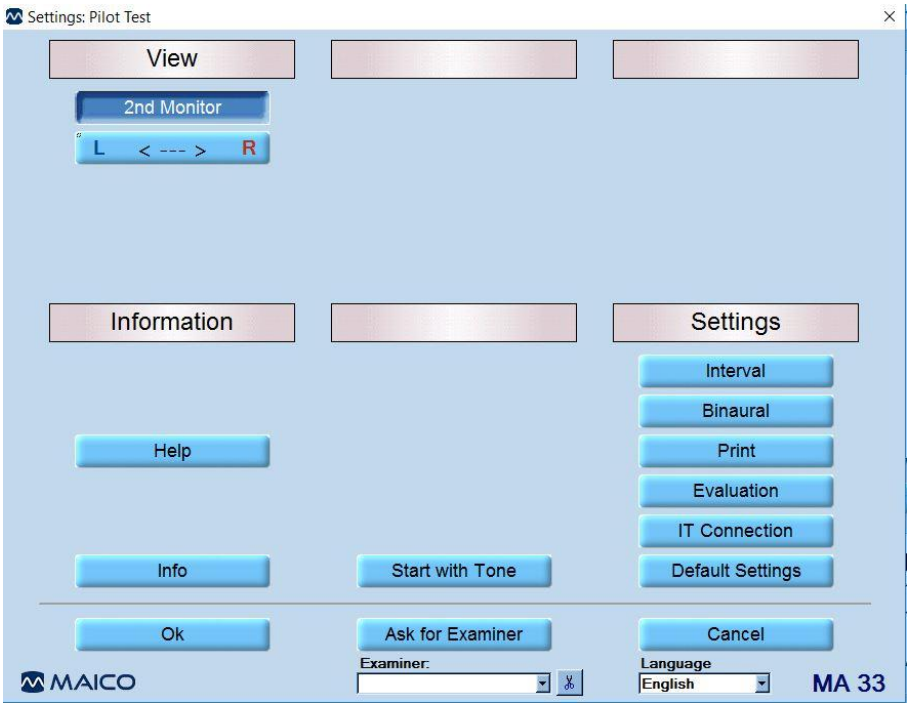


Figure 107

Binaural testing must first be enabled by clicking the ***B*** button in the upper screen. The test will then be presented on both ears (Figure 108).

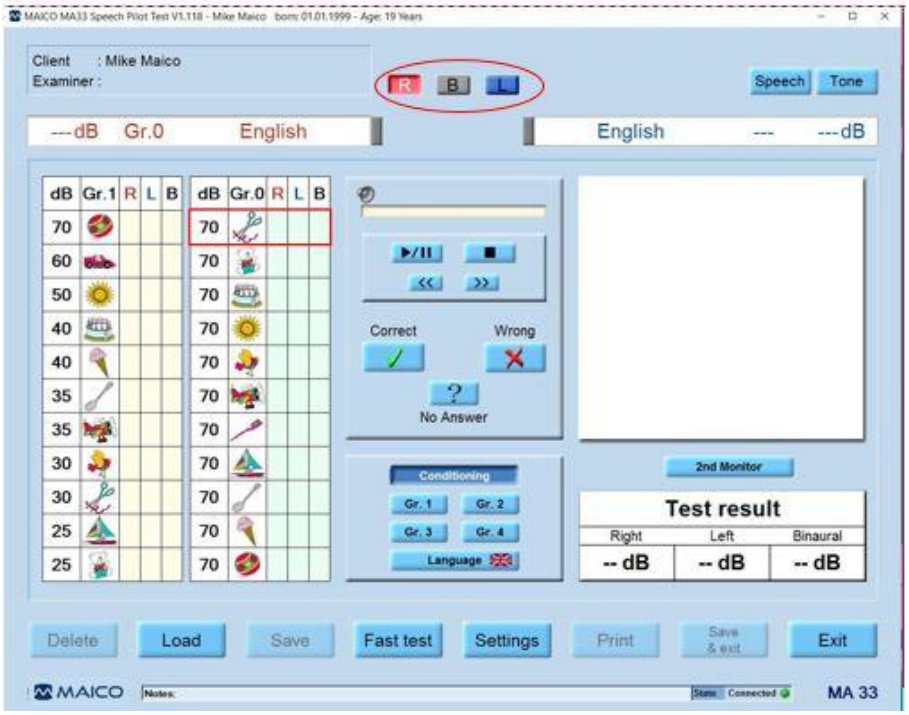


Figure 108

5.7.6 Settings – Pilot Test

The ***Settings*** option allows different settings to be modified for the following: ***View***, ***Information***, and ***Settings*** (Figure 109).

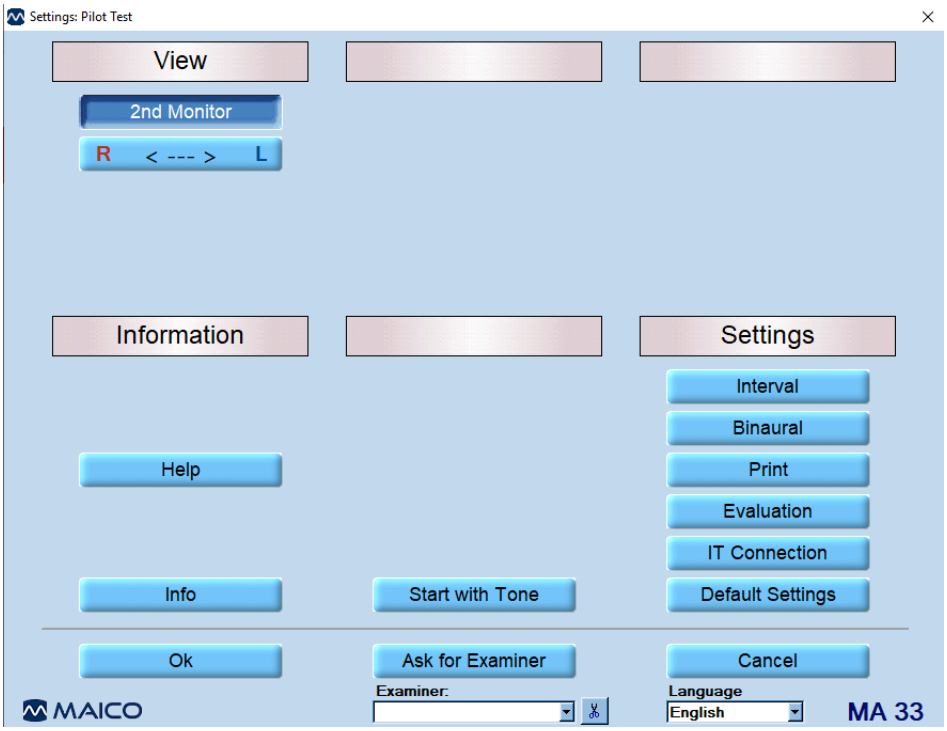
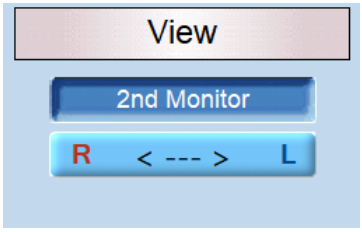


Figure 109

The settings can be changed by clicking on the different setting options. Click ***OK*** to apply the new setting.

5.7.6.1 View

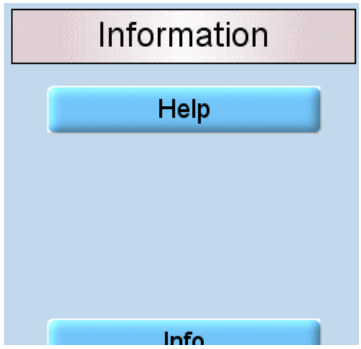


2nd Monitor: Activates the ***2nd Monitor*** button on the screen for touch screen operation (touch screen necessary).

R <---> L: Choose on which side of the screen the right and left channel are to be displayed (Figure 110).

Figure 110

5.7.6.2 Information



Help: Opens the Operation manual.

Info: Shows information such as serial number and software version (Figure 111).

Figure 111

5.7.6.3 Middle Section

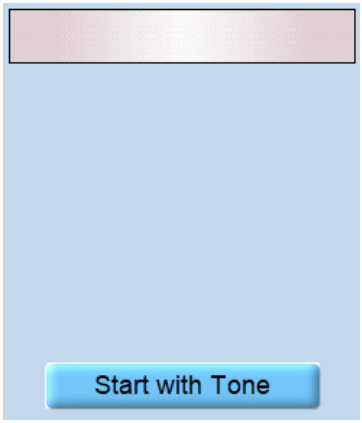


Figure 112

Start with Tone: Pressing the ***Start with Tone*** button opens a message box that allows for the selection of the test the programm shall start with (Figure 112 and Figure 113).

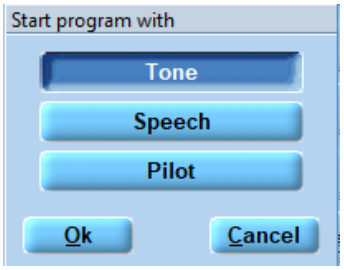


Figure 113

5.7.6.4 Settings

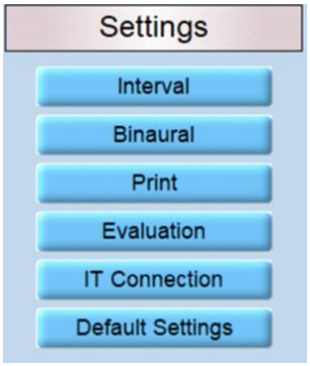


Figure 114

Interval: Defines the pause duration between sentences in the Pilot Test. You can change the pause length between the sentences by selecting the pause length from the drop-down menu ***Interval*** (***3 s*** to ***20 s*** or ***Correct/Incorrect***) in the ***Pilot test*** settings screen (Figure 115 and Figure 116).

Activating the option ***Response while presenting*** allows for confirmation during the presentation of words.

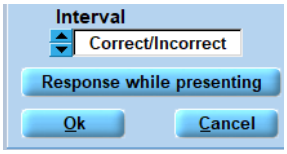


Figure 115

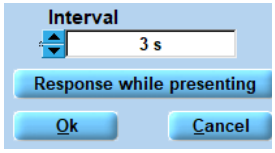


Figure 116

Binaural: Binaural measurement can be performed individually or simultaneously.

Individual to change the levels for the right and left ear individually. Select ***Simultaneous*** if you want the left and right ear levels to match (Figure 117).

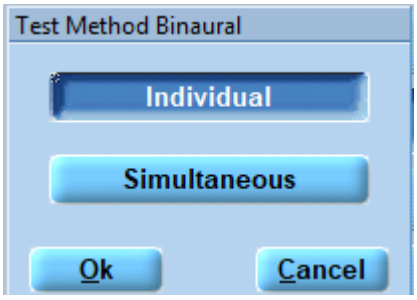


Figure 117

Print: Offers different print settings such as ***Color*** Print (Standard Setting B/W), ***DIN A5*** (Standard A4) and other print options.

Pressing ***Address/Phone*** opens a window, in which you can enter the data as well as the address and telephone number of the examiner. Note that these are not two separate lines. So first fill in the first line completely and then write on the second line. You can also select an image for the print head from your drive. Activate the ***Header bitmap*** function and load an image for the print head by pressing the ***Load*** button (Figure 118).

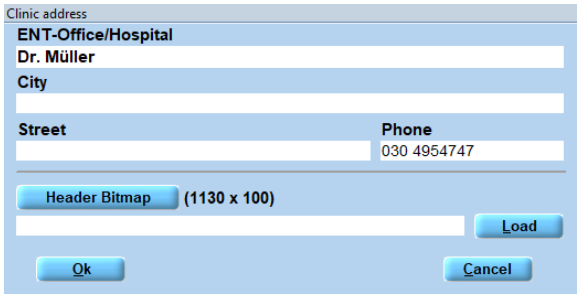


Figure 118

Evaluation: Setting for a pure evaluation workstation (no device check).

IT Connection: Changes the IT Connection. For more details see section 5.5.3.7.

5.7.6.5 General Function Keys

Figure 112 shows the general function keys. See Table 16 for explanation.

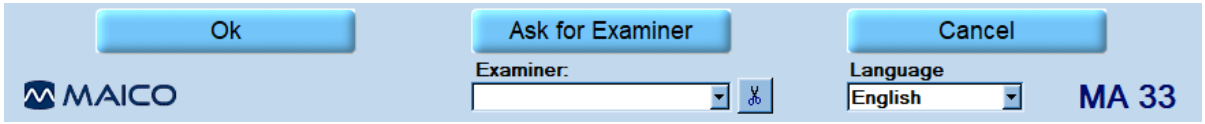


Figure 119

Table 16 Explanation of Function Keys

Button	Function
Ok	By clicking ***Ok***, changes will be applied and the program returns to the start screen.
Ask for Examiner	In the event that more than one examiner is using the program, each examiner can save his/her customized settings for future use and reference. When the program starts, enter the examiner´s name.
Cancel	Returns to start screen without saving the changed settings.
Examiner	Several different settings can be customized and saved for different examiners, should more than one examiner be using the MA 33 program.
Language	Displays current language.

6 Technical Specifications

This section offers you important information about

- **the MA 33 hardware and software specifications**
- **connections**
- **the pin assignment**
- **immittance and audiometry calibration values**
- **electromagnetic compatibility (EMC)**
- **electrical safety, EMC and associated standards**

6.1 MA 33 Hardware and Software

CE 0123

The MA 33 is an active, diagnostic medical product according to class IIa of the Medical Device Regulation (EU) 2017/745.

General Information About Specifications

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

MAICO Diagnostics provides circuit diagrams and service manuals to authorized service centers.

STANDARDS	
Safety Standards	IEC 60601-1:2005+AMD1:2012+AMD2:2020, Type B applied parts The protection class according EN 60601-1 depends on the used computer (USB connection).
EMC Standard	IEC 60601-1-2:2014+AMD1:2020
Audiometer Standards	Tone: IEC 60645-1:2017/ANSI S3.6-2010 Type 4 (Air Conduction only)/Type 3 (with Bone) Speech Functionality: The MA 33 does not meet all requirements for Speech of IEC 60645-1:2017/ANSI S3.6-2010.
Calibration	ISO 389-1:2017 (Reference equivalent threshold sound pressure levels for pure tones and supra-aural earphones) ISO 389-3:2016 (Reference equivalent threshold sound pressure levels for pure tones and bone vibrators) ISO 389-4:1994 (Reference levels for narrow-band masking noise)

DEVICE SPECIFICATIONS

Environmental conditions 	Operation	Temperature: +15 °C to +35 °C / +59 °F to +95 °F Humidity: 30% – 90%, non-condensing Ambient pressure: 98 kPa to 104 kPa
	Storage	Temperature: 0 °C to +50 °C / +32 °F to +122 °F Humidity: 10% – 95%, non-condensing
	Transport	Temperature: -20 °C to +50 °C / -4 °F to +122 °F Humidity: 10% – 95%, non-condensing
Altitude Rating	Max operating altitude 2000 m / 6561 ft above sea level	
Weight	300 g	
Dimensions	W x D x H: 154 mm x 103 mm x 27 mm (6.1 in x 4.1 in x 1.1 in)	
Warm-up Time	Approx. 1 minute (incl. boot-up time)	
Mode of Operation	Continuous	
User Interface	PC-based audiometer	
Language Settings	German, English, French, Italian, Spanish, Netherlands, Polish	

AUDIOMETRY

Patient response switch	One push button	
Patient communication	Talk Forward (optional, PC only)	
Masking signals	Narrowband noise masking for tone: with the same center frequency resolution as pure tone Speech noise for speech: 12 dB/octave above 1 kHz (± 5 dB), manually or automatically adjustable Tone: Effective Masking: ISO 389-4, ANSI S3.6 Speech: Selectable effective masking or SPL	
Air Conduction	DD45:	MAICO Standard Values
	DD45 HB-7:	MAICO Standard Values
	DD65 v2:	MAICO Standard Values
Bone Conduction	B71W	ISO 389-3, ANSI S3.6, Mastoid Placement
Transducers – Headband tension	DD45	Headband Static Force 4.5 N ± 0.5 N
	DD45 with HB-7:	Headband Static Force 4.5 N ± 0.5 N
	DD65 v2:	Headband Static Force 10.0 N ± 0.5 N
	B71W	Headband Static Force 5.4 N ± 0.5 N
Tone Audiometry		
Tone Tests	HL, MCL, UCL, Stenger, PTA, SISI Hughson-Westlake (option): Time window (Pause) selectable between 0.5 s and 3.5 s, 5 dB steps (increase)/10 dB (decrease)	
Selection	PTA, selectable frequencies	
Inputs	Sinus or warble tone (pulsed and continuous)	
Outputs	Left, Right, Bone (L+R)	
Accuracy	Frequency ± 2 %, Level ± 3 dB	

AUDIOMETRY

Stimuli	
Tone	AC: 125 Hz to 8000 Hz BC: 250 Hz to 6000 Hz
Warble Tone	5 Hz sine ± 5 % modulation
Pulse Tone	Pulse Length: 250 ms
Presentation	Presenter or Interrupter
Intensity	AC: -10 dB HL to 105 dB HL, BC: -10 dB HL to 75 dB HL Available Intensity steps: 5 dB Safety limit: Intensity > 70 dB HL
Frequency range	AC: 125 Hz to 8000 Hz, BC: 250 Hz to 6000 Hz
Calibration	Calibration information and instructions are located in the MA 33 Service Manual.
Speech Functionality	
Speech Functionality	SRT, SAT, WRS, MCL, UCL, Stenger
Speech Signals	Microphone, WAVE files or CD-ROM
Speech Intensity Range	AC: -10 dB HL to 90 dB HL, user interface limited from 0 dB HL to 90 dB HL instead of -10 dB HL to 100 dB HL according to IEC 60451-1:2017 5 dB intensity steps
Pilot Test	
Intensity Range	AC: 25 dB HL to 70 dB HL; 5 dB intensity steps
Test Languages	International configuration: Afrikaans, Arabic, Basque, Catalan, Croatian, Czech, Danish, Dutch, English, Finnish, French, Galician, German, Greek, Hungarian, Italian, Japanese, Korean, Norwegian, Polish/Polish (Audifon), Portuguese, Romanian, Russian, Serbian, Slovakian, South Sotho, Spanish, Swedish, Swiss German, Turkish, Vietnamese, Xhosa, Zulu US configuration: English (US) and Spanish (US)
SISI Test	
Test signal Modulation	4.8/0.2 s; 1 dB (test) 4.8/0.2 s; 4.8/0.2 s; 5 dB, 3 dB, 2 dB (preparation)

PC REQUIREMENTS

Operating system	Windows® 11 64-bit
Processor	Intel Core i5, i7
Memory	8 GB RAM
Graphic display	1280 x 1024 (optimal), min. 1024 x 768
Data Connection	USB
Silent PC for use in audiometric room	

6.2 Calibration Values and Maximum Levels

6.2.1 Calibration Values and Maximum Levels – Air Conduction

Calibration values and Max Levels: Headphone DD45

Coupler IEC 60318-3, Force 4-5 N, PTB-DTU Report 2009-2010

Frequency [Hz]	Tone RETSPL dB re 20µPa	NBN RETSPL dB re 20µPa	Max Tone [dB HL]	Max NBN [dB HL]	SOUND ATTENUA-TION [dB] ISO 4869-1
125	47.5	51.5	70	60	3
250	27.0	31.0	90	80	5
500	13.0	17.0	100	90	7
750	6.5	11.5	105	95	-
1000	6.0	12.0	105	95	15
1500	8.0	14.0	105	95	-
2000	8.0	14.0	105	95	26
3000	8.0	14.0	105	95	-
4000	9.0	14.0	105	95	32
6000	20.5	25.5	95	85	-
8000	12.0	17.0	90	80	24

Signal	IEC 60645-1 RETSPL	IEC Max Level [dB HL]	ANSI S3.6 RETSPL	ANSI Max Level [dB HL]
Speech	20.0	90.0	18.5	90.0
Speech Noise	20.0	80.0	18.5	80.0

Calibration values and Max Levels: Headphone DD65 v2

Coupler IEC 60318-1, PTB Report 2018, AAU Report 2018

Frequency [Hz]	Tone RETSPL dB re 20µPa	NBN RETSPL dB re 20µPa	Tone Max Level [dB HL]	Max NBN [dB HL]	Sound Attenuation [dB] ISO 4869-1
125	30.5	34.5	70	60	8.3
250	17.0	21.0	90	80	15.5
500	8.0	12.0	100	90	26.1
750	5.5	10.5	105	95	-
1000	4.5	10.5	105	95	32.4
1500	2.5	8.5	105	95	-
2000	2.5	8.5	105	95	43.6
3000	2.0	8.0	105	95	-
4000	9.5	14.5	105	90	43.8
6000	21.0	26.0	95	80	-
8000	21.0	26.0	90	75	45.6

Signal	IEC 60645-1 RETSPL	IEC Max Level [dB HL]	ANSI S3.6 RETSPL	ANSI Max Level [dB HL]
Speech	20.0	75.0	17.0	80.0
Speech Noise	20.0	70.0	17.0	75.0

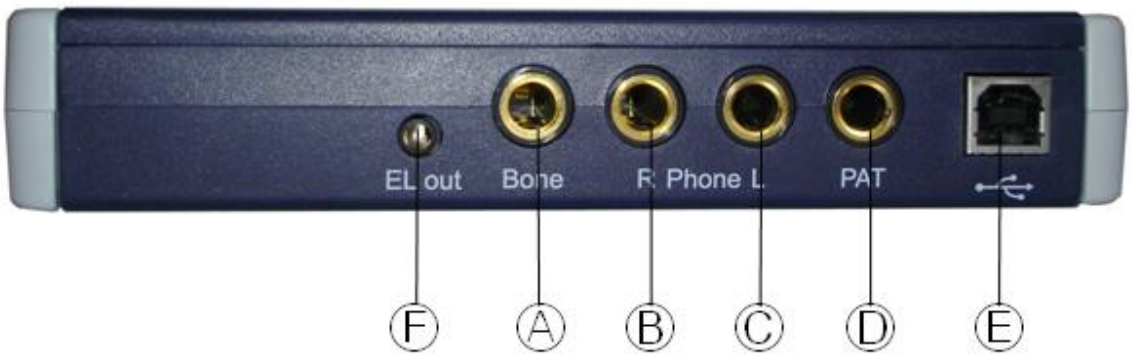
6.2.2 Calibration Values and Maximum Levels – Bone Conduction (MA 33 BC)

Calibration values: Bone Conduction Headphone Radioear B71W
Force: 4.9 ... 5.9 N Mastoid placement

Coupler IEC 60318-6, ANSI 3.6-2010 and ISO 389-3

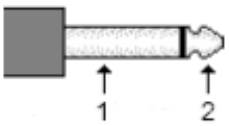
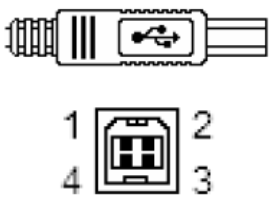
Frequency [Hz]	Reference equivalent threshold force level for tone	Air radiation*	Max level
	[dB] (re 1µN)	Average/ Max. [dB]	Tone [dB HL]
250	67.0	-	35
500	58.0	-	60
750	48.5	-	65
1000	42.5	-	70
1500	36.5	-	70
2000	31.0	-	70
3000	30.0	4/18	70
4000	35.5	-	70
6000	40.0	10.5/31	45

6.3 Connections



Connection Port		Connection Specification
A	Bone Conduction Headphone	Z_A = 10 Ω, U_A = 2 V_{rms}
B, C	Air Conduction Headphone L/R	Z_A = 10 Ω, U_A = 2 V_{rms}
D	Patient Response Switch	R_I = 500 Ω
E	PC Connection	1 x USB port
F	Connector not used	

6.4 Pin Assignment

Socket	Connector	Pin 1	Pin 2
A to D	 6.3 mm	Ground	Signal
E		1 +5 VDC 2 Data - 3 Data + 4 Ground	

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+AMD1:2020, emission class B group 1.

NOTICE: There are no deviations from the collateral standard and allowances uses

NOTICE: All necessary instruction for maintaining compliance with regard to EMC can be found in the general maintenance section in this instruction. No further steps required.

NOTICE: If Non-Medical Electronic Equipment (typical information technology equipment) is attached, it is the responsibility of the operator to ensure that this equipment comply to applicable standards and the system as whole complies to the EMC requirements. Commonly used standards for EMC testing information technology equipment and similar equipment[1] are:

Emissions testing	
EN 55032 (CISPR 32)	Electromagnetic compatibility of multimedia equipment - Emission requirements
EN 61000-3-2	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤16 A per phase)
EN 61000-3-3	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection)
Immunity testing	
EN 55035 (CISPR 35)	Electromagnetic compatibility of multimedia equipment — Immunity requirements

[1] Products include personal computer, PC, tablet, laptop, notebook, mobile device, PDA, Ethernet hub, router, WiFi, computer peripheral, keyboard, mouse, printer, plotter, USB storage, Hard drive storage, solid-state storage and many more.

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 Headphones	Radioear	DD45
Audiometric Headphones	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 Headphones	2.0	Yes
Patient response switch	2.0	Yes

Electromagnetic Compatibility (EMC)

Portable and mobile RF communications equipment can affect the ***MA 33.*** Install and operate the ***MA 33*** according to the EMC information presented in this chapter.
The ***MA 33*** has been tested for EMC emissions and immunity as a standalone ***MA 33.*** Do not use the ***MA 33*** adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.
The use of accessories, transducers and cables other than those specified, with the exception of servicing parts sold by MAICO as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device.
Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

Guidance and manufacturer's declaration - electromagnetic emissions		
The *MA 33* is intended for use in the electromagnetic environment specified below. The customer or the user of the *MA 33* should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The *MA 33* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The *MA 33* is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Recommended separation distances between portable and mobile RF communications equipment and the *MA 33*.			
The *MA 33* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *MA 33* can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *MA 33* as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.17\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note 1** At 80 MHz and 800 MHZ, the higher frequency range applies. **Note 2** These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The *MA 33* is intended for use in the electromagnetic environment specified below. The customer or the user of the *MA 33* 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%.
Immunity to proximity fields from RF wireless communications equipment IEC 61000-4-3	Spot freq. 385-5.785 MHz Levels and modulation defined in table 9	As defined in table 9	RF wireless communications equipment should not be used close to any parts of the *MA 33*.
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	Not applicable +1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	+1 kV Line to line +2 kV Line to earth	Not applicable	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	0% *U*T (100% dip in *U*T) for 0.5 cycle, @ 0, 45, 90, 135, 180, 225, 270 and 315° 0% *U*T (100% dip in *U*T) for 1 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles 0% *U*T (100% dip in *U*T) for 250 cycles	Not applicable	Mains power quality should be that of a typical commercial or residential environment. If the user of the *MA 33* requires continued operation during power mains interruptions, it is recommended that the *MA 33* 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.
Radiated fields in close proximity — Immunity test IEC 61000-4-39	9 kHz to 13.56 MHz. Frequency, level and modulation defined in AMD 1: 2020, table 11	As defined in table 11 of AMD 1: 2020	If the *MA 33* contains magnetically sensitive components or circuits, the proximity magnetic fields should be no higher than the test levels specified in Table 11
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The *MA 33* is intended for use in the electromagnetic environment specified below. The customer or the user of the *MA 33* 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 *MA 33,* 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 (and amateur radio bands for Home Healthcare environment.)	3 Vrms 6 Vrms	$d = \frac{3,5}{Vrms}\sqrt{P}$
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,7 GHz 10 V/m 80 MHz to 2,7 GHz Only for Home Healthcare environment	3 V/m 10 V/m (If Home Healthcare)	$d = \frac{3,5}{V/m}\sqrt{P}$ 80 MHz to 800 MHz $d = \frac{7}{V/m}\sqrt{P}$ 800 MHz to 2,7 GHz
			Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *MA 33* is used exceeds the applicable RF compliance level above, the *MA 33* should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *MA 33.* **b)** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

6.6 Electrical Safety, EMC and Associated Standards

1. IEC 60601-1:2005+AMD1:2012+AMD2:2020: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2. ANSI/AAMI ES60601-1:2005+A2:2010+A1:2012: Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
3. CAN/CSA-C22.2 No. 60601-1:14: Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
4. IEC 60601-1-6:2010+AMD1:2013+AMD2:2020: Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability
5. IEC 62368-1:2018: Audio/video, information and communication technology equipment - Part 1: Safety requirements
6. IEC/EN 60601-1-1: General requirements for safety; Collateral standard: Safety requirements for medical electrical systems
7. IEC 60601-1-2:2014+AMD1:2020: Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and tests
8. ISO 14971 - Application of risk management to medical devices
9. Essential Requirements of the current European Union Medical Device Directive 93/42/EEC General Safety and Performance Requirements of the current REGULATION (EU) 2017/745
10. 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
11. DIRECTIVE 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)

6.7 Checklist for Subjective Audiometer Testing

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

Test Signal Quality

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

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

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

Air Conduction Audiogram

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

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

Bone Conduction Audiogram

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

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

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

Specifications are subject to change without notice.

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