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MAICO Diagnostics GmbH Sickingenstr. 70-71 10553 Berlin Germany

Tel.: + 49.30.70 71 46-50 Fax: + 49.30.70 71 46-99 E-mail: sales@maico.biz Internet: www.maico.biz

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## Compliance

MAICO Diagnostics is an ISO 13485 certified corporation.

# 1 Introduction

#### 1.1 General

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

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

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

**NOTE**: Figures shown in the operation manual are exemplary and may vary depending on the device used.

The MAICO Audiometry Module is capable of showing measurements of:

- Pure Tone Audiometry
- Speech Audiometry
- Short Increment Sensitivity Index (SISI)
- Decay
- Alternate binaural loudness balance (ABLB)

The MAICO Audiometry Module can be run with the following MAICO devices:

- MA 25e
- MA 27e
- MA 28
- MA 41
- MA 42
- touchTymp

The MAICO Audiometry Module is meant to be run with and started from one of the following databases:

- MAICO Database
- Noah
- Practice Management Software (via BDT/GDT-interface, only for Germany, Austria and Switzerland)

**NOTE**: Installation procedure and operation of the MAICO Database is also described in this Operation Manual (see sections 2.1 and 3.1.2).

# 1.2 PC and System Requirements

## **System Requirements**

**NOTE**: You need administrator privileges to install the MAICO Audiometry Module.

The MAICO Audiometry Module can be run under the following systems:

- Windows 10
- Windows 8
- Windows 7
- Preinstalled Medical Practice Software with BDT/GDT Interface
- Preinstalled .NET Framework 3.5 SP1 or higher



If the .NET Framework is not installed, yet, a message box will be shown asking you to install it (Figure 1).

Figure 1

To install it enter system control → Programs → "Turn Windows features on or off" and select the checkbox for .NET Framework 3.5 SP1 (Figure 2).

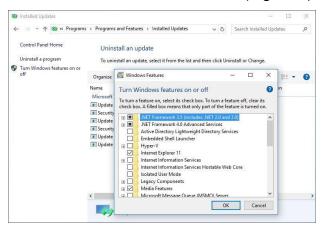


Figure 2

#### **PC-Requirements**

The minimum PC-requirements are as follows:

- CPU: Pentium 4 Processor
- Memory: 1 GB
- Graphic Display: ≥ 1024\*768
- USB Port 2.0
- CD- or DVD-ROM Drive

#### **Needed Components**

The following components are needed to run the MAICO Audiometry Module:

USB cable

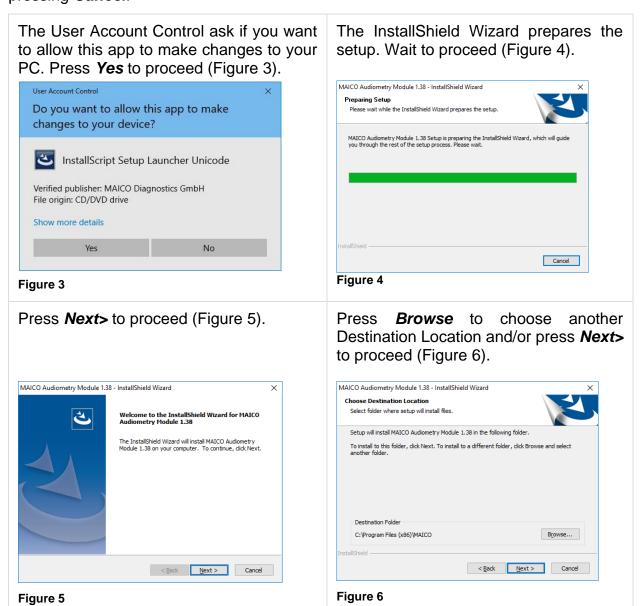
# 2 Installation

# 2.1 Starting the installation Process

**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 MAICO Audiometry Module, the MAICO Database will automatically be updated. It is recommended to make a backup of the client data prior to initiating the installation process.

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



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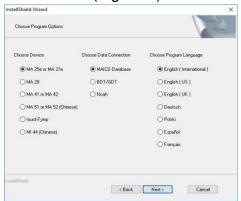


# 2.2 Choose Program Options

Choose the program options for the device, the data connection and program settings:

- **Choose Device**: Choose one of the offered devices (Figure 7).
- Choose Data Connection:
  - **MAICO Database:** The setup for the MAICO database will be started with the setup of the MAICO Audiometery Module. In case an older version of the database is already installed, the setup will update the database. Is the same version already installed, a message box for repair or remove (Figure 8) will appear. For reinstallation refer to section 2.3.
  - o BDT/GDT: allows the connection of the MAICO Audiometry Module to your existing practice management software.
  - Noah: Connects the MAICO Audiometry Module to Noah.

• Program Settings: sets the program option for operating the MAICO Audiometry Module (Figure 7).



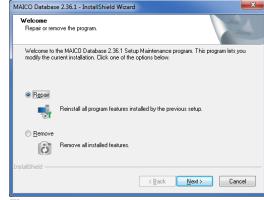
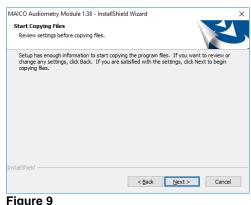


Figure 7

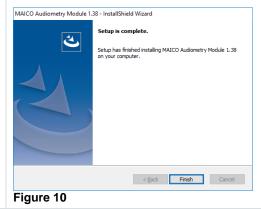
Figure 8

**NOTE**: The choice of a device or program setting will be set as default. Nevertheless, it is possible to switch the device afterwards (see section 3.7.3).

Press **Back** if a review or change of the settings is wanted. Press Next> to proceed (Figure 9). MAICO Audiometry Module 1.38 - InstallShield Wizard



Setup of the MAICO Audiometry Module is complete. Press *Finish* to complete the installation (Figure 10).



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



#### 2.3 Reinstallation

NOTE: In case the MAICO Audiometry Module 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 MAICO Audiometry Module 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 11). Select one of the options to proceed.

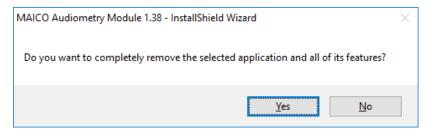
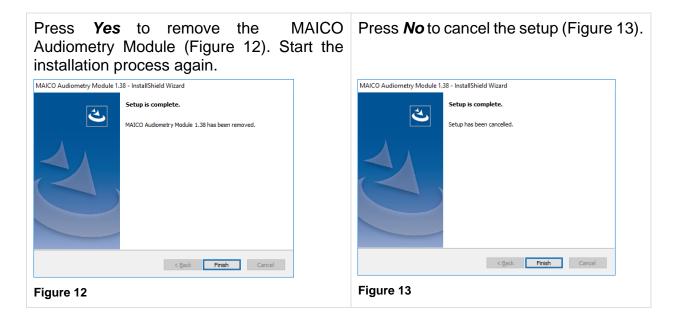


Figure 11



#### 2.4 Database Connection

#### 2.4.1 Connection to MAICO Database

The connection to the MAICO database is made automatically during installation (See section 2.2).

#### 2.4.2 Connection to Noah

Noah has to be installed prior to installation of the MAICO Audiometry Module.



## 2.4.3 Connection to Practice Management Software

The MAICO Audiometry Module can be connected with the practice management software via the BDT/GDT Interface.

Open the **Settings** menu and select **IT-**Browse in the fields Import path and file OAS Connection (Figure 14). --->MAICO and Export path and file MAICO ---> OAS (1) to select the exchange data for the data based communication with the Practice Management Software. Changes will be activated after restart of program. 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* (2) (Figure 15). IT Connection
Import path and file OAS ---> MAICO\* MAICO Audiometry Module V1.45 - Max Mustermann born: 02.( Export path and file MAICO ---> OAS\* <u>Audiogram Settings Previous Sessions! Info!</u> Examiner: A Diagram settings LEFT Printer Settings \*Changes will be activated after restart of progra Device Type -- Hz C:\ProgramData\MAICO\Daten Connection to Device IT-Connection -10 Ok Program language 0 Figure 15 10 20 Figure 14

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# 3 Working with the MAICO Audiometry Module

# 3.1 Starting the MAICO Audiometry Module

#### 3.1.1 General

The MAICO Audiometry Module is started from the connected database (MAICO Database, Noah or Practice Management Software). See the instructions in section 3.1.2 for MAICO Database, section 3.1.3 for Noah or section 3.1.4 for Practice Management Software.

## 3.1.2 Starting the MAICO Audiometry Module from the MAICO Database

#### 3.1.2.1 General

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

NOTE: The MAICO Database cannot be accessed while working with the Audiometry Module. Close the MAICO Audiometry Module to access the MAICO Database.

## 3.1.2.2 Starting the MAICO Database

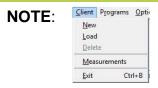
Click on the icon to open the MAICO database. The main screen of the database will be displayed (Figure 16).



Figure 16

#### 3.1.2.3 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. \_\_\_\_\_\_ or \_\_\_\_ or \_\_\_\_\_ ).



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



#### 3.1.2.4 Menu Items and Buttons

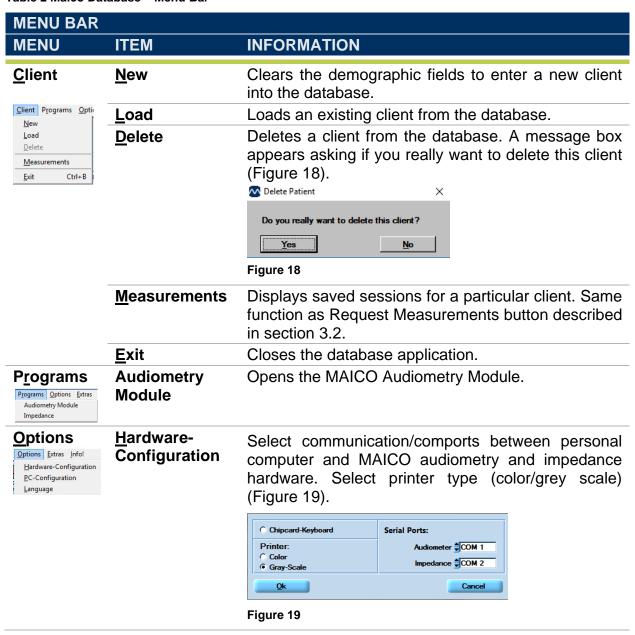
The buttons on the screen are described in Table 1.

Table 1 Maico Database - Buttons

<b>BUTTON SE</b>	ELECTION
BUTTON	INFORMATION
<u>S</u> earch	Displays list of patients saved within the Database.
<u>M</u> easurements	Displays list of saved test for the selected patient.
S <u>a</u> ve	Saves patient demographic information entered.

The items offered in the Menu bar are described in Table 2.

Table 2 Maico Database - Menu Bar



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## **MENU BAR MENU ITEM INFORMATION** PC-To network the database. If so, enter the pathway for Configuration the database in the **Device** field and click **Ok** (Figure 20). PC-Configuration C Network Browse Qk Figure 20 **E**xtras New Program Select to add a module into the database.



1. The following window will appear (Figure 21):

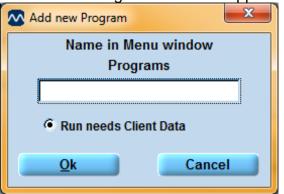


Figure 21

- 2. Type name of program as it should appear in the Programs menu and click OK.
- 3. The following window will appear (Figure 22). Open the AudiometryModule folder and select the "AudiometryModule.exe" file for the program that is being added to the database. Click **OK** (Figure 23).

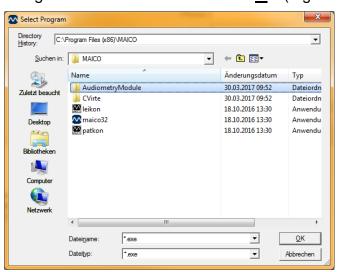


Figure 22



#### **MENU BAR MENU ITEM INFORMATION**

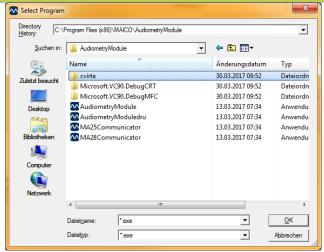


Figure 23

4. The following window will appear. If an argument for the program is required, enter the code here and click **OK** (Figure 24).

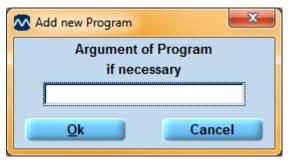


Figure 24

## **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).

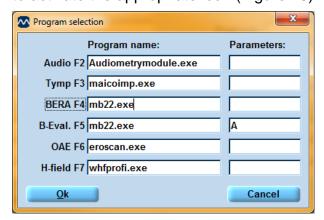
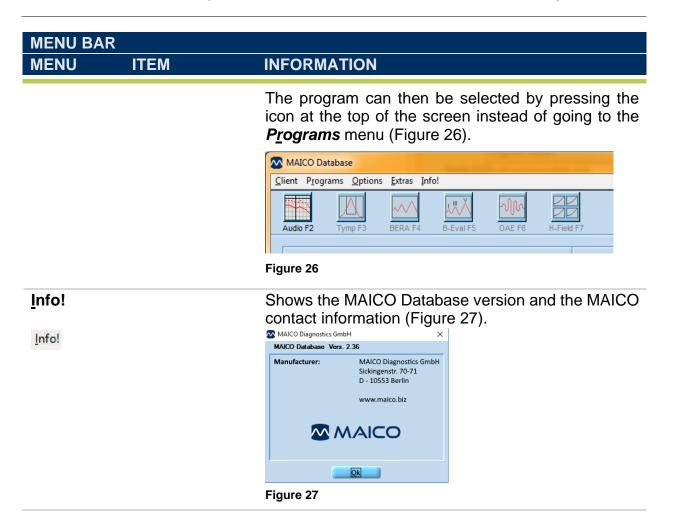


Figure 25



## 3.1.2.5 Selecting a Client in the MAICO Database

Enter a new client or select an existing client prior to starting the MAICO Audiometry Module.

#### **Enter a New Client**

Select <u>Client</u> – <u>New</u> to clear the demographic fields to enter a new client into the database. Enter the client's demographic information and click <u>Save</u>. The following fields have to be entered: <u>Surname</u>, <u>Firstname</u>, <u>Birthday</u>, and <u>Sex</u>. Otherwise it is not possible to save the data or proceed to the MAICO Audiometry Module. 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*.

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## Select an Existing Client

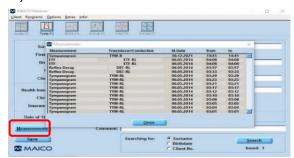
Use the **Search** button to choose an existing client. This will display a list of clients which are already in the database. Narrow the search by typing information into one of the demographic fields (1) and then selecting a search category (2): **Surname**, **Birthday**, or **Client-No.** (Figure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



Figure 29

Figure 30

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.



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

Figure 31



Figure 32

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

#### Changing a client



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 (Figure 33). Select **New client** to save a new client or **Change Client Data** to make changes. Press **Cancel** to go back to the main screen.

Figure 33

## 3.1.2.6 Starting the MAICO Audiometry Module

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

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## 3.1.3 Starting the MAICO Audiometry Module from Noah

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

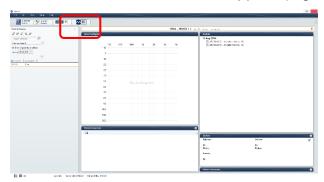


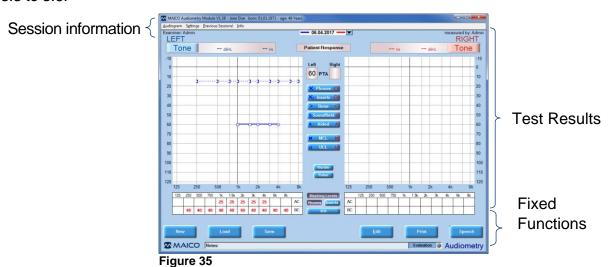
Figure 34

## 3.1.4 Starting the MAICO Audiometry Module from Practice Management Software

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

## 3.2 Screen Areas of MAICO Audiometry Module

Table 3 to 5 give explanation to the Screen Areas **Session Information**, **Fixed Functions** and **Test Results** (Figure 35). Information on the different test screens are given in section 3.3 to 3.6.



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#### **Table 3 Session Information**

SESSION INFORMATION ITEM	INFORMATION
MAICO Audiometry Module V1.38 - Jane Doe born: 01.01.1970 - age: 47 Years     Figure 36	Shows the name of the software, the client's first and surname, birthday and age (Figure 36).
Examiner: Admin measured by: Admin Figure 37	Shows the current examiner's name and name of the examiner, which actually made the measurements (Figure 37).
— 06.04.2017 — ▼ — 06.04.2017 — ▼	Shows the date of the measurement. Furthermore you can add different measurements and see the date of the measurement with a different color. The audiogram shows the different measurements also with the related color.

**Table 4 Fixed Functions** 

Request Measurement

# **FIXED FUNCTIONS** ITEM/BUTTON **INFORMATION** To reset the screen and delete the current measurements. New Load

To view all existing measurements for the selected patient. To select a specific measurement, use the vertical arrow keys on the keyboard, or the mouse and click *Enter* on the keyboard, doubleclick with the mouse or press the **Load** button (Figure 38).

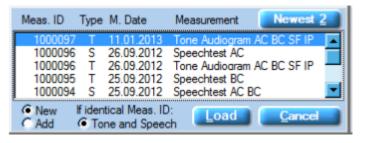
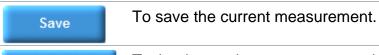


Figure 38



To load saved measurements with MA 25e, MA 27e or MA 28. (Figure 39).

Data transfer is running Please wait . . .

Figure 39



## **FIXED FUNCTIONS**

## ITEM/BUTTON INFORMATION



The **Edit** button enables the different options for the different devices (refer to table 5). With the device type MA 28 the **Edit** button is also used to change the tone option between **Hughson Westlake** or **Threshold** (Figure 40).



Figure 40



To print the currently shown measurent. For adjusting the printing settings see section 3.7.2 (*Printer Settings*).



If the **Speech** button is pressed, the speech audiometry user interface will be displayed on the PC monitor.

Notes:

Allows entering comments into the test session to be saved and printed. To activate the field place the cursor in the **Notes** field (Figure 41). Press **Enter** on the keyboard to enter a new line. Use the arrow keys on the keyboard to display hidden lines again.



Figure 41

**NOTE**: Maximum of four lines will display on the printout.



Figure 42

**State** indicates the connections status between the MAICO Audiometry Module and the MA 41 or MA 42 device. The state is indicated Green (**Connected**) Red (**Not connected**) or Grey (**Evaluation**) (Figure 42).

#### **Table 5 Test Results**

#### **FIXED FUNCTIONS**

#### ITEM/BUTTON INFORMATION



The selection of the different buttons (Figure 43) can be enabled with the *Edit* button (see table 5 Fixed Function). The buttons between the audiograms differ from device to device.

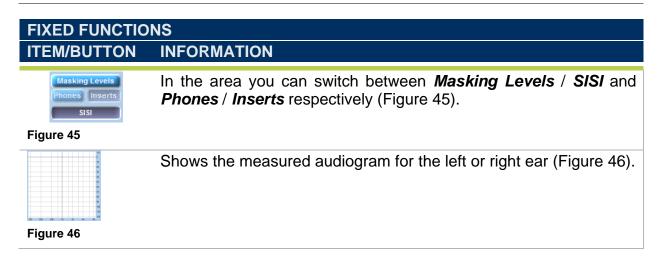
Figure 43



**Warble** or **Pulse** (Figure 44) is set with the device and cannot be set with the software. The software is only showing the current used seeting from the device.

Figure 44

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# 3.3 Pure Tone Audiometry

When the MAICO Audiometry Module is started, the tone audiometry screen is displayed (Figure 47). If the device is connected to the PC, the PC software will change its screen according to the currently selected test displayed on the audiometer.

On the pure tone audiometry screen, two audiograms are displayed - one for the left ear results and the other for the right ear results. The current level, frequency and selected signal are displayed above each audiogram. The selected level and frequency of the audiometer are also indicated by the position of the red or blue curser in the pure tone audiogram. The left and right pure tone average (PTA) value is displayed between the audiograms, once all required frequencies have been tested and a dB value has been stored.

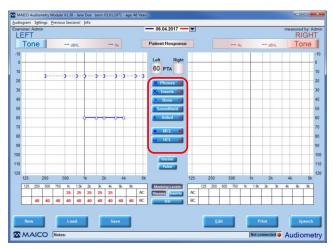


Figure 47

Below the audiogram tables, the masking values or SISI test results are displayed. This is based on what is selected between these boxes (i.e. masking levels or SISI). Between the audiograms are buttons of the selected transducer, test and signal configuration. These buttons cannot be clicked by the user. They display the status of the selected transducer of the connected audiometer.

If the touchTymp, MA 25e, MA 27e or MA 28 is connected the selected transducer, buttons between the audiograms appear flat. The MAICO Audiometry Module does not receive the information about the transducer from the device (Figure 40).

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## 3.3.1 Editing Pure Tone Results

Recorded results on the PC can be edited, if the <u>Edit</u> button is pressed. Select the transducer for the results that need to be edited (i.e. transducer button between the audiograms). To change the dB value, click on the audiogram at the level and frequency where the change needs to occur. If no result at this frequency and level has been stored, a new value will be created. For masking values use the table below the diagram. Click the **Edit** button again when editing has been completed.

## 3.4 Transfer Measurement Data to the MAICO Audiometry Module

#### 3.4.1 General

Transferring of a measurement requires the MAICO Audiometry Module to be open, and connection established. Perform the measurement within the MAICO Audiometer as described in the device operation manual.

Data transfer between the device and the MAICO Audiometry Module is performed differently based on the MAICO Audiometer (e.g. MA 25e, MA 42). Each MAICO device transferring function is explained below.

#### 3.4.2 Store Data with the MA 41 or MA 42 Audiometer



Figure 48

To transfer data between MA 41 and MA 42 (Figure 48) and the MAICO Audiometry Module, connect the MA 41 or MA 42 to the PC via USB. If the user presses the Store button on the MA 41 or MA 42 audiometer, this value will immediately be displayed on the audiogram. The patient response and stimulus presentation will also be displayed within the software by turning the icon green. Once the user switches the audiometer to the speech test, the screen of the PC software will also display the speech audiometry screen.

## 3.4.3 Transfer Data from the MA 25e, MA 27e or MA 28 Audiometer

If the MA 25e, MA 27e or MA 28 is connected, the Request Measurement button appears (Figure 49). To transfer stored data from the device, click on Request Measurement and the tone audiometry values are displayed. Once the values are transferred, they are deleted from the device.



Figure 49

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## 3.4.4 Data Transfer Between touchTymp and MAICO Audiometry Module



Figure 50

## 3.5 Speech Audiometry

If the user changes to the speech test on the MA 41 or MA 42 audiometer, or if the Speech button is pressed, the speech audiometry user interface will be displayed on the PC monitor. A speech audiogram will be displayed on the left side of the screen and a speech table is displayed on the right side. All results will be stored in the corresponding column of the table, and WRS results will be stored additionally in the speech audiogram. The current level of the speech signal and masking noise, if masking is activated on the device, is displayed. Also, the selected ear is displayed above the channel information and is indicated by the red and blue color of the channel information for the right and left ear (Figure 51).

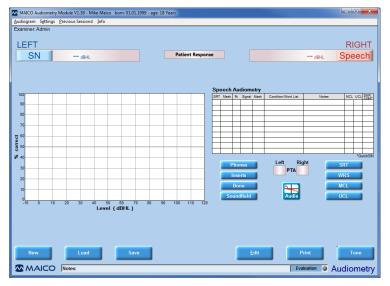


Figure 51

The buttons below the speech table are available to select the transducer, the speech test (i.e. SRT, WRS, etc.) or preview of the pure tone audiogram. For the SRT test, the level of the speech recognition threshold and the condition of the transducer and speech source (microphone, CD or Wave) is stored in the table.

When WRS test is selected the level, percentage and condition will be stored. This occurs when the store button is pressed on the MA 41 or MA 42 audiometer. The level and percentage value are displayed in the speech audiogram and the speech table.

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## 3.5.1 Edit Speech Test Results

Click on the Edit button in the speech test screen to start the edit mode, and click on R or L to select either the right or left ear results. To change the value of a stored result, click on the entry in the column Condition/Word List of the speech test result table. Use the up/down arrow of your PC keyboard to change the signal level, page up/page down for masking level and right/left arrow for % of WRS. Make sure the correct speech test icon is selected when editing (i.e. SRT, WRS, MCL or UCL. To add a new result, click on a blank line under the Condition/Word List column and use the appropriate keys listed above for entry. To delete a line, right click on the measurement and select delete. Click the Edit button a second time to terminate the edit mode.

#### 3.6 Advanced Tests

If the MA 42 is used, the MAICO Audiometry Module can display and store results of advanced tests like the SISI, Decay or ABLB test. If an advanced test is selected, the required information is displayed by the PC software. E.g. if the SISI or Decay test is selected, the audiogram of the contra lateral ear disappears and the selected test is displayed. The results are transferred to the MAICO Audiometry Module if they are stored in the device (Figure 52).

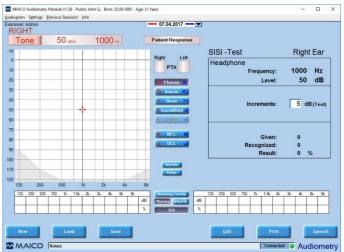
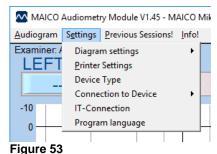


Figure 52

If the SISI button is selected, the SISI test results will be displayed in the table below the tone audiogram. The level of equal loudness of the ABLB test will be displayed as a ladder diagram in the tone audiogram, and the tested frequency will be indicated by a green circle. Please note that for the ABLB test results for only one frequency can be stored.

# 3.7 Settings



Within the menu bar is a **Settings** menu. This selection allows **Diagram Settings**, **Printer Settings**, **Device Type**, **Connection to the Device**, **IT-Connection** and **Program Language** to be modified (Figure 53).

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## 3.7.1 Diagram Settings

**Diagram Settings** (Figure 54) allows for selection of **Degrees HL, Speech Sounds** and **Symbol** selection. **Degrees HL** allows for selection of **Children, Adults** or **Off** (**Off** is the default selection). This will display a severity scale on the audiogram chart. **Speech Sounds** provides the frequency specific information of consonants and vowels to be displayed on the audiogram. Furthermore, regional symbol settings can be changed by clicking on the item **Symbols**. The following symbols can be selected: **International**, **USA, UK**, **Germany**, **Hong Kong**, or **Australia**. Lastly, the order of viewing the measurement of the right and left ear can be changed by clicking on **Switching Ear**: Select **On** to view the measurement of the right ear on the right side and the measurement of the left ear on the left side or **Off** to view the measurements the other way around.

**NOTE:** Switching Ear function is not available if the MAICO Audiometry Module is used with the MA 41 or MA 42.

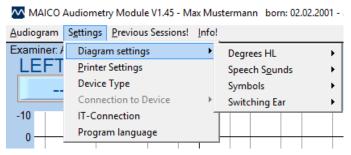


Figure 54

## 3.7.2 Printer Settings

**Printer Settings** allows clinic and tester information to be displayed on the printout. A window is displayed to enter the name, address and phone of the site. In addition, a picture or logo can be added to the printout by selecting the **Load** icon and clicking the button (1). This allows the selection of a picture/logo to be loaded from the computer. The **Examiner** field allows names to be entered for the printout. To enter the name, put the cursor in the box and type in the name. When there is more than one name to enter, type in the new name and press enter. A pop up can be incorporated in the software start up for the examiner name to be selected. Select the scissors button (2), if you want to delete the examiner. Select the radio button beside **Ask at module start** to activate this option. When all settings are established, select **Ok.** To leave without saving, select **Cancel** (Figure 55).



Figure 55

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## 3.7.3 Device Type

In the settings (Figure 56) you can change the device (Figure 57), which was chosen the first time at the setup from the software. A restart of the MAICO Audiometry Module is required, if the device type is changed. (Figure 58).

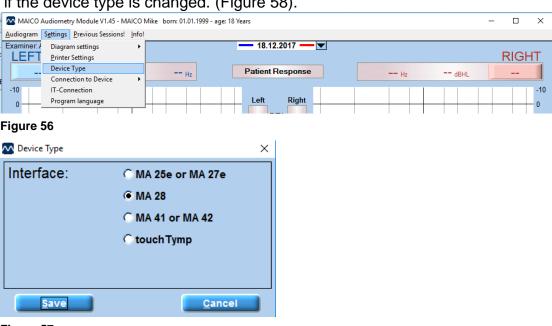


Figure 57

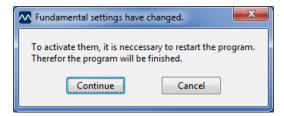


Figure 58

#### Connection to the Device

In the settings menu, the connection to the device can be deactivated or activated by selecting Connection to Device *Off* or *On* (Figure 59).

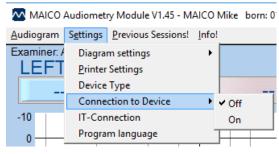


Figure 59

**NOTE**: The connection between the software and the device can only be changed with MA 41 or MA 42.



#### 3.7.4 IT Connection

Press *IT Connection* to open a menu to change the IT Connection (Figure 60):

Import path and file OAS> MAICO*	
import path and mo or to 1 m add	
	Browse
Export path and file MAICO> OAS*	
	Browse
*Changes will be activated after restart of program	
Data base path local	Browse
Data base path local C:\ProgramData\MAICO\Daten	Browse
Data base path local C:\ProgramData\MAICO\Daten	Browse
*Changes will be activated after restart of program Data base path local C:\ProgramData\MAICO\Daten Data base path network	

Figure 60

See section 2.4.3 for more information.

#### 3.7.5 Language

Select a language from the drop-down menu.

## 3.8 Transferring a Sessions from the MA 41 or MA 42 Audiometer

Full sessions stored in the *patient list* of the MA 41 or MA 42 can be transferred to the MAICO Audiometry Module. Connect the audiometer to the PC and make sure that a new session is started in the MAICO Audiometry Module. Enter the *patient list* of the Audiometer, select a Session and load the session. All the results of the session will be transferred to the PC and also displayed in the MAICO Audiometry Module. The results can then be stored in the PC Database. If there are already results stored in the MAICO Audiometry Module, a message is displayed on the PC screen to store the current results before loading the new results from the device into the MAICO Audiometry Module.

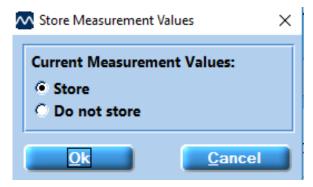


Figure 61

Select Store and click the **OK** button, to store the current results of the MAICO Audiometry Module in the connected database (Figure 61). A new session will be started and the results from the device will be transferred and displayed. Select do not store, to delete the currently displayed results without saving. A new session will be started and the results of the device will be transferred and displayed.

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MAICO Diagnostics GmbH Sickingenstr. 70-71 10553 Berlin Germany

Tel.: + 49 30 / 70 71 46-50 Fax: + 49 30 / 70 71 46-99 E-mail: sales@MAICO.biz Internet: www.MAICO.biz