

Operation Manual

touchTymp

MI 36 Version



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

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Compliance

MAICO Diagnostics is an ISO 13485 certified corporation.

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

1 Introduction

This section offers you important information about:

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

1.1 Intended Use Statement

The touchTymp impedance audiometer is a combination device that includes an impedance meter module (instrument for the measurement of aural acoustic impedance/admittance (immittance) and an audiometer module. The primary operation is an impedance meter.

The impedance meter module is designed to assess middle ear function and eustachian tube function.

The audiometer module is designed to quantitatively measure and monitor an individual's hearing threshold across different frequencies.

1.2 Indications for Use Statement

There are no medical indications for this device.

1.3 Patient Population

The target population of the impedance meter module includes all ages.

The target population of the audiometer module is children from 3 years to adults.

1.4 Contraindications

Contraindications to testing include

- recent stapedectomy or middle ear surgery,
- a discharging ear,
- acute external auditory canal trauma, discomfort (e.g., severe otitis externa),
- occlusion of the external auditory canal, or
- the presence of tinnitus, hyperacusis or other sensitivity to loud sounds may contraindicate testing when high intensity stimuli are used.

For audiometry, contraindications include additionally if the patient is sick or uncooperative.

1.5 Intended Operator

The touchTymp is intended to be used by trained personnel only, such as audiologists, ENT surgeons, doctors, hearing healthcare professionals or personnel with a similar level of education. The device should not be used without the necessary knowledge and training to understand its use and how results should be interpreted.

1.6 Features and Benefits

Table 1 shows the features and benefits for each touchTymp version.

The touchTymp is supplied with the optional features as ordered. Subsequently purchased licenses can be activated by entering a license code in the settings.

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

Table 1 Features and Benefits of the touchTymp Versions

| Features | MI 24 | MI 26 | MI 34 | MI 36 |
|--|-------|-------|-------|-------|
| Full Touch Screen Operation | X | X | X | X |
| Immittance | | | | |
| Tympanometry, Acoustic Reflex Tests | X | X | X | X |
| Reflex Decay, Eustachian Tube Function Tests | - | - | X | X |
| 226 Hz Probe Tone | X | X | X | X |
| 678 Hz, 800 Hz Probe Tones | - | - | X | X |
| High Frequency Probe Tone (1000 Hz) | O | O | O | O |
| RaceCar Animation | X* | X* | X* | X* |
| Multiple Transducer Options for Contralateral Reflex Testing | X | X | X | X |
| Automatic Test Function in Immittance Modules | X | X | X | X |
| Included Test Cavities for Quick and Easy Calibration Verification | X | X | X | X |
| Audiometry | | | | |
| Air Conduction Pure Tone Audiometry | - | X | - | X |
| Bone Conduction Pure Tone Audiometry | - | O | - | X |
| Managing Test Results | | | | |
| Print directly from device with built-in printer | O | O | O | O |
| Automatic printing ability with placement of probe in holder | O | O | O | O |
| PC Connection (for Connection with MAICO Sessions) | O | O | O | O |
| Transfer touchTymp test data into the PC Software and Print Results on Your PC | O | O | O | O |

X = Included, O = Optional

*Optional for devices purchased until 08/2024, standard for devices purchased from 08/2024

1.7 Description

1.7.1 General

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

It also includes **Reflex Decay** and **Eustachian Tube Function (ETF)** tests.

The touchTymp MI 36 also includes Audiometry functions:

- **Air Conduction**
- **Bone Conduction** incl. **Masking**

The functions are described in detail in the following sections.

1.7.2 Tympanometry

Tympanometry is the objective measurement of middle ear mobility (compliance¹) and pressure² 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 probe. This tone is used to measure the change in compliance in the middle ear system while the air pressure varies automatically from a positive value (i.e., +200 daPa) to a negative value (i.e., -400 daPa max). The compliance is obtained as aural acoustic admittance (Y), which consists of the parts susceptance (B) and conductance (G).

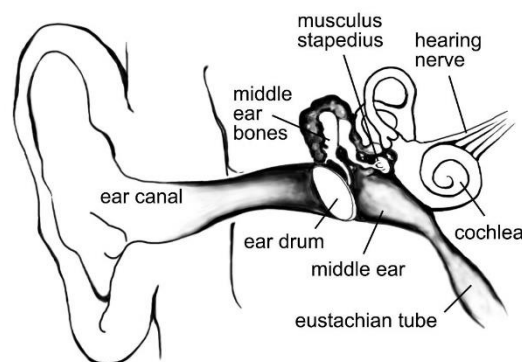


Figure 1

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 \cong 1 ml for 226 Hz probe tone

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).

1.7.3 Acoustic Reflex

An **Acoustic Reflex**, or contraction of the stapedius 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 acoustic 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 acoustic 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.

1.7.4 Acoustic Reflex Decay

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.

1.7.5 Eustachian Tube Function (ETF)

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.

1.7.6 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.

1.7.7 Bone Conduction Testing

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.

1.7.8 Masking

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

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

For Bone Conduction measurements the interaural attenuation is 0 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 Reading this Operation Manual

This operation manual contains information pertinent to the use of the touchTymp 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 Operation Manual.

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

In this Operation Manual the following two labels identify potentially dangerous or destructive conditions and procedures:



WARNING

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



CAUTION

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 always observed. Failure to observe these precautions could result in damage to the equipment and injury to the operator or subject.

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

It is understood that safety rules within individual organizations vary. If a conflict exists between the material contained in this 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.









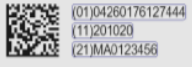













2.3 Manufacturer's Liability

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 failure to follow the operating instructions, operation by unqualified personnel, and unauthorized modifications to the equipment.

2.4 Regulatory Symbols

The following Table 2 explains the symbols used on the device itself, on the packaging and the accompanying documents including the Operation Manual.

Table 2 Regulatory Symbols

| REGULATORY SYMBOLS | |
|---|--|
| SYMBOL | DESCRIPTION |
|  | Serial number |
|  | Date of manufacture |
|  | Manufacturer |
|  | Caution, consult accompanying documents |
|  | Warning, consult accompanying documents |
|  | Return to authorized representative, special disposal required |
|  | Reference number |
|  | Medical Device |
|  | UDI information: (01) GTIN (Global Trade Item Number), (11) Date, (21) Serial number |
|  | Applied part type B according to IEC 60601-1 |
|  | Refer to operation manual (mandatory) |
|  | Keep away from rain |
|  | Transport and storage temperature range |
|  | Transport and storage humidity limitations |
|  | Transport and storage atmospheric pressure limitations |
|  | Voltage transformer |
|  | Do not reuse |
|  | CE label with notified body ID |
|  | Non-ionizing electromagnetic radiation |
|  | Direct Current (DC) |
|  | ETL listed mark |
|  | Logo |

2.5 General Precautions



WARNING

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

Use and store the device indoors only. For operation, storage and transport conditions see table in Section 6.

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



WARNING

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



WARNING

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



WARNING

Do not modify this equipment without authorization of the manufacturer.

Equipment is not user repairable. Repairs must be performed by a qualified service representative only. No modifications of the equipment are allowed by anyone other than a qualified MAICO representative. Modification of the equipment could be hazardous.

No part of the equipment can be serviced or maintained while in use with the patient.



WARNING

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

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



WARNING

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



WARNING

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.



WARNING

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

2.6 Electrical and Electrostatic Safety



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



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

In Case of Emergency



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

In Case of Emergency

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.



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 electrical equipment/nonmedical electrical equipment) 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 62368-1 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 in 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 a qualified medical technician or your local representative.



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.



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.



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 rich environment, such as a hyperbaric chamber, oxygen tent, etc. If the device is not used, switch it off and disconnect it from the power supply.

Never short-circuit the terminals.



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



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

2.7 Electromagnetic Compatibility (EMC)



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

The device fulfills the relevant EMC requirements.

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



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



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

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



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.

2.8 Cyber Security and Data Protection

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

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

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

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

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

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

2.9 Device Control

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

For annual calibration, see Sections 2.5 and 3.2.

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 1 year. Ask your authorized local distributor for more information.

This warranty is extended to the original purchaser of the device by MAICO through the distributor from whom it was purchased and covers defects in material and workmanship for a period of at least 1 year from date of delivery to the original purchaser.

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

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

3.2 Maintenance

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

The service and calibration must be performed by your distributor, or a service center authorized by MAICO.

When returning the device for repairs or calibration it is essential to send the acoustic transducers with the device. Include a detailed description of faults. To prevent damage in transit, use the original packaging when returning the device.

3.3 Cleaning and Disinfection Recommendations

3.3.1 General

It is recommended that parts (device and accessories 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



CAUTION

To avoid damage of the device and its accessories, 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 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:

[touchTymp Tympanometer Part 1 | MAICO Training | Hearing Screening Diagnostic Tests - Cleaning the device](https://youtu.be/3xEglQewj38?si=Oy3geDbBwjDD9fx7&t=362)

<https://youtu.be/3xEglQewj38?si=Oy3geDbBwjDD9fx7&t=362>



CAUTION

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:

[touchTymp Tympanometer Part 1 | MAICO Training | Hearing Screening Diagnostic Tests - How to clean the probe](https://youtu.be/3xEglQewj38?si=b6xi3F-JYP8XmMQG&t=290)

<https://youtu.be/3xEglQewj38?si=b6xi3F-JYP8XmMQG&t=290>

To secure correct immittance measurements it is important to make sure that the probe system is always kept clean. Therefore, 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, follow the illustrated instructions below. The pictures show the procedure on the Pen Probe (left) and the Shoulder Box Probe (right).



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

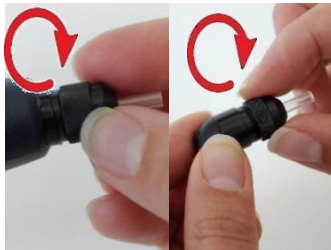


Figure 2

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



Figure 3

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



Figure 4

To access and clean the channels, it may be necessary to remove the gasket from inside the probe tip. You can do this using a fine pin. Push the gasket back into place after cleaning (Figure 4).

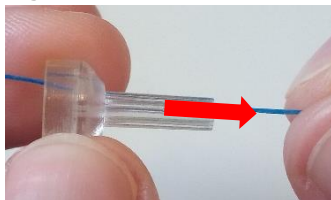


Figure 5

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 5).

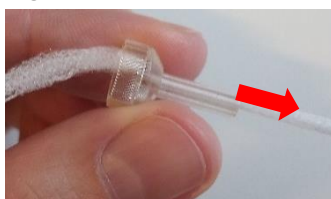


Figure 6

Proceed in the same way with all 4 probe channels. Use the floss only once (Figure 6).

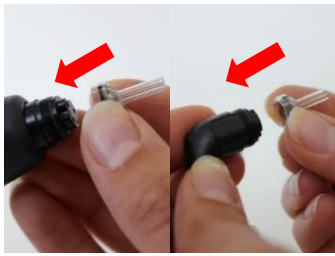


Figure 7

Place the probe tip back onto the probe. Make sure that the plastic pegs are inserted into the appropriate corresponding cavities (Figure 7).



Figure 8

Screw the probe cap back on the probe (Figure 8). 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 9

Use the cleaning set from the eartip box (Figure 9): Take the cleaning tool apart to find the thin brush and thin rigid plastic cord (Figure 10).



Figure 10



Figure 11

Use the plastic cord or brush to push debris out of the probe tip (Figure 11).



Figure 12

Always enter the probe tip from the rear to avoid accumulation of debris inside the vents (Figure 12).



Figure 13



Never clean the probe itself with the cleaning devices. The probe will be damaged (Figure 13).



Figure 14



Never clean the probe tip while the tip is still attached. The probe will be damaged (Figure 14).

3.4 Disposables

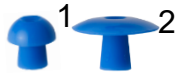


Figure 15

Operating the touchTymp requires the use of eartips – either mushroom shaped (1) or umbrella (2) eartips (Figure 15).



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



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


MAICO strongly recommends using Sanibel® eartips only. In case you want to purchase further disposables, 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 these replacement parts available (as appropriate for your touchTymp device configuration).

3.6 Troubleshooting

Table 3 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 | <ol style="list-style-type: none"> 1. Clean the probe tip as described in the manual. If the system still does not run proceed with step 2. 2. Use a new probe tip. If the system still does not run proceed with step. 3. Change the complete probe and check if the system is running. |
| Screen is frozen | | Hold the Power button button for 10 s 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), MAICO Sessions is opened and the green connection icon  is displayed. |
| Error Message when connected to PC | Outdated software | The touchTymp (FW version 1.12 and higher) can only be connected to MAICO Sessions. |

| Problem | Reason | Suggestion |
|-------------------------------|--------------------------------------|------------------------------|
| 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, contact your customer service. It will be helpful to use the function **Export error log** (see Section 5.6.21) 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 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE), MAICO has changed their sales policy. To avoid additional distribution costs, we assign the responsibility for the proper collection and treatment according to legal regulations to our customers.

Non-European countries

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

4 Unpacking and 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 Probe**
 - **getting to know the built-in printer**
 - **adjusting the feet height**
 - **mounting the Shoulder Box Probe 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 packaging materials.
- Verify that all components are included as shown on the packing list 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 ensure 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 packaging material and the shipping container, so the device can be properly packed if it needs to be returned for service or calibration.

The touchTymp comes with different components (see Table 4). The availability of configurations with the following components are country specific. Contact your local distributor for more information.

Table 4 List of Components

| Components |
|--|
| General Components |
| Base Unit (with or without Printer) |
| Power Supply Unit UES65-240250SPA3 |
| Country-Specific Mainscable |
| USB Cable |
| Thermal Paper Rolls*** |
| Eartip Kit |
| Probe Floss Kit |
| Touch Pen |
| MAICO Sessions Kit |
| Operation Manual* |
| Quick Guide* |
| Components for Testing Tympanometry and Acoustic Reflexes |
| Pen Probe** |
| Shoulder Box Probe** |
| Shoulder Box Probe Adapter Kit**** |
| Shoulder Box Probe Attachment Kit**** |
| IP30 (6.3 mm Plug)** |
| IP30 (3.5 mm Plug)** |
| DD45C (6.3 mm Plug)** |
| DD45C (3.5 mm Plug)** |
| Volume cavity 0.2/0.5 cc, 2/5 cc |
| Components for Audiometry |
| Headphones***** |
| DD45** |
| DD65 v2** |
| IP30** |
| DD450** |
| Bone Conductor***** |
| B71** |
| B81** |
| Patient Response Switch** |
| Mic/Monitor Headset** |
| Talk Back Microphone** |

*As download from the download center – see accompanying leaflet

**Applied parts according to IEC 60601-1

***Only if sold with base unit with printer

****Only if sold with Shoulder Box Probe

*****Selection of one transducer at time of purchase

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)
RaceCar (for Devices Purchased From 08/2024)

Extra Licenses

Tympanometry 1000 Hz
RaceCar (for Devices Purchased Until 08/2024)
PC Connection

Disposables Supplied

NOTE: MAICO strongly recommends using 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

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 earphones

4.2 Hardware Orientation

4.2.1 Display



Figure 16

The display on the touchTymp is a touch screen (Figure 16). 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 17 shows the connections on the backside of the device. The connections are explained in Table 5.



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.

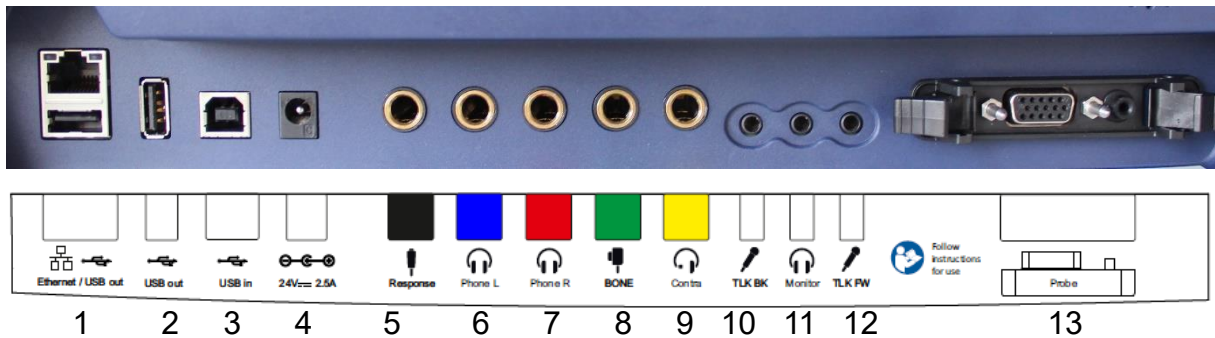


Figure 17

Table 5 Connections on Backside of Device

| CONNECTIONS | | |
|-------------|---------------------------|--|
| 1 | Ethernet / USB out | Dual connector: Ethernet – no function in actual device 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 | 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 Headphones |
| 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:

touchTym Tympanometer Part 1 | MAICO Training |
Hearing Screening Diagnostic Tests

<https://youtu.be/3xEglQewj38?si=Gr7TcHC798CnTAKR>

Connect and disconnect the probe as follows:

1. To connect position the probe connector over the locating pins (Figure 18)
2. Push the connector until the clips lock-in (Figure 19, 1).
3. Confirm the clips have locked in properly, push them to the center (2).
4. To disconnect the probe open the 2 locks by pushing them to the sides (Figure 20).



Figure 18

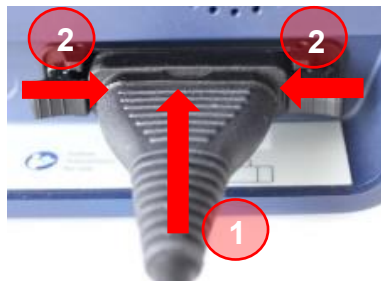


Figure 19



Figure 20

4.2.4 Establishing a PC Connection via USB

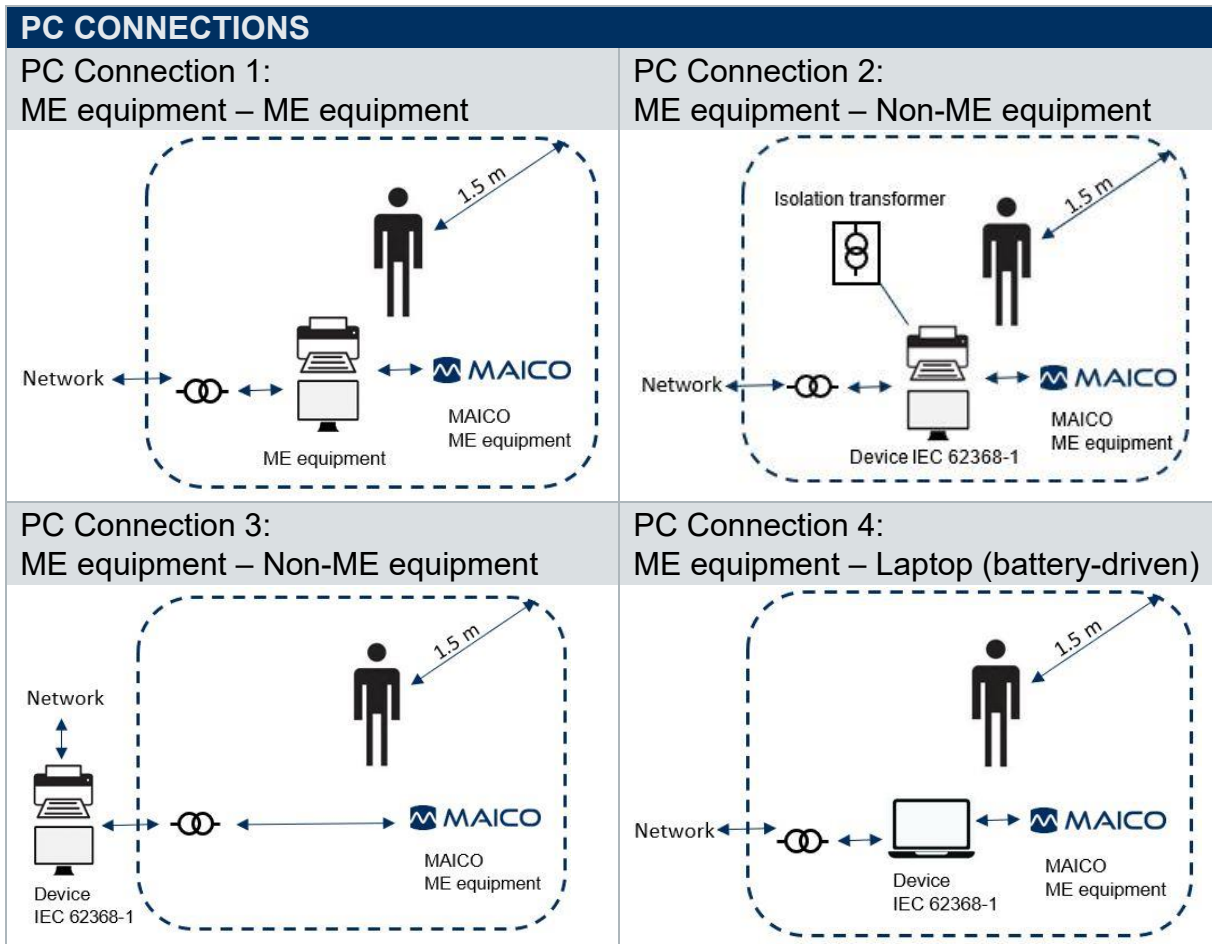
Data transfer to a PC can be done via USB connection.

If the touchTymp is used with office equipment that is not medical electrical equipment (ME equipment) itself (see Table 6, PC Connection 1), make sure to establish the PC connection in one of the following ways (see Table 6, PC Connection 2, 3 or 4).



Make sure you use only office equipment with the device that is medical electrical equipment itself or meets the requirements of IEC 62368-1. If nonmedical electrical equipment is used within the patient environment (1.5 m from patient as defined in IEC 60601-1) an isolation transformer must be used (exception: a battery-driven laptop is used).

Table 6 PC Connections



4.2.5 Probes

There are two probes available for the touchTympanometer: Pen Probe and Shoulder Box Probe. 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. The Shoulder Box Probe allows hands-free work while performing diagnostic measurements. Additionally, the Shoulder Box has a 3.5 mm jack for the Contralateral headphone (Figure 23). Both, the Pen Probe (Figure 21) and the Shoulder Box Probe (Figure 22) are connected to the device in plug 13 (Figure 17).

Table 7 shows the explanation of the probe design for both Pen Probe and Shoulder Box Probe. The further explanation of the indication light and the light bar in this section applies to both probes.

Table 7 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 ear side 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 Response , etc.) |
| (5) | (Jack for Contralateral headphone) | Only for Shoulder Box Probe: Possibility to connect a Contralateral headphone (see description following in this section) |

Pen Probe



Figure 21



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

Shoulder Box Probe

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 22



Figure 23



Figure 24

Contralateral Headphone with the Shoulder Box Probe

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 Probe (see Figure 17, plug 9).

The Indication Light

The indication light displays the different states of the measurement by color and the presentation modes (flashing/continuous). Table 8 gives explanation to the different indications.





Table 8 Indication Light

| PROBE | DEVICE VERSION | EXPLANATION |
|-------|----------------|--|
| | From 08/2024 | Right or left ear is selected. Probe is out of ear. |
| | Until 08/2024 | Right ear is selected. Probe is out of ear. |
| | Until 08/2024 | Left ear is selected. Probe is out of ear. |
| | All | Probe is in the ear and is sealing, test is running or done. |
| | All | 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: <ol style="list-style-type: none"> 1. Reinsert the probe for better placement. 2. Inspect the probe tip for any blockage. 3. Verify eartip has the correct size, new eartip may be required. |
| | All | 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 (Table 9).

Table 9 Light Bar Functions 1

| PROBE | COLOR | TEST | 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 10.

Table 10 Light Bar Functions 2

| Lightbar Colors | INTERNATIONAL | | US |
|---|----------------------------|-----------------------------|----------------------------|
| | 226 Hz Range Compliance | 1000 Hz Range Compliance | 226 Hz Range Compliance |
|  | Value < 0.3̄ | Value < 0.2 | Value < 0.23̄ |
|  | 0.3̄ ≤ Value < 0.6̄ | 0.2 ≤ Value < 0.4 | 0.23̄ ≤ Value < 0.46̄ |
|  | 0.6̄ ≤ Value < 1.0 | 0.4 ≤ Value < 0.6 | 0.46̄ ≤ Value < 0.69̄ |
|  | 1.0 ≤ Value < 1.3̄ | 0.6 ≤ Value < 0.8 | 0.69̄ ≤ Value < 0.93̄ |
|  | 1.3̄ ≤ Value < 1.6̄ | 0.8 ≤ Value < 1.0 | 0.93̄ ≤ Value < 1.16̄ |
|  | 1.6̄ ≤ Value | 1.0 ≤ Value | 1.16̄ ≤ 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.

4.2.6 Built-In Printer

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

To change paper rolls:

- Push the marker on the left side of the touchTymp to open the printer cover (Figure 25).
- Pull the blue lever upwards (Figure 26).
- 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 27).



Figure 25



Figure 26



Figure 27

4.2.7 Test Cavities

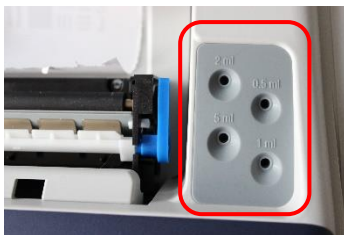


Figure 28

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 28). 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 $\pm 5\%$ 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.

4.2.8 Adjusting the Feet Height

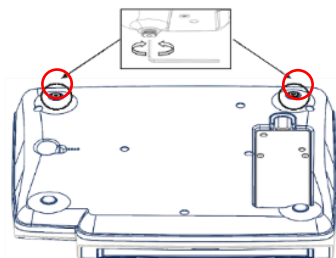


Figure 29

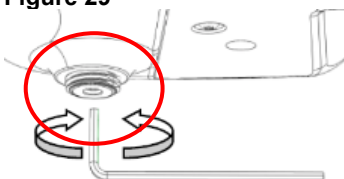


Figure 30

Use the Allen key to adjust the touchTymp feet (Figure 29 and Figure 30).

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.

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

4.3 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.

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 is 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.

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 near the audiometer as it may lead to incorrect test results.

5.1.3 Turning On the Device



Figure 31

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

Briefly press the **Power button** on the front of the touchTymp to turn on the device (Figure 31). The boot up process will take approximately 2 min. 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 32

Calibration Reminder: If a detected transducer is within one month of expiration of the calibration date, a reminder message (Figure 32) will appear (once per day). See Section 5.6.21.

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

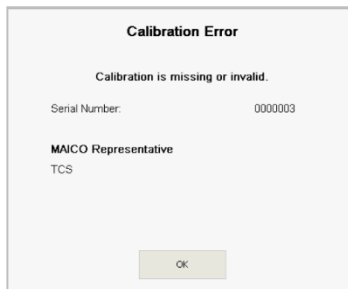


Figure 33

Calibration Error: If a calibration is missing or invalid a message box will appear (Figure 33). 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.

5.1.4 Switching Off the Device



Figure 34

The device can be shut down from any screen by pressing the **Power button**. To confirm the Shutdown of the device, press **OK** or **Cancel** and go back to the screen (Figure 34).

NOTE: In case the screen is frozen press the **Power button** for 10 s and the device will turn off.

5.1.5 Automatic Power-Off

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

5.2 The Home Screen

The **Home** screen displays the buttons controlling entry into the major functions of the touchTymp including the specific test selection (Figure 35).

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

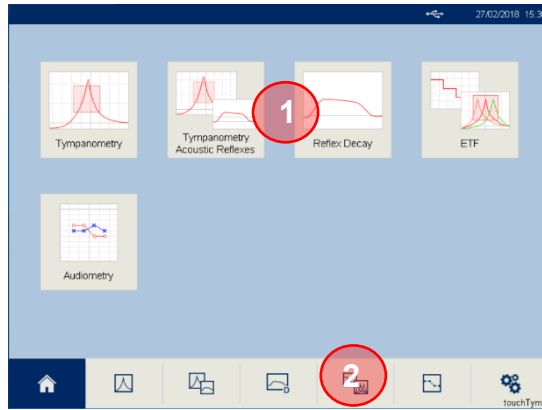


Figure 35

5.3 Immittance Testing

5.3.1 Screen Format – Immittance

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

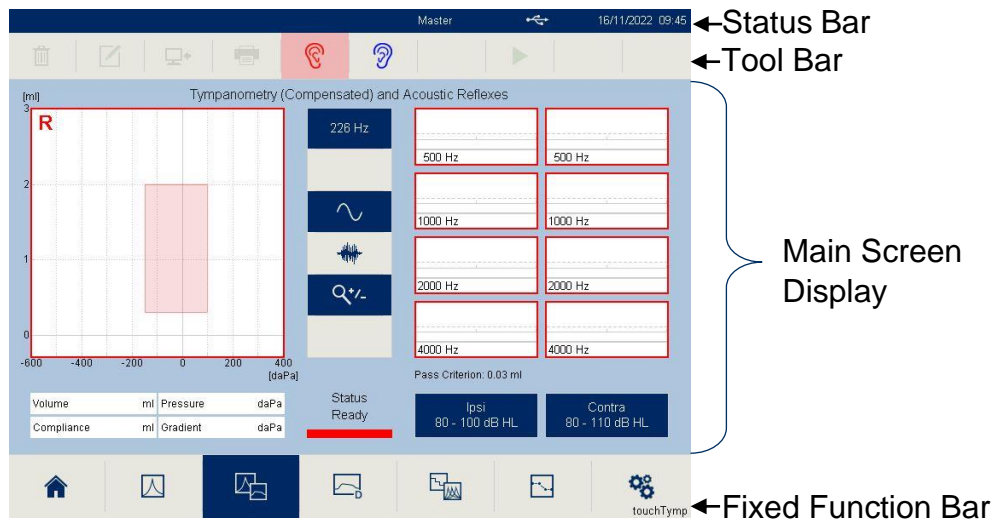













Figure 36

Status Bar: displays the Date/Time and the status of PC connection ■ (if connected to MAICO Sessions (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 11):

Table 11 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 if manual transfer has been selected in the settings. The data is deleted upon manual data transfer. |
| |  | Print | Print: to print the results of all completed tests and of all probe tones. |
| |   | Ear selection | Ear: to select an ear for testing or repeating the measurement on the same ear (Blue = Left Ear, Red = Right Ear). 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 testing. For a detailed explanation of the different test screens see Section 5.3.4.

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 12):

Table 12 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. |
|  | Audiometry | Audiometry: to open the Audiometry module |
|  | Settings | Settings: to access a list of all the device settings. |
|  | Reflex Decay | Reflex Decay: to open the Reflex Decay module |
|  | ETF | ETF: to open the ETF module for intact or perforated ETF testing. |

5.3.2 Preparing for Testing – Immittance

5.3.2.1 Preparing the Patient



Sehen Sie sich auch unsere Schulungsvideos an:

touchTymp Tympanometer Part 1 | MAICO Training | Hearing Screening Diagnostic Tests - How to set up the test environment

<https://youtu.be/3xEglQewj38?si=4ENklmwIFepFrypN&t=43>

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.

5.3.2.2 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.

5.3.2.3 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 to test the integrity of the CN VIII. One tone is presented above the acoustic reflex threshold measurement for a minimum period of 10 s.

- The aim of **ETF** is to test the condition of the Eustachian tube.

ETF Intact: three tympanograms are completed while the patient performs a maneuver between each tympanogram.

ETF Perforated: pressure level is obtained in the ear canal and the patient swallows to measure change of pressure.

5.3.2.4 Handling the Eartips

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



Figure 37

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 38

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 39

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

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.

5.3.3 Status Indicator

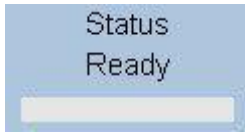


Figure 40

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

The same information is shown on the probe with the single LED (Table 13).

Table 13 Test Status Indication

| TEST STATUS INDICATION | | | |
|------------------------|----------------------|---------------------|---|
| PROBE | DEVICE UNTIL 08/2024 | DEVICE FROM 08/2024 | INFORMATION |
| | - | | Right or left ear is selected. Probe is out of ear. |
| | | - | Right ear is selected. Probe is out of ear. |
| | | - | Left ear is selected. Probe is out of ear. |
| | | | Probe is in the ear and is sealing, test is running or test is done. |
| | | | Probe is in the ear and blocked or leaking. 1. Reinsert probe for better placement. 2. Check eartip size and condition. 3. Inspect probe tip for any blockage. |
| No Light | | | Probe is not attached properly. Check probe connection. |
| No Light | | | Probe tone is not given. This status is shortly shown while the frequency is being changed. |

5.3.4 Testing – Immittance

5.3.4.1 Performance and Evaluation of Tympanometry Test

Figure 41 shows the *Tympanometry* test screen.

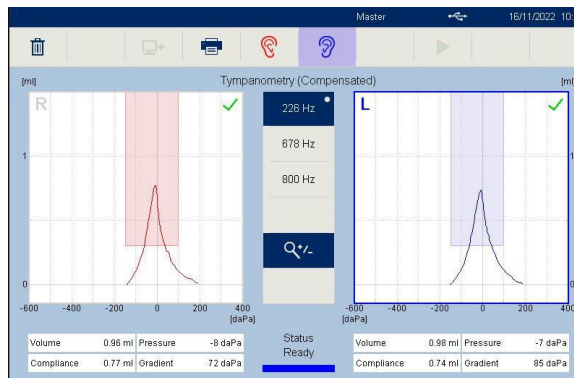


Figure 41

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

Performing a Measurement



Also, check out our training videos:

[touchTymp Tympanometer Part 1 | MAICO Training | Hearing Screening Diagnostic Tests – How to conduct a measurement](https://youtu.be/3xEgIQewj38?si=U9PdYlwRg78-iEC1&t=65)

<https://youtu.be/3xEgIQewj38?si=U9PdYlwRg78-iEC1&t=65>

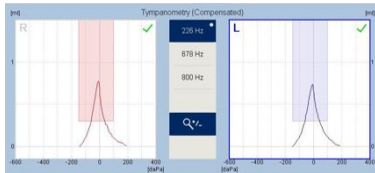


Figure 42

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

NOTE: The view of the Tympanogram depends on the settings (**Compensated/Uncompensated** (see Section 5.6.8) and **Auto zoom**, (see Section 5.6.7)).

The Tympanometry components (Y, B, G) displayed depend on the setting (see Section 5.6.7).

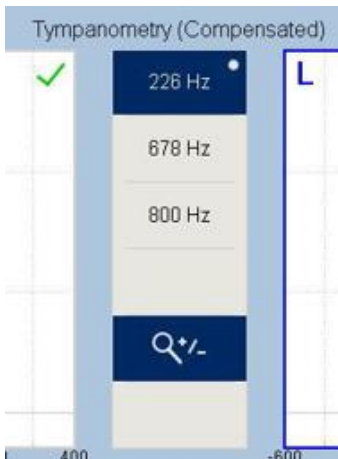


Figure 43

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 half a year.
- **678 Hz:** Test frequency of 678 Hz
- **800 Hz:** Test frequency of 800 Hz
- **1000 Hz:** Licensed function, to be chosen if patient is younger than half a year.
- Press to activate/deactivate the **Auto zoom** function.
- **RaceCar** : to display **RaceCar** animation during testing. See Section 5.3.4.3 for more information (Figure 43).

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

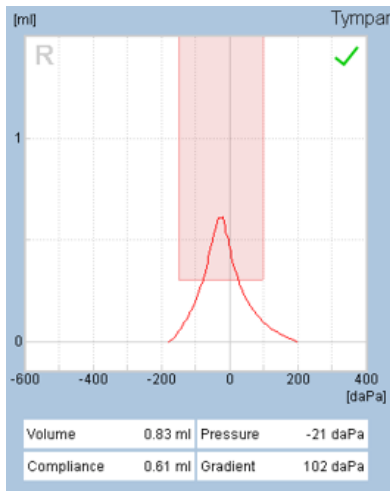


Figure 44

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.

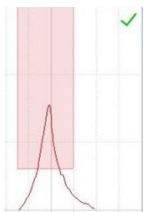


Figure 45

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.

✓ 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:

[touchTymp Tympanometer Part 1 | MAICO Training | Hearing Screening Diagnostic Tests – Tympanometry test result](https://youtu.be/3xEglQewj38?si=cSyfJx5oR3lY3qfJ&t=126)

<https://youtu.be/3xEglQewj38?si=cSyfJx5oR3lY3qfJ&t=126>

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.

5.3.4.2 Performance and Evaluation of the Acoustic Reflexes Test

Selection of the **Tympanometry and Acoustic Reflexes** icon leads to the **Tympanometry and Acoustic Reflex** screen (Figure 46). Review Section 5.3.4 for **Tympanometry**.

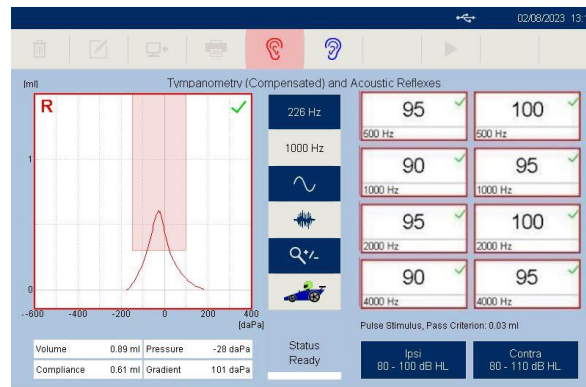


Figure 46

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:

[touchTympanometer Part 1 | MAICO Training | Hearing Screening Diagnostic Tests – Acoustic Reflexes](https://youtu.be/3xEglQewj38?si=m8Rr2JTEIHGJZreQ&t=172)

<https://youtu.be/3xEglQewj38?si=m8Rr2JTEIHGJZreQ&t=172>

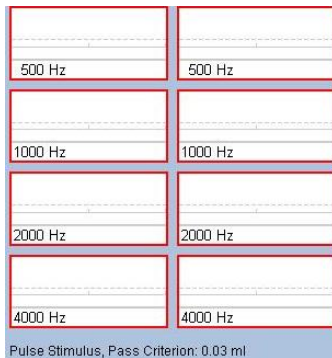


Figure 47

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:

[touchTymp Tympanometer Part 1 | MAICO Training | Hearing Screening Diagnostic Tests – How does the test result look](https://youtu.be/3xEglQewj38?si=snLlloSns_g256zQ&t=245)

https://youtu.be/3xEglQewj38?si=snLlloSns_g256zQ&t=245

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

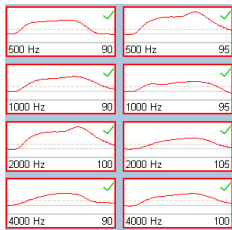


Figure 48

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.

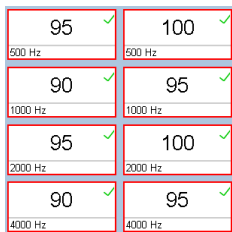


Figure 49

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 in the graphical view as well 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



Figure 50

The MI 36 version includes pure tone and noise stimuli for **Acoustic Reflex** testing (Figure 50).

: **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.

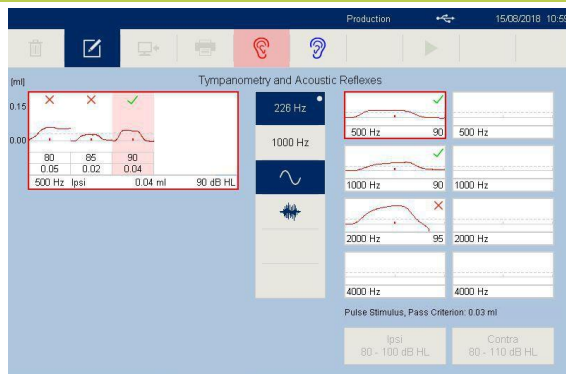


Figure 51

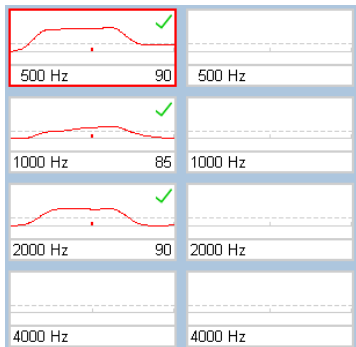


Figure 52

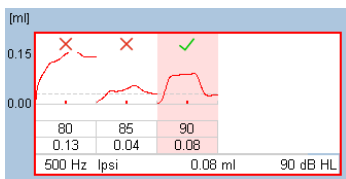


Figure 53

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 **Settings** menu. See Section 5.6.9.

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

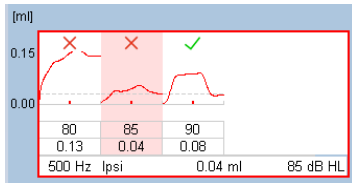


Figure 54

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).

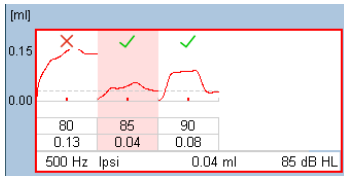


Figure 55

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.

5.3.4.3 RaceCar Operation



Also, check out our training videos:

[touchTymp Tympanometer Part 2 | MAICO Training | Hearing Screening Diagnostic Test – RaceCar - Measurement and Result](https://youtu.be/qto7kja4QUU?si=1HNfO7jaCh_VvATs&t=443)

https://youtu.be/qto7kja4QUU?si=1HNfO7jaCh_VvATs&t=443

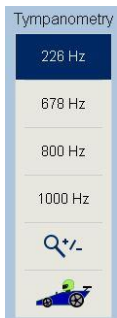


Figure 56

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.

5.3.4.4 Performance and Evaluation of Reflex Decay Test



Also, check out our training videos:
touchTymp Tympanometer Part 2 | MAICO Training | Hearing Screening Diagnostic Tests – Reflex Decay measurement
<https://youtu.be/qto7kja4QUU?si=dvnbP2pa2XSehAa&t=1>



Also, check out our training videos:
touchTymp Tympanometer Part 2 | MAICO Training | Hearing Screening Diagnostic Tests – Test Result
<https://youtu.be/qto7kja4QUU?si=NCvrWz27Hj4sB9a9&t=80>

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

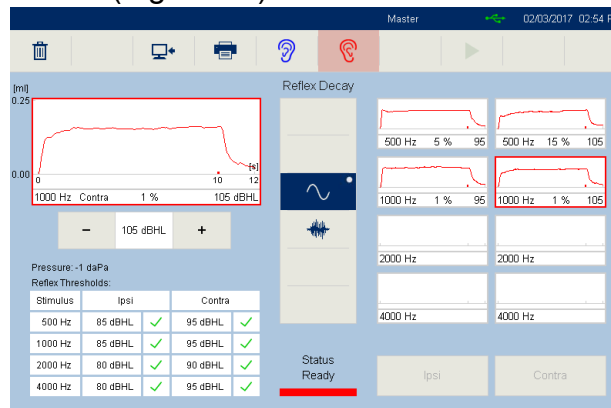


Figure 58

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.

| Stimulus | Ipsi | Contra |
|----------|-----------|-----------|
| 500 Hz | 85 dBHL ✓ | 95 dBHL ✓ |
| 1000 Hz | 80 dBHL ✓ | 95 dBHL ✓ |
| 2000 Hz | 80 dBHL ✓ | 85 dBHL ✓ |
| 4000 Hz | 80 dBHL ✓ | 80 dBHL ✓ |

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).

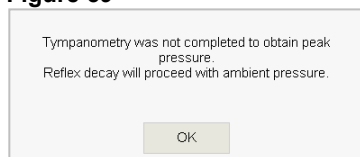


Figure 60

When a test is started without **Tympanometry and Acoustic Reflex** measurements, a dialog 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)

NOTE: All stimuli can be presented steady or pulsed. See Section 5.6.8 for more information.

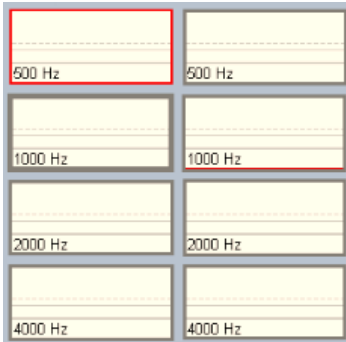


Figure 62

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).



Figure 63

Manual presentation is required within **Reflex Decay** measurements. Press the **Play** 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** .

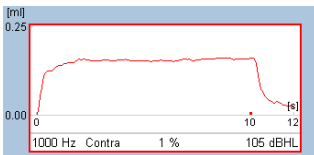


Figure 64

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 testing:

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

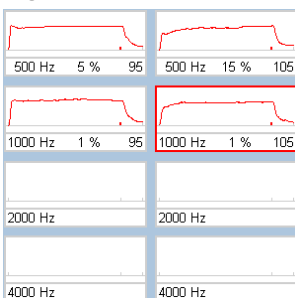


Figure 65

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).

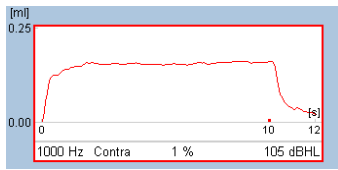


Figure 66

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.

5.3.4.5 Performance and Evaluation of Eustachian Tube Function (ETF)



Also, check out our training videos:

touchTymp Tympanometer Part 2 | MAICO Training | Hearing Screening Diagnostic Tests – Eustachian Tube Function

<https://youtu.be/qto7kja4QUU?si=16koiYnCJ3GMNXur&t=111>

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



Also, check out our training videos:

[touchTymp Tympanometer Part 2 | MAICO Training | Hearing Screening Diagnostic Tests – Eustachian Tube Function - Intact](https://youtu.be/qto7kja4QUU?si=ZjAl7p5QDNyFMYiR&t=151)

<https://youtu.be/qto7kja4QUU?si=ZjAl7p5QDNyFMYiR&t=151>

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 1st **Tympanogram** is complete, the pressure at the maximum compliance appears under **Pressure 1** (Figure 69).

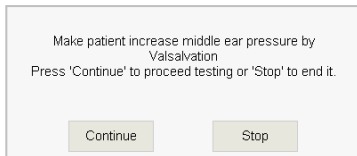


Figure 70

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 2nd **Tympanogram** to be completed. The pressure at the maximum compliance appears under **Pressure 2**.

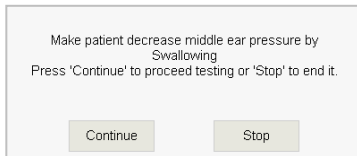


Figure 71

Once again, the pressure is held while the instruction is displayed for the patient to perform the 2nd maneuver (Figure 71). Press **Continue** to perform the 3rd **Tympanogram**. The pressure at the maximum compliance displays under **Pressure 3**.

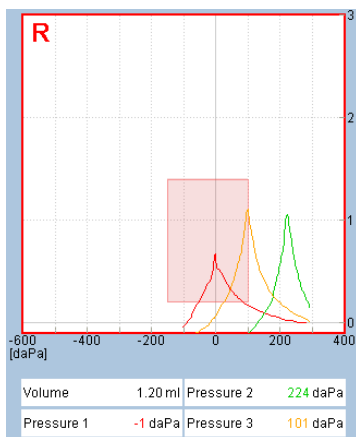


Figure 72

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



Also, check out our training videos:

[touchTymp Tympanometer Part 2 | MAICO Training | Hearing Screening Diagnostic Tests – Eustachian Tube Function - Perforated](#)

<https://youtu.be/qto7kja4QUU?si=H9Adot4xun8YemY2&t=243>



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).

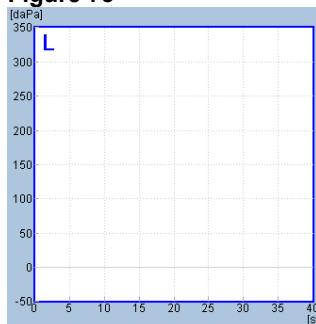


Figure 74

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 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 s) as defined in the settings or the examiner manually stops the test.

5.4 Audiometry Testing

5.4.1 Screen Format – Audiometry

Figure 76 shows the **Audiometry** screen of the touchTymp MI 36. It includes the **Status Bar**, the **Tool Bar**, and the **Main Screen Display**.

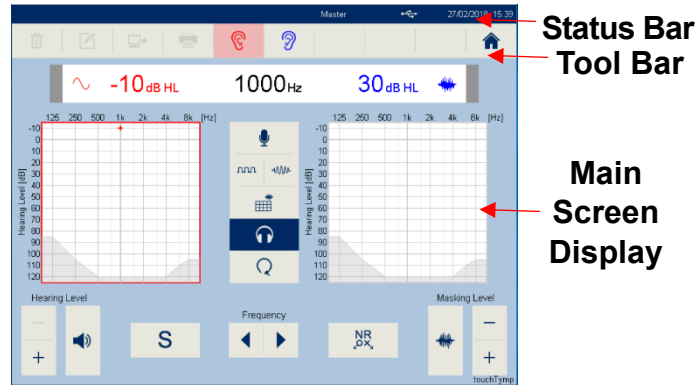











Figure 76

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

Tool Bar: A row of buttons that activate key functions when selected. Some buttons in the tool bar 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 14):

Table 14 Icons in the Tool Bar

| ICON FUNCTION EXPLANATION | | | |
|---------------------------|---|-----------------------|---|
| N | | | |
| 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 Table 15 for more information. |
| |  | Transfer to PC | Transfer to PC: to transfer the currently measured data if manual transfer has been selected in the settings. |
| |  | Print | Print: to print the results of all completed tests and of all probe tones. |
| |  | Ear selection | Ear: to select an ear for testing or repeating the measurement on the same ear (Blue = Left Ear, Red = Right Ear). 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. |
| Setting screen |  | Home | Home (only for Audiometry test screen): to return to the Home screen for test selection. |
| |  | 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

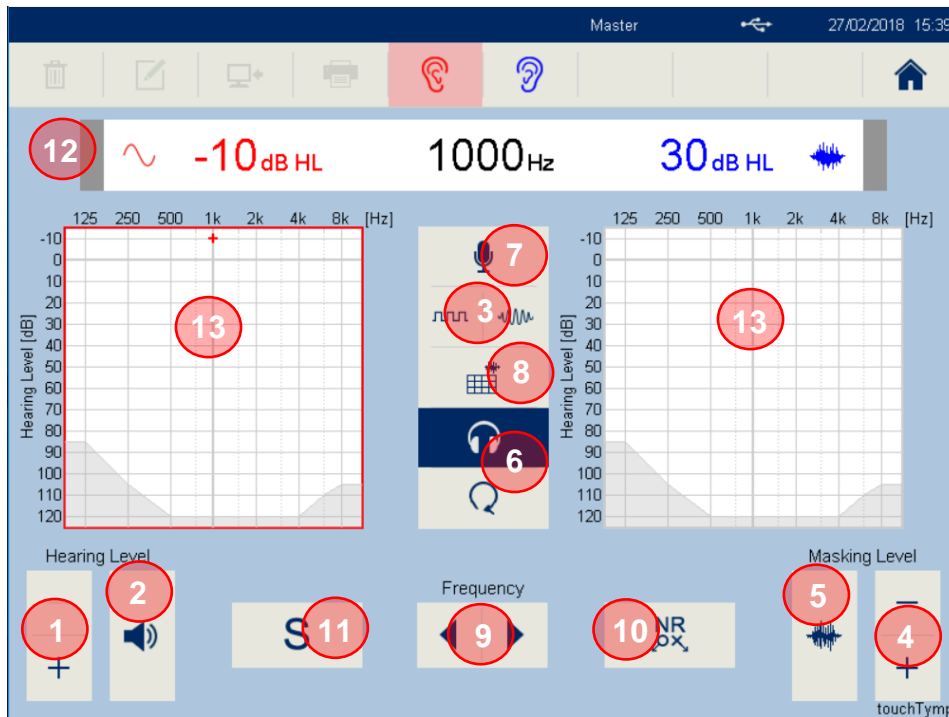

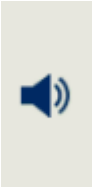








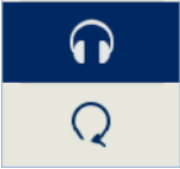


Figure 77


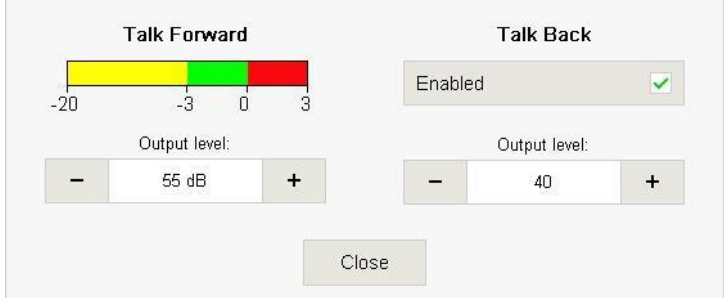






For explanation of the **Audiometry Main Screen Display** with Bone Conduction, see Table 16.

Table 16 Explanation of Main Audiometry Screen (with Bone Conduction)

| # | 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. <ul style="list-style-type: none"> • 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. • Interrupter mode: Touch to stop the signal being presented. |

NOTE: See **Settings** to change the **Test mode**.

| # | Name(s) / Function(s) | Description |
|---|---|---|
| 3 | Test Stimulus | Selection of the stimulus to present. <ul style="list-style-type: none">  Steady stimulus  Pulse stimulus  Warble stimulus  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 transducer. |
| |  | |
| 6 | Transducer | Selection between Air or Bone conduction transducer. |
| |  | <ul style="list-style-type: none">  Air Conduction/Headphones  Bone Conduction/Bone Oscillator |

| # | Name(s) / Function(s) | Description |
|---|--|--|
| 7 | Microphones  | <p>Selection allows two microphone changes when accessories are connected.</p> <ol style="list-style-type: none"> Talk Forward: Allows tester to provide instruction to the patient while the headphones are in place. Increase/decrease the volume by selecting the +/- (Figure 78). The lighted bar/VU meter allows the examiner to monitor their voice for optimal sound quality. When speaking, 0 is the optimal level. 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 78) prior to setting the volume. The volume dial on the mic/monitor headset must also be controlled for optimal volume. |
|  | | |
| <p>Figure 78</p> | | |
| 8 | Show masking  | <p>Selection allows the masking table to be displayed.</p> |
| 9 | Frequency  | <p>Touch  to increase the frequency (Hz). Touch  to decrease the frequency (Hz).</p> |
| 10 | No Response (NR)  | <p>Touch to store No Response result within the graph or table display.</p> |
| 11 | Store  | <p>Touch to display a test result within the graph or table display.</p> |

| # | Name(s) / Function(s) | Description |
|---|-----------------------|-------------|
|---|-----------------------|-------------|

12 Status Bar The numerical display for the testing operation of the device (Figure 79).

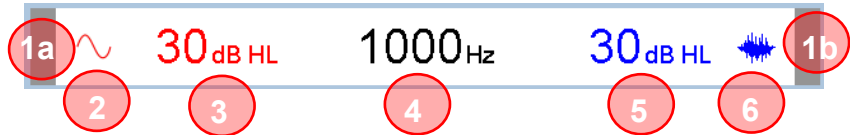


Figure 79

The information includes (Table 17):

Table 17 Status Bar explanation

| # | Status Bar Explanation |
|--------|---|
| 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. |
| 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. |
| 5 | Masking level displayed in the color of the non-test ear. |
| 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.


NOTE: **None**-setting display does not allow storing of results.

Delete point



Press **Edit**  button in the tool bar to enter the edit mode.

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.

5.4.2 Preparing for Testing – Audiometry

5.4.2.1 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.

5.4.2.2 Placement of Headphones (for Testing with Headphones)

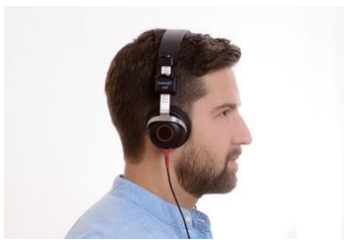


Figure 80

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

Ensure that the headphones (Figure 80) 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).

5.4.3 Placement of Foam Eartips (for Testing with Insert Earphones Only)



Figure 81

The insertion of the insert earphones into the ear canal without an eartip can scratch the ear canal.

Always apply a foam eartip before inserting the insert earphones into the ear canal.

First, place the foam eartip securely on the 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 81). Check to be sure that the foam does not obstruct the opening of the black sound tube.

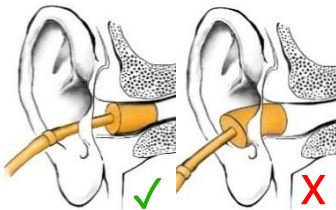


Figure 82

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 eartip 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 82).

5.4.4 Testing – Audiometry



Also, check out our training videos:

[touchTymp Tympanometer Part 2 | MAICO Training | Hearing Screening Diagnostic Test – Audiometry - Controls](https://youtu.be/qto7kja4QUU?si=IU7aMI8e-qj0ws2G&t=344)

<https://youtu.be/qto7kja4QUU?si=IU7aMI8e-qj0ws2G&t=344>

5.4.4.1 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 a screening protocol. Each state may have their own screening protocol. Contact your state health department for guidelines in your area.

5.4.4.2 Bone Conduction Testing

Place the bone conductor 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.

5.4.4.3 Masking

To ensure that the patient will not experience crossover (see Section 1.7.8), 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.


5.4.4.4 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 83).



Figure 83

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

5.5 Managing Test Results



5.5.1 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.

5.5.2 Completed Results

When a test is completed within a module the button will display a circle a circle icon ● for indication a test is stored in this module.

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 84).

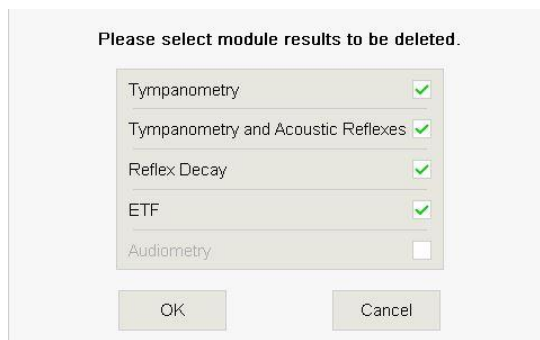



Figure 84

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

5.5.4 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.

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

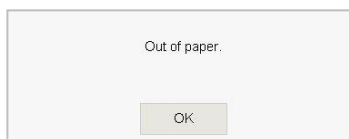


Figure 85

If the printer is out of paper a message box will appear (Figure 85). You can reorder paper from your local distributor. For detailed information about how to change the paper rolls see Section 4.2.6.

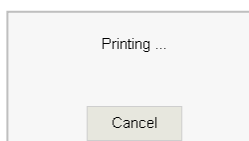



Figure 86

Press **Cancel** to cancel the printing process if needed (Figure 86). When cancelled, printing can be restarted by pressing the **Print**  button.

5.5.5 Understanding the Print-Out for Tympanometry and Acoustic Reflexes

The print-out displays the following information (Figure 87 and Figure 88).

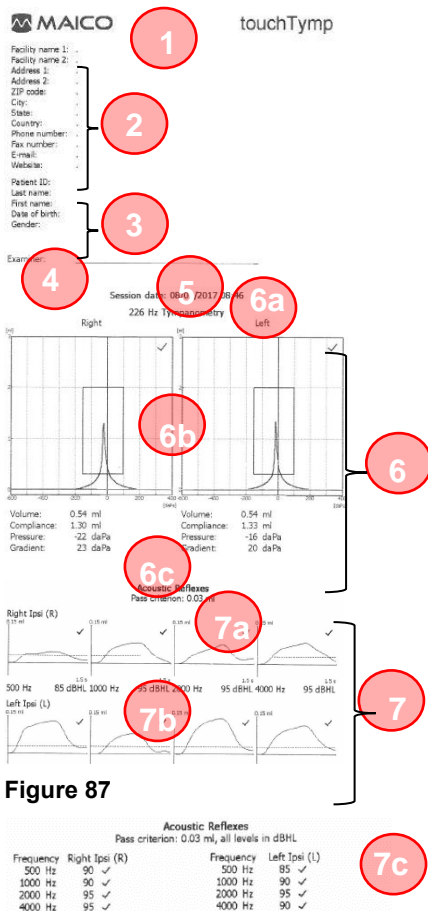


Figure 87

Acoustic Reflexes
Pass criterion: 0.03 ml, all levels in dBHL

| Frequency | Right Ipsi (R) | Left Ipsi (L) |
|-----------|----------------|---------------|
| 500 Hz | 90 ✓ | 95 ✓ |
| 1000 Hz | 90 ✓ | 95 ✓ |
| 2000 Hz | 95 ✓ | 95 ✓ |
| 4000 Hz | 95 ✓ | 90 ✓ |

Figure 88

- 1 **MAICO logo and name of device**
- 2 **Facility info:** Automatically prints 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 the 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.

5.5.6 Understanding the Print-Out for Audiometry

The following describes the printout for Audiometry only (Figure 89).

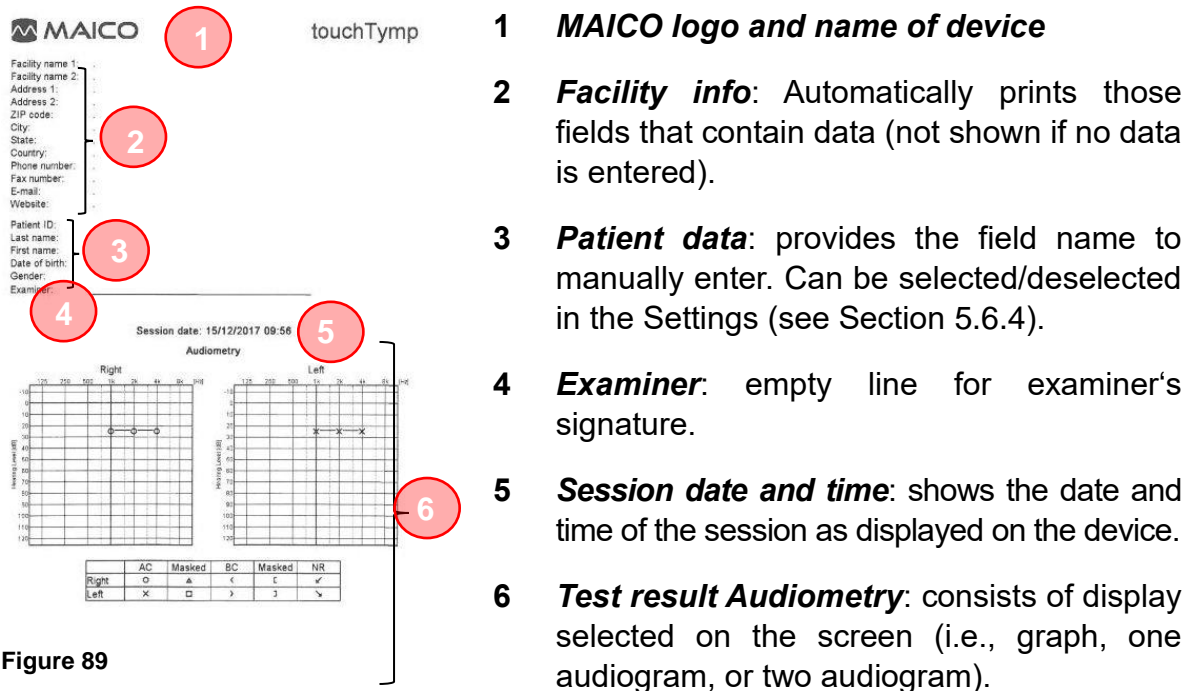


Figure 89

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**. Show **masking table** must be active to print masking levels.

5.5.7 Transferring Test Results to PC

Note: For data transfer between the 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 MAICO Sessions 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 non-medical equipment.

Open MAICO Sessions on the PC.

If the PC connection is properly established and MAICO Sessions is running, the green connection icon is displayed in the status bar.

Transfer data manually or automatically according to the settings.

5.5.8 Editing Test Results

Test results can be edited for

- Acoustic Reflex (see Section 5.3.4.2)
- Audiometry (see Section 5.4.1 - Table 18)

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 (Figure 90).

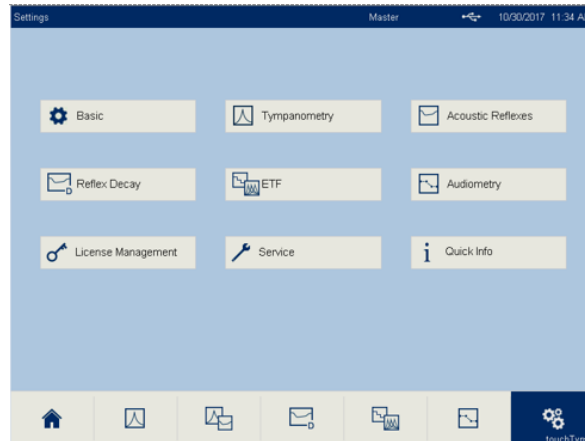


Figure 90

Each menu consists of one or more tabs. Each tab contains one or more settings (Figure 91). When a tab is greyed out, it is not available due to a license must be purchased.

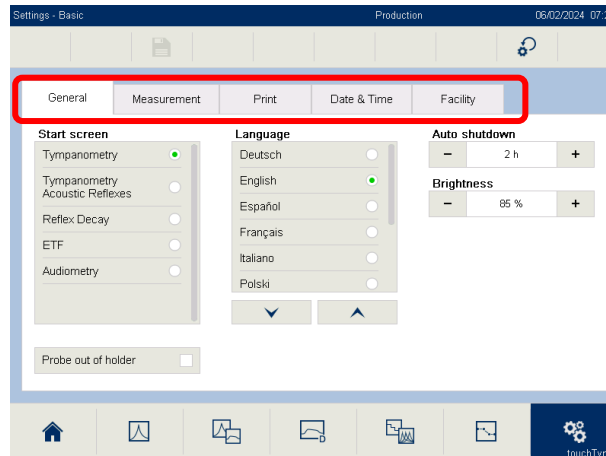




Figure 91

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 92

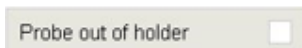


Figure 93

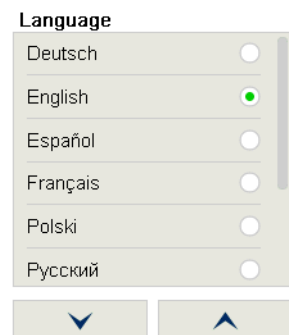


Figure 94



Figure 95



Figure 96

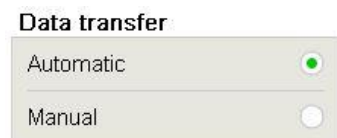


Figure 97

Start screen: Select the test screen that shall be displayed when starting the device (Figure 92).

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 93). Setting is inactive if Audiometry is selected as start screen.


Language: Choose one of the supported languages incorporated in the device (Figure 94).

Auto shutdown: After a period of inactivity the device will turn off automatically (Figure 95).

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

Brightness: Set the maximum brightness of the display (Figure 96).

Data Transfer: Select how data shall be transferred to the MAICO Sessions:

- **Automatic:** Data are transferred automatically as soon as a measurement is finished. Data must be deleted manually on the device.
- **Manual:** Data are transferred as soon as the *Transfer to PC*  button is pressed. Data are deleted automatically on the device.

5.6.3 Settings – Basic – Measurement



Figure 98

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 98).

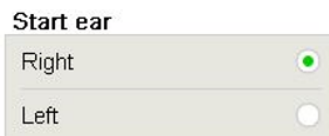


Figure 99

Start ear: Defines which ear is the default upon entering the test modules (Figure 99).

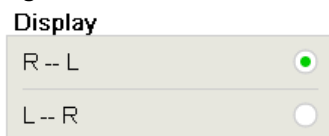


Figure 100

Display: Defines on which side of the screen the button and graph for the left and the right ear shall be displayed (Figure 100).



Figure 101

Light bar: Activates or deactivates the light bar function on the probe (Figure 101).

5.6.4 Settings – Basic – Print

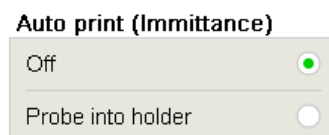


Figure 102

Auto print (Immittance): An automatic printout is directly generated upon the return of the probe into the probe holder when **Probe into holder** is selected (Figure 102).

HINWEIS: Wenn die Einstellung aktiv ist, müssen Audiometrie-Testergebnisse manuell gedruckt werden.

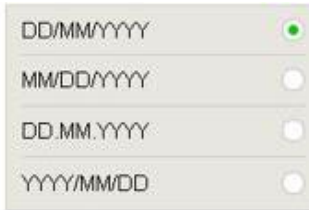


Figure 103

Info on printout: Select or deselect if the printout shall show the **Facility** and **Patient** fields (Figure 103).

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

5.6.5 Settings – Basic – Date & Time



DD/MM/YYYY

MM/DD/YYYY

DD.MM.YYYY

YYYY/MM/DD

Figure 104

Date format: Select the preferred date format to be displayed in the **Status Bar** and printout (Figure 104).

Set date

| DD | MM | YYYY |
|----|----|------|
| + | + | + |
| 28 | 06 | 2016 |
| - | - | - |

Figure 105

Set date: Set the current date using the date control (Figure 105).

Time format

24 h

12 h

Figure 106

Time format: Select the preferred clock, using the 12- or 24-hour time format (Figure 106).

Set time

| HH | MM |
|----|----|
| + | + |
| 10 | 05 |
| - | - |

Figure 107

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 107).

5.6.6 Settings – Basic – Facility

| | |
|-----------------|--------------|
| Facility name 1 | State |
| Facility name 2 | Country |
| Address 1 | Phone number |
| Address 2 | Fax number |
| ZIP code | E-mail |
| City | Website |

Figure 108

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 108).

5.6.7 Settings – Tympanometry – General



Figure 109

Auto zoom: Auto zoom allows the best possible display of the results in the Tympanogram.


Activate to set the Auto zoom as default. The view can still be changed in the test screen using the  button (Figure 109).



Figure 110

Pump speed: Selection of pump speed determines how precisely and quickly the test will proceed (Figure 110).

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

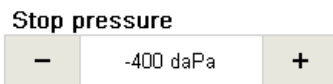
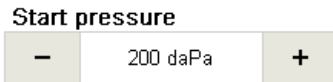


Figure 111

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

Stop pressure: the end pressure of the tympanometry measurement (Figure 111).

NOTE: 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/678 Hz/800 Hz/1000 Hz

The following explanations are for the tabs Probe tone 226 Hz as well as Probe tone 1000 Hz.



Figure 112

Components: Select how the values shall be displayed in the Tympanogram (Figure 112):

Y: Only the Y component (admittance) is displayed as compliance (Figure 113).

Y, B, G: The compliance is displayed as single components (Y – admittance, B – susceptance, G – conductance) (Figure 114).

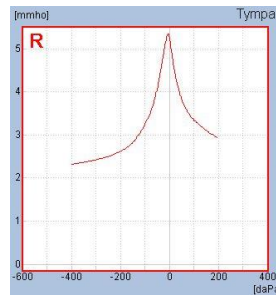


Figure 113

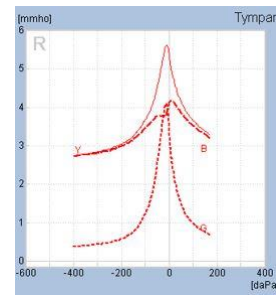


Figure 114

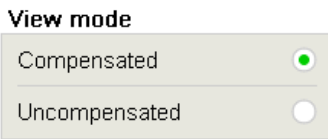


Figure 115

View mode: Set the for viewing the Tympanogram (Figure 115):

- **Compensated:** compensates the Tympanogram according to the measured ear canal volume (default display range: 3 ml/mmho).
- **Uncompensated:** shows absolute values (default display range: 6 ml/mmho).



Figure 116

Auto stop: will automatically stop measurement once it reaches the zero line. This lessens the test time without affecting results (Figure 116).

NOTE: Auto stop is only available for compensated view mode.



Figure 117

Normative boxes: Normative boxes are available for 226 Hz (Figure 117) and 1000 Hz (Figure 118). 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.



Figure 118

- **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. 678 Hz and 800 Hz allow for a user defined normative box only.

- **User defined:** allows the user to define own normative boxes. 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

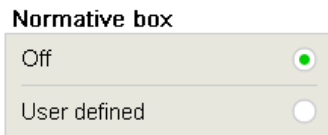


Figure 119



Figure 120

678 Hz and 800 Hz allows for a **User defined** normative box only (Figure 119).

Display pass / no response: Activates a **Pass** ✓ or **No Response** ✗ to be displayed after the completion of a measurement (Figure 120).

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 121



Figure 122

Presentation: Defines the **Acoustic Reflex** screen to start in graphical or table format (Figure 121).

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 122).

The selection here will also define the graphical presentation on the print-out and Reflex Decay display.

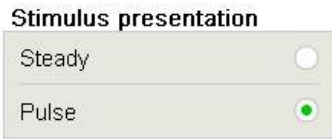


Figure 123

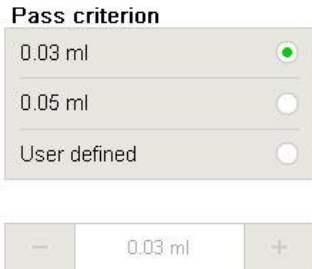


Figure 124



Figure 125

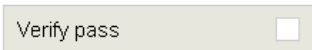


Figure 126

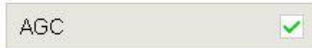


Figure 127

Stimulus Presentation: Defines the type of stimulus presentation (Figure 123). This information is also displayed on the *Tympanometry and Acoustic Reflex* screen.

Pass criterion: Defines the deflection value that must be measured for the reflex to be considered an accepted measurement (Figure 124). 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 125).

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 126).

AGC (Automatic gain control): If **AGC** is selected (Figure 127), the Ipsi stimulus level will be reduced for small ear canal volumes (< 2 ml) correspondingly to the values in Table 19.

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 Ipsi 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 19: 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 reflex stimulation level. Without **AGC**, the reflex activating stimuli in these smaller ear canals would be higher than the referenced calibration value.

5.6.10 Settings – Acoustic Reflexes – Level



Figure 128

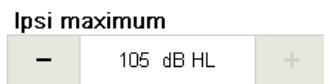
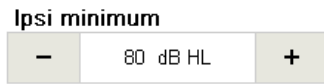


Figure 129



Figure 130

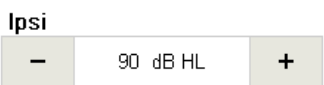


Figure 131

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

- **Automatic:** The touchTymp starts the **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 128).
- 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 129).
 - **Fixed:** The measurement is performed at one level as defined in the **Settings** (Figure 130 and Figure 131).

5.6.11 Settings – Acoustic Reflexes – Stimulus



Figure 132

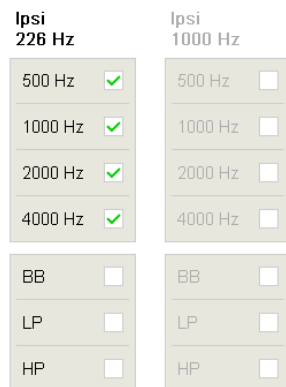


Figure 133

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 132).

When options are greyed out in the settings screen, the license is not active (Figure 133).

5.6.12 Settings – Decay – General



Figure 134

Duration: Defines the length the tone will be presented to the patient (Figure 134). **Duration** can be configured in by 5 second increments from 10 s to 30 s.

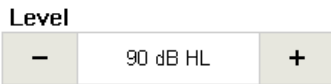


Figure 135

Level: Defines the default intensity of the stimulus upon entering the screen (Figure 135). 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



Figure 136

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 maneuver** (Figure 136).

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

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



Figure 137

Pump speed: Selection of pump speed determines how precisely and quickly the test will proceed (Figure 137).

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 138

Auto stop: will automatically stop measurement when hitting the zero line to lessen the test time without affecting results (Figure 138).

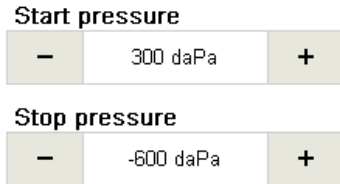


Figure 139

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

Stop pressure: the end pressure of the **ETF – Intact** measurement (Figure 139).

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

5.6.14 Settings – ETF – Perforated

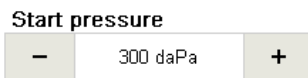


Figure 140

Start pressure: the pressure that is first introduced when performing **ETF – Perforated** measurement (Figure 140). This is a default setting and can be configured within the test screen.



Figure 141

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

Test duration: Defines the length the time the test will be conducted (Figure 141). Test duration can be configured in 5 s increments from 30 s to 100 s.

5.6.15 Settings – Audiometry – General



Figure 142

Signal: Select a default signal for the Audiometry Module. Choose **Steady, Pulse, Warble** or **Pulse & Warble** (Figure 142).



Figure 143

Pulse length: The length of each tone when Pulse is selected (Figure 143). Choose between **250 ms** and **500 ms**.

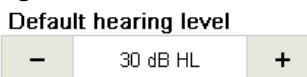


Figure 144

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 144).

Level steps



Figure 145

Test mode



Figure 146

Presenter duration



Figure 147

Monitor phone

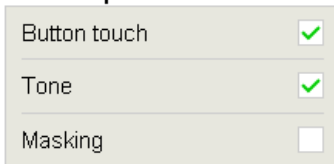


Figure 148

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 145).

Test mode: Selection of the operation mode of the audiometer (Figure 146). Choose between:

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

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 147).

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

Monitor phone: Allows audible presentation through the Monitor phone of the device (Figure 148). 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

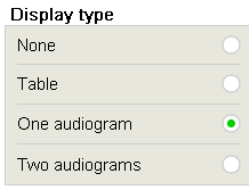


Figure 149

Display type: Select the display for Audiometry measurements (Figure 149).



Figure 150

- **None:** The test screen removes any stored results as no results can be stored within the device. **Store S** and **NR** buttons are removed from screen display (Figure 150).



Figure 151

- **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** (Figure 151).

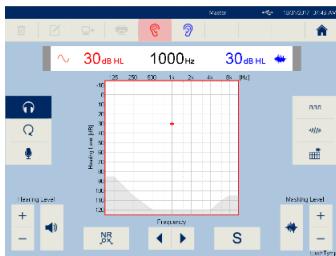


Figure 152

- **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** (Figure 152).



Figure 153

- **Two audiograms:** 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** (Figure 153). **Right** and **Left** graph is placed based on ear **Display** (see Section 5.6.3).



Figure 154

Symbol set: Selection of country specific symbols to be plotted on the audiogram displays. Choose between: **Australia**, **Hong Kong**, **International**, **UK**, and **US** (Figure 154).



Bone lines: Displaying of bone lines when an audiogram is selected as the Display Type. Choose between: **Dash**, **Solid** or **No line** (Figure 155)

Figure 155



Store position: Allows the **Store** button to be placed on the **Right** or **Left** side of the screen for user preference in operation (Figure 156).

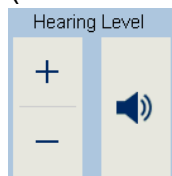
Figure 156



Level position: Change of the level control to swap the placement of these buttons (Figure 157). Choose between:

Figure 157

- **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

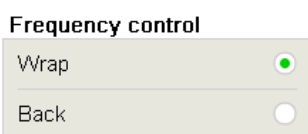


Figure 158


Frequency control: Movement of the test frequency when selecting the frequency ◀ / ▶ buttons (Figure 158). 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.

Store control

| | |
|--------|----------------------------------|
| Remain | <input type="radio"/> |
| Wrap | <input checked="" type="radio"/> |
| Back | <input type="radio"/> |

Figure 159

Store control: Movement of the test frequency when **Store S** or **NR**  is pressed (Figure 159). Choose between:

- **Remain:** Test frequency does not move when **Store S** or **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.

Level change after store

| | | |
|---|--------|---|
| - | Remain | + |
|---|--------|---|

Figure 160

Level change after store: Movement of the volume level when Store or No Response is selected (Figure 160). Choose between: **Default level, -30 dB, -20 dB, -10 dB, Remain, +10 dB, +20 dB.**

AC

| | |
|---------|-------------------------------------|
| 125 Hz | <input checked="" type="checkbox"/> |
| 250 Hz | <input checked="" type="checkbox"/> |
| 500 Hz | <input checked="" type="checkbox"/> |
| 750 Hz | <input checked="" type="checkbox"/> |
| 1500 Hz | <input checked="" type="checkbox"/> |
| 2000 Hz | <input checked="" type="checkbox"/> |
| 3000 Hz | <input checked="" type="checkbox"/> |
| 4000 Hz | <input checked="" type="checkbox"/> |
| 8000 Hz | <input checked="" type="checkbox"/> |
| 8000 Hz | <input checked="" type="checkbox"/> |

Figure 161

AC: 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 161).

BC

| | |
|---------|-------------------------------------|
| 250 Hz | <input checked="" type="checkbox"/> |
| 500 Hz | <input checked="" type="checkbox"/> |
| 750 Hz | <input checked="" type="checkbox"/> |
| 1500 Hz | <input checked="" type="checkbox"/> |
| 2000 Hz | <input checked="" type="checkbox"/> |
| 3000 Hz | <input checked="" type="checkbox"/> |
| 4000 Hz | <input checked="" type="checkbox"/> |
| 6000 Hz | <input checked="" type="checkbox"/> |
| 8000 Hz | <input checked="" type="checkbox"/> |

Figure 162

BC: 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 162).

5.6.18 Settings – Audiometry – Masking

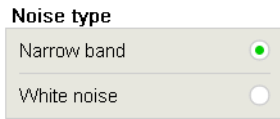


Figure 163

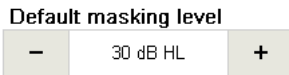


Figure 164

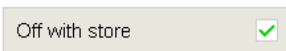


Figure 165

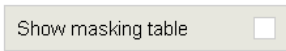


Figure 166

Noise type: Selection of the masking noise (Figure 163). Choose between: **Narrow band** and **White noise**.

Default masking level: Select a level the masking signal defaults to when turned on. Choose a value between **0 dB** and **50 dB** (Figure 164).

Off with store: Turns off masking signal with the selection of **Store S** or **NR** (Figure 165).

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 155).

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.

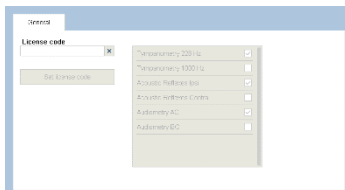


Figure 167



Figure 168

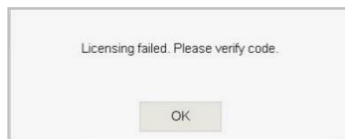


Figure 169

The tab **General** contains a field to enter a new license code 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 167).

To enter a new license code, activate the keyboard by pressing into the field **License code** and type in the code (Figure 168).

If the code entered is invalid a message box will be shown telling you to verify the code (Figure 169).

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 – Audiometry – PTA

Custom PTA: Select/deselect frequencies for the calculation of the PTA value for the default transducer. You can select 8 frequencies each for **AC** and **BC** (Figure 170).

NOTE: It is possible to select the same frequency several times and thus change the weighting.

| General | Display | Frequency | Masking | PTA |
|---------|---------|-----------|---------|-----|
| | | AC | | |
| - | 500 Hz | + | | |
| - | 1000 Hz | + | | |
| - | 2000 Hz | + | | |
| - | -- | + | | |
| - | -- | + | | |
| - | -- | + | | |
| - | -- | + | | |
| - | -- | + | | |
| | | BC | | |
| - | 500 Hz | + | | |
| - | 1000 Hz | + | | |
| - | 2000 Hz | + | | |
| - | -- | + | | |
| - | -- | + | | |
| - | -- | + | | |
| - | -- | + | | |
| - | -- | + | | |

Figure 170

5.6.21 Settings – Service – General



Figure 171

Calibration reminder: Annual calibration of the device 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 171).

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

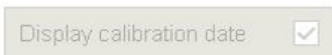


Figure 172

Display calibration date: Only for service (Figure 172).



Figure 173

Device calibration: Only for service (Figure 173).

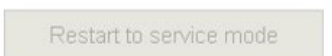


Figure 174

Restart to service mode: Only for MAICO Technical customer support (Figure 174).



Figure 175

Screen calibration: Only for service (Figure 175).



Figure 176

Test printout: prints a test printout (without a session result, Figure 176).

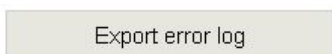


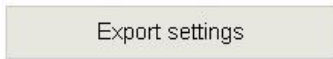
Figure 177

Export error log: If an error is occurring you can export the error log data onto a USB flash drive (Figure 177). If there is no USB flash drive connected the message box (Figure 178) will be shown with further information.



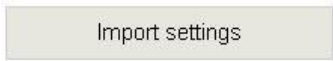
Figure 178

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



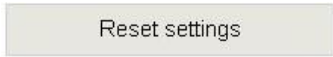
Export Settings: Export file onto USB flash drive (Figure 179).

Figure 179



Import Settings: Import file from USB flash drive (Figure 180).

Figure 180



Reset Settings: Resets settings to default. Facility information will also be deleted (Figure 181).

Figure 181

5.6.22 Settings – Service – About

On this screen the most important device information is presented. Additionally, the Qt License Agreement is shown (Figure 182).

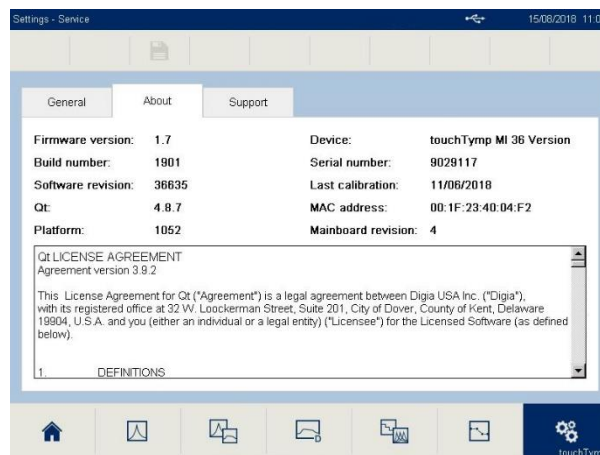


Figure 182

5.6.23 Settings –Service – Support

Dealer company name
TCS

Phone number

Custom 1

Custom 2

This menu is only for editing by service. The dealer can enter his contact information to display in the **Quick Info** screen (Figure 183).

Figure 183

5.6.24 Quick Info

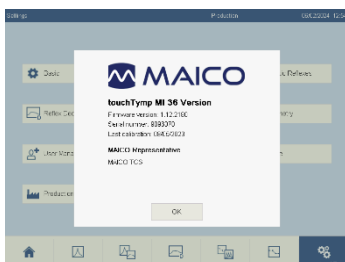


Figure 184

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 184.

6 Technical Data

This section offers you important information about

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

6.1 touchTymp Hardware



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

General Information About Specifications

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

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


STANDARDS

| | |
|-------------------------------|---|
| Safety Standards | IEC 60601-1:2005+A1:2012/ ANSI/AAMI ES60601-1: 2005/A2:2010/ CAN/CSA-C22.2 No. 60601-1:14 Type B Applied Parts |
| EMC Standards | IEC 60601-1-2:2014+AMD1:2020 |
| Tympanometer Standards | IEC 60645-5:2004, Type 2 / ANSI/ASA S3.39-1987 (R2020), Type 2 |
| Audiometer Standards | Tone: IEC 60645-1:2017 Type 3 / ASA/ANSI S3.6-2018 (R2023) Type 3 |

DEVICE SPECIFICATIONS

| | | |
|--------------------------|------------|------------------------------------|
| Power supply unit | Type | UES65-240250SPA3 |
| | Input | 100-240 VAC ±10 %, 50/60 Hz, 2.0 A |
| | Output | 24.0 DC, 2.5 A MAX |
| | Safety | IEC 60601-1, Class I |
| Mode of operation | Continuous | |

DEVICE SPECIFICATIONS

| | | |
|--|---|--|
| Environmental conditions  | Operation | +15 °C to +35 °C / + 59 °F to +95 °F Relative humidity 30 % to 90 % (non-condensing) Air pressure 98 kPa to 104 kPa ³ Maximum altitude: 2000 m / 6561 ft above sea level Warm-up time: 10 min (including boot-up time) |
| | Storage | 0 °C to + 50 °C / 32 °F to +122 °F Humidity 10 to 95 % (non-condensing) |
| | Transport | -20 °C to + 50 °C / -4 °F to +122 °F Humidity 10 % to 95 % (non-condensing) |
| | Weight | 3.2 kg / 7.1 lbs |
| Dimensions | 300 mm x 345 mm x 148 mm 11.81 in x 13.58 in x 5.83 in | |
| Dimensions Pen Probe | 204 mm x 25 mm x 26 mm 8.03 in x 0.98 in x 1.02 in | |
| Dimensions Shoulder Box Probe | 104 mm x 36 mm x 24 mm / 4.09 in x 1.42 in x 0.94 in 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, Swedish, Turkish | |
| Connectors | External / USB out, USB in, USB out, power socket, Contra headphone jack, probe connector | |
| Data interfaces | USB 2.0 / Ethernet (not implemented) | |
| PC Connection | USB; the system can not be operated from a PC. 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 To be printed on paper roll: 200 Tympanograms 87 Tympanograms with Acoustic Reflexes for both ears |
| | Time | 4 s (one Tympanogram) to 12 s (Tympanogram with Acoustic Reflexes for both ears) |

³ Environmental conditions during operating according to 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, 678 Hz, 800 Hz, 1000 Hz each with $\pm 1\%$ (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. The level is constant for all volumes in the measurement range. | |
| Distortion | Max. 1 % THD ⁴ | |
| Control Tympanometry | Automatic, where the start and stop pressure can be user-programmed in the setup function | |
| Air pressure^f | 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): 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 |
| Compliance range | 0.1 ml to 8.0 ml at 226 Hz probe tone; 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 s | |
| Accuracy | Pressure | $\pm 5\%$ or ± 10 daPa, whichever is greater |
| | Compliance | $\pm 5\%$ or ± 0.1 ml, whichever is greater |
| Precision | Pressure | 1 daPa |
| | Compliance | 0.01 ml |
| Graphical display | x-axis: Pressure in daPa y-axis: Compliance in ml (226 Hz, 678 Hz, 800 Hz) and mmho (1000 Hz) View modes: Compensated/Uncompensated ETF Intact: Compensated view mode only | |
| Additional test types | Eustachian tube function 1 | Williams test |
| | Intact eardrum | |
| | Eustachian tube function 2 | Toynbee test |
| | – Perforated eardrum | |

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: Broadband, High Pass, Low Pass |
| Test level | Ipsilateral: 70 dB HL to 105 dB HL Contralateral: 70 dB HL to 120 dB HL |
| Distortion | Max. 1 % Total Harmonic Distortion |
| Control Acoustic Reflexes | Automatic |
| Test types | Single intensities (Fixed Level) Reflex threshold (Automatic Level in 5 dB steps) |
| Stimulus Presentation Control | ON-OFF ratio = ≥ 70 dB Rise time = 27.0 ms Fall time = 24.6 ms Signal-to-noise ratio > 70 dB A-weighted noise in OFF condition < 25 dB SPL |
| Temporal reflex characteristics (Steady) | <ul style="list-style-type: none"> • Initial latency = 35 ms (± 5 ms) • Rise time = 45 ms (± 5 ms) • Terminal latency = 25 ms (± 5 ms) • Fall time = 45 ms (± 5 ms) • Overshoot = max. 1 % • Undershoot = max. 1 % ON and OFF time = 750 ms |
| Temporal reflex characteristics (Pulse) | <ul style="list-style-type: none"> • Initial latency = 35 ms (± 5 ms) • Rise time = 18 ms (± 2 ms) • Terminal latency = 25 ms (± 5 ms) • Fall time = 18 ms (± 2 ms) • Overshoot = max. 1 % • Undershoot = max. 1 % • ON and OFF time = 1500 ms • 500 Hz: 12 pulses each 124 ms All other test signals: 13 pulses each 115 ms |
| Temporal characteristics are measured in accordance with the procedure described in IEC 60645-5:2005 Annex C. | |
| Normative data | MAICO Standard Values |
| Graphical display | x-axis: Volume in ml y-axis: Time in ms Level in dB HL |
| Ipsi earphone | Earphone integrated in probe |
| Contralateral headphone | Insert earphone IP30 Headphone DD45 C |
| Test types | Automated Reflex Automatic/fixed Reflex Decay Manual, 10 dB above threshold and stimulus durations of 10 s. |

IMMITTANCE CALIBRATION PROPERTIES

| | | |
|-------------------|-------------------------------|--|
| Compliance | Temperature dependence | -0.003 ml/°C -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). |
| | | |

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 RadioEar Standard Values for DD45C |
| 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 |
| | DD65 v2 | RadioEar Standard Values |
| | IP30 | ISO 389-2, ANSI S3.6 |
| | DD450 | RadioEar Standard Values |
| Bone Conduction | B71 | ISO 389-3, ANSI S3.6 |
| | B-81 | 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 |
| | DD65 v2 | Headband Static Force 10.0 N ± 0.5 N |
| | DD450 | Headband Static Force 10.0 N ± 0.5 N |
| | B71/B-81 | Headband Static Force 5.4 N ± 0.5 N |
| Patient Response switch | One push button | |
| Patient communication | Talk Forward | |
| | 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 | Narrowband noise: IEC 60645-1, 5/12 Octave filter with the same center frequency resolution as pure tone. Synchronous masking: Locks channel 1 to channel 2. Alternative: White 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 Available Level Steps are 1 dB or 5 dB. 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

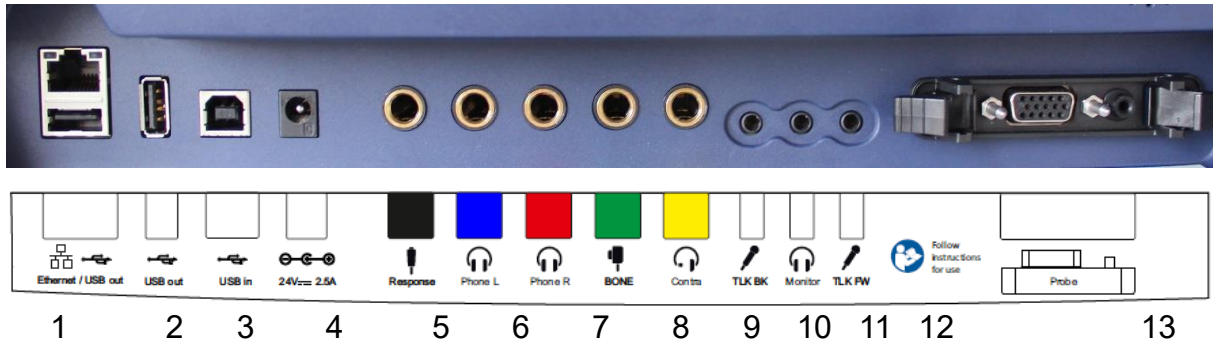


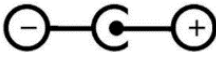
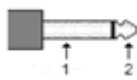

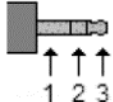




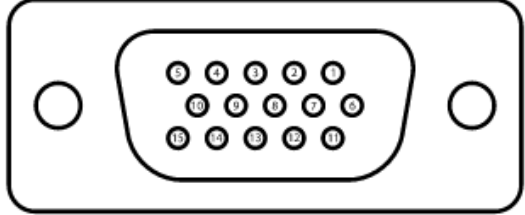
Figure 185

Table 20 Connections on Backside of Device

| No. | Connection socket | Specification |
|-----|-------------------|--|
| 1 | Ethernet | Not applicable in actual version |
| 1/2 | USB out | 2 x USB 2.0 |
| 3 | USB in | USB 12.0 |
| | 24 V/2,5 A | 24V DC, 2.5A, Part. No. Power Supply Unit UES65-240250SPA3 |
| 5 | Response | $R_I = 2000 \Omega$ |
| 6 | Phone L | $Z_A = 10 \Omega$, $U_A = 3 V_{eff}$ |
| 7 | Phone R | $Z_A = 10 \Omega$, $U_A = 3 V_{eff}$ |
| 8 | Bone | $Z_A = 10 \Omega$, $U_A = 3 V_{eff}$ |
| 9 | Contra | $Z_A = 10 \Omega$, $U_A = 3 V_{eff}$ |
| 10 | TLK BK | $Z_I = 1 k\Omega$, $U_I = 0.38 - 500 mV_{eff}$ |
| 11 | Monitor | $Z_A = 250 \Omega$, $U_A = 3 V_{eff}$ |
| 12 | TLK FW | $Z_I = 1 k\Omega$, $U_I = 0.38 - 500 mV_{eff}$ |
| 13 | Probe | See Table 21. |

6.3 Pin Assignment

Table 21 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) | | |
|   4 3 2 1 | 1. +5 VDC 2. Data - 3. Data + 4. Ground |   1 2 4 3 | 1. +5 VDC 2. Data - 3. Data + 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: Headphones 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 |
|----------------|-------------------------------------|------------------------------------|------------------------|------|-----------------------|------|-----------------------------------|
| | | | IEC | ANSI | IEC | ANSI | |
| 125 | 47.5 | 51.5 | 85 | 85 | 65 | 60 | 3 |
| 250 | 27.0 | 31.0 | 105 | 105 | 85 | 80 | 5 |
| 500 | 13.0 | 17.0 | 120 | 120 | 100 | 95 | 7 |
| 750 | 6.5 | 11.5 | 120 | 120 | 105 | 100 | - |
| 1000 | 6.0 | 12.0 | 120 | 120 | 105 | 100 | 15 |
| 1500 | 8.0 | 14.0 | 120 | 120 | 105 | 100 | - |
| 2000 | 8.0 | 14.0 | 120 | 120 | 105 | 100 | 26 |
| 3000 | 8.0 | 14.0 | 120 | 120 | 105 | 100 | - |
| 4000 | 9.0 | 14.0 | 120 | 120 | 105 | 100 | 32 |
| 6000 | 20.5 | 25.5 | 110 | 110 | 95 | 85 | - |
| 8000 | 12.0 | 17.0 | 105 | 105 | 95 | 95 | 24 |
| White Noise | - | 0.0 | - | - | 120 | 115 | - |

Calibration Values and Max Levels: Headphones DD65 v2

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

| 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 |
|----------------|-------------------------------------|------------------------------------|------------------------|------|-----------------------|------|-----------------------------------|
| | | | IEC | ANSI | IEC | ANSI | |
| 125 | 30.5 | 34.5 | 80 | 80 | 65 | 65 | 3 |
| 250 | 17.0 | 21.0 | 100 | 100 | 85 | 85 | 5 |
| 500 | 8.0 | 12.0 | 110 | 110 | 95 | 95 | 7 |
| 750 | 5.5 | 10.5 | 115 | 115 | 100 | 100 | - |
| 1000 | 4.5 | 10.5 | 115 | 115 | 100 | 100 | 15 |
| 1500 | 2.5 | 8.5 | 115 | 115 | 100 | 100 | - |
| 2000 | 2.5 | 8.5 | 115 | 115 | 95 | 95 | 26 |
| 3000 | 2.0 | 8.0 | 115 | 115 | 100 | 100 | - |
| 4000 | 9.5 | 14.5 | 110 | 110 | 95 | 95 | 32 |
| 6000 | 21.0 | 26.0 | 100 | 100 | 85 | 85 | - |
| 8000 | 21.0 | 26.0 | 95 | 95 | 80 | 80 | 24 |
| White Noise | - | 0.0 | - | - | 110 | 110 | - |

Calibration Values: Insert Earphones IP30

Reference equivalent threshold sound pressure level

| 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 Attenuation [dB] ISO 4869-1 |
|------------------------|--|---|------------------------------|------|-----------------------------|------|--|
| | | | IEC | ANSI | IEC | ANSI | |
| 125 | 26.0 | 30.0 | 90 | 90 | 85 | 85 | 33.5 |
| 250 | 14.0 | 18.0 | 105 | 105 | 100 | 95 | 34.5 |
| 500 | 5.5 | 9.5 | 110 | 110 | 105 | 105 | 34.5 |
| 750 | 2.0 | 7.0 | 115 | 115 | 110 | 105 | - |
| 1000 | 0.0 | 6.0 | 120 | 120 | 110 | 105 | 35.0 |
| 1500 | 2.0 | 8.0 | 120 | 120 | 110 | 105 | - |
| 2000 | 3.0 | 9.0 | 120 | 120 | 110 | 105 | 33.0 |
| 3000 | 3.5 | 9.5 | 120 | 120 | 110 | 105 | - |
| 4000 | 5.5 | 10.5 | 115 | 115 | 105 | 100 | 39.5 |
| 6000 | 2.0 | 7.0 | 100 | 100 | 95 | 95 | - |
| 8000 | 0.0 | 5.0 | 90 | 90 | 90 | 90 | 43.5 |
| White Noise | - | 0.0 | - | - | 110 | 110 | - |

Calibration Values: High Frequency Headphones 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 Attenuation [dB] ISO 4869-1 |
|------------------------|--|---|------------------------------|------|-----------------------------|------|--|
| | | | IEC | ANSI | IEC | ANSI | |
| 125 | 30.5 | 34.5 | 90 | 90 | 65 | 65 | 12.5 |
| 250 | 18.0 | 22.0 | 105 | 105 | 80 | 80 | 12.7 |
| 500 | 11.0 | 15.0 | 110 | 110 | 85 | 85 | 9.4 |
| 750 | 6.0 | 11.0 | 115 | 115 | 90 | 90 | - |
| 1000 | 5.5 | 11.5 | 115 | 115 | 90 | 90 | 12.8 |
| 1500 | 5.5 | 11.5 | 105 | 105 | 90 | 90 | - |
| 2000 | 4.5 | 10.5 | 110 | 110 | 90 | 90 | 15.1 |
| 3000 | 2.5 | 8.5 | 110 | 110 | 90 | 90 | - |
| 4000 | 9.5 | 14.5 | 105 | 105 | 90 | 90 | 28.8 |
| 6000 | 17.0 | 22.0 | 100 | 100 | 85 | 85 | - |
| 8000 | 17.5 | 22.5 | 95 | 95 | 80 | 80 | 26.2 |
| White Noise | - | 0.0 | - | - | 105 | 105 | - |

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 B-81

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+AMD1:2020, emission class B group 1.

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

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

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

Commonly used standards for EMC testing information technology equipment and similar equipment⁵ are:

Emissions testing

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

Immunity testing

| | |
|---------------------|---|
| EN 55035 (CISPR 35) | Electromagnetic compatibility of multimedia equipment — Immunity requirements |
|---------------------|---|

⁵ Products include personal computer, PC, tablet, laptop, notebook, mobile device, PDA, Ethernet hub, router, WiFi, computer peripheral, keyboard, mouse, printer, plotter, USB storage, Hard drive storage, solid-state storage and many more.

To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the 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 | 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 Unit | 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.

| 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 CISPR 11 | Group 1 | The touchTymp 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. The touchTymp is suitable for use in all commercial, industrial, business, and residential environments. |
| RF emissions CISPR 11 | Class B | |
| Harmonic emissions IEC 61000-3-2 | Complies Class A Category | |
| Voltage fluctuations / flicker emissions IEC 61000-3-3 | Complies | |

| Recommended separation distances between portable and mobile RF communications equipment and the 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. Note 1 At 80 MHz and 800 MHz, the higher frequency range applies. Note 2 These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

| Guidance and Manufacturer's Declaration - Electromagnetic Immunity | | | |
|---|---|---|---|
| The 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) IEC 61000-4-2 | +8 kV contact +15 kV air | +8 kV contact +15 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%. |
| Immunity to proximity fields from RF wireless communications equipment IEC 61000-4-3 | Spot freq. 385-5.785 MHz Levels and modulation defined in table 9 | As defined in table 9 | RF wireless communications equipment should not be used close to any parts of the touchTymp. |
| Electrical fast transient/burst IEC61000-4-4 | +2 kV for power supply lines +1 kV for input/output lines | +2 kV for power supply lines +1 kV for input/output lines | Mains power quality should be that of a typical commercial or residential environment. |
| Surge IEC 61000-4-5 | +1 kV Line to line +2 kV Line to earth | +1 kV Line to line +2 kV Line to earth | Mains power quality should be that of a typical commercial or residential environment. |
| Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11 | 0% <i>UT</i> (100% dip in <i>UT</i>) for 0.5 cycle, @ 0, 45, 90, 135, 180, 225, 270 and 315° 0% <i>UT</i> (100% dip in <i>UT</i>) for 1 cycle 40% <i>UT</i> (60% dip in <i>UT</i>) for 5 cycles 70% <i>UT</i> (30% dip in <i>UT</i>) for 25 cycles 0% <i>UT</i> (100% dip in <i>UT</i>) for 250 cycles | 0% <i>UT</i> (100% dip in <i>UT</i>) for 0.5 cycle, @ 0, 45, 90, 135, 180, 225, 270 and 315° 0% <i>UT</i> (100% dip in <i>UT</i>) for 1 cycle 40% <i>UT</i> (60% dip in <i>UT</i>) for 5 cycles 70% <i>UT</i> (30% dip in <i>UT</i>) for 25 cycles 0% <i>UT</i> (100% dip in <i>UT</i>) for 250 cycles | 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) IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment. |
| Radiated fields in close proximity — Immunity test IEC 61000-4-39 | 9 kHz to 13.56 MHz. Frequency, level and modulation defined in AMD 1: 2020, table 11 | As defined in table 11 of AMD 1: 2020 | If the touchTymp contains magnetically sensitive components or circuits, the proximity magnetic fields should be no higher than the test levels specified in Table 11 |
| Note: <i>UT</i> 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 IEC / EN 61000-4-6 | 3 Vrms 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. Recommended separation distance: $d = \frac{3,5}{V_{rms}} \sqrt{P}$ |
| | 6 Vrms In ISM bands (and amateur radio bands for Home Healthcare environment.) | 6 Vrms | |
| Radiated RF IEC / EN 61000-4-3 | 3 V/m 80 MHz to 2,7 GHz | 3 V/m | $d = \frac{3,5}{V/m} \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \frac{7}{V/m} \sqrt{P} \quad 800 \text{ MHz to } 2,7 \text{ GHz}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol:  |
| | 10 V/m 80 MHz to 2,7 GHz Only for Home Healthcare environment | 10 V/m (If Home Healthcare) | |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies | | | |
| NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |
| ^{a)} Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 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 re-orienting or relocating the touchTymp. | | | |
| ^{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

- IEC 60601-1:2005+A1:2012: Medical Electrical Equipment, Part 1 General Requirements for Safety
- ANSI/AAMI ES 60601-1:2005 / A2:2010: Medical Electrical Equipment, Part 1 General Requirements for Safety
- CAN/CSA-C22.2 No. 60601-1:14: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 62368-1:2018: Audio/video, information and communication technology equipment - Part 1: Safety requirements
- IEC 60601-1-1:2000: General requirements for safety; Collateral standard: Safety requirements for medical electrical systems
- 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
- General Safety and Performance Requirements of the current REGULATION (EU) 2017/745
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2)
- DIRECTIVE 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)

6.7 Checklist for Subjective Audiometer Testing

| | |
|--|---|
| <ul style="list-style-type: none"> - Clean the ear and head cushion! - Untangle all lines when necessary! - Are the headphone cushions in good condition? If not → replace. - Are plugs and leads in good condition/ undamaged? - Are all controls working properly? - Is the Patient Response Key working properly (if available)? - Check batteries and renew if necessary! | <p>Instrument:.....</p> <p>Manufacturer:.....</p> <p>Serial No.:.....</p> <p>Examiner:.....</p> |
|--|---|

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 | | | | | | | | | | |
| | | | | | | | | | 50 | | | | | | | | | | |
| | | | | | | | | | 70 | | | | | | | | | | |
| BC | | | | | | | | | 30 | | | | | | | | | | |
| | | | | | | | | | 50 | | | | | | | | | | |

* 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 | | | | | | | | | | Left Earpiece |
| | | | | | | | | | dB _{HL} | | | | | | | | | | |
| Right Earpiece | | | | | | | | | Is | | | | | | | | | | Right Earpiece |
| ** | | | | | | | | | dB _{HL} | | | | | | | | | | ** |

* 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

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Specifications are subject to change without notice.



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