# Operation Manual touchTymp

MI 26 and MI 36 Version


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

## Table of Contents

**Title: Operation Manual touchTymp – MI 26 and MI 36 Version**

Date of issue/last revision: 30/06/2021

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

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

Germany:

https://www.maico-diagnostics.com/german/support/resources/

International:

https://www.maico-diagnostics.com/support/resources/



**Compliance**

MAICO Diagnostics GmbH is an ISO 13485 certified corporation.

**Caution for USA:** Federal Law restricts this device to sale by or on the order of a licensed medical professional.

# 1 Introduction

**This section offers you important information about:**

- **the intended use of the device**
- **indications and contraindications of use**
- **essential performance**
- **features and benefits**
- **a description of the device**

## 1.1 General

This operation manual is for the touchTymp MI 26 and MI 36 versions. If sections or parts of sections of this operation manual apply only to certain versions of the device, they are marked with "MI 26" or "MI 36 ". 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 touchTymp when performing Immittance tests. If you have questions or suggestions for further improvements, please, do not hesitate to contact MAICO.

## 1.2 Intended Use Statement

The touchTymp Tympanometer is used to obtain information on medical conditions affecting the middle ear and to assess hearing.

The touchTymp Tympanometer with Audiometry intended to be used for the identification of hearing loss and the factors that contribute to the occurrence of the hearing loss in the age range of children to adults. Output and specificity of this type of device are based on the test characteristics defined by the user, and may vary depending on environmental and operating conditions. Testing for hearing loss using this type of audiometer requires interaction with the patient.

**Indications of Use Statement**

The touchTymp Tympanometer is an electroacoustic test instrument that produces controlled levels of test tones and signals intended for use in conducting screening or diagnostic middle ear function or hearing evaluations. It features Tympanometry, Acoustic Reflex and Audiometry to assist in the diagnosis of possible otologic disorders.

The touchTymp Tympanometer is intended to be used by an audiologist, ENT, hearing healthcare professionals, or other trained technicians in a hospital, clinic, healthcare facility or other suitable quiet environment as defined in ANSI S3.1 / ISO 8253-1 or equivalent.

## 1.3 Contraindications of Use

***Tympanometry and Acoustical Reflex*** testing should not be performed on patients with one of the following symptoms without a medical doctor's approval:

- Recent stapedectomy or other middle ear surgery
- Discharging ear
- Acute external auditory canal trauma
- Discomfort (e.g. severe otitis externa)
- Occlusion of the external auditory canal
- Presence of tinnitus, hyperacusis or other sensitivity to loud sounds may contraindicate testing when high intensity stimuli are used

Visual inspection for obvious structural abnormalities of the external ear structure and positioning as well as the external ear canal should be performed before testing.

***Audiometry*** testing should not be performed if the patient is too young, sick or uncooperative to perform the tasks.

## 1.4 Features and Benefits of the touchTymp

### 1.4.1 General Information About the touchTymp

The touchTymp is available as a version with or without a printer. The touchTymp gives you the benefit of:

- Full touchscreen operation
- Screening Immittance test battery – MI 26 version (i.e. Tympanometry, Acoustic Reflex Tests)
- Diagnostic Immittance test battery – MI 36 version (i.e. Tympanometry, Acoustic Reflex, Reflex Decay, Eustachian Tube Function)
- Optional high frequency probe tone
- Optional RaceCar animation
- Multiple transducer options for contralateral reflex testing
- Automatic test function in Immittance modules
- Included test cavities for quick and easy calibration verification
- Air Conduction pure tone audiometry – MI 26 version
- Bone Conduction pure tone audiometry – MI 26 (with bone conduction upgrade) and MI 36 version
- Print directly from device with built-in printer
- Automatic printing cability with placement of probe in holder

### 1.4.2 Licenses

The touchTymp comes with some optional measurements which can be activated by entering a license key. In the settings (see section 5.6.19) this key can be added.

The following functions are available:

- ***Tympanometry 1000 Hz*** (all versions)
- ***Acoustic Reflexes Contra*** (MI 26 version only, included in MI 36 version)
- ***Audiometry Bone Conduction*** incl. ***Masking*** (MI 26 version only, included in MI 36 version)
- ***RaceCar*** (all versions)
- ***PC Connection*** (all versions, for connection with MAICO Sessions)

It might appear that the touchTymp already contains licenses due to the version you ordered (e.g. if ordered touchTymp MI 26 version comes with a probe tone of 1000 Hz for ***Tympanometry*** and ***Acoustic Reflexes***).

**NOTE**: Each license key is specific for the serial number of your device.

In case you want to purchase another license, please, contact MAICO or your local distributor to determine eligibility.

### 1.4.3 Printing Options

Printing test results from the touchTymp are accomplished in a variety of ways:

- Use the build-in printer to directly print results.
- Transfer touchTymp test data into the PC-software and print results on your PC-printer.

## 1.5 Description

### 1.5.1 General

The touchTymp is designed for Immittance testing as ***Tympanometry*** and ***Acoustic Reflex*** (i.e. ***Ipsilateral*** and ***Contralateral***) testing (MI 26 and MI 36 version).

MI 36 version also includes ***Reflex Decay*** and ***Eustachian Tube Function (ETF)*** tests.

MI 26 and MI 36 also include Audiometry functions:

- ***Air Conduction*** (all versions)
- ***Bone Conduction*** incl. ***Masking*** (extra Licenses for MI 26, included in MI 36 version)

The functions are described in detail in the following sections.

### 1.5.2 Tympanometry

***Tympanometry*** is the objective measurement of middle ear mobility (compliance[1]) and pressure[2] within the middle ear system (Figure 1). During the test, a low-pitched probe tone (226 Hz) is presented to the ear canal by means of the hand-held probe. This tone is used to measure the change in compliance in the middle ear system while

[1] Compliance is measured with respect to an equivalent volume of air, with the scientific quantity milliliter (ml).
[2] Air pressure is measured in deca-Pascals (daPa).

the air pressure is varied automatically from a positive value (i.e. +200 daPa) to a negative value (i.e. -400 daPa max).

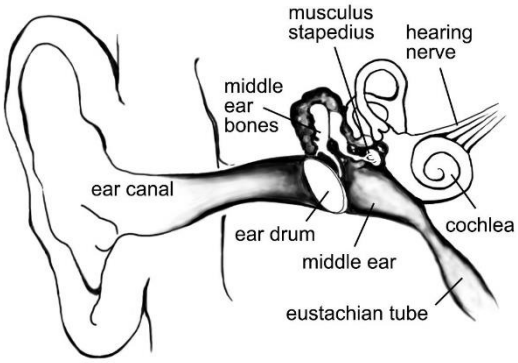



**Figure 1**

Maximum compliance of the middle ear system occurs, when the pressure in the middle ear cavity is equal to the pressure in the external auditory canal. This is the highest peak of the curve as it is recorded on the chart. The position of the peak on the horizontal axis and on the vertical axis of the chart will provide diagnostic information regarding the function of the middle ear system. Gradient calculations are reported as the Tympanogram width at half of peak compliance expressed in daPa. A normative box is available on both the display and printout to aid in diagnosis.

**NOTE**: 1 mmho ≙ 1 ml for 226 Hz probe tone

### 1.5.3 Acoustic Reflex

An ***Acoustic Reflex***, or contraction of the stapedial muscle, occurs under normal conditions when a sufficiently intense sound is presented to the auditory pathway. This contraction of the muscle causes a stiffening of the ossicular chain which changes the compliance of the middle ear system. As in ***Tympanometry***, a probe tone is used to measure this change in compliance.

When the stimulus presentation and measurement are made in the same ear by means of the probe, this acoustical reflex is referred to as an ***Ipsilateral Acoustic Reflex***. When the stimulus presentation is made in the opposite ear of where the measurement is made, this acoustical reflex is referred to as a ***Contralateral Acoustic Reflex***.

For best results, this reflex measurement is automatically conducted at the air pressure value where the compliance peak occurred during the ***Tympanometric*** test. Stimulus tones of varying intensities at 500 Hz, 1000 Hz, 2000 Hz or 4000 Hz are presented as short bursts. If a change in compliance greater than the selected value is detected, a reflex is considered present. Because this is an extremely small compliance change, any movement of the probe during the test may produce an artifact (false response). The test result is recorded as ***Pass/No Response (NR***), and in graphical form.

If the ***Tympanometric*** results display any abnormal findings, the results of the ***Acoustic Reflex*** testing may be inconclusive and should be interpreted with care. Theoretically, a compliance peak is necessary to observe a reflex at peak pressure.

### 1.5.4 Acoustic Reflex Decay (MI 36 Version Only)

***Acoustic reflex decay***, also known as adaptation, is the measurement of the acoustic reflex response during sustained stimulus presentation. ***Ipsilateral*** and ***Contralateral Reflex Decay*** can be performed.

### 1.5.5 Eustachian Tube Dysfunction (ETF) (MI 36 Version Only)

The Eustachian tube connects the middle ear with the nasopharynx. Its function is to equalize pressure between the middle ear and the atmosphere.
The Eustachian tube test can be used to determine if the Eustachian tube is functioning properly in patients.

- ***ETF Intact:*** performed on patients with normal tympanic membrane (TM).
- ***ETF Perforated:*** determines if the patient can open his/her Eustachian tube when the TM is perforated or an open PE-tube is in place.

### 1.5.6 Air Conduction Testing

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.

### 1.5.7 Bone Conduction Testing (MI 26 Version – Extra License, MI 36 Version – Included)

Hearing threshold levels can be determined by presenting test signals to the test subject with the included bone conductor (***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.

### 1.5.8 Masking (MI 26 Version – Extra Bone Conduction License, MI 36 Version – Included)

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 dB to 15 dB. ***Bone Conduction crossover*** is therefore possible even with a slight difference in hearing loss between ears.

# 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 device system including safety information as well as maintenance and cleaning recommendations.

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

Use this device only as described in this manual.

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

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


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


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

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

## 2.2 Customer Responsibility

All safety precautions given in this operation manual must be observed at all times. Failure to observe these precautions could result in damage to the equipment and injury to the operator or subject.

The employer should instruct each employee in the recognition and avoidance of unsafe conditions and the regulations applicable to his or her work environment to control or eliminate any hazards or other exposure to illness or injury.

It is understood that safety rules within individual organizations vary. If a conflict exists between the material contained in this manual and the rules of the organization using this device, the more stringent rules should take precedence.


This product and its components will perform reliably only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and/or inserts. A defective product should not be used. Make sure all connections to external accessories are snug and secured properly. Parts which may be broken or missing or are visibly worn, distorted, or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from MAICO.

**NOTE:** Customer responsibility includes proper maintenance and cleaning of the device (see sections 3.2 and 3.3). Breach of the customer responsibility can lead to limitations of Manufacturer's Liability and Warranty (see sections 2.3 and 3.1).

**NOTE:** In the unlikely case of a serious incident, inform MAICO as well as the competent authority in the country where the user is established.

## 2.3 Manufacturer's Liability

Usage of the device in a way deviant from the intended use will lead to a limitation or termination of the manufacturer's liability in case of damage. Improper use includes disregarding the operation manual, the operation of the device by underqualified personnel as well as making unauthorized alterations on the device.

## 2.4 Regulatory Symbols

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

**Table 1 Regulatory Symbols**

| REGULATORY SYMBOLS<br>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 |
| | Patient applied part type B according to IEC 60601-1 |
| | Refer to instruction manual (mandatory) |
| | Keep away from rain |
| | Transport and storage temperature range |
| | Transport and storage humidity limitations |
| | Transport and storage atmospheric pressure limitations |
| | Voltage transformer |
| | Do not reuse |
| CE | Conforms to Medical Device Regulation (EU) 2017/745 |
| | Non-ionizing electromagnetic radiation |
| ETL CLASSIFIED Intertek | ETL listed mark |
| MAICO | Logo |

## 2.5 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.

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


No modification of this equipment is allowed.

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

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


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

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


This device contains a coin-type lithium battery. The cell can only be changed by service personnel. Batteries may explode or cause burns, if disassembled, crushed or exposed to fire or high temperatures. Do not short-circuit.

## 2.6 Electrical Safety and Measuring Security

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

The protection class of the system is IEC 60601-1 class I.


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

In Case of Emergency


WARNING

In Case of Emergency

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

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

Do not use the device if the power supply unit and/or the plug is damaged.


WARNING

To transfer data to a PC, establishing a PC-connection via USB is required. See section 4.2.4 on how to safely establish a connection with a power supplied PC or laptop (medical device/non-medical device) or to a battery-driven laptop.

This equipment is intended to be connected to other equipment thus forming a Medical Electrical System. External equipment intended for connection to signal input, signal output or other connectors shall comply with the relevant product standard e.g. IEC 60950-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations – Medical Electrical Systems – shall comply with the safety requirements stated the general standard IEC 60601-1, edition 3, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support or shall be supplied via a separation transformer to reduce the leakage currents. Any person who connects external equipment to signal input, signal output or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements. If in doubt, contact qualified medical technician or your local representative.


WARNING

A Separation Device (isolation device) is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. In particular such a Separation Device is required when a network connection is made. The requirement for the Separation Device is defined in IEC 60601-1 clause 16.


WARNING

If the device is connected to a PC (IT equipment forming a system) assembly and modifications shall be evaluated by qualified medical technician according to safety regulations in IEC 60601-series.


WARNING

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

If the device is connected to a PC (IT equipment forming a system) do not touch the patient and the IT equipment at the same time.

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


The device is not intended for operation in areas with an explosion hazard. Do NOT use the device in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc. If the device is not used switch it off and disconnect it from the power supply.

Never short-circuit the terminals.


To avoid the risk of electric shock, this equipment must only be connected to the medical power supply originally delivered by MAICO. Using another power supply can also lead to electrical damage on the device.


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

## 2.7 Device Control

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

For annual calibration see section 2.5 and 3.2.

## 2.8 Electromagnetic Compatibility (EMC)


This device is suitable in hospital environments except for near active HF surgical equipment and RF shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.


The device fulfills the relevant EMC requirements. Avoid unnecessary exposure to electromagnetic fields, e.g. from mobile phones etc.

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

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

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


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 touchTymp, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result in improper operation.

# 3 Warranty, Maintenance and After-Sales Service

**This section offers you important information about:**

- **warranty conditions**
- **maintenance**
- **cleaning and disinfection recommendations**
- **handling disposables**
- **troubleshooting**
- **recycling and disposal of the device**

## 3.1 Warranty

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

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

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

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

## 3.2 Maintenance

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

The service and calibration must be performed by your dealer or to a service center authorized by MAICO.

When returning the device for repairs or calibration it is essential to send the acoustic transducers with the device. Please include a detailed description of faults. In order to prevent damage in transit, please use the original packing when returning the device.

## 3.3 Cleaning and Disinfection Recommendations

### 3.3.1 General

It is recommended that parts (device like headphones, ear cushions) which come in direct contact with the patient be subjected to standard cleaning and disinfecting procedure between patients.

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

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

- Before cleaning always switch off and disconnect the device from power supply.
- For cleaning use a lightly dampened cloth with soap water solution.
- Disinfect the plastic housing of the touchTymp and its accessories by wiping the surfaces with disinfectant wipes or a comparable product. Follow the instructions on the specific disinfection product.
    - Wipe before and after each patient
    - After contamination
    - After infectious patients


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

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

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

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

For more detailed cleaning recommendations see the following sections 3.3.2 to 3.5.

### 3.3.2 Cleaning the Touch Screen

Use a lens cleaning or microfiber cloth to clean the touchTymp touchscreen.

### 3.3.3 Cleaning the Case and Cables

Also, check-out our training videos:

MAICO Training | touchTymp Part 1 | 8/8 Cleaning - YouTube

https://www.youtube.com/watch?v=9o3QkyGCNLg&list=PLonI5JzuDcd7lxKobEy7BW3DS59QCsbAG&index=8


Use caution while cleaning.

Use a damp cloth to clean the plastic parts of the touchTymp.

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 such as the edges around the touch screen.

Follow the instructions on the disinfection product.

### 3.3.4 Cleaning the Probe Tip

Also, check-out our training videos:

MAICO Training | touchTymp Part 1 | 7/8 Cleaning the probe - YouTube

https://www.youtube.com/watch?v=r7Wj5wDFQDg&list=PLonI5JzuDcd7lxKobEy7BW3DS59QCsbAG&index=7

In order to secure correct immittance measurements it is important to make sure that the probe system is kept clean at all times. Therefore please clean the probe on a periodic basis. It is indispensable to remove cerumen from the probe tip's small acoustic and air pressure channels. Therefore please follow the illustrated instructions below. The pictures show the procedure on the Pen Probe (left) and the Shoulder Box (right).

CAUTION

Never clean the probe tip while the tip is still attached to the probe

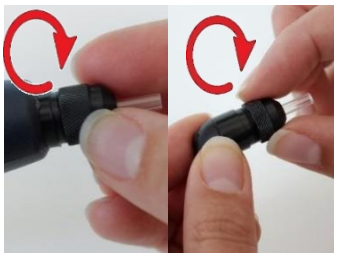


Figure 2

Unscrew the probe cap by turning it in a counter clockwise direction (Figure 2).

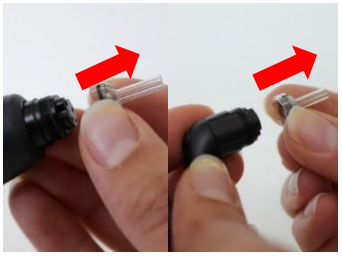


Figure 3

Take the plastic probe tip out of the probe (Figure 3).

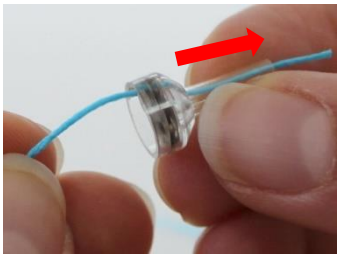


Figure 4

Insert the blue end of the floss from back to front through one of the probe channels. Pull the floss along its entire length through the channel (Figure 4).

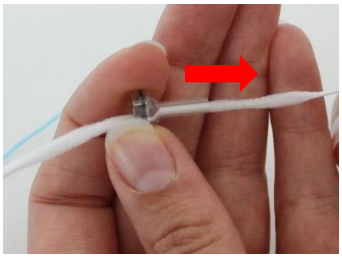


Figure 5

Proceed in the same way with all 4 probe channels. Use the floss only once (Figure 5).

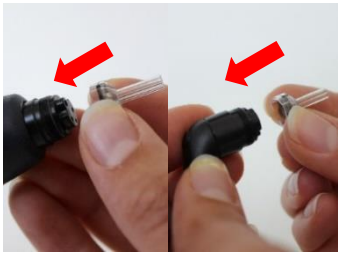


Figure 6

Place the probe tip back onto the probe. Make sure that the plastic pegs are inserted into the appropriate corresponding cavities (Figure 6).

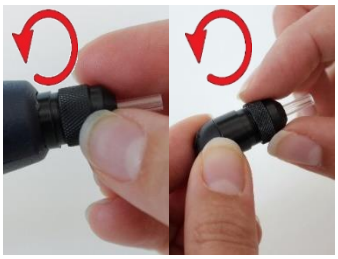


Figure 7

Screw the probe cap back on the probe (Figure 7). The force of tightening the cap will tighten the screw sufficiently. Never use tools to fix the probe cap!

If any blockage or damage occurs to the sealing gasket, the probe system can only be serviced by MAICO.

## Cleaning alternative

Figure 8

Use the cleaning set from the eartip box (Figure 8): Take the cleaning tool apart to find the thin brush and thin rigid plastic cord (Figure 9).

Figure 9

Figure 10

Use the plastic cord or brush to push debris out of the probe tip (Figure 10).

Figure 11

Always enter the probe tip from the rear to avoid accumulation of debris inside the vents (Figure 11).

Figure 12

CAUTION

Never clean the probe itself with the cleaning devices. The probe will be damaged (Figure 12).

Figure 13

CAUTION

Never clean the probe tip while the tip is still attached. The probe will be damaged (Figure 13).

## 3.4 Disposables


**Figure 14**

Operating the touchTymp will require the use of eartips – either mushroom shaped (1) or umbrella (2) eartips (Figure 14).

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

WARNING

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

MAICO strongly recommends to use Sanibel eartips only. In case you want to purchase further disposables, please contact MAICO or your local distributor.

## 3.5 Components/Replacement Parts

Some reusable components are subject to wear with use over time. MAICO recommends that you keep theses replacement parts available (as appropriate for your touchTymp device configuration).

## 3.6 Troubleshooting

**Table 2 Troubleshooting**

| Problem | Reason | Suggestion |
|---|---|---|
| **No start of measurement** | Probe | Make sure the probe is connected to the back of the device correctly and the brackets are closed. Otherwise, follow the suggestions in Probe tip. |
| **No start of measurement** | Probe tip | 1. Clean the probe tip as described in the manual. If the system still does not run proceed with step 2.<br>2. Use a new probe tip. If the system still does not run proceed with step.<br>3. Change the complete probe and check if the system is running. |
| **Screen is frozen** | | Hold the ***Front key*** button for 10 seconds in order to shut-off the device. Restart. |
| **Probe light stays white** | | Turn off the device. Confirm/reconnect the probe before restarting. |
| **Transfer to PC not possible** | Connection to PC | Make sure the USB/PC-connection is established (PC connection license needs to be activated), the PC software is opened and the device and the connection icon is displayed green. |
| **Buttons are greyed out** | No license | Purchase license if wanted. |
| | Missing transducer calibration | Calibrate transducer. |
| | Combinations of settings not allowed | Verify settings are correct. |

**NOTE**: If there are any problems that you cannot solve yourself, please, contact your customer service. It will be helpful to use the function ***Export error log*** (see section 5.6.20) to send the customer service the data needed for solving the problem.

## 3.7 Recycling and Disposal

Within the European Union it is illegal to dispose of electric and electronic waste as unsorted municipal waste. According to this, all MAICO products sold after August 13, 2005, are marked with a crossed-out wheeled bin. Within the limits of Article (9) of DIRECTIVE 2002/96/EC on waste electrical and electronic equipment (WEEE), MAICO has changed their sales policy. To avoid additional distribution costs we assign the responsibility for the proper collection and treatment according to legal regulations to our customers.

Non-European countries

Outside the European Union, local regulations should be followed when disposing of the product after its useful life.

# 4 Unpacking and Installation

**This section provides information on:**

- **unpacking the system**
- **becoming familiar with the hardware inclusive connections**
- **how to store the device**
- **becoming familiar with the Pen Probe and the Shoulder Box**
- **getting to know the built-in printer**
- **adjusting the feet height**
- **mounting the Shoulder Box Adapter Kit**

## 4.1 Unpacking the System

### Check Box and Contents for Damage

- It is recommended that you unpack your touchTymp carefully making sure that all components are removed from the packing materials.
- Verify that all components are included as shown on the packing slip included with your shipment.
- If any component is missing, contact your distributor immediately to report the shortage.
- If any component appears to be damaged in shipment, contact your distributor immediately to report it. Do not attempt to use any component or device that appears to be damaged.

### Reporting Imperfections

Notify the carrier immediately if any mechanical damage is noted. This will insure that a proper claim is made. Save all packaging material so the claim adjuster can inspect it as well.

### Report Immediately any Faults

Any missing part or malfunction should be reported immediately to the supplier of the device together with the invoice, serial number, and a detailed report of the problem.

### Keep Packaging for Future Shipment

Save all the original packing material and the shipping container so the device can be properly packed if it needs to be returned for service or calibration (see section 3.2).

The touchTymp comes with different components (see the following tables). The availability of configurations with the following components is country and version specific. Contact your local distributor for more information.

| Components |
|---|
| **General components** |
| Base Unit (with or without Printer) |
| MAICO USB Flash Drive Kit |
| Power Supply UES18LCPU-050200SPA |
| Country-Specific Mainscable |
| USB Cable |
| Thermal Paper Rolls*** |
| EarTip Kit |
| Probe Floss Kit |
| Cleaning Cloth |
| Touch Pen |
| MAICO Sessions Kit |
| Operation Manual |
| Quick Guide |
| **Components for Testing Tympanometry and Acoustic Reflexes** |
| Pen Probe** |
| Shoulder Box** |
| Shoulder Box Adapter Kit* |
| Shoulder Box Attachment Kit* |
| IP30 (6.3 mm Plug)** |
| IP30 (3.5 mm Plug)** |
| DD45C (6.3 mm Plug)** |
| DD45C (3.5 mm Plug)** |
| **Components for Audiometry** |
| Headphones**** |
| DD45** |
| IP30** |
| DD450** |
| Bone Conductor**** |
| B71** |
| B81** |
| Patient Response Switch** |
| Mic/Monitor Headset** |
| Talk Back Microphone** |

*Only if sold with Shoulder box
**Applied parts according to IEC 60601-1
***Only if sold with base unit with printer
****Selection of one transducer at time of purchase

### MI 26 Licenses

| Standard Licenses |
|---|
| Tympanometry 226 Hz |
| Acoustic Reflexes Ipsi |
| Audiometry – Air Conduction |

| Extra Licenses |
|---|
| Tympanometry 1000 Hz |
| Acoustic Reflexes Contra* |
| RaceCar |
| Audiometry – Bone Conduction (Includes Masking) |
| PC Connection |

*Additional transducer required

### MI 36 Licenses

| Standard Licenses |
|---|
| Tympanometry 226, 678 and 800 Hz |
| Acoustic Reflexes Ipsi and Contra |
| Reflex Decay Ipsi and Contra |
| ETF |
| Audiometry – Air Conduction |
| Audiometry – Bone Conduction (Includes Masking) |

| Extra Licenses |
|---|
| Tympanometry 1000 Hz |
| RaceCar |
| PC Connection |

### Disposables Supplied

**NOTE**: MAICO strongly recommends to use Sanibel eartips for reliable results.

| Eartip Box |
|---|
| Samples of Sanibel ear tips |
| Probe Tip |
| Probe Cleaning Tool |
| Eartip Removal Tool |
| Allen key SW: s = 2 mm (see section 4.2.9) |

**NOTE**: It is possible to purchase either the whole Eartip Box or single items listed.

| Replacement Parts and Disposables for Audiometry Testing |
|---|
| Foam Eartips** |

**Only for use with insert phones

## 4.2 Hardware Orientation

### 4.2.1 Display

Figure 15

The display on the touchTymp is a touch screen (Figure 15). This design feature allows use while wearing latex gloves. A rubber-tipped stylus can also be used to select the desired function on the screen.

### 4.2.2 Connections for Accessories, Power Supply and USB-Devices

Figure 16 shows the connections on the backside of the device. The connections are explained in Table 3.

CAUTION

Insert plugs with care into the appropriate connection. Do not wiggle the plug or pull with force while connected. Disconnect plugs cautiously. Consider instructions for Changing the Probe System given in this section.

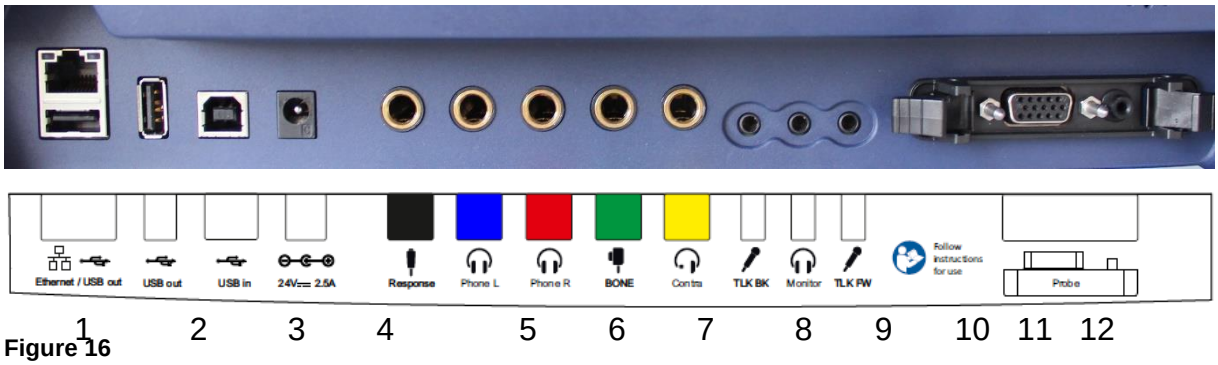



Figure 16

Table 3 Connections on Backside of Device

| CONNECTIONS | | |
|---|---|---|
| 1 | **Ethernet / USB out** | Dual connector: Ethernet – no function in actual touchTymp version / USB A-connection for connection of USB flash drive |
| 2 | **USB out** | USB A-connection for connection of USB flash drive |
| 3 | **USB in** | USB B-connection for data transfer to PC |
| 4 | ⊖—C—⊕ **24 V/2,5 A** | Power socket for power supply UES65-240250SPA3 |
| 5 | **Response** | Connection for the Patient Response Switch |
| 6 | **Phone L** | Connection for Headphones Left |
| 7 | **Phone R** | Connection for Headphones Right |
| 8 | **Bone** | Connection for Bone Conductor |
| 9 | **Contra** | Connection of Contralateral headphone |
| 10 | **TLK BK** | Connection for Talk Back Microphone |
| 11 | **Monitor** | Connection for Monitor Headset |
| 12 | **TLK FW** | Connection for Talk Forward Microphone |
| 13 | **Probe** | Connection for probe |

See section 6.3 for more information on the pin assignment.

### 4.2.3 Connecting the Probe System

Also, check-out our training videos:

MAICO Training | touchTymp Part 1 | 1/8 Setup - YouTube

https://www.youtube.com/watch?app=desktop&v=Hawp43VS3_Y&list=PLonI5JzuDcd7lxKobEy7BW3DS59QCsbAG

Connect and disconnect the probe as follows:

1. To connect position the probe connector over the locating pins (Figure 17)
2. Push the connector until the clips lock-in (Figure 18, 1). If the clips haven
3. Confirm the clips have locked in properly, push them to the center (2).
4. To disconnect the probe open the two locks by pushing them to the sides (Figure 19).

**Figure 17**

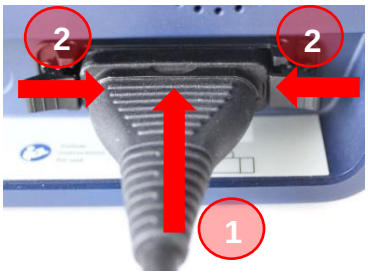



**Figure 18**

**Figure 19**

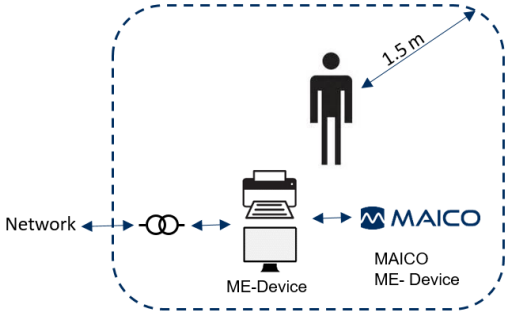
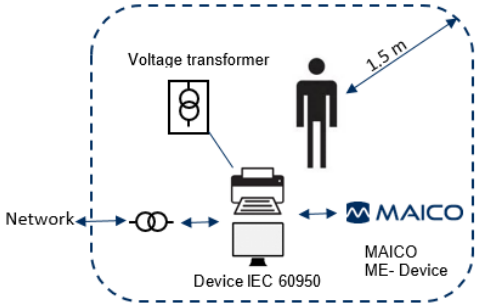
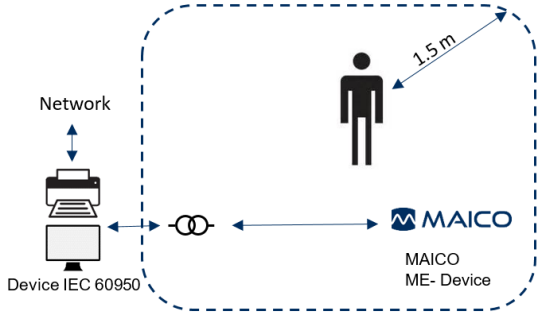
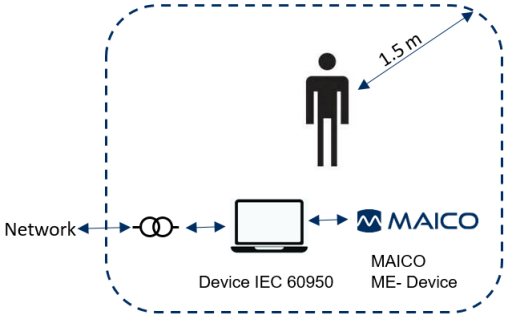
### 4.2.4 Establishing a PC-Connection

To transfer data to a PC, establishing a PC-connection via USB is required. If the touchTymp is used with office equipment that is not a medical device itself (see Table 4), make sure to establish the PC-connection in one of the following ways (see Table 4, PC Connection 2, 3 or 4).

WARNING

Make sure you use only office equipment with the device that is a medical device itself or meets the requirements of IEC 60950. If a non-medical device is used within the patient environment (1.5 m from patient as defined in IEC 60601) a voltage transformer must be used (exception: a battery driven laptop is used).

**Table 4 PC-Connections**

| PC CONNECTIONS | |
|---|---|
| PC Connection 1:<br>Medical device – Medical Device | PC Connection 2:<br>Medical device – Non-Medical Device |
|  |  |
| PC Connection 3:<br>Medical device – Non-Medical Device | PC Connection 4:<br>Medical device – Laptop (battery-driven) |
|  |  |

### 4.2.5 Storage

When the touchTymp is not in use, store in a location where it will be safe from damage to the touchscreen or other sensitive components such as the acoustic transducers and cables. Store according to the recommended temperature conditions described in section 6.1.

### 4.2.6 The Probes

There are two probes available for the touchTymp, Pen Probe and Shoulder Box. The main functionalities are the same. The Pen Probe is most suitable for screening since you can fit it on the patient with high sensitivity and is standard with MI 26 versions. The Shoulder Box allows hands free work while performing diagnostic measurements and is the standard probe for MI 36 versions. Additionally, the Shoulder Box has a 3.5 mm jack for the Contralateral headphone (Figure 22). Both, the Pen Probe (Figure 20) and the Shoulder Box (Figure 21) are connected to the device in plug 13 (Figure 16).

Table 5 shows the explanation of the probe design for both Pen Probe and Shoulder Box. The further explanation of the indication light and the light bar in this section applies to both probes.

**Table 5 Probe design**

| PROBE DESIGN | | |
|---|---|---|
| **1** | **Probe Tip** | Attach the eartip to the probe tip in order to perform a measurement. |
| **2** | **Probe button** | Control of measurement. Use this key to start a measurement or change test ear. |
| **3** | **Indication Light** | Status of current measurement. Display of selected earside and condition of probe (e.g. Leaking, proper placement, etc.). |
| **4** | **Light Bar** | Result of last measurement. Display of the final result (e.g. ***Pass*** / ***No Respone***, etc.) |
| **(5)** | **(Jack for Contralateral headphone)** | Only for Shoulder Box: Possibility to connect a Contralateral headphone (see description following in this section) |

### The Pen Probe


**Figure 20**

CAUTION

Do not use the Pen Probe to operate on the touch screen.

### The Shoulder Box

Use the clothing clip on the Shoulder Box to secure the probe to clothing or bedding and insert the probe gently into the ear of the subject.

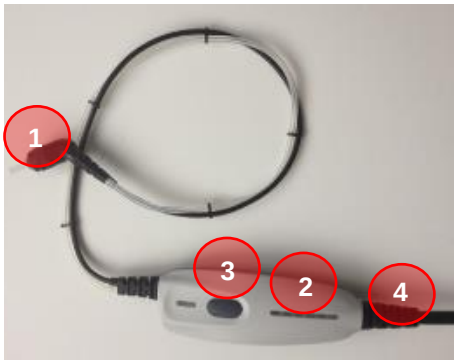



**Figure 21**


**Figure 22**

**Figure 23**

### Contralateral headphone with the Shoulder Box

An additional jack on the Shoulder Box allows connection of the Contralateral headphone (3.5 mm jack).

**NOTE:** The 6.3 mm Contralateral headphone jack on the back of the device can be used with the Pen Probe or the Shoulder Box (see Figure 16, plug 9).

### The Indication Light

The indication light displays the different states of the measurement by color and the presentation modus (flashing/continuous). Table 6 gives explanation to the different indications.

**Table 6 Indication Light**

| PROBE | COLOR | EXPLANATION |
|---|---|---|
| | Red | Right ear is selected. Probe is out of ear. |
| | Blue | Left ear is selected. Probe is out of ear. |
| | Green | Probe is in the ear and is sealing, test is running or done. |
| | Yellow | Probe is in the ear and blocked or leaking. If the indicator remains “yellow” (sealing), the screener must improve the position of the probe in the ear:<br>1. Reinsert the probe for better placement.<br>2. Inspect the probe tip for any blockage.<br>3. Verify eartip has the correct size, new eartip may be required. |
| | White | An error has occurred. Confirm connection of probe and/or restart the device. |

### The Light Bar

The ***light bar*** function on the probe allows the examiner to view test progression and final compliance for patient focused operation. It can be set on or off in the ***Basic settings*** menu (see section 5.6.3). If set on, the light bar offers the following functionalities dependent on the test modus (Table 7).

**Table 7 Light Bar Functions 1**

| PROBE | COLOR | EXPLANATION | |
|---|---|---|---|
|  | 2x orange | Tympanometry & Acoustic Reflex: | Shows result: ***No Response (NR)*** |
|  | 2x green | Tympanometry & Acoustic Reflex: | Shows result: ***Pass*** |
|  | 2x yellow | Acoustic Reflex: | Stimulus is being given (additionally the last result is shown) |
|  | All colours | Tympanometry: | Lights up (rolling up) dependent on the values (normative box) |

While completing Tympanometry testing the Light Bar will light up indicating the height of the compliance according to the following Table 8.

**Table 8 Light Bar Functions 2**

| | INTERNATIONAL | | US |
|---|---|---|---|
| Lightbar Colors | 226 Hz Range Compliance | 1000 Hz Range Compliance | 226 Hz Range Compliance |
|  | Value < $0.\overline{3}$ | Value < 0.2 | Value < $0.2\overline{3}$ |
|  | $0.\overline{3}$ ≤ Value < $0.\overline{6}$ | 0.2 ≤ Value < 0.4 | $0.2\overline{3}$ ≤ Value < $0.4\overline{6}$ |
|  | $0.\overline{6}$ ≤ Value < 1.0 | 0.4 ≤ Value < 0.6 | $0.4\overline{6}$ ≤ Value < $0.6\overline{9}$ |
|  | 1.0 ≤ Value < $1.\overline{3}$ | 0.6 ≤ Value < 0.8 | $0.6\overline{9}$ ≤ Value < $0.9\overline{3}$ |
|  | $1.\overline{3}$ ≤ Value < $1.\overline{6}$ | 0.8 ≤ Value < 1.0 | $0.9\overline{3}$ ≤ Value < $1.1\overline{6}$ |
|  | $1.\overline{6}$ ≤ Value | 1.0 ≤ Value | $1.1\overline{6}$ ≤ Value |

**NOTE**: The indication of ***Pass/No Response*** can be set on or off individually for 226 Hz and 1000 Hz for ***Tympanometry*** and ***Acoustic Reflex*** testing (see section 5.6.8).

The light bar will not show any indication of test result when set off (see section 5.6.3). However, the ***Pass/No Response*** indicators will be shown on the screen or in the diagram.

### 4.2.7 The Built-In Printer

**NOTE**: This section only applies to touchTymp devices purchased with a built-in printer.

In order to change paper rolls:

- Push the marker on the left side of the touchTymp to open the printer cover (Figure 24).
- Pull the blue lever upwards (Figure 25).
- Insert a paper roll in the compartment with its loose end to the front of the printer and the loose paper positioned underneath the roll as shown in the picture. Position the loose end into the printer roll and hoist it by rotating the printer roll with your finger.
- Push the blue lever down. Close printer cover (Figure 26).

**Figure 24**

**Figure 25**

**Figure 26**

### 4.2.8 Test Cavities

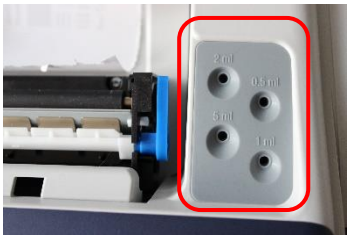


**Figure 27**

You can use the 0.5 ml, 1.0 ml, 2.0 ml and 5.0 ml test cavities for validity check of the probe calibration (Figure 27). To perform a probe check, select a protocol that measures a tympanogram. Check the volume that was measured.

The allowed tolerance in the volume measurement is ±0.1 ml for cavities up to 2.0 ml and ±5 % for larger cavities. These tolerances are applicable for all probe tone frequencies.

**NOTE:** A probe check does not replace annual calibration by your customer service. See also section 3.2.

### 4.2.9 Adjusting the Feet Height

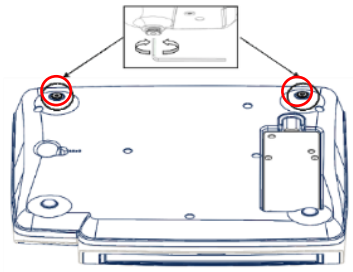


**Figure 28**

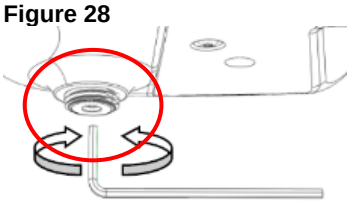


**Figure 29**

Use the Allen key to adjust the touchTymp feet (Figure 28 and Figure 29).

**NOTE:** An Allen key is enclosed in the packaging of the eartip box to enable adjustment of the pair of adjustable feet located on the bottom of the touchTymp.

Please ensure that the Allen key is only used for the purposes mentioned in this Operation Manual.

# 5 Operating the Device

**This section offers you information about:**

- **how to get started with the touchTymp**
- **the main screen format and the home screen**
- **performing immittance testing and audiometry testing**
- **preparing the patient for testing**
- **managing the test results**
- **settings to be made**

## 5.1 Getting Started with the touchTymp

### 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 touchTymp 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 ISO 8253 series or ANSI S3.1. For use in noisier environments, headphones with optional sound insulation muffs are available. Electronic devices, which emit strong electromagnetic fields (e.g. microwaves or radiotherapy devices), can influence the audiometric function. Therefore, it is not recommended to use these devices in close proximity to the audiometer as it may lead to incorrect test results.

### 5.1.3 Switching On the Device


**Figure 30**

**NOTE:** The warm up time for the device including boot up process takes 10 minutes. If the device has not been used for a while (e.g. overnight), wait for the recommended period of time before operating the device.

Briefly press the ***Front key*** on the front of the touchTymp to turn on the device (Figure 30). The boot up process will take approximately 2 minutes. During this time the display will show the MAICO splash screen.

Important information or reminders may be displayed during the boot up process. This could include:


**Figure 31**

**Calibration Reminder:** If a detected transducer is within one month of expiration of the calibration date, a reminder message (Figure 31) will appear (once per day). See section 5.6.20.

Pressing ***OK*** will lead to the start screen.

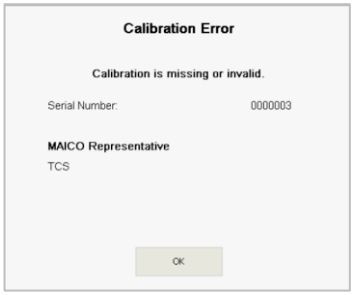



**Figure 32**

**Calibration Error:** If a calibration is missing or invalid a message box will appear (Figure 32). Pressing ***OK*** will lead to the home screen. The test screens are not available. The service and calibration must be performed by your dealer or by a service center authorized by MAICO. See section 3.2.

### 5.1.4 Switching Off the Device


**Figure 33**

The device can be shut down from any screen by pressing the ***Front key***. Choose one of the options (Shutdown or Standby) offered in a message box and press ***OK*** to shut down the device or ***Cancel*** and go back to the screen (Figure 33).

**NOTE:** In case the screen is frozen press the ***Front key*** for 10 seconds and the device will turn off.

## 5.2 Power-Saving Mode and Automatic Power-Off

After a period of inactivity, the device will go into standby mode in which the display will turn off. Pressing the ***Front key*** or the touch screen will awaken the device. Upon awakening from standby, the screen will display as it was when it went into standby mode.

A longer period of inactivity will activate the device to power off automatically. The period of inactivity can be changed in the ***Settings*** menu (see section 5.6.2). Current results will be deleted when power off occurs.

## 5.3 The Home Screen

The ***Home*** screen displays the buttons controlling entry into the major functions of the touchTymp. These functions include the specific test selection for MI 26 version (Figure 34) and MI 36 version (Figure 35).

To access the test, select the module from the ***Home*** screen (1) or Fixed Function Bar (2).

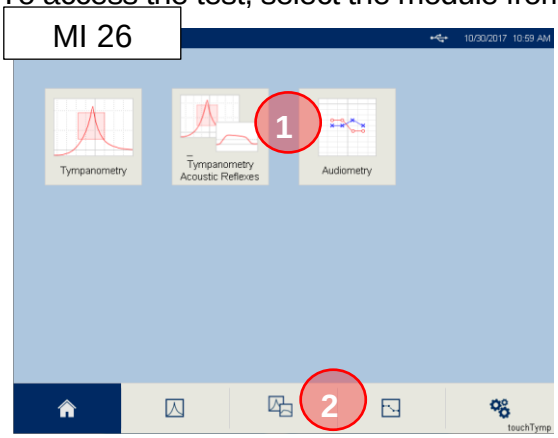



**Figure 34**

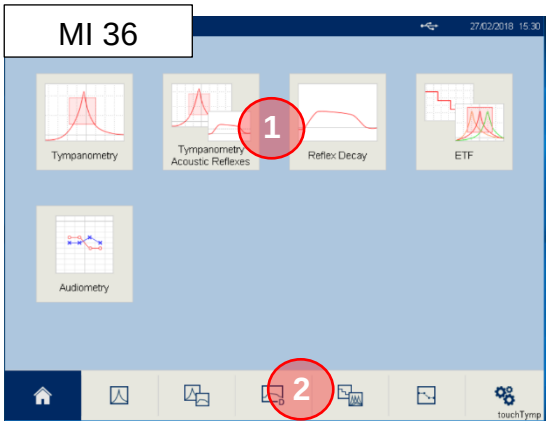



**Figure 35**

## 5.4 Immittance Testing

### 5.4.1 General – Immittance

The following sections 5.4.2 to 5.4.5 offer information about the modules ***Tympanometry***, ***Tympanometry and Acoustic Reflexes*** (MI 26 and MI 36 version)***,*** ***Reflex Decay***, and ***Eustachian Tube Function*** (MI 36 version only***)***.

### 5.4.2 The Screen Format – Immittance

The general touchTymp screen format includes (e.g. Figure 36) the following:

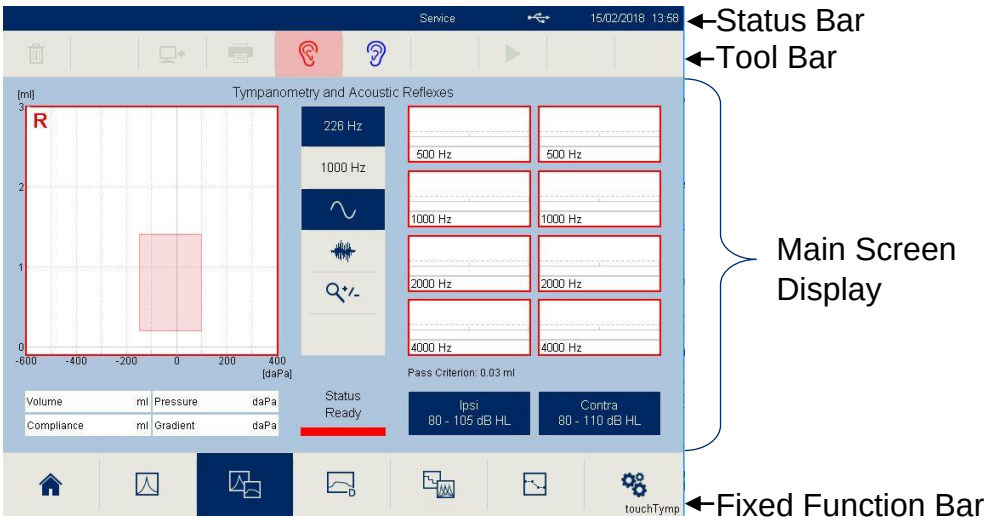



**Figure 36**

**Status Bar:** displays the Date/Time and the status of PC-connection (highlighted green if connected to PC-software (PC license must be activated) and MAICO Sessions is running).

**Tool Bar:** A row of icons that activate key functions when selected. Some buttons in the toolbar will be ghosted when not useable. These buttons will change based on test or setting screen visible.

The available icons for the ***Tool Bar*** include (Table 9):

**Table 9 Icons in the Tool Bar**

| | ICON | FUNCTION | EXPLANATION |
|---|---|---|---|
| Test Screen |  | **Delete** | ***Delete***: to delete the stored measurements. Select the button and a message box will appear to confirm which test modules to delete or select all. |
| |  | **Edit** | ***Edit:*** to edit reflex results. Select the button to enter the edit reflex screen. |
| |  | **Transfer to PC** | ***Transfer to PC:*** to transfer the currently measured data. Dependent on the measurement (right, left or both ears) all data of the measurement completed will be transferred. Only the test results of the currently selected probe tone will be transferred. |
| |  | **Print** | ***Print:*** to print the results of all completed tests and of all probe tones. |
| |  | **Selection of ears** | ***Ear:*** to select an ear for testing or repeating the measurement on the same ear (Blue = Left Ear, Red = Right Ear).<br>**NOTE:** The ear can be selected in different ways. Use the ear buttons on the screen or the ***Probe*** button to change the ear. Also, you can touch the left or right diagram. |
| |  | **Start / Stop / Pause** | ***Start***, ***Stop***, ***Pause***: to start, stop or pause a measurement. Icon will show only when applicable to the test method. |
| Setting screen |  | **Default** | ***Default:*** to set the device back to factory settings. |
| |  | **Save** | ***Save:*** to save current selection. |

**NOTE**: An active button is displayed in blue.

**Main Screen Display:** The middle or blue section displays the test configuration and results when in the test mode. For a detailed explanation of the different test screens see section 5.4.4.

**Fixed Function Bar:** This bar stays constant through device operation and the allowable test modules are based on the version purchased. The icons include (Table 10):

**Table 10 Icons in the Fixed Function Bar**

| ICON | FUNCTION | EXPLANATION |
|---|---|---|
| | Home | ***Home:*** to return to the ***Home*** screen for test selection. |
| | Tympanometry | ***Tympanometry:*** to open the ***Tympanometry*** module. |
| | Tympanometry & Acoustic Reflexes | ***Tympanometry & Acoustic Reflexes***: to open the ***Tympanometry and Acoustic Reflex*** module. |
| | Settings | ***Settings:*** to access a list of all the device settings. |
| ***Additional icons for MI 36 Version:*** | | |
| | Reflex Decay | ***Reflex Decay***: to open the ***Reflex Decay*** module |
| | ETF | ***ETF:*** to open the ***ETF*** module for ***intact*** or ***perforated ETF*** testing. |

### 5.4.3 Preparing for Testing – Immittance

#### *5.4.3.1 Preparing the Patient*

Also, check-out our training videos:

MAICO Training | touchTymp Part 1 | 2/8 Test environment - YouTube

https://www.youtube.com/watch?v=uY4jkbMc10c&list=PLonI5JzuDcd7lxKobEy7BW3DS59QCsbAG&index=2

Make sure that the patient is comfortable on a chair or on an examination table if necessary. Small children may feel more comfortable sitting on a parent's lap.

WARNING

Keep in mind the indication and contraindications of use given in sections 1.2 and 1.3.

#### *5.4.3.2 Visual Inspection of the Ear Canal*

Check the external ear canal for wax with an otoscope. Excessive wax should be removed by a qualified professional to prevent the probe opening from clogging which will inhibit testing. Excessive hairs may have to be cut for a seal to be obtained.

#### *5.4.3.3 Immittance Measurements*

Show the probe to the patient and then explain the following:

- An eartip is placed on the tip of the probe and inserted into the ear canal. A seal must be achieved for the test to progress.
- Coughing, talking and swallowing will disturb test results.
- The aim of ***Tympanometry*** is to test the mobility of the eardrum and the condition of the middle ear.
  - A small amount of air will flow through the probe to move the eardrum; it produces a sensation equal to pressing a finger slightly into the ear canal.
  - One or more tones will be heard during the test. No participation is expected from the patient.
- The aim of ***Acoustic Reflexes*** is to test the condition of the Musculus stapedius.
  - One or more louder tones will be heard during the test. No participation is expected from the patient.
- The aim of ***Reflex Decay*** is test the integrity of the CN VIII.
  - One tone is presented above the acoustic reflex threshold measurement for a minimum period of 10 seconds.
- The aim of ***ETF*** is to test the condition of the Eustachian tube.
  - ***ETF Intact***: three tympanograms are completed while the patient performs a manueaver between each tympanogram.
  - ***ETF Perforated***: pressure level is obtained in the ear canal and the patient swallows to measure change of pressure.

### *5.4.3.4 Handling the Eartips*

Choose the proper size of eartips based on your inspection of the size of the patient's ear canals.

WARNING

Do not insert the probe without having an eartip attached to prevent damage to the patient's ear canals.

Put the eartip tightly on the probe tip making sure it is pushed all the way down (Figure 37).

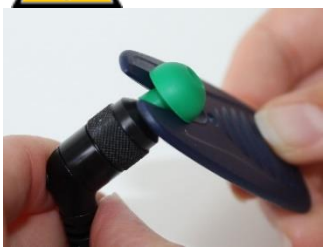
**Figure 37**

Insert the probe with eartip attached into the patient's ear. For children and adults, pull gently up and back on the outer ear (i.e. Pinna) during insertion to straighten the ear canal. Hold the adapter and aim and twist (gently) the eartip into the ear canal. The fit of the eartip should be secure; not superficial (Figure 38). Release the earlobe. When testing infants, gently pull the Pinna down and back to straighten the ear canal.

**Figure 38**

WARNING

Each eartip should only be used once. For more detailed information see section 3.4.



In order to remove the eartip, grasp the eartip at the base using the eartip removal tool and pull it smoothly straight off the probe tube (Figure 39).

**NOTE:** If the probe tip becomes dirty or clogged, it must be cleaned (see section 3.3.4) or replaced.

**Figure 39**

### *5.4.3.5 Status Indicator*


The status indicator (Figure 40) in the middle of each test screen provides the probe status on the display screen.

**Figure 40**

The same information is shown on the probe with the single LED (Table 11).

**Table 11 Test Status Indication**

| TEST STATUS INDICATION | | |
|---|---|---|
| **PROBE** | **SCREEN** | **INFORMATION** |
| | Status Ready | Right ear is selected. Probe is out of ear. |
| | Status Ready | Left ear is selected. Probe is out of ear. |
| | Status In Ear / Status Testing / Status Done | Probe is in the ear and is sealing, test is running or test is done. |
| | Status Blocking / Status Leaking | Probe is in the ear and blocked or leaking.<br>1. Reinsert probe for better placement.<br>2. Check eartip size and condition.<br>3. Inspect probe tip for any blockage. |
| No Light | Status No Probe | Probe is not attached properly. Check probe connection. |
| No Light | Status Unknown | Probe tone is not given. This status is shortly shown while the frequency is being changed. |

## 5.4.4 Testing – Immittance

### *5.4.4.1 Performance and Evaluation of Tympanometry Test*

Figure 41 shows the ***Tympanometry*** test screen.

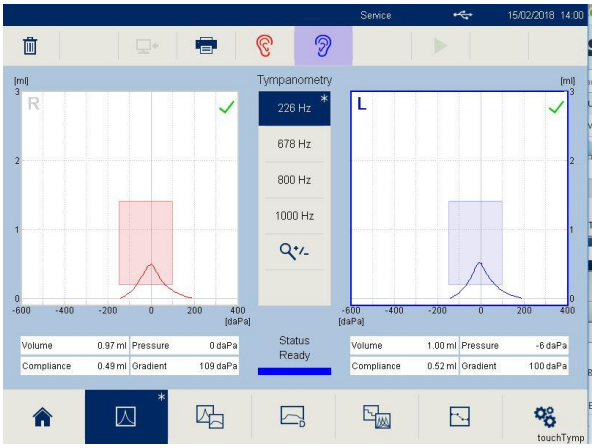



**Figure 41**

**NOTE**: Tympanometry test screen explanation apply to the ***Tympanometry*** module and the ***Tympanometry and Acoustic Reflex*** module.

## Performing a measurement

Also, check-out our training videos:

MAICO Training | touchTymp Part 1 | 3/8 Tympanometry - YouTube

https://www.youtube.com/watch?v=EMcGlihc_Aw&list=PLonI5JzuDcd7lxKobEy7BW3DS59QCsbAG&index=3

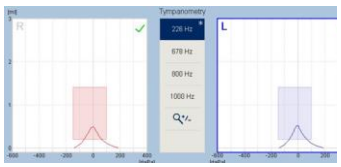


Figure 42

Choose the ear by pressing on the corresponding ***tympanogram,*** the ***ear*** buttons (Figure 42) or the ***Probe*** button.

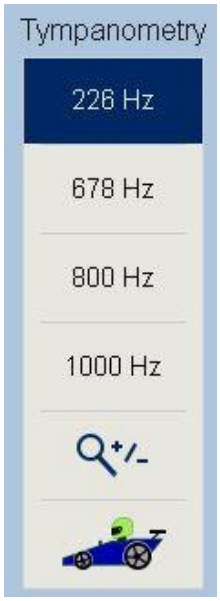



Figure 43

Choose the test frequency by pressing on the corresponding button.

- ***226 Hz***: Test frequency of 226 Hz is always preselected as default. A 226 Hz testing is recommended for adults and children older than ½ year.
- ***678 Hz***: Test frequency of 678 Hz (MI 36 version only).
- ***800 Hz***: Test frequency of 800 Hz (MI 36version only).
- ***1000 Hz***: Licensed function, to be chosen if patient is younger than half a year.
- Press to increase or decrease the intercepts of the graphs.
- **RaceCar** : Licensed function, to display ***RaceCar*** animation during testing. See section 5.4.4.3 for more information (Figure 43).

**NOTE:** If you print the test results, it will be printed with the view as displayed on the screen.

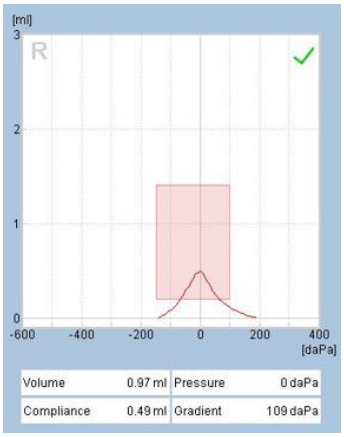
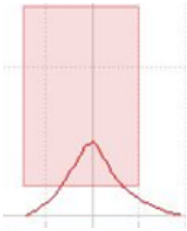



Figure 44

The measurement will be started as soon as the probe is properly placed in the ear when ***automatic*** is selected within the ***Settings*** menu, see section 5.6.3. When ***manual*** start of the measurement is selected, the ***Play*** ▶ button or the ***Probe*** button is pressed. The measured curve will be displayed simultaneously to the ongoing test. Below the graphic the numerical values are shown (Figure 44):

- **Volume:** indicates the volume of the section of the auditory canal between the eartip and the eardrum in ml.
- **Compliance:** indicates the maximum value of the compliance from the Tympanogram in ml or mmho.
- **Pressure:** indicates the pressure in daPa at the highest measured Compliance.
- **Gradient:** calculations are reported as the ***Tympanogram*** width at half of peak compliance expressed in daPa.



A normative box can be displayed for easier evaluation of the test result as a shaded area on the ***Tympanogram*** (Figure 45). The normative box is displayed based on US or International Standards as selected in the setting menu. A user defined normative box is also available.

**Figure 45**

In the Tympanogram the result symbol appears at the right top of the graph (***Pass*** ✓ or ***No Response (NR)*** ✗). This evaluation is based on the normative box displayed (see section 5.6.8).

**NOTE:** When ***user defined*** normative boxes are used, the ***Pass/No Response (NR)*** signs will not be displayed.

**Normative Data / Pass and No Response Criteria**

Also, check-out our training videos:

MAICO Training | touchTymp Part 1 | 4/8 Test result - YouTube

https://www.youtube.com/watch?v=jdXFM2_S3Dg&list=PLonI5JzuDcd7lxKobEy7BW3DS59QCsbAG&index=4

If switched on, the normative boxes can be shown for 226 Hz and 1000 Hz. The box indicates the normative area where the peak of the ***Tympanogram*** is expected. The ***Pass*** and ***No Response*** criteria are based on the placement of the ***Tympanogram*** peak within the normative box.

A result is considered a ***Pass*** ✓ when the maximum compliance is in the normative box. A result is considered a ***No Response (NR)*** ✗ when the maximum compliance is outside of the normative box. If the normative boxes are inactive, no evaluation of the measurement is given.

### *5.4.4.2 Performance and Evaluation of the Acoustic Reflex Test*

Selection of the ***Tympanometry and Acoustic Reflex*** icon leads to the ***Tympanometry and Acoustic Reflex*** screen (Figure 46). Review section 5.4.4.1 for ***Tympanometry***.

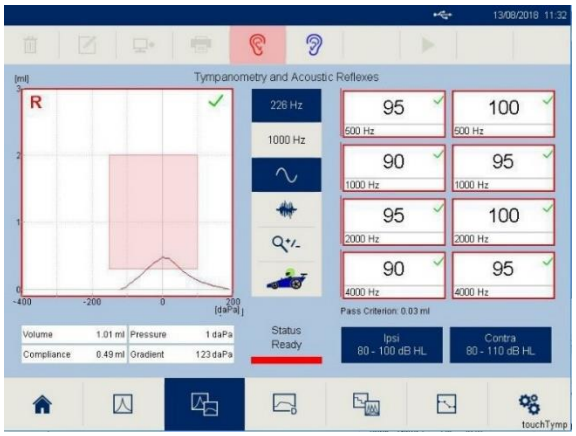



**Figure 46**

**NOTE**: A ***Tympanometry*** measurement is performed before each ***Acoustic Reflex*** test to find the maximum compliance pressure for better performance. However, it is possible to perform pure ***Tympanometry*** testing in this module if the ***Acoustic Reflexes*** are deactivated in the settings or on the screen (see section 5.6.10).

## Performing a measurement

Also, check-out our training videos:

MAICO Training | touchTymp Part 1 | 5/8 Acoustic Reflexes - YouTube

https://www.youtube.com/watch?v=g0PA5TtkBsQ&list=PLonI5JzuDcd7lxKobEy7BW3DS59QCsbAG&index=5

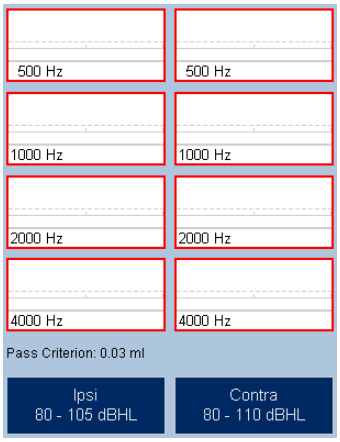



**Figure 47**

The screen (Figure 47) shows the buttons for ***Ipsi*** and ***Contra*** as well as the different frequency buttons. They are always presented according to the default settings in the setting menu and from low to high frequencies. It is possible to select or deselect one of the frequencies by pressing on it. Pressing the ***Ipsi*** or ***Contra*** button will turn on/off all frequencies or set the selection back to default settings.

**NOTE:** If there are no frequencies chosen in the default settings it is not possible to turn on an ***Acoustic Reflex*** test by pressing the ***Ipsi*** or ***Contra*** button. To turn on a Reflex, press the individual frequency to be tested.

The ***Ipsi*** and ***Contra*** button also show the level range (for automatic level adjustment) or the level (for fixed levels). See section 5.6.10.

The measurement starts when the probe is properly placed in the ear (when in the ***Basic Settings*** menu the automatic start of the measurement is selected (see section 5.6.3) or the ***Play*** ▶ button is pressed (when the manual start of the measurement is selected).

When performing Acoustic Reflex testing it is possible to interrupt the measurement for pausing by pressing the ***Pause*** ⏸ button, the ***Probe*** button (both only possible in manual mode) or removing the probe from the ear (no seal state). While having the probe removed from the ear the display will show a message box asking if you want to stop the measurement. Press ***Stop*** ■ to stop the measurement. Continue the measurement by inserting the probe into the ear again.

## Evaluation

Also, check-out our training videos:

MAICO Training | touchTymp Part 1 | 6/8 Acoustic reflex result - YouTube

https://www.youtube.com/watch?v=FbQ5Zk1SGdM&list=PLonI5JzuDcd7lxKobEy7BW3DS59QCsbAG&index=6

The evaluation of the ***Acoustic Reflex*** test results depends on the configuration displayed as a graph or table.

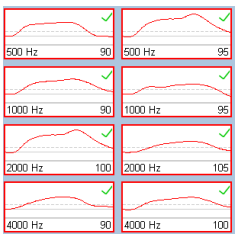



**Figure 48**

***Graph:*** The measured curves are displayed simultaneously to the ongoing test. For easier evaluation the pass criterion threshold and the zero line are shown in the graph. Underneath each diagram the frequency and the intensity level in dB HL are displayed (Figure 48).

**NOTE:** The deflection of the graph can be modified in the settings. See section 5.6.9.


**Figure 49**

***Table:*** The measured intensity level in dB HL is displayed simultaneously to the ongoing test. Underneath each diagram the frequency is displayed (Figure 49).

At the conclusion of the test, the result symbol appears at the top right corner of the box either in the graphical view as in the table view. This is displayed for the ***Acoustic Reflex*** measurement that meets the criteria as defined in the setup menu. A green checkmark ✓ indicates a present reflex. A red cross ✗ indicates ***No Response***. To be considered as a ***Pass*** ✓ the maximum amplitude of the reflex shape must reach a defined value (sensitivity) for a defined time. Otherwise it is considered as ***No Response*** ✗.

## Noise stimuli (MI 36 Version Only)


**Figure 50**

The MI 36 version includes pure tone and noise stimuli for ***Acoustic Reflex*** testing.

: ***Pure tone*** (500 Hz, 1000 Hz, 2000 Hz, 4000 Hz)

: ***Noise*** (BB – Broadband, HP – High Pass, LP – Low Pass)

Select the stimulus type to set or confirm test stimuli prior to starting test. When the button is blue, this notes there is an active stimulus to be tested. When both buttons are blue *at least* one pure tone and one noise stimulus will be presented during the test.

## Edit Acoustic Reflex

Acoustic reflex results can be reviewed by the ***Edit*** button within the tool bar. When this button is selected, the device is in edit mode where results can be reviewed or modified prior to printing or software transfer (Figure 51). The edit mode is only available when the display ***Presentation*** mode is set to ***Graph*** in the ***Settings*** (see section 5.6.9).

**NOTE**: ***Edit*** button is only available for selection when a result has been stored on the screen.


**Figure 51**

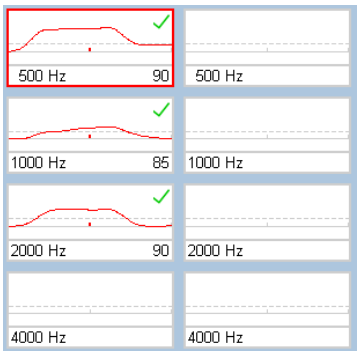



**Figure 52**

The stimulus selected upon entering the ***Edit*** screen is always the first reflex performed. A red or blue line will outline the selected box based on which ear is selected (Figure 52).

**NOTE:** The direction of deflection can be modified in the in the ***Settings*** menu. See section 5.6.9.

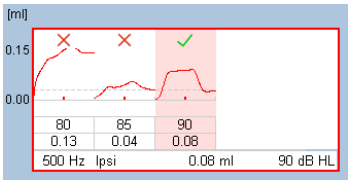



**Figure 53**

The large window displays multiple reflexes performed for the selected stimulus. Up to the last five reflexes are displayed. Intensity level and deflection value are displayed below each reflex graph (Figure 53).

The bottom row of the display provides result information for the highlighted reflex (i.e. stimulus: 500 Hz Ipsi, deflection value: .08 ml, intensity: 90 dB HL)

## Editing the displayed reflex

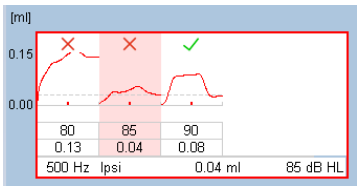



**Figure 54**

To change the reflex level, touch the column where the graph is displayed. This will move the highlighted box to the new level and place the result in the small box on the right (Figure 54).

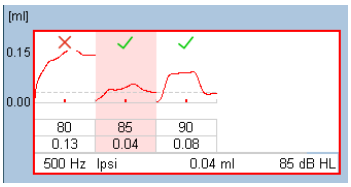



**Figure 55**

When a ***Pass*** ✓ or ***No Response*** ✗ is displayed, the examiner can change this by touching the highlighted column. This will toggle the notation with each touch. (Figure 55).

**IMPORTANT NOTE**: Careful review should be taken when making changes to automatic threshold results.

To return to the test module, select the ***Edit*** button from the tool bar. All changes are saved for printing and/or transferring to the PC upon exiting the edit mode.

### *5.4.4.3 RaceCar Operation (Extra License)*


**Figure 56**

The RaceCar is an animation to provide a visual distraction while the test is being performed. The RaceCar goes through an animation series starting upon the seal of Tympanometry and continue through the finish line. Within this RaceCar screen, the bottom fourth displays the test progress for the examiner.

The ***RaceCar*** button is displayed (when licensed) within the middle column of the ***Tympanometry*** or ***Tympanometry and Acoustic Reflexes*** test modules.

Figure 57 shows the RaceCar screen. The RaceCar test sequence is described below.

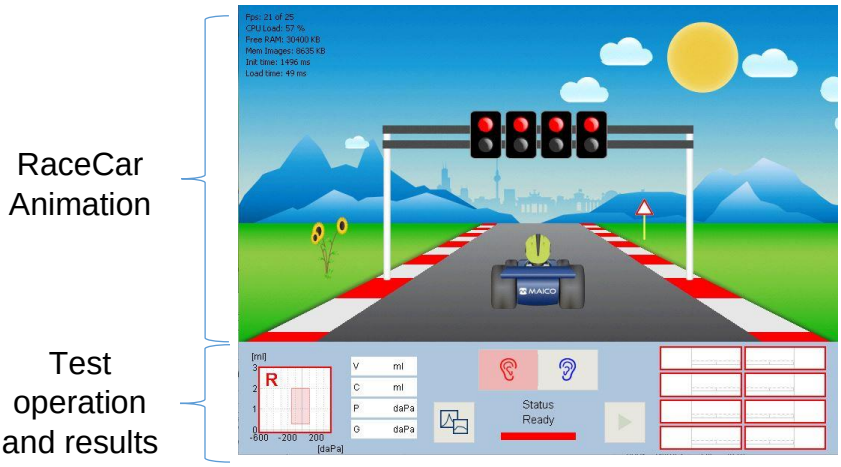



**Figure 57**

**RaceCar Test Sequence**

1. Verify the device is set to preferred test sequence before entering the RaceCar screen.
2. Select the ***RaceCar*** icon within the Tympanometry or ***Tympanometry and Acoustic Reflex*** test modules.
3. Once entered, the RaceCar screen shows the car running and waiting to start the race.
4. Inform the child to sit very still and watch their car ***RACE*** to the finish line.
5. The race starts with probe seal when ***Automatic*** is selected in the ***Settings***. When ***Manual*** is selected, the examiner will initiate the start of the test by selecting the ***Play*** ▶ or ***Probe*** button.
6. RaceCar will change the animation based on the probe status.
   a. Probe ***Status Ready***, the car is running while waiting for the Race to start. Also ***Status Ready*** can be shown when a test wasn't completed. The tire goes flat until the test is started again.
   b. Probe ***Status Testing***, the lights turn green and race begins.
   c. Probe ***Status Done***, the finish line appears and the race will be completed shortly.
   d. Probe ***Status Leaking*** the car slows down or the tire is flat.
7. When one ear is done, select the next ear within the RaceCar screen and start a new race.
8. Examiner returns to the test module to print, transfer and/or delete test results.

Active Buttons within the RaceCar screen are:

- ***Ear*** buttons: Select test ear or touch the Tympanometer graph (***Tympanometry*** module only).
- ***Play*** ▶ button: to start the test when manual operation is defined.
- ***Tympanometry*** or ***Tympanometry and Acoustic Reflexes*** returns the examiner to the test module.

### *5.4.4.4 Performance and Evaluation of Reflex Decay Test – MI 36 Version*

Selection of the ***Reflex Decay*** icon on the ***Home*** screen or ***Fixed Function Bar*** moves to the ***Reflex Decay*** screen (Figure 58).

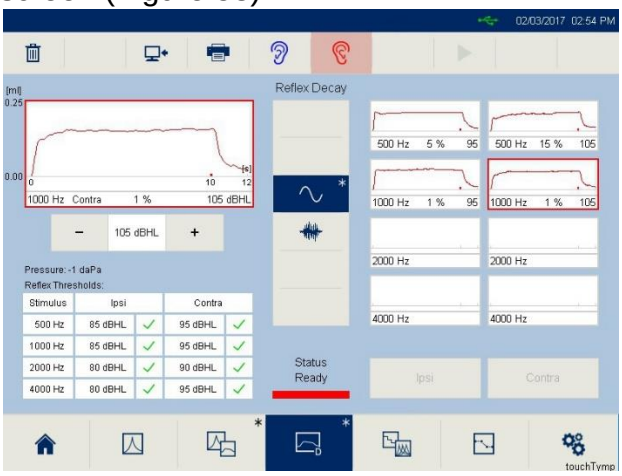



**Figure 58**

## Performing a measurement

**NOTE:** Tympanometry and ***Acoustic Reflex*** measurements are recommended to be performed before each ***Reflex Decay*** test to find the maximum compliance pressure and ***Acoustic Reflex*** threshold. The results will be displayed on the screen for instant review.

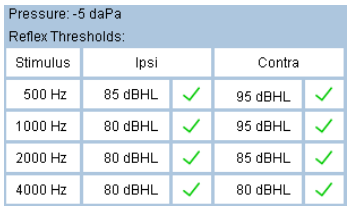



**Figure 59**

**Pressure:** is the peak pressure of the ***Tympanogram*** performed.

**Reflex Thresholds:** the results from the ***Tympanometry and Acoustic Reflex*** module for ease of selecting the ***Reflex Decay*** presentation level (Figure 59).

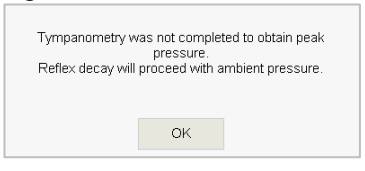



**Figure 60**

When a test is started without ***Tympanometry and Acoustic Reflex*** measurements, a message box appears to continue operation (Figure 60).

**Figure 61**

Choose the test stimulus by first pressing on the stimulus type button (Figure 61):

: ***Pure tone*** (500 Hz, 1000 Hz, 2000 Hz, 4000 Hz)

: ***Noise*** (Broadband, High Pass, Low Pass)


**Figure 62**


**Figure 63**

Select the stimulus by pressing the small box on the right. A red or blue line will outline the selected box based on which ear is selected (Figure 62).

**NOTE:** 1000 Hz is the default frequency when entering the ***Reflex Decay*** test screen.

Press the **-** and **+** to change the presentation level of the stimulus selected. When a ***+/-*** is greyed out, the device has reached the minimum or maximum level for the stimulus and transducer selected (Figure 63).

Manual presentation is required within ***Reflex Decay*** measurements. Press the ***Play*** ▶ button or the ***Probe*** button to start the measurement.

When performing ***Reflex Decay*** testing it is possible to interrupt the measurement by pressing the ***Stop*** ■ icon, the ***Probe*** button or removing the probe from the ear (no seal state). To restart the measurement insert the probe into the ear again and press ***Play*** ▶.

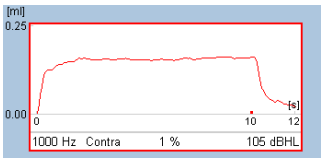



**Figure 64**

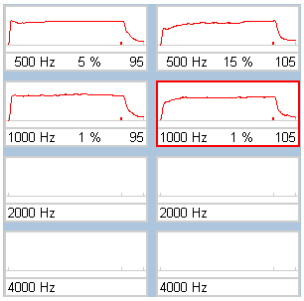



**Figure 65**

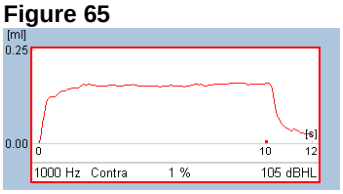



**Figure 66**

The measurement values of the ***Reflex Decay*** test result are displayed in the large window while the test is performing and immediately duplicated in the small window upon the completion of the test (Figure 64). To continue on testing:

1. Select the next stimulus.
2. Confirm or set the level.
3. Press the Play ▶ button.

When testing is complete, previous measurements can be displayed in the large window by selecting the small stimulus box on the right side of the screen (Figure 65).

The measurement values are displayed simultaneously to the ongoing test. Measured results are shown following the measurement (Figure 66):

**Y-Axis*:*** Displays the compliance scale to display the deflection of the reflex (i.e. 0.00 ml - 0.25 ml). The y-axis is static.

**X-Axis:** Displays the time. This includes the time the stimulus is active (i.e. 10 s), which is configured in the settings, and the time of the active window (i.e. 12 s).

**Status Bar:** The bottom block of the display provides test information that includes:

- ***Stimulus***: 1000 Hz Contra
- ***Decay result***: 1 %
- ***Intensity***: 105 dB HL

The small **red/blue** dash/tick moves along the 0.00 ml line which corresponds to the stimulus presentation.

**NOTE:** The direction of deflection can be modified in the ***Settings*** menu. See section 5.6.9.

### *5.4.4.5 Performance and Evaluation of Eustachian Tube Function (ETF) – MI 36 Version*

Selection of the ***ETF*** icon from the ***Home*** screen or ***Fixed Function Bar*** leads to the ***ETF*** screen (Figure 67). ***ETF*** has two operations:

- **ETF Intact** : performed on patients with normal tympanic membrane (TM).
- **ETF Perforated** : performed on patients with a perforated TM or open PE tubes in place.

***ETF Intact*** is the default selection when the module is entered.

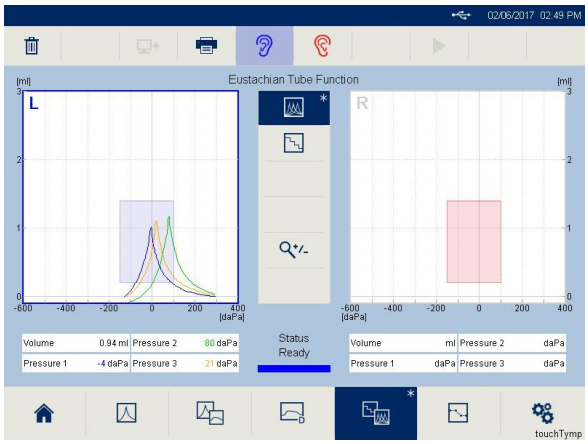



**Figure 67**

## Performing a Measurement

**Figure 68**

Select the test type ***ETF Intact*** , or ***ETF Perforated*** (Figure 68).

## Performing an ETF Intact Measurement

***ETF Intact*** is performed by measuring three tympanograms on a multilayer display. Before testing begins, instruct the patient not to move or talk until the test is completed. Any sound or movement may give unreliable results.

| | | | |
|---|---|---|---|
| Volume | ml | Pressure 2 | daPa |
| Pressure 1 | daPa | Pressure 3 | daPa |

**Figure 69**

As the test is progressing the numerical information below the graph is displayed. Once the first ***tympanogram*** is complete, the pressure at the maximum compliance appears under ***Pressure 1*** (Figure 69).

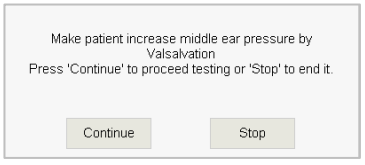



**Figure 70**

The pressure is held as the patient is instructed to perform a maneuver (i.e. ***Swallow***, ***Valsalva***) (Figure 70). When completed, press continue for the second ***tympanogram*** to be completed. The pressure at the maximum compliance appears under ***Pressure 2***.

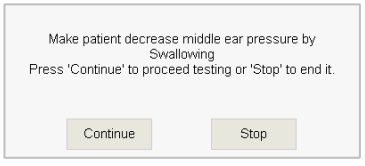



**Figure 71**

Once again, the pressure is held while the instruction is displayed for the patient to perform the second maneuver (Figure 71). Press continue to perform the third ***tympanogram***. The pressure at the maximum compliance displays under ***Pressure 3***.

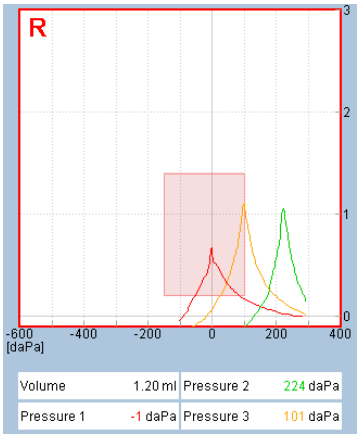



**Figure 72**

Compare the single tympanograms in the multilayered tympanogram (Figure 72). Tympanograms displayed include:

- ***Red* or *Blue***: represents test ear
- ***Orange***: represents "***Swallow***"
- ***Green***: represents "***Valsalva maneuver***"

**NOTE:** The order of instructions displayed can be configured in the ***Settings***, see section 5.6.13).

## Performing an ETF Perforated Measurement


**Figure 73**

***ETF Perforated*** determines if the patient can open his/her Eustachian tube when the TM is perforated or an open PE-tube is in place. ***ETF Perforated*** will put the middle ear under a certain ***Start pressure*** based on the default setting, but can be modified in 25 daPa steps by the on screen pressure setting (Figure 73).

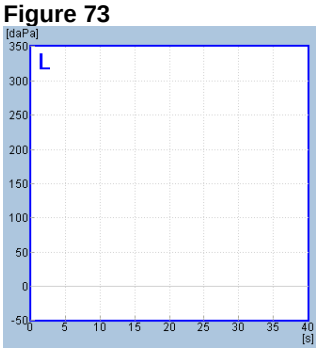



**Figure 74**

The graph displays the vertical axis as pressure, and the horizontal axis as time (Figure 74).

Instruct the patient not to move or talk until the test is over. When a seal is obtained, the device displays a message to swallow as many times during the test duration.

**NOTE**: Automatic and manual mode are operated the same for this ***ETF Perforated*** test as a start operation is required.


**Figure 75**

Pressure will increase to the predetermined setting.

Let the pressure run a few seconds at peak pressure to verify a successful seal. Once the peak pressure has been obtained ask the patient to swallow as many times as they can while the test is running.

If the ***Eustachian tube*** opens, a drop in pressure will be recorded. Repeated attempts to swallow will display a downward stair step effect, or a complete drop to 0 daPa (Figure 75).

Numerical results of the test are displayed below the graph. Each time the device detects opening and closing of the ***Eustachian tube***, the results are recorded. An open and close result is displayed up to three values.

The test will stop after the allotted time (i.e. 30 seconds) as defined in the settings or the examiner manually stops the test.

## 5.4.5 Managing Test Results – Immittance

### *5.4.5.1 General*

There are different possibilities to manage the results. It is possible to print the session directly with the built-in printer or transfer the data to a PC for further processing.

### *5.4.5.2 Completed Results*

When a test is completed within a module the button will display an ***asterisk*** ∗, for indication a test is stored in this module. These notations will change when printing or transferring results are completed as described in sections 5.4.5.4 and 5.4.5.6.

### *5.4.5.3 Deleting Test Results*

Results are deleted by the ***Delete*** button or turning-off the device. When ***Delete*** is selected, each module is listed to confirm deletion (Figure 76).

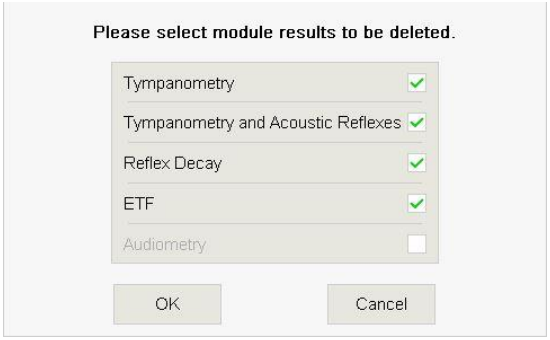



**Figure 76**

**NOTE**: It is best practice to delete results after testing is completed for each patient.

### *5.4.5.4 Printing Test Results with the Built-in Printer*

Test results can be directly printed with the built-in printer. Press on the ***Print*** button and a message box ***"Processing print job"*** will display. Printing from the device will print all test results at once (i.e. 226 Hz and 1000 Hz).

**NOTE**: The printout will contain the same content as the diagrams on the screen.

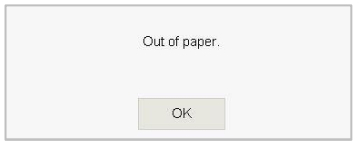



**Figure 77**

If the printer is out of paper a message box will appear (Figure 77). You can reorder paper from your local distributor. For detailed information about how to change the paper rolls see section 4.2.7.


**Figure 78**

A message box will appear once printing has started to cancel printing (Figure 78). When cancelled, printing can be restarted by pressing the ***Print*** button.

**Figure 79**

At the completion of the printing, a ***Print*** icon is displayed on the button to note the printing of the tests (Figure 79). This is only displayed when all tests have been printed.

### *5.4.5.5 Understanding the Print-Out (Built-In Printer)*

The print-out displays the following information (Figure 80 and Figure 81).

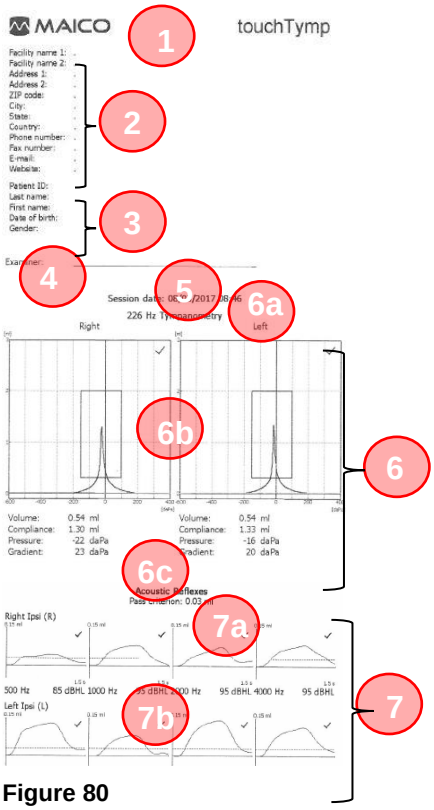



**Figure 80**

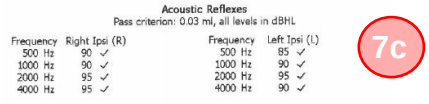



**Figure 81**

1 ***MAICO logo and name of device***

2 ***Facility info***: Prints automatically those fields that contain data (not shown if no data is entered).

3 ***Patient data***: provides the field name to manually enter. Can be selected/deselected in settings (see section 5.6.4).

4 ***Examiner***: empty line for examiner's signature.

5 ***Session date and time***: shows the date and time of the session as displayed on the device.

6 ***Test result Tympanometry***: consists of frequency of probe tone (6a), graphical display (6b) and numerical data (6c).

7 ***Test result Acoustic Reflexes***: shows pass criterion (7a) and test result as a graph (7b) or a table (7c).

**NOTE:** ***ETF*** and ***Decay*** results are printed with graphical and numerical information.

### *5.4.5.6 Transferring Test Results to PC*

**Note**: For data transfer between touchTymp and MAICO Sessions it is necessary to activate the license for PC connection which can be additionally purchased.

Before transferring data to a PC make sure that you have installed the PC software properly according to the separately delivered operation manual. Before establishing the PC connection you will have to consider the recommendations given in section 4.2.4 in case the touchTymp is connected to a non-medical device.

If the PC connection is properly established and MAICO Sessions is running, the connection icon in the status bar will be highlighted green. To transfer the data to the PC, press the ***Transfer to PC*** button. It is only possible to transfer data of each test separately (***226 Hz*** or ***1000 Hz***, ***Tympanometry*** or ***Decay***).

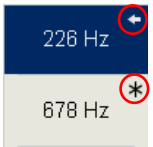



**Figure 82**

**Figure 83**

At the completion of the transfer, an ***arrow*** icon is displayed on the button to note the transfer of the tests. This is displayed for each test transferred. The module button will remain with an ***asterisk*** ∗ until all tests have been transferred (i.e. Tymp 226 Hz, Tymp 678 Hz). See Figure 82 and Figure 83.

## 5.5 Audiometry Testing

### 5.5.1 General – Audiometry

The following sections 5.5.2 to 5.5.5 offer information about testing with the Audiometry module.

### 5.5.2 The Screen Format – Audiometry

The appearance of the ***Audiometry*** screen depends on the purchased device version (MI 26 Air Conduction only – Figure 84, MI 26 with Bone Conduction and MI 26 – Figure 85). It includes the ***Status Bar***, the *Tool Bar* and the ***Main Screen Display***.

MI 26 Air Conduction only

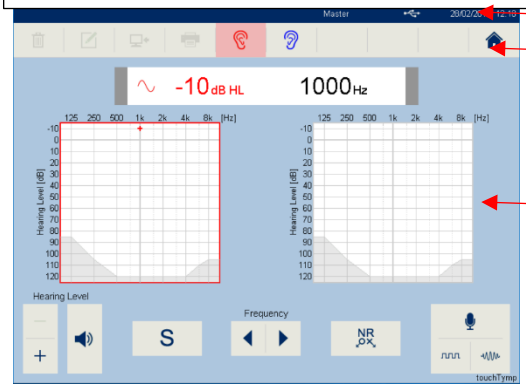



Figure 84

MI 26 with Bone Conduction and MI 36


Figure 85

**Status Bar**: displays the Date/Time and the status of PC-connection (highlighted green if connected to PC-software and Module is running).

**Tool Bar**: A row of buttons that activate key functions when selected. Some buttons in the toolbar will be ghosted when not useable. These buttons will change based on test or setting screen visible.

The available buttons for the **Tool Bar** include (Table 12):

**Table 12 Icons in the Tool Bar**

| | ICON | FUNCTION | EXPLANATION |
|---|---|---|---|
| **Test Screen** | | **Delete** | **Delete**: to delete the stored measurements. Select the button and a message box will appear to confirm which test modules to delete or select all. |
| | | **Edit** | **Edit** (only for ***Audiometry*** test screen): to edit Audiometry results. See section 5.5.5.7 for more information. |
| | | **Transfer to PC** | **Transfer to PC**: to transfer the currently measured data. Dependent on the measurement (right, left or both ears) all data of the measurement completed will be transferred. Only the test results of the currently selected probe tone will be transferred. |
| | | **Print** | **Print**: to print the results of all completed tests and of all probe tones. |
| | | **Selection of ears** | **Ear**: to select an ear for testing or repeating the measurement on the same ear (Blue = Left Ear, Red = Right Ear).<br>**NOTE**: The ear can be selected in different ways. Use the ear buttons on the screen or the ***Probe*** button to change the ear. Also, you can touch the left or right diagram. |

| | ICON | FUNCTION | EXPLANATION |
|---|---|---|---|
| | | **Home** | ***Home*** (only for ***Audiometry*** test screen): to return to the Home screen for test selection. |
| **Setting screen** | | **Default** | ***Default***: to set the device back to factory settings. |
| | | **Save** | ***Save***: to save current selection. |

**NOTE**: An active button is displayed in blue.

**Audiometry Main Screen Display (Versions MI 26 with Bone Conduction and MI 36)**

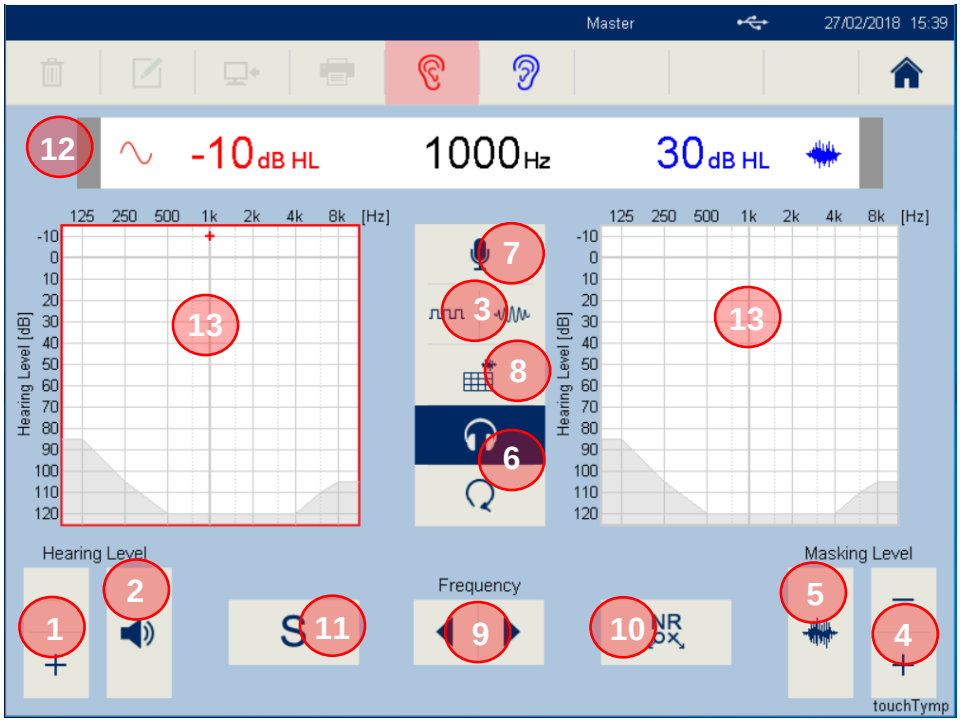
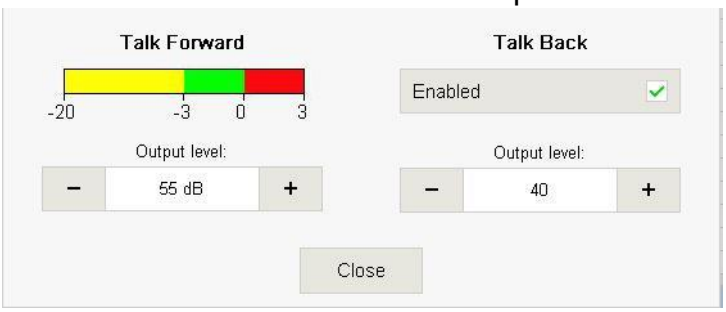
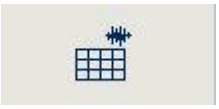


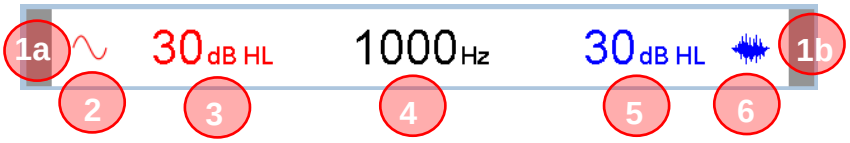

**Figure 86**

For explanation of the ***Audiometry Main Screen Display*** (Versions MI 26 with ***Bone Conduction*** and MI 36) see Table 13.

**Table 13 Explanation of Main Audiometry Screen – Versions MI 26 with Bone Conduction and MI 36**

| # | Name(s) / Function(s) | Description |
|---|---|---|
| 1 | **Hearing Level**  | Turns the volume/level of the tone up/down. |
| 2 | **Present**  | The function of ***Present*** is determined by the ***Test mode*** of the device.<br>• ***Presenter mode***: Touch to present the signal. When this button is blue, it is presenting the stimulus to the patient. Also a green indicator is displayed on the left side of the status bar. See Status Bar for more information.<br>• ***Interrupter mode***: Touch to stop the signal being presented.<br>**NOTE**: See ***Settings*** to change the ***Test mode***. |
| 3 | **Test Stimulus** | Selection of the stimulus to present.<br>  Steady stimulus<br>  Pulse stimulus<br>  Warble stimulus<br>  Pulse/Warble stimulus |
| 4 | **Masking Level dB**  | Turns the volume/level of the masking noise up/down. This does not turn the signal on, only changes the volume. |
| 5 | **Masking button**  | Activates the masking noise to the opposite transsducer. |
| 6 | **Transducer**  | Selection between Air or Bone conduction transducer.<br>  Air Conduction/Headphone<br>  Bone Conduction/Bone Oscillator |

| # | Name(s) / Function(s) | Description |
|---|---|---|
| 7 | **Microphones**  | Selection allows two microphone changes when accessories are connected.<br>1. ***Talk Forward***: Allows tester to provide instruction to the patient while the headphones are in place. Increase/decrease the volume by selecting the **+/-** (Figure 87). The lighted bar/VU meter allows the examiner to monitor their voice for optimal sound quality. When speaking, 0 is the optimal level.<br>2. ***Talk Back***: Allows the tester to hear the patient through the monitor headphone via an optional talk back microphone. The talk back microphone must first be ***Enabled*** (Figure 87) prior to setting the volume. The volume dial on the mic/monitor headset must also be controlled for optimal volume.<br>  <br>**Figure 87** |
| 8 | **Show masking**  | Selection allows the masking table to be displayed. |
| 9 | **Frequency**  | Touch ▶ to increase the frequency (Hz).<br>Touch ◀ to decrease the frequency (Hz). |
| 10 | **No Response (NR)**  | Touch to store ***No Response*** result within the ***graph*** or ***table*** display. |
| 11 | **Store**  | Touch to display a test result within the ***graph*** or ***table*** display. |

| # | Name(s) / Function(s) | Description |
|---|---|---|
| **12** | **Status Bar** | The numerical display for the testing operation of the device (Figure 88).<br>  <br><br>**Figure 88**<br>The information includes (Table 14):<br>**Table 14 Status Bar explanation**<br>**#** / **Status Bar Explanation**<br>**1a/ 1b**: When a stimulus is presented to the patient the small box on the edge of the bar turns green. The left is for the test signal and the right box is for the masking noise.<br>**2**: Stimulus symbol (i.e. pure tone, pulse, etc.) for test ear.<br>**3**: Hearing level of test signal, displayed in the color of the ear being tested (Right ear/Red, Left ear/Blue).<br>**4**: Frequency of test signal.<br>**5**: Masking level displayed in the color of the non-test ear.<br>**6**: Noise symbol for masking |
| **13** | **Result Display** | Results are stored on the device for later printing or transferring to the PC. The display can be configured to ***Graph***, ***Table*** or ***None*** within the settings. See section 5.6.16 for more information.<br>**NOTE**: ***None***-setting display does not allow storing of results. |
| | **Delete point**<br>  | Only shown in ***Edit mode*** (see Table 12). Single measurement results can be deleted. |

## Audiometry Main Screen Display (MI 26 with Air Conduction only)

Figure 89 shows the Main Screen Display for MI 26 Air Conduction only. Table 15 gives further explanation.

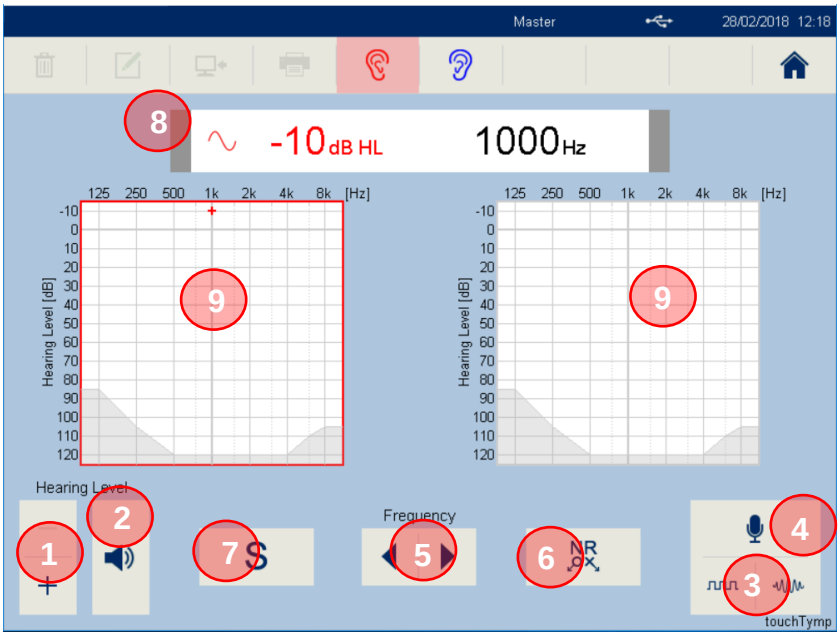
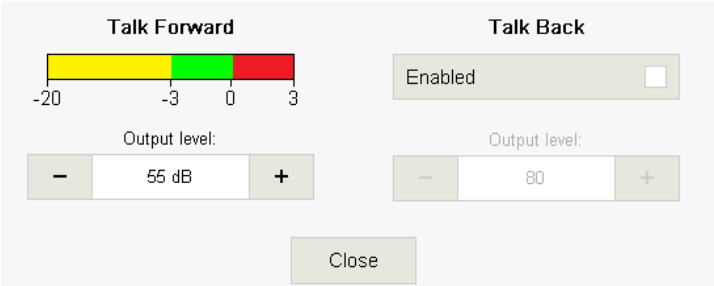



**Figure 89**

**Table 15 Explanation of the Audiometry Main Screen Display (MI 26 – Air Conduction Only)**

| # | Name(s) / Function (s) | Description |
|---|---|---|
| 1 | **Hearing Level**  | Turns the volume/level of the tone up/down. |
| 2 | **Present**  | The function of ***Present*** is determined by the ***Test mode*** of the device.<br>• ***Presenter mode***: Touch to present the signal. When this button is blue, it is presenting the stimulus to the patient. Also a green indicator is displayed on the sides of the status bar. See Status Bar for more information.<br>• ***Interrupter mode***: Touch to stop the signal being presented.<br>**NOTE**: See ***Settings*** to change the ***Test mode***. |
| 3 | **Test stimulus** | Selection of the stimulus to present.<br>  Pure tone stimulus<br>  Pulse stimulus<br>  Warble stimulus<br>  Pulse/Warble stimulus |

| # | Name(s) / Function (s) | Description |
|---|---|---|
| 4 | **Micro-phones**  | Selection allows two microphone changes when accessories are connected.<br>1. ***Talk Forward***: Allows tester to provide instruction to the patient while the headphones are in place. Increase/decrease the volume by selecting the ***+/-*** (Figure 90). The lighted bar/VU meter allows the examiner to monitor their voice for optimal sound quality. When speaking, ***0*** is the optimal level.<br>2. ***Talk Back***: Allows the tester to hear the patient through the monitor headphone via an optional talk back microphone. The talk back microphone must first be ***Enabled*** (Figure 90) prior to setting the volume. The volume dial on the mic/monitor headset must also be controlled for optimal volume.<br>  <br>**Figure 90** |
| 5 | **Frequency**  | Touch ▶ to increase the frequency (Hz).<br>Touch ◀ to decrease the frequency (Hz). |
| 6 | **No Response (NR)**  | Touch to store ***No Response (NR)*** result within the graph or table display. |
| 7 | **Store**  | Touch to display a test result within the graph or table display. |

| # | Name(s) / Function (s) | Description |
|---|---|---|
| 8 | **Status Bar** | The numerical display for the testing operation of the device (Figure 88). |


**Figure 91**

The information includes (Table 14):

**Table 16 Status Bar explanation**

| # | Explanation |
|---|---|
| **1** | When a stimulus is presented to the patient the small boxes on the edge of the bar turn green. |
| **2** | Stimulus symbol (i.e. pure tone, pulse, etc.) for test ear. |
| **3** | Hearing level of test signal, displayed in the color of the ear being tested (Right ear/Red, Left ear/Blue). |
| **4** | Frequency of test signal. |

| | | |
|---|---|---|
| **9** | **Result Display** | Results are stored on the device for later printing or transferring to the PC. The display can be configured to ***Graph, Table*** or ***None*** from the ***Settings***. See section 5.6.16 for more information. |
| | | **NOTE**: ***None***-display does not allow storing of results. |
| | **Delete point**  | Only shown in ***Edit mode*** (see Table 12). Single measurement results can be deleted again. |

## 5.5.3 Preparing for Testing – Audiometry

### *5.5.3.1 Preparing the Patient*

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

Prior to hearing threshold level measurements, the following instructions should be given. ***"You will now hear a variety of tones with various loudness levels, raise your hand, or press the response switch, as soon as you hear the tone in either ear."***

**NOTE**: This is an example of patient preparation. Each state may have their own preparation procedure. Contact your state health department for guidelines in your area.

#### *5.5.3.2 Placement of Headphones (for Testing with Headphones)*

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

#### *5.5.3.3 Placement of Foam Eartips (for Testing with Insert Earphones Only)*

**Figure 92**

First, place the eartip securely on the white adapter at the end of the insert earphone tubing. To prepare the foam eartip for insertion in the ear canal, you must compress the foam by rolling it in your fingers to narrow its diameter (Figure 92). Check to be sure that the foam does not obstruct the opening of the black sound tube.

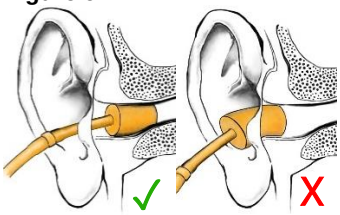


**Figure 93**

Quickly, while the foam is still compressed, grasp the patient's ear and gently pull it up and back to open and straighten the ear canal. While holding the canal open, slide the compressed foam ear tip into the ear canal. The foam should be completely surrounded by the canal with virtually none of the foam sticking out of the canal (Figure 93).

### 5.5.4 Testing – Audiometry

#### *5.5.4.1 Air Conduction Testing*

**Threshold Determination**

The test normally starts at 1000 Hz on the patient's better ear. Select Right/Left. A procedure of ***"down 10 dB, up 5 dB"*** is typically utilized to establish a threshold at each frequency.

**Screening**

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

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

#### *5.5.4.2 Bone Conduction Testing (MI 26 Version – Extra License, MI 36 Version – Included)*

Place the bone conduction oscillator on the patient's head so that the flat, circular side of the transducer is placed on the mastoid, at the noticeable ledge of the cranial bone behind, but not touching the pinna. The other side of the headband is placed in front of the opposite ear.

Perform the test utilizing the same method as air conduction testing.

#### *5.5.4.3 Masking (MI 26 Version – Extra Bone Conduction License, MI 36 Version – Included)*

To ensure that the patient will not experience crossover (see section 1.5.8), mask the opposite ear. Masking may increase the hearing threshold of the test ear. For bone conduction the masking signal is automatically routed to the opposite output of the phones or inserts, based on the test ear selected.

When masking is turned on, the masking sound should be continuously presented for effective masking. The 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 level of the masking noise for the appropriate level to be presented.

#### *5.5.4.4 High Level Warning*

A visual warning in the numerical bar is displayed at high volumes (i.e. 100 dB or more). Visual warnings include:

Numerical bar turns yellow when 100 dB HL or greater is presented (Figure 94).


**Figure 94**

Warning icon displayed in numerical bar when a level is 100 dB HL or greater.

### 5.5.5 Managing Test Results – Audiometry

#### *5.5.5.1 General*

There are different possibilities to manage the results. It is possible to edit results, print the session directly with the built-in printer or transfer the data to a PC for further processing.

#### *5.5.5.2 Completed Results*

When a test is completed within the Audiometry module the ***Home*** button will display an ***asterisk*** ✳, to indicate a test is stored in this module. The notations will change when printing or transferring results are completed.

**NOTE**: The other test modules display **notations** within the ***Fixed Function Bar***. When exiting the ***Audiometry*** module the notation will also be displayed on the ***Audiometry*** button within the ***Fixed Function Bar***.

### *5.5.5.3 Deleting Test Results*

Results are deleted by the ***Delete*** button or turning-off the device. When ***Delete*** is selected, each module is listed to confirm deletion (Figure 95).

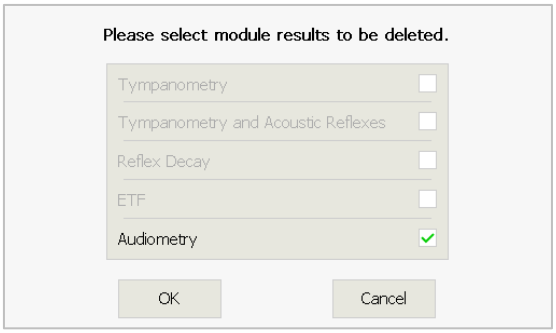



**Figure 95**

**NOTE**: It is best practice to delete results when patient testing is complete.

### *5.5.5.4 Printing Test Results with the Built-in Printer*

Test results can be directly printed with the built-in printer. Touch on the ***Print*** button and a message box ***"Processing print job"*** will display. Printing from the device will print all test results at once (i.e. ***Tympanometry***, ***Acoustic Reflex, Audiometry***, etc.).

**NOTE**: The printout will contain the same content as displayed on the touchTymp.

### *5.5.5.5 Understanding the Print-Out for Audiometry (Built-In Printer)*

The following describes the printout for Audiometry only (Figure 96).

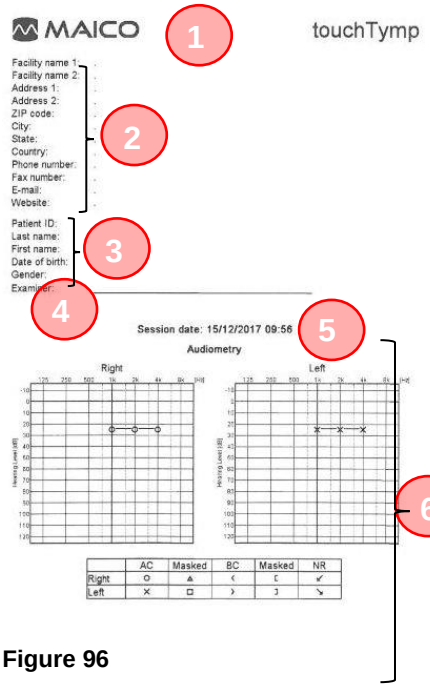



**Figure 96**

1 ***MAICO logo and name of device***

2 ***Facility info***: Prints automatically those fields that contain data (not shown if no data is entered).

3 ***Patient data***: provides the field name to manually enter. Can be selected/deselected in Settings (see section 5.6.4).

4 ***Examiner***: empty line for examiner's signature.

5 ***Session date and time***: shows the date and time of the session as displayed on the device.

6 ***Test result Audiometry***: consists of display selected on the screen (i.e. graph, one audiogram, or two audiogram).

**NOTE**: The printout will match what is displayed on the screen. The ***Display mode*** (***One audiogram***, ***Two audiograms*** or ***Table***) is defined in the ***Settings*** (see section 5.6.16). Show ***masking table*** must be active to print masking levels.

#### *5.5.5.6 Transferring Test Results to PC*

Before transferring data to a PC make sure that you have installed the PC software properly according to the separately delivered operation manual. Before establishing the PC connection you will have to consider the recommendations given in section 4.2.4 in case the touchTymp is connected to a non-medical device.

If the PC connection is properly established, the ***connection*** icon in the status bar will be highlighted green. To transfer the data to the PC, touch the ***Transfer to PC*** button. This will only transfer audiometry results as a separate PC module is required for immittance results. Review section 5.7.6 for Transferring Test Results to PC for Immittance.

**NOTE**: The ***PC software*** must be opened prior to selecting transfer for successful transfer to occur.

#### *5.5.5.7 Editing Test Results*

Stored results can be edited by the ***Edit*** button within the tool bar. When this button is selected, the device is in edit mode with limited device operation.

To delete a stored response, select the ear, frequency and transducer before selecting ***Delete point***. The stored result will be deleted.

To return to standard device function, select the ***Edit*** button from the tool bar.

## 5.6 Settings

### 5.6.1 General

The touchTymp has an extensive setting menu to tailor the device to a user needs. The review of all settings is discussed in this section. Some settings might not be available based on the licenses activated in your system.

Select the ***Settings*** button in the ***Fixed Function Bar*** to access the list of setting menus. MI 36 version offers two additional menus: ***Reflex Decay*** and ***ETF*** (MI 26 – Figure 97, MI 36 – Figure 98).

MI 26

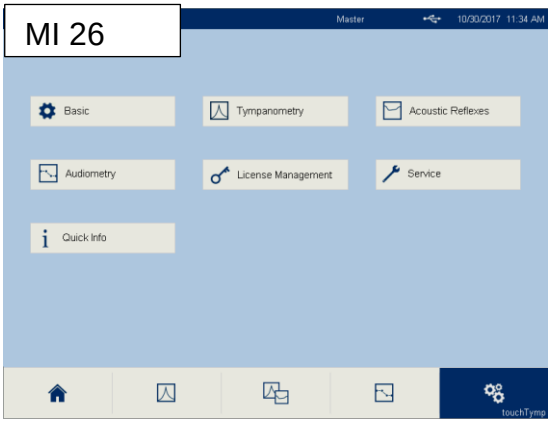



**Figure 97**

MI 36

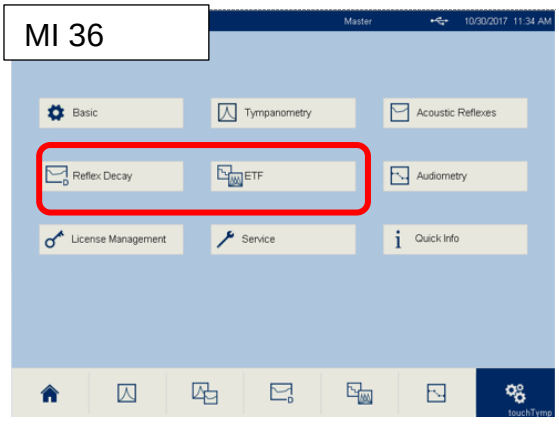



**Figure 98**

Each menu consists of one or more tabs. Each tab contains one or more settings (Figure 99). When a tab is greyed out, it is not available due to a license must be purchased.

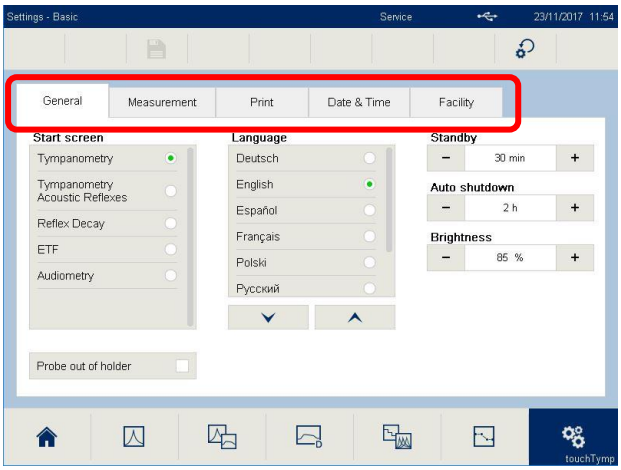



**Figure 99**

Radio buttons allow the selection of only one item in a submenu. Check boxes allow to select or deselect several items at the same time. The ***Settings*** menus are described in the following sections.

### 5.6.2 Settings – Basic – General

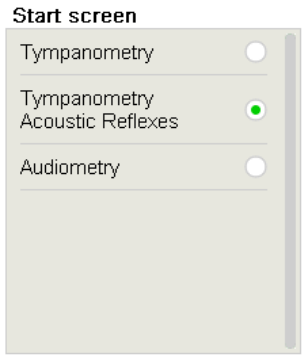



**Figure 100**

**Start Screen:** Adjust the start screen to your needs. Choose ***Tympanometry*** or ***Tympanometry and Acoustic Reflexes*** for upon boot-up the chosen screen is automatically entered (Figure 100).

**NOTE**: MI 36 Version will offer ***Reflex Decay*** and ***ETF*** within this menu setting.

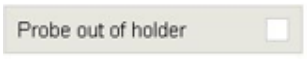



**Figure 101**

**Probe out of holder:** Select ***Probe out of holder*** for automatic changing from the setting or home screen to the test screen as soon as the probe is taken out of the probe holder (Figure 101). Setting is inactive if ***Audiometry*** is selected as ***Start*** Screen (Figure 100).

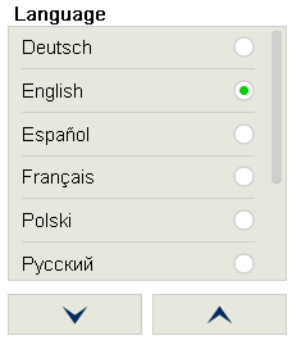



**Figure 102**

**Language**: Choose one of the supported languages incorporated in the device (Figure 102).


**Figure 103**

**Standby**: Set the period of inactivity, after which the display will turn off. Pressing the screen or the ***Front key*** will awaken the device (Figure 103).

**NOTE:** It is possible to turn off this function by setting the value to "***never***". When in standby mode the probe light is lit to indicate device is on.

While in Audiometry, the device will not go in standby when a signal is presented through a transducer (i.e. ***Pure Tone***, ***Masking*** or ***Talk Forward***).


**Figure 104**

**Auto shutdown**: After a period of inactivity (greater than the ***Standby Mode*** setting) the device will turn off automatically (Figure 104).

**NOTE:** Data will be lost when the device turns off. It is possible to turn off this function by setting the value to "***never***".


**Figure 105**

**Brightness*:*** Set the maximum brightness of the display (Figure 105).

### 5.6.3 Settings – Basic – Measurement


**Figure 106**

**Start measurement** (Tympanometry and Acoustic Reflex only): Select ***Automatic*** if the measurement shall be started automatically as soon as the probe is placed in the ear properly. Select ***Manual*** if the test shall start by pressing the ***Play*** ▶ button or the ***Probe*** button (Figure 106).


**Figure 107**

**Start ear**: Defines which ear is the default upon entering the test modules (Figure 107).


**Figure 108**

**Display**: Defines on which side of the screen the button and graph for the left and the right ear shall be displayed (Figure 108).


**Figure 109**

**Light bar**: Activates or deactivates the light bar function on the probe (Figure 109).

### 5.6.4 Settings – Basic – Print


**Figure 110**

**Automatic printout (Immittance)**: An automatic printout is directly generated upon the return of the probe into the probe holder when ***Probe into holder*** is selected (Figure 110).

**NOTE**: When setting is active, ***Audiometry*** must be printed manually.


**Figure 111**

**Info on printout**: Select or deselect if the printout shall show the ***Facility*** and ***Patient*** fields (Figure 111).

**NOTE:** Facility information can be entered into the device. See section 5.6.6.

### 5.6.5 Settings – Basic – Date & Time

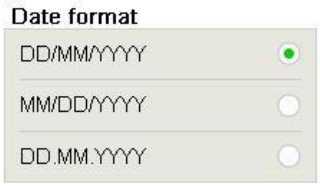



**Figure 112**

**Date format**: Select the preferred date format to be displayed in the ***Status Bar*** and printout (Figure 112).


**Figure 113**

**Set date**: Set the current date using the date control (Figure 113).


**Figure 114**

**Time format**: Select the preferred clock, using the 12 or 24 hour time format (Figure 114).


**Figure 115**

**Set time**: Set the time by using the time control. If time format 12 h is chosen a further setting is available for selection of ***AM/PM*** (Figure 115).

### 5.6.6 Settings – Basic – Facility

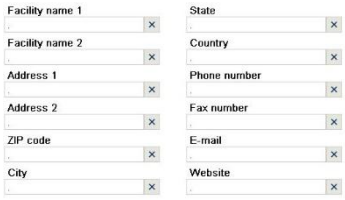



**Figure 116**

**Facility**: Enter Facility information. The information entered in these fields will be shown on the printout when active. Empty fields will not be printed (Figure 116).

Also see section 5.5.5.4.

### 5.6.7 Settings – Tympanometry – General


**Figure 117**

**Pump speed**: Selection of pump speed determines how precisely and quickly the test will proceed (Figure 117).

**NOTE:** A slow speed is more time consuming, but may give more detailed information.

There are four different pump speed settings:

- ***Automatic*** (Dynamic from 600 daPa/s for low gradient and 200 daPa/s for a gradient larger than 5 daPa)
- ***Minimum*** (50 daPa/s): slow, very precise results
- ***Medium*** (250 daPa/s): compromise of speed and precision
- ***Maximum*** (>400 daPa/s): fast, screening


**Figure 118**

**Auto stop**: will automatically stop measurement when hitting the zero line to lessen the test time without affecting results (Figure 118).

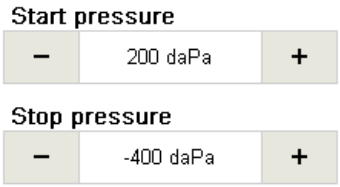



**Figure 119**

**Start pressure*:*** the pressure that is first introduced when performing tympanometry.

**Stop pressure*:*** the end pressure of the tympanometry measurement (Figure 119).

**NOTE:** MI 26 version, the start pressure must be a higher value than the stop pressure. MI 36 version, the start pressure can be higher or lower than the stop pressure. This way, ***Tympanometric*** measurements can be performed with decreasing or ascending pressure.

### 5.6.8 Settings – Tympanometry – Probe Tone 226 Hz/1000 Hz (MI 36 Version Only: 678 Hz/800 Hz)

The following explanations are for the tabs Probe tone 226 Hz (Figure 120) as well as Probe tone 1000 Hz (Figure 121).

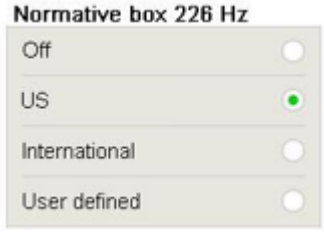



**Figure 120**

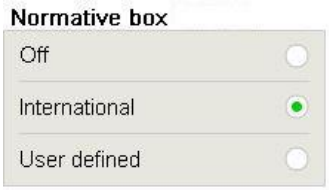



**Figure 121**

**Normative boxes**: Normative boxes are available for 226 Hz and 1000 Hz. Normative boxes are displayed based on established US and International standards.

**Normative Box** options include:

- ***Off***: to not display any normative box in the Tympanometry screen. ***Display Pass /No Response*** is disabled with this setting.
- ***US:*** to use the values defined for US.

> **NOTE: *US*** standards only exist for 226 Hz probe tone. When any other probe tone is selected, the normative box will not be displayed.

- ***International***: to use a normative box based on literature outcomes (see Appendix A for further information).

> **NOTE:** Values of ***US*** and ***International*** normative boxes will be displayed, but cannot be changed.

- ***User defined***: allows the user to define their own normative box. Define the minimum and maximum values for the pressure (in daPa) and the compliance (in ml or mmho) in the range of:
  - Pressure: -400 daPa to 200 daPa
  - Compliance 226 Hz: 0.1 ml to 3.0 ml
  - Compliance 1 kHz: 0.1 mmho to 3.0 mmho

> **NOTE:** When user defined ***Settings*** are activated, Pass ✓ and ***No Response*** ✗ functions are disabled from screen, probe display and printout. ***Settings*** for normative box is individually set for 226 Hz and 1000 Hz.


**Figure 122**

**678 Hz and 800 Hz** allows for a ***User defined*** normative box only (MI 36 version only) (Figure 122).

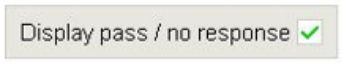



**Figure 123**

**Display pass / no response**: Activates a ***Pass*** ✓ or ***No Response*** ✗ to be displayed after the completion of a measurement (Figure 123).

> **NOTE:** Can be selected and deselected for evaluation (only for ***US*** and ***International*** normative boxes). Result display will automatically be disabled when user defined normative boxes are used.

### 5.6.9 Settings – Acoustic Reflexes – General


**Figure 124**

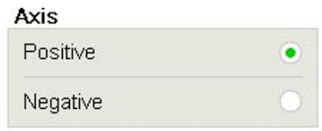



**Figure 125**

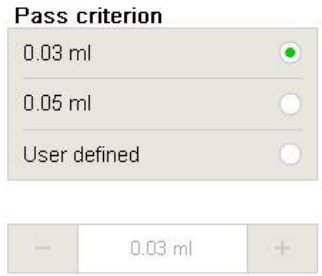



**Figure 126**


**Figure 127**


**Figure 128**


**Figure 129**

**Presentation:** Defines the ***Acoustic Reflex*** screen to start in graphical or table format (Figure 124).

The selection here will also define the presentation on the print-out.

**Axis**: Defines the reflex deflection is displayed negative or positive on the graphical display (Figure 125). The selection here will also define the graphical presentation on the print-out and **Reflex Decay** display for MI 36 version.

**Pass criterion**: Defines the deflection value that must be measured for the reflex to be considered an accepted measurement (Figure 126). The options for selection include:

- ***0.03 ml (default):*** If a change in compliance greater than 0.03 ml is detected, a reflex is considered present.
- ***0.05 ml:*** If a change in compliance greater than 0.05 ml is detected, a reflex is considered present.
- ***User defined:*** Define user's own pass criterion out of 0.01 to 0.1 ml. Once user defined is checked the ***+/-*** are active to make a selection.

**Display pass / no response**: If active the result (***Pass*** ✓ ***No Response*** ✗) will be displayed (Figure 127).

**NOTE:** This function cannot be deactivated if the ***Table*** view is selected.

**Verify pass**: If active the reflex test will require two consecutive ***Pass*** ✓ responses before moving to the next stimuli. When inactive only one ***Pass*** ✓ is required (Figure 128).

**AGC (Automatic gain control):** If ***AGC*** is selected (Figure 129), the stimulus level will be reduced for small ear canal volumes (< 2 ml) correspondingly to the values in Table 17.

**NOTE:** ***AGC*** can only be used on Ipsilateral stimuli.

For instance, when during the ***Tympanometry*** a 1.0 ml ear volume is measured, the intensity of the stimuli during the ***Acoustic Reflex*** measurement will be reduced by 6 dB, with ***AGC*** active this results in a more accurate reflex threshold measurement.

**Table 17: AGC Active, Relative SPL Level Corrections**

| EAR CANAL VALUE | RELATIVE SPL LEVEL |
|---|---|
| Ear Canal Value | Relative SPL Level |
| 2 ml (cc) | 0 dB |
| 1 ml (cc) | -6 dB |
| 0.5 ml (cc) | -12 dB |
| 0.2 ml (cc) | -20 dB |
| 0.1 ml (cc) | -26 dB |

In general, ***AGC*** is used to hold the level of the tone constant. Especially in smaller ear canal volumes ***AGC*** provides an accurate and safe intensity reflex stimulation. Without ***AGC***, the reflex activator stimuli in these smaller ear canals would be higher than the referenced calibration value.

### 5.6.10 Settings – Acoustic Reflexes – Level


**Figure 130**

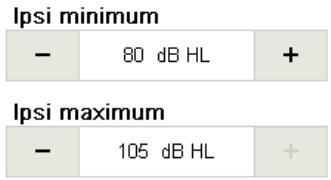



**Figure 131**


**Figure 132**


**Figure 133**

**Level**: Defines the test operation on which level change is used when entering the ***Acoustic Reflex*** module. Options include:

- ***Automatic***: touchTymp starts ***Acoustic Reflex*** test at the minimum level and increases in 5 dB steps automatically until a reflex is registered or the maximum level is reached (Figure 130).
- You can adjust the minimum and maximum level for ***Ipsi*** and ***Contra*** in 5 dB steps either for the level range (if ***Automatic*** is selected) or a single level (if ***Fixed*** is selected). Levels can be selected between:
- ***Ipsi***: min: 70 dB HL, max: 105 dB HL,
- ***Contra***: min : 70 dB HL , max : 120 dB HL (Figure 131).
- ***Fixed*****:** The measurement is performed at one level as defined in the ***Settings*** (Figure 132 and Figure 133).

### 5.6.11 Settings – Acoustic Reflexes – Stimulus


**Figure 134**

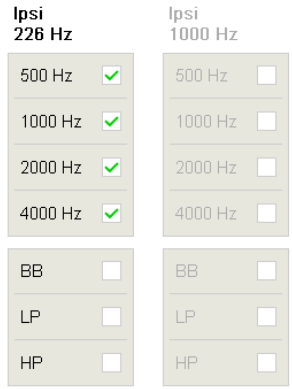



**Figure 135**

**Ipsi 226 Hz, Ipsi 1000 Hz, Contra 226 Hz, Contra 1000 Hz:** Defines the default frequencies for ***Ipsilateral*** and ***Contralateral*** measurements when the ***Acoustic Reflex*** screen is entered for testing. Default frequencies can be modified within the test screen and will return to the default settings when the screen has been exited (Figure 134).

**NOTE:** Stimuli for MI 26 version are frequencies ***500 Hz, 1000 Hz, 2000 Hz, 4000 Hz***. Stimulus options for MI 36 version also include noise stimuli (***BB*** – Broadband, ***HP*** – High Pass, ***LP*** – Low Pass).

When options are greyed out in the settings screen, the license is not active (Figure 135).

### 5.6.12 Settings – Decay – General (MI 36 Version)


**Figure 136**

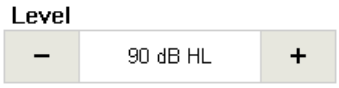



**Figure 137**

**Duration:** Defines the length the tone will be presented to the patient (Figure 136). ***Duration*** can be configured in by 5 second increments from 10 s to 30 s.

**Level**: Defines the default intensity of the stimulus upon entering the screen (Figure 137). You can adjust the level in 5 dB steps.

**NOTE:** The deflection of the acoustic reflex is defined within the ***Acoustic Reflex*** settings.

### 5.6.13 Settings – ETF – Intact (MI 36 Version)


**Figure 138**

**First Test:** Defines the message while the test is in progression. The end user can select which maneuver will be displayed first, ***Swallow*** *or* ***Valsalva*** (Figure 138).

**NOTE:** The selection also determines the color of the tympanometry graphs:

- **Swallow** represented by **Orange**
- **Valsalva** represented by **Green**


**Figure 139**

**Pump speed**: Selection of pump speed determines how precisely and quickly the test will proceed (Figure 139).

**NOTE:** A slow speed is more time consuming, but may give more detailed information.

There are four different ***pump speed*** Settings:

- ***Automatic*** (Dynamic from 600 daPa/s for low gradient and 200 daPa/s for a gradient larger than 5 daPa)
- ***Minimum*** (50 daPa/s): slow, very precise results
- ***Medium*** (250 daPa/s): compromise of speed and precision
- ***Maximum*** (>400 daPa/s): fast, screening


**Figure 140**

**Auto stop**: will automatically stop measurement when hitting the zero line to lessen the test time without affecting results (Figure 140).

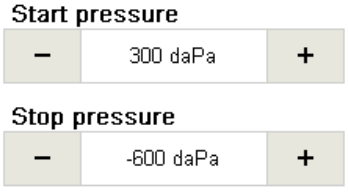



**Figure 141**

**Start pressure*:*** the pressure that is first introduced when performing ***ETF – Intact*** measurement.

**Stop pressure:** the end pressure of the ***ETF – Intact*** measurement (Figure 141).

**NOTE:** You can adjust the pressure in 25 daPa steps.

### 5.6.14 Settings – ETF – Perforated (MI 36 Version)

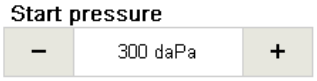



**Figure 142**

**Start pressure:** the pressure that is first introduced when performing ***ETF – Perforated*** measurement (Figure 142). This is a default setting and can be configured within the test screen.

**NOTE:** You can adjust the pressure in 25 daPa steps.


**Figure 143**

**Test duration**: Defines the length the time the test will be conducted (Figure 143). Test duration can be configured in 5 s increments from 30 s to 100 s.

### 5.6.15 Settings – Audiometry – General

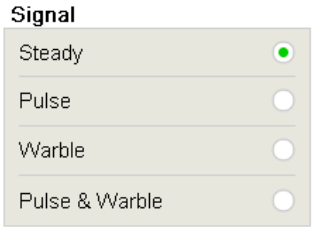



**Figure 144**

**Signal**: Select a default signal for the Audiometry Module Choose ***Steady, Pulse, Warble*** or ***Pulse & Warble*** (Figure 144).

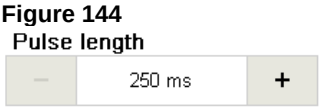



**Figure 145**

**Pulse length**: The length of each tone when Pulse is selected (Figure 145). Choose between ***250 ms*** and ***500 ms***.

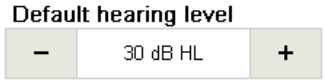



**Figure 146**

**Default hearing level**: Select a level the test signal will return to with the following actions:

- Enter Audiometry module
- Change ear
- Change transducer
- Delete
- Print
- Transfer to PC.

Choose between -***10 dB HL*** to ***50 dB HL*** in ***5 dB*** steps (Figure 146).


**Figure 147**

**Level steps**: Select the change in volume with each + or - selection of Hearing Level and Masking Level. Choose between: 1 dB and 5 dB steps (Figure 147).

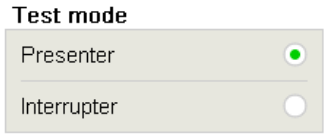



**Figure 148**

**Test mode**: Selection of the operation mode of the audiometer (Figure 148). Choose between:

- ***Presenter***: Tone is presented when the ***Present*** icon is touched.
- ***Interrupter***: Tone is interrupted/stopped when the ***Present*** Icon is touched.


**Figure 149**

**Presenter duration**: The length of the signal with one touch of the **Present** button. Choose between ***200 ms, 300 ms, 400 ms, 500 ms, 700 ms, 1000 ms, 2000 ms, 3000 ms*** or ***Unlimited*** (will present only when button is touched) (Figure 149).

**NOTE**: Setting is only relevant when ***Presenter*** is selected for ***Test mode***.


**Figure 150**

**Monitor phone**: Allows audible presentation through the Monitor phone of the device (Figure 150). These signals include:

- ***Button touch***: A click sound is delivered to the monitor phone.
- ***Tone***: The test signal is delivered to the monitor phone as it is being delivered to the patient.
- ***Masking***: Masking signal is delivered to the monitor phone as it is being delivered to the patient.

### 5.6.16 Settings – Audiometry – Display

**Display type**: Selection of the test screen display (Figure 151). Choose between:

- ***None***: The test screen removes any stored results as no results can be stored within the device. ***Store*** S and ***NR*** NR buttons are removed from screen display (Figure 152).

**MI26 –None display**


**MI 36 – None display**


**Figure 152**

- ***Table***: The test screen displays a table to store numerical results. Results are plotted based on earside, transducer and level at the time of selecting ***Store*** S /***NR*** NR (Figure 153).

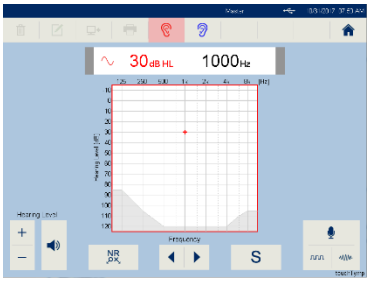
**MI26 –Table display**


**MI 36 – Table display**


**Figure 153**

- ***One audiogram***: The test screen display one audiogram where standard audiometric symbols are plotted within the same graph based on earside, transducer and level at the time of selecting ***Store*** S/ ***NR*** NR (Figure 154).

**MI26 –One audiogram**




**MI 36 – One audiogram**

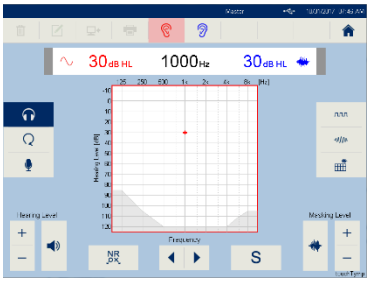
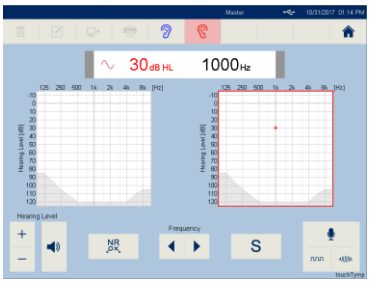



**Figure 154**

***Two audiogram***: The test screen displays two audiograms where standard audiometric symbols are plotted based on earside, transducer and level at the time of selecting ***Store*** S/***NR*** NR (Figure 155). ***Right*** and ***Left*** graph is placed based on ear ***Display*** (see section 5.6.3, Figure 108).

**MI26 –Two audiogram**




**MI 36 – Two audiogram**

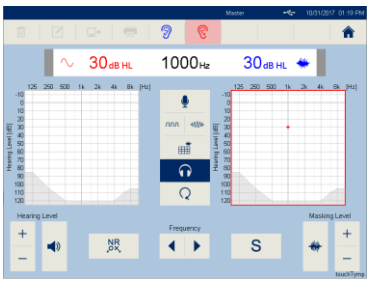



**Figure 155**


**Figure 156**

**Symbol set**: Selection of country specific symbols to be plotted on the audiogram displays. Choose between: ***Australia, Hong Kong, International, UK***, and ***US*** (Figure 156).

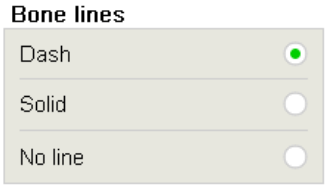



**Figure 157**

**Bone lines**: Displaying of bone lines when an audiogram is selected as the Display Type. Choose between: ***Dash, Solid*** or ***No line*** (Figure 157)

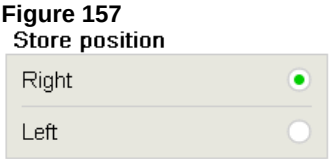



**Figure 158**

**Store position**: Allows the ***Store*** button to be placed on the ***Right*** or ***Left*** side of the screen for user preference in operation (Figure 158).


**Figure 159**

**Level position**: Change of the level control to swap the placement of these buttons (Figure 159). Choose between:

- ***Increase top***: **+** is in the top position and **–** is in bottom (usual setting for ***Display type None*** and ***Table***)


- ***Increase bottom***: **-** is in the top position and **+** is in bottom (usual setting for ***Display type One audiogram*** or ***Two audiograms***).


Selecting **+** increases the level and selecting **–** decreases the level.

### 5.6.17 Settings – Audiometry – Frequency


**Figure 160**

**Frequency control**: Movement of the test frequency when selecting the frequency ◀/▶ buttons (Figure 160). Choose between:

- ***Wrap***: When the highest frequency is reached and ▶ is selected, frequency movement is to the lowest frequency (i.e. at 8000 Hz frequency selection moves to 125 Hz). When the lowest frequency is reached and ◀ is selected, frequency movement is to the highest frequency (i.e. 125 Hz moves to 8000 Hz).
- ***Back***: Frequency movement return to 1000 Hz when the minimum and maximum has been reached.


**Figure 161**

**Store control**: Movement of the test frequency when ***Store*** S or ***NR*** NR is pressed (Figure 161). Choose between:

- ***Remain***: Test frequency does not move when **Store** S or **NR** NR is selected.
- ***Wrap***: Test frequency will move up in frequency and moves (i.e. wraps) to the lowest frequency when the highest frequency is reached.
- ***Back***: Test frequency moves up in frequency and returns to 1000 Hz when the highest frequency is reached.


**Figure 162**

**Level change after store**: Movement of the volume level when Store or No Response is selected (Figure 162). Choose between: ***Default level, -30 dB, -20 dB, -10 dB, Remain, +10 dB, +20 dB***.

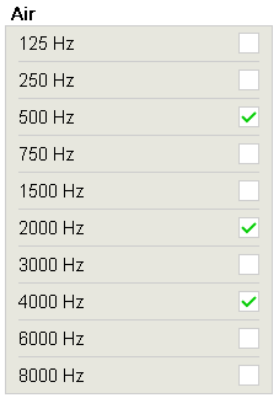



**Figure 163**

**Air**: Select frequencies that are active during the air conduction test. Device only cycles through active frequencies in the test screen. 1000 Hz is not available for deselection and excluded from the list. Choose between: ***125 Hz, 250 Hz, 500 Hz, 750 Hz, 1500 Hz, 2000 Hz, 3000 Hz, 4000 Hz, 6000 Hz***, and ***8000 Hz*** (Figure 163).

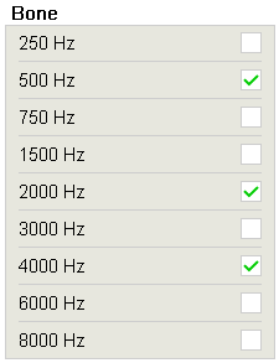



**Figure 164**

**Bone**: Select frequencies that are active during the bone conduction test. Device only cycles through active frequencies in the test screen. 1000 Hz is not available for deselection and excluded from the list. Choose between: ***250 Hz, 500 Hz, 750 Hz, 1500 Hz, 2000 Hz, 3000 Hz, 4000 Hz, 6000 Hz***, and ***8000 Hz*** (Figure 164).

**NOTE**: ***Bone Conduction*** is an optional license within the MI 26 version. If this is not licensed, ***Bone*** is greyed out.

### 5.6.18 Settings – Audiometry – Masking

**NOTE**: ***Masking*** is included in the optional ***Bone Conduction*** license with the MI 26 version. If device is not licensed the ***Masking*** tab is greyed out and not accessible.

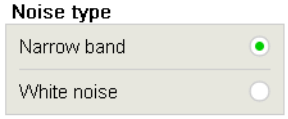



**Figure 165**

**Noise type**: Selection of the masking noise (Figure 165). Choose between: ***Narrow* band** and ***White noise***.

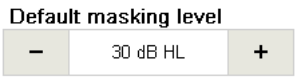



**Figure 166**

**Default masking level**: Select a level the masking signal defaults to when turned on. Choose a value between ***0 dB*** and ***50 dB*** (Figure 166).


**Figure 167**

**Off with store**: Turns off masking signal with the selection of ***Store*** S or ***NR*** NR (Figure 167).

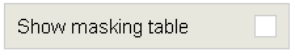



**Figure 168**

**Show masking table**: ***Masking*** table is displayed for documentation of the masking level. Activating this setting defaults the device to always show the masking table within the test screen (Figure 157).

**NOTE**: ***Masking*** is included in the optional ***Bone Conduction*** license with the MI 26 version. If device is not licensed the setting will be greyed out.

### 5.6.19 Settings – License Management – General

The License Management screen allows additional feature/test operation to be incorporated into a base model by entering a license key. Contact MAICO or your local distributor for more information.

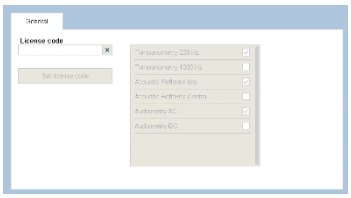


**Figure 169**

The tab ***General*** contains a field to enter a new license code in order to activate the license on the device. In the middle, all available licenses are shown. The checkboxes are activated automatically as soon as a license is activated (Figure 169).

**Figure 170**

To enter a new license code, activate the keyboard by pressing into the field ***License code*** and type in the code (Figure 170).

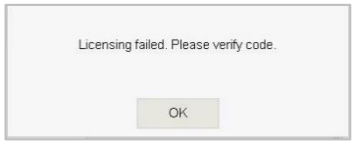



**Figure 171**

If the code entered is invalid a message box will be shown telling you to verify the code (Figure 171).

Ask your local distributor if any problems occur. If you entered a correct code a message box will tell you ***"Licensing completed***".

### 5.6.20 Settings – Service – General

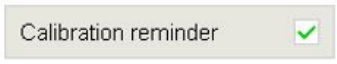



**Figure 172**

**Calibration reminder**: Annual calibration of the touchTymp and its transducers is recommended.

Select or deselect this item to enable or disable a reminder that will display daily. The reminder starts 1 month prior to the expiration of the calibration date for your acoustic transducer(s) (Figure 172).

The user can always bypass the reminder message and continue with screening.

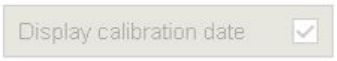



**Figure 173**

**Display calibration date**: Only for service (Figure 173).

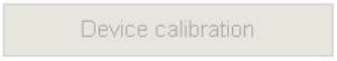



**Figure 174**

**Device calibration:** Only for service (Figure 174).

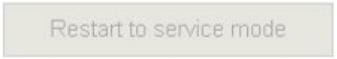



**Figure 175**

**Restart to service mode:** Only for MAICO Technical customer support (Figure 175).

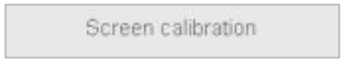



**Figure 176**

**Screen calibration:** Only for Service (Figure 176).

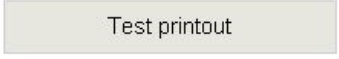



**Figure 177**

**Test printout:** prints a test printout (without a session result, Figure 177).

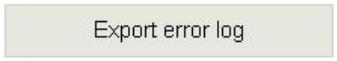



**Figure 178**


**Figure 179**

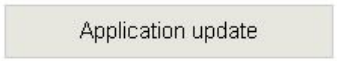



**Figure 180**


**Figure 181**

**Export error log:** If an error is occurring you can export the error log data onto a USB flash drive (Figure 178). If there is no USB flash drive connected the message box (Figure 179) will be shown with further information.

**NOTE:** Detection of the USB flash drive can take up to 10 seconds.

**Application update:** for updating via USB flash drive (Figure 180). A message box will be shown to ask you if you want to continue updating (Figure 181).

**NOTE:** The device will be restarted after application update.

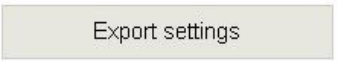



**Figure 182**

**Export Settings:** Export file onto USB flash drive (Figure 182).

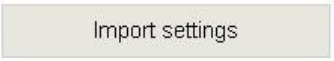



**Figure 183**

**Import Settings:** Import file from USB flash drive (Figure 183).


**Figure 184**

**Reset Settings:** Resets settings to default. Facility information will also be deleted (Figure 184).

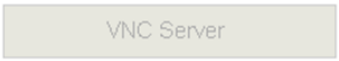



**Figure 185**

**VNC Server:** Only for service (Figure 185).

### 5.6.21 Settings – Service – About

On this screen the most important device information are presented. Additionally, the Qt License Agreement is shown (Figure 186).

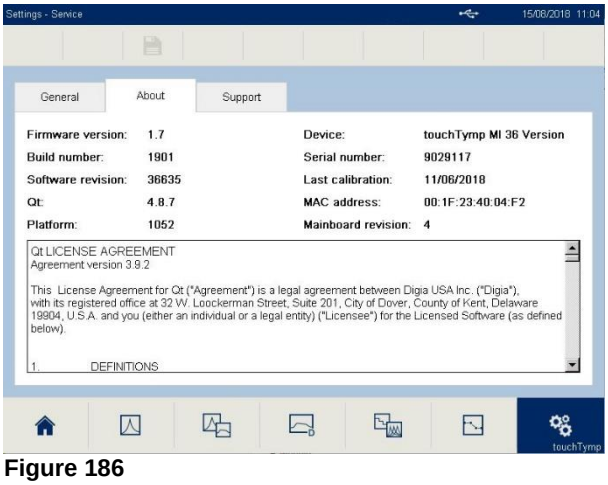



**Figure 186**

### 5.6.22 Settings –Service – Support


**Figure 187**

This menu is only for editing by service. The dealer can enter his contact information to display in the ***Quick Info*** screen (Figure 187).

### 5.6.23 Quick Info


**Figure 188**

Shows information in a message box about the firmware version, the serial number, the calibration date (if activated) and the MAICO representative (if entered by the dealer). See Figure 188.

# 6 Technical Data

**This section offers you important information about**

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

## 6.1 touchTymp Hardware

CE 0123

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

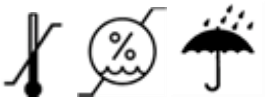
**General Information About Specifications**

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

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

| STANDARDS | |
|---|---|
| **Medical CE-mark** | Yes |
| **Safety Standards** | IEC 60601-1:2005+A1:2012/<br>ANSI/AAMI ES60601-1: 2005 / A2:2010/<br>CAN/CSA-C22.2 No. 60601-1:14<br>Type B Applied Parts |
| **EMC Standards** | IEC 60601-1-2 |
| **Audiometer Standards** | Tone: IEC 60645-1 Type 3/ANSI S3.6 Type 3 |
| **Tympanometer Standards** | IEC 60645-5, Type 2/ANSI S3.39, Type 2 |

| DEVICE SPECIFICATIONS | | |
|---|---|---|
| **Power supply** | Type | UES65-240250SPA3 |
| | Input | 90 to 264 V AC, 50/60 Hz, 2.0 A |
| | Output | 24.0 DC, 2.5 A MAX |
| | Safety | IEC 60601-1, Class I |
| **Mode of operation** | Continuous | |

| | | |
|---|---|---|
| **Environmental conditions:**  | **Operation:** | +15 °C to +35 °C /<br>+ 59 °F to +95 °F |
| | | Relative humidity 30 % to 90 % (non-condensing) |
| | | Air pressure 98 kPa to 104 kPa[3]<br>Maximum altitude: 2000 m / 6561 ft above sea level |
| | | Warm up time: 10 minutes (including boot up time) |
| | **Storage:** | 0 °C to + 50 °C / 32 °F to +122 °F<br>Humidity 10 to 95 % (non-condensing) |
| | **Transport:** | -20 °C to + 50 °C / -4 °F to +122 °F<br>Humidity 10 % to 95 % (non-condensing) |
| **Weight:** | 3.2 kg / 7.1 lbs | |
| **Dimensions:** | 300 mm x 345 mm x 148 mm<br>11.81 in x 13.58 in x 5.83 in | |
| **Dimensions Pen Probe:** | 204 mm x 25 mm x 26 mm<br>8.03 in x 0.98 in x 1.02 in | |
| **Dimensions Shoulder Box:** | 104 mm x 36 mm x 24 mm / 4.09 in x 1.42 in x 0.94 in<br>Tubing: 2175 mm / 85.63 in | |
| **Display:** | 10.4 in full color display with high bright white LED back-light | |
| **User Interface:** | Touch screen (resistive) | |
| **User Feedback:** | Integrated speaker | |
| **Language Settings:** | Chinese, English, French, German, Italian, Polish, Russian, Spanish, Turkish | |
| **Connectors:** | External / USB out, USB in, USB out, power socket, Contra headphone jack, probe connector | |
| **Data interfaces:** | USB 1.1 / Ethernet (not implemented) | |
| **PC Connection:** | USB; the system can not be operated from a PC.<br>Using MAICO Sessions together with the OtoAccess Database, Noah or a Practice Management Software via BDT/GDT-interface (only for Germany, Austria and Switzerland), data can be transferred and saved on the PC. | |
| **Thermal printer (configuration dependent):** | **Paper:** | 110 mm width, 20 m length<br>To be printed on paper roll:<br>200 Tympanograms<br>87 Tympanograms with Acoustic Reflexes for both ears |
| | **Time:** | 4 s (one Tympanogram) to 12 s<br>(Tympanogram with Acoustic Reflexes for both ears) |

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

## TYMPANOMETRY

| | | |
|---|---|---|
| **Test signals:** | Pure tone: 226 Hz, 1000 Hz each with ± 1 %<br>Additional for MI 36: 678 Hz, 800 Hz each with 1 %<br>(continuous tones) | |
| **Test level:** | 85 dB SPL ±1.5 dB SPL measured in an IEC 60318-5 acoustic coupler according to IEC 60645-5:2004 / ANSI S3.39:1987.<br>The level is constant for all volumes in the measurement range. | |
| **Distortion:** | Max 1 % THD[4] | |
| **Control Tympanometry:** | Automatic | |
| **Air pressure:** | **Control:** | Automatic |
| | **Indicator:** | Measured value shown in the display. |
| | **Range:** | -600 daPa to +400 daPa |
| | **Pressure limitation:** | -800 daPa and +600 daPa |
| | **Pressure change rate:** | Speed at compliance peak (change in settings):<br>**Automatic** (Dynamic from 600 daPa/s for low gradient and 200 daPa/s for a gradient larger than 5 daPa)<br>**Minimum** (50 daPa/s): slow, very precise results<br>**Medium** (250 daPa/s): compromise of speed and precision<br>**Maximum** (>400 daPa/s): fast, screening |
| **Compliance range:** | 0.1 ml to 8.0 ml at 226 Hz probe tone;<br>0.1 mmho to 15.0 mmho at 678 Hz, 800 Hz and 1000 Hz probe tone | |
| **Volume range:** | 0.0 ml to 6.0 ml (compensated) | |
| **Test time:** | ~5 seconds | |
| **Accuracy:** | **Pressure:** | ±5 % or ±10 daPa, whichever is greater |
| | **Compliance:** | ±5 % or ± 0.1 ml, whichever is greater |
| **Precision:** | **Pressure:** | 1 daPa |
| | **Compliance:** | 0.01 ml |
| **Graphical display:** | x-axis: Pressure in daPa<br>y-axis: Compliance in ml (226 Hz, 678 Hz, 800 Hz) and mmho (1000 Hz) | |
| **Test types:** | Tympanometry | Automatic, where the start and stop pressure can be user-programmed in the setup function. |
| | Eustachian tube function 1 – Intact eardrum | Williams test |
| | Eustachian tube function 2 – Perforated eardrum | Toynbee test |

[4] THD = Total Harmonic Distortion

## ACOUSTIC REFLEXES

| | | |
|---|---|---|
| **Test methods:** | Ipsilateral and Contralateral | |
| **Test signals:** | **Pure Tones:** | 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz each with ±1 % |
| | **Noise (MI 36):** | Broadband, High Pass, Low Pass |
| **Test level:** | Ipsilateral: 70 dB HL to 105 dB HL<br>Contralateral: 70 dB HL to 120 dB HL | |
| **Control Acoustic Reflexes:** | Automatic | |
| **Test types:** | Single intensities (Fixed Level)<br>Reflex threshold (Automatic Level in 5 dB steps) | |
| **Stimulus Presentation Control:** | ON-OFF ratio = ≥ 70 dB<br>Rise time = 27.0 ms<br>Fall time = 24.6 ms<br>Signal to noise Ratio > 70 dB<br>A-weighted noise in OFF condition < 25 dBSPL | |
| **Normative data:** | MAICO Standard Values | |
| **Graphical display:** | x-axis: Volume in ml<br>y-axis:Time in ms<br>Level in dB HL | |
| **Ipsi earphone:** | Earphone integrated in probe | |
| **Contralateral headphones:** | **Insert earphone:** | IP30 |
| | **Headphones:** | DD45 C |
| **Test types:** | **Automated Reflex:** | Automatic/Fixed |
| | **Reflex Decay:** | Manual, 10 dB above threshold and stimulus durations of 10 seconds. |

## IMMITTANCE CALIBRATION PROPERTIES

| | | |
|---|---|---|
| **Compliance:** | **Temperature dependence:** | -0.003 ml/°C<br>-0.031 ml/°F |
| | **Pressure dependence:** | -0.0002 ml/daPa |
| **Reflex:** | **Sensitivity:** | 0.001 ml is the lowest detectable volume change. |
| | **Reflex artifact level:** | ≥95 dB SPL (measured in the 711 coupler, 0.2 ml, 0.5 ml, 2.0 ml and 5.0 ml hardwalled cavities). |
| | **Temporal reflex character-istics:** | • Initial latency = 35 ms (±5 ms)<br>• Rise time = 45 ms (±5 ms)<br>• Terminal latency = 35 ms (±5 ms)<br>• Fall time = 45 ms (±5 ms)<br>• Overshoot = max. 1 %<br>• Undershoot = max. 1 %<br>• ON and OFF time = 750 ms |

There is no deviation between static and dynamic mode.

## REFLEX CALIBRATION STANDARDS AND SPECTRAL PROPERTIES

General Specifications for stimulus and audiometer signals are made to follow IEC 60645-5/ANSI S3.39.

| | | |
|---|---|---|
| Ipsilateral Earphone: | Pure Tone: | MAICO Standard Values |
| Contralateral Earphone: | Pure Tone: | ISO 389-2 for IP 30<br>RadioEar Standard Values for DD45 C |
| Ipsilateral Earphone: | Broad-band noise (BBN): | MAICO Standard Values |
| Contralateral Earphone: | Broad-band noise (BBN): | RadioEar Standard Values |
| Ipsi- and Contralateral Earphone: | Spectral Properties | As “Broad-band noise” specified in IEC 60645-5, but with 500 Hz as lower cut-off frequency. |
| | General about levels: | The actual sound pressure level at the eardrum will depend on the volume of the ear. |

The risk of artifacts at higher stimulus levels in reflex measurements are minor and will not activate the reflex detection system.

## AUDIOMETRY

| | | |
|---|---|---|
| Air Conduction: | DD45: | RadioEar Standard Values |
| | IP30: | ISO 389-2, ANSI S3.6 |
| | DD450: | RadioEar Standard Values |
| Bone Conduction: | B71:<br>B81: | ISO 389-3, ANSI S3.6<br>ISO 389-3, ANSI S3.6 |
| | Placement: | Mastoid |
| Effective masking: | ISO 389-4, ANSI S3.6 | |
| Transducers – Headband tension: | DD45: | Headband Static Force 4.5 N ± 0.5 N |
| | DD450: | Headband Static Force 10.0 N ± 0.5 N |
| | B71/B81: | Headband Static Force 5.4 N ± 0.5 N |
| Patient Response switch: | One push button | |
| Patient communication: | Talk Forward<br>Talk Back | |
| Inputs: | Tone, Warble Tone ± 5 %, 5 Hz (true sine wave frequency modulation). | |
| Outputs: | Left, Right, Bone L+R | |
| Accuracy: | Frequency ± 2 %, Level ± 3 dB | |
| Stimuli | | |
| Warble Tone: | 5 Hz sine ± 5 % modulation | |
| Pulse Tone: | Pulse Length: 250 ms or 500 ms | |
| Masking: | Narrow band noise: IEC 60645-1, 5/12 Octave filter with the same centre frequency resolution as pure Tone. Synchronous masking: Locks channel 2 attenuator to channel 1 attenuator Alternative: White band noise. | |
| Presentation: | Presenter or Interrupter. Single, Pulse or Warble. | |
| Level: | AC: -10 dB HL to 120 dB HL, BC: -10 dB HL to 80 dB HL<br>Available Level Steps are 1 dB or 5 dB.<br>Extended range function: Warning displayed when 100 dB HL reached. Extended range is accessed automatically. | |
| Frequency range: | AC: 125 Hz to 8000 Hz, BC: 250 Hz to 8000 Hz. Frequencies can be freely deselected (except 1000 Hz). | |

## 6.2 Connections

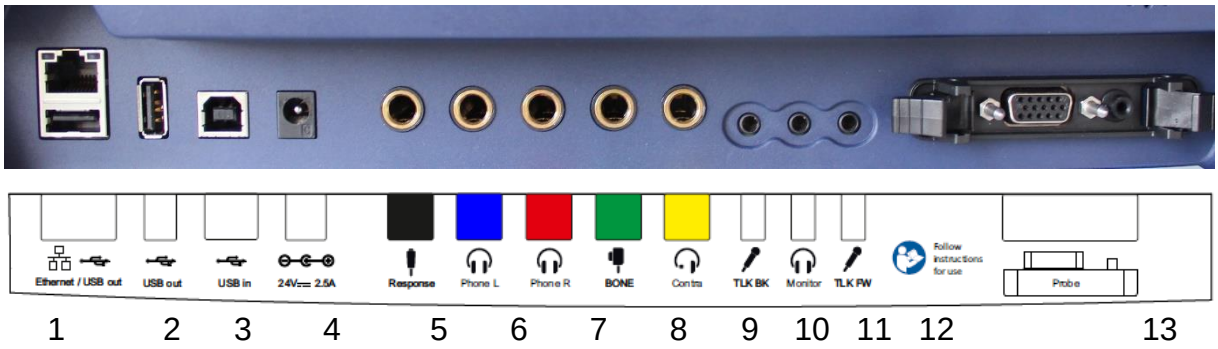


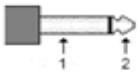
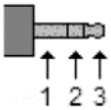

**Figure 189**

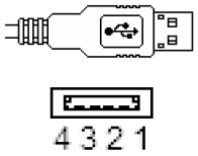
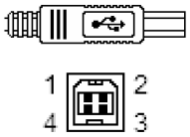
**Table 18 Connections on Backside of Device**

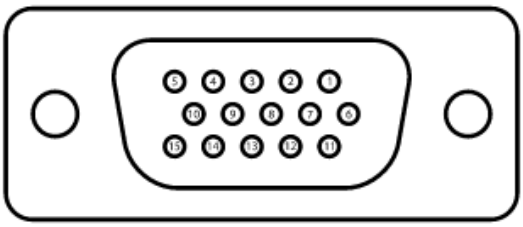
| CONNECTIONS | | |
|---|---|---|
| No. | Connection socket | Specification |
| **1** | **Ethernet** | Not applicable in actual version |
| **1/2** | **USB out** | 2 x USB 1.1 |
| **3** | **USB in** | USB 1.1 |
| **4** | ⊖—C—⊕ **24 V/2,5 A** | 24V DC, 2.5A, Part. No. Power Supply UES65-240250SPA3 |
| **5** | **Response** | RI = 2000 Ω |
| **6** | **Phone L** | ZA =10 Ω, UA = 3 $V_{eff}$ |
| **7** | **Phone R** | ZA =10 Ω, UA = 3 $V_{eff}$ |
| **8** | **Bone** | ZA= 10 Ω, UA= 3 $V_{eff}$ |
| **9** | **Contra** | ZA =10 Ω, UA = 3 $V_{eff}$ |
| **10** | **TLK BK** | $Z_I$= 1 kΩ, $U_I$= 0.38 - 500 $mV_{eff}$ |
| **11** | **Monitor** | $Z_A$= 250 Ω, $U_A$= 3 $V_{eff}$ |
| **12** | **TLK FW** | $Z_I$= 1 kΩ, $U_I$= 0.38 - 500 $mV_{eff}$ |
| **13** | **Probe** | See Table 19 below. |

## 6.3 Pin Assignment

**Table 19 Pin Assignment**

| SOCKET | CONNECTOR | PIN 1 | PIN 2 | PIN 3 |
|---|---|---|---|---|
| Mains |  DC socket 24 V/2,5 A | - | - | - |
| Contra |  6.3 mm Mono | Ground | Signal | - |
| Phone L | | | | |
| Phone R | | | | |
| Bone | | | | |
| Response | | - |  | |
| Monitor |  3.5 mm Stereo | Ground | Signal | - |
| TLK FW | | Ground | Right | Left |
| TLK BK | | Ground | Right | Left |

| USB A (OUT) | | USB B (IN) | |
|---|---|---|---|
|  | 1. +5 VDC |  | 1. +5 VDC |
| | 2. Data - | | 2. Data - |
| | 3. Data + | | 3. Data + |
| | 4. Ground | | 4. Ground |

| PROBE CONNECTOR | PIN | FUNCTION |
|---|---|---|
|  15-pin D-sub highdensity with air connection | Pin 1 | DSP_I2C_INTERRUPT |
| | Pin 2 | GND |
| | Pin 3 | IPSI_OUT |
| | Pin 4 | GND_CONTRA |
| | Pin 5 | GND_PROBE-MIC |
| | Pin 6 | DSP_I2C_SCLK |
| | Pin 7 | GND |
| | Pin 8 | GND_IPSI |
| | Pin 9 | PROBETONE_OUT |
| | Pin 10 | MIC-IN |
| | Pin 11 | DSP_I2C_DATA |
| | Pin 12 | +5 Vprobe |
| | Pin 13 | CONTRA_OUT |
| | Pin 14 | GND_PROBETONE |
| | Pin 15 | MIC-+IN |

## 6.4 Calibration Values and Maximum Levels

### 6.4.1 Calibration Values and Maximum Levels – Immittance

| COUPLER TYPES USED BY CALIBRATION | |
|---|---|
| **IOWA Probe (probe system):** | Calibrated using a IEC 60318-5 (2cc) acoustic coupler made in accordance to MAICO Standard Values |
| **IP30:** | Calibrated using a IEC 60318-5 (2cc) acoustic coupler made in accordance to ISO 389-2:1994 |
| **DD45C:** | Calibrated using a IEC 60318-3 (6cc) acoustic coupler made in accordance to RadioEar Standard Values |

| REFERENCE VALUES FOR STIMULUS CALIBRATION | | | | |
|---|---|---|---|---|
| **Fre-quency [Hz]** | **Reference equivalent threshold sound pressure level [RETSPL, dB re. 20 µPa]** | | | |
| | **IP30 ISO 389-2** | **DD45 C** | | **IOWA Probe MAICO Standard Values** |
| | | **RadioEar Standard Values** | **SOUND ATTENUA-TION [dB] ISO 4869-1** | |
| 500 | 5.5 | 13.0* | 7 | 9.5* |
| 1000 | 0.0 | 6.0* | 15 | 6.5* |
| 2000 | 3.0 | 8.0* | 26 | 12.0* |
| 4000 | 5.5 | 9.0* | 32 | 3.5* |
| BB | -5.0* | -8.0* | - | -5.0* |
| LP | -7.0* | -6.0* | - | -7.0* |
| HP | -8.0* | -10.0* | - | -8.0* |
| *All values marked with a star are RadioEar/MAICO Standard Values. | | | | |

| FREQUENCIES AND MAXIMUM VALUES FOR IMMITTANCE | | | |
|---|---|---|---|
| **Center Frequency [Hz]** | **Intensities [dB HL]** | | |
| | **IP30** | **DD45 C** | **IOWA Probe** |
| | **Tone/Noise** | **Tone/Noise** | **Tone/Noise** |
| 500 | 110 | 120 | 100 |
| 1000 | 120 | 120 | 105 |
| 2000 | 120 | 120 | 105 |
| 4000 | 120 | 120 | 100 |
| BB | 115 | 120 | 95 |
| LP | 120 | 120 | 100 |
| HP | 120 | 120 | 95 |

### 6.4.2 Calibration Values and Maximum Levels – Audiometry

**Calibration Values and Max Levels: Headphone DD45**
**Coupler IEC 60318-3**

| Frequency [Hz] | Tone IEC 60318-3 RETSPL dB re 20µPa | NBN IEC 60318-3 RETSPL dB re 20µPa | Tone Max Level [dB HL] | NBN Max Level [dB HL] | SOUND ATTENUATION [dB] ISO 4869-1 |
|---|---|---|---|---|---|
| 125 | 47.5 | 51.5 | 85 | 65 | 3 |
| 250 | 27.0 | 31.0 | 105 | 85 | 5 |
| 500 | 13.0 | 17.0 | 120 | 100 | 7 |
| 750 | 6.5 | 11.5 | 120 | 105 | - |
| 1000 | 6.0 | 12.0 | 120 | 105 | 15 |
| 1500 | 8.0 | 14.0 | 120 | 105 | - |
| 2000 | 8.0 | 14.0 | 120 | 105 | 26 |
| 3000 | 8.0 | 14.0 | 120 | 105 | - |
| 4000 | 9.0 | 14.0 | 120 | 105 | 32 |
| 6000 | 20.5 | 25.5 | 110 | 95 | - |
| 8000 | 12.0 | 17.0 | 105 | 95 | 24 |
| White Noise | - | 0.0 | - | 120 | - |

**Calibration Values: Insert Earphone IP30**
**Reference equivalent threshold sound pressure level**

| Frequency [Hz] | Tone IEC 60318-5 RETSPL dB re 20µPa | NBN IEC 60318-5 RETSPL dB re 20µPa | Tone Max Level [dB HL] | NBN Max Level [dB HL] | SOUND ATTENUATION [dB] ISO 4869-1 |
|---|---|---|---|---|---|
| 125 | 26.0 | 30.0 | 90 | 85 | 33.5 |
| 250 | 14.0 | 18.0 | 105 | 100 | 34.5 |
| 500 | 5.5 | 9.5 | 110 | 105 | 34.5 |
| 750 | 2.0 | 7.0 | 115 | 110 | - |
| 1000 | 0.0 | 6.0 | 120 | 110 | 35.0 |
| 1500 | 2.0 | 8.0 | 120 | 110 | - |
| 2000 | 3.0 | 9.0 | 120 | 110 | 33.0 |
| 3000 | 3.5 | 9.5 | 120 | 110 | - |
| 4000 | 5.5 | 10.5 | 115 | 105 | 39.5 |
| 6000 | 2.0 | 7.0 | 100 | 95 | - |
| 8000 | 0.0 | 5.0 | 90 | 90 | 43.5 |
| White Noise | - | 0.0 | - | 110 | - |

**Calibration Values: High Frequency Headphone DD450**

**Coupler IEC 60318-1**

| Fre-quency [Hz] | Tone IEC 60318-3 RETSPL dB re 20µPa | NBN IEC 60318-3 RETSPL dB re 20µPa | Tone Max Level [dB HL] | NBN Max Level [dB HL] | SOUND ATTENUA-TION [dB] ISO 4869-1 |
|---|---|---|---|---|---|
| 125 | 30.5 | 34.5 | 95 | 70 | 12.5 |
| 250 | 18.0 | 22.0 | 105 | 85 | 12.7 |
| 500 | 11.0 | 15.0 | 115 | 90 | 9.4 |
| 750 | 6.0 | 11.0 | 115 | 95 | - |
| 1000 | 5.5 | 11.5 | 115 | 95 | 12.8 |
| 1500 | 5.5 | 11.5 | 110 | 95 | - |
| 2000 | 4.5 | 10.5 | 110 | 95 | 15.1 |
| 3000 | 2.5 | 8.5 | 115 | 95 | - |
| 4000 | 9.5 | 14.5 | 110 | 95 | 28.8 |
| 6000 | 17.0 | 22.0 | 100 | 85 | - |
| 8000 | 17.5 | 22.5 | 100 | 85 | 26.2 |
| White Noise | - | 0.0 | - | 110 | - |

**Calibration Values: Bone Conductor Radioear B71**

**Coupler ISO 389-3, ANSI S3.6**

| Frequency [Hz] | Reference equivalent threshold force level for tone | Max level |
|---|---|---|
| | ISO 389-3 [dB] (re 1µN) | Tone [dB HL] |
| 250 | 67.0 | 45 |
| 500 | 58.0 | 65 |
| 750 | 48.5 | 70 |
| 1000 | 42.5 | 70 |
| 1500 | 36.5 | 70 |
| 2000 | 31.0 | 75 |
| 3000 | 30.0 | 70 |
| 4000 | 35.5 | 70 |
| 6000 | 40.0 | 50 |
| 8000 | 40.0 | 40 |
| White Noise | 42.5 | 65 |

**Calibration Values: Bone Conductor Radioear B81**
**Coupler ISO 389-3, ANSI S3.6**

| Frequency [Hz] | Reference equivalent threshold force level for tone | Max level |
|---|---|---|
| | ISO 389-3 [dB] (re 1µN) | Tone [dB HL] |
| 250 | 67.0 | 45 |
| 500 | 58.0 | 70 |
| 750 | 48.5 | 75 |
| 1000 | 42.5 | 80 |
| 1500 | 36.5 | 85 |
| 2000 | 31.0 | 80 |
| 3000 | 30.0 | 75 |
| 4000 | 35.5 | 70 |
| 6000 | 40.0 | 50 |
| 8000 | 40.0 | 40 |
| White Noise | 42.5 | 65 |

## 6.5 Electromagnetic Compatibility (EMC)

ESSENTIAL PERFORMANCE for this device is defined by the manufacturer as:

- This device does not have an ESSENTIAL PERFORMANCE
- Absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk. Final diagnosis shall always be based on clinical knowledge.

This device is in compliance with IEC 60601-1-2:2014, emission class B group 1

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

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

To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the accessories listed in the following table. Conformance to the EMC requirements as specified in IEC 60601-1-2 is ensured if the cable types and cable lengths are as specified.

| Item | Manufacturer | Model | Cable | | SIP/SOP | |
|---|---|---|---|---|---|---|
| | | | Length [meter] | Screened [Y/N] | Socket ID | Type |
| Probe System: | | | | | | |
| Pen Probe (Hand-held) | Maico | 8105703 | 2.1 | Combined | 13 | Various |
| Contra Headset | Radioear | DD45 C | 2.0 | Y | 9 | Audio output |
| Headsets: | | | | | | |
| Audiometric Headset | Radioear | IP30 | 2.0 | Y | 6 & 7 | Audio output |
| Bone Conductor | Radioear | B71W | 2.0 | Y | 8 | Audio output |
| Monitor Headset w. microphone | Sennheiser | PC131 | 2.9 | Y | 11 | Audio output |
| | | | | | 12 | Audio input |
| Various: | | | | | | |
| Talk Back Microphone | Radioear | EMS400 | 2.0 | Y | 10 | Audio input |
| Patient response switch | Radioear | APS3 | 2.0 | Y | 5 | DC level |
| LAN | For production and service use only | | | | 1 | Data |
| Cable USB A/B (w. dummy) | Sanibel | 8011241 | 2.0 | Y | 3 | Data |
| USB A | Only for connection of USB flash drive during firmware update or error log export. Socket has no use on daily basis | | | | 1 | Data |
| USB A | | | | | 2 | Data |
| Power Supply | UE / Fuhua | UES65-240250SPA3 | 1.0 | Y | 4 | DC power |

Portable and mobile RF communications equipment can affect the touchTymp. Install and operate the touchTymp according to the EMC information presented in this section.
The touchTymp has been tested for EMC emissions and immunity as a standalone touchTymp. Do not use the touchTymp 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 *touchTymp* is intended for use in the electromagnetic environment specified below. The customer or the user of the *touchTymp* should assure that it is used in such an environment. | | |
| **Emissions Test** | **Compliance** | **Electromagnetic environment - guidance** |
| RF emissions<br>CISPR 11 | Group 1 | The t***ouchTymp*** 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<br>CISPR 11 | Class B | The t***ouchTymp*** is suitable for use in all commercial, industrial, business, and residential environments. |
| Harmonic emissions<br>IEC 61000-3-2 | Complies<br>Class A Category | |
| Voltage fluctuations / flicker emissions<br>IEC 61000-3-3 | Complies | |

| **Recommended separation distances between portable and mobile RF communications equipment and the *touchTymp*.** | | | |
|---|---|---|---|
| The ***touchTymp*** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ***touchTymp*** can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ***touchTymp*** 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.<br>**Note 1** At 80 MHz and 800 MHZ, the higher frequency range applies.<br>**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 ***touchTymp*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***touchTymp*** should assure that it is used in such an environment. | | | |
| **Immunity Test** | **IEC 60601 Test level** | **Compliance** | **Electromagnetic environment - guidance** |
| Electrostatic Discharge (ESD)<br><br>IEC 61000-4-2 | +8 kV contact<br><br>+15 kV air | +8 kV contact<br><br>+15 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%. |
| Electrical fast transient/burst<br><br>IEC61000-4-4 | +2 kV for power supply lines<br><br>+1 kV for input/output lines | +2 kV for power supply lines<br><br>+1 kV for input/output lines | Mains power quality should be that of a typical commercial or residential environment. |
| Surge<br><br>IEC 61000-4-5 | +1 kV differential mode<br><br>+2 kV common mode | +1 kV differential mode<br><br>+2 kV common mode | Mains power quality should be that of a typical commercial or residential environment. |
| Voltage dips, short interruptions and voltage variations on power supply lines<br><br>IEC 61000-4-11 | < 5% *U*T (>95% dip in *U*T) for 0.5 cycle<br><br>40% *U*T (60% dip in *U*T) for 5 cycles<br><br>70% *U*T (30% dip in *U*T) for 25 cycles<br><br><5% *U*T (>95% dip in *U*T) for 5 sec | < 5% *U*T (>95% dip in *U*T) for 0.5 cycle<br><br>40% *U*T (60% dip in *U*T) for 5 cycles<br><br>70% *U*T (30% dip in *U*T) for 25 cycles<br><br><5% *U*T for 5 sec | Mains power quality should be that of a typical commercial or residential environment. If the user of the ***touchTymp*** requires continued operation during power mains interruptions, it is recommended that the ***touchTymp*** be powered from an uninterruptable power supply or its battery. |
| Power frequency (50/60 Hz)<br><br>IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment. |
| **Note:** *U*T is the A.C. mains voltage prior to application of the test level. | | | |

| Guidance and manufacturer's declaration — electromagnetic immunity | | | |
|---|---|---|---|
| The ***touchTymp*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***touchTymp*** should assure that it is used in such an environment, | | | |
| **Immunity test** | **IEC / EN 60601 test level** | **Compliance level** | **Electromagnetic environment – guidance** |
| Conducted RF<br>IEC / EN 61000-4-6 | 3 Vrms<br>150kHz to 80 MHz | 3 Vrms | Portable and mobile RF communications equipment should be used no closer to any parts of the ***touchTymp,*** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>**Recommended separation distance:**<br>$d = 1{,}2\sqrt{P}$<br>$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2{,}3\sqrt{P}$ 800 MHz to 2,7 GHz<br>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).<br>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]<br>Interference may occur in the vicinity of equipment marked with the following symbol: |
| Radiated RF<br>IEC / EN 61000-4-3 | 3 V/m<br>80 MHz to 2,7 GHz | 3 V/m | |
| NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies<br>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 ***touchTymp*** is used exceeds the applicable RF compliance level above, the ***touchTymp*** should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ***touchTymp.***<br>**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+A1:2012: Medical Electrical Equipment, Part 1 General Requirements for Safety
2. ANSI/AAMI ES 60601-1: 2005 / A2:2010: Medical Electrical Equipment, Part 1 General Requirements for Safety
3. CAN/CSA-C22.2 No. 60601-1:14: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
4. UL/IEC/EN 60950-1:2005: Information Technology Equipment - Safety - Part 1: General Requirements
5. IEC 60601-1-1:2000: General requirements for safety; Collateral standard: Safety requirements for medical electrical systems
6. IEC 60601-1-2:2014: Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and tests
7. ISO 14971:2012 - Application of risk management to medical devices
8. General Safety and Performance Requirements of the current REGULATION (EU) 2017/745
9. DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2)
10. Directive 2002/96/EC on waste electrical and electronic equipment (WEEE)

## 6.7 Checklist for subjective Audiometer Testing

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

# Appendix A Literature

L. Macedo de Resende; J. dos Santos Ferreira; S. Alves da Silva Carvalho; I. Oliveira; I. Barreto Bassi, „Tympanometry with 226 and 1000 Hertz tone probes in infants" Braz. j. otorhinolaryngol. vol.78 no.1 São Paulo Jan./Feb. 2012

Carvallo RMM, „Medida de imitância acústica em crianças de zero a oito meses de idade." São Paulo: Universidade Federal de São Paulo – Escola Paulista de Medicina; 1992

Lu JS, Zhang J, Tang L, Ding W, Zhang L, Guo XP, Zai NL."Analysis of the 1000 Hz Tympanometry in normal hearing neonates", Zhonghua Er Bi Yan Hou Tou Jing Wai Ke Za Zhi. 2011 Nov;46(11):905-8

Rafidah Mazlan, Joseph Kei, Louise Hickson, Asaduzzaman Khan, John Gavranich, Ron Linning, „High Frequency (1000 HZ) Tympanometry Findings in Newborns: Normative Data Using a Component Compensated Admittance

Approach" Australian and New Zealand Journal of Audiology, Volume 31, Issue 1, May 2009, pages 15-24 DOI: 10.1375/audi.31.1.15

Kei J, Allison-Levick J, Dockray J, Harrys R, Kirkegard C, Wong J, "Highfrequency (1000 Hz) Tympanometry in normal neonates." J Am Acad Audiol. 2003;14(1):20-8

Shanks, J., & Shohet, J (2009), "Tympanometry in clinical practice." In J. Katz, L. Medwetsky, R. Burkard, & L. Hood (Eds.), Handbook of clinical audiology (6th ed.) (pp. 157-188)

Baltimore: Lippincott, Williams & Wilkins Mrowinski, D., Scholz, G., "Audiometrie – Eine Anleitung für die praktische Hörprüfung." 2006, 3. Auflage, Thieme Verlag

Jerger, J., Northern, J.,"Clinical impedance audiometry" 1980, Thieme Verlag

Specifications are subject to change without notice.

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