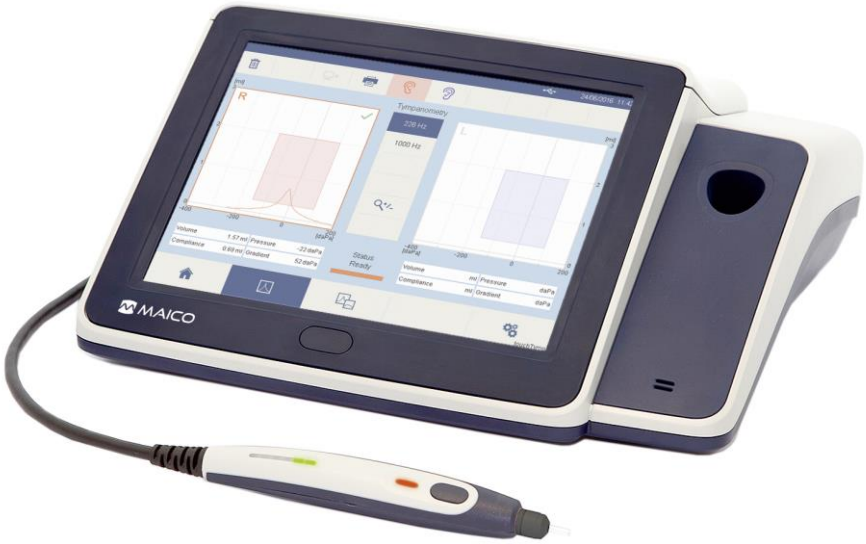
Operation Manual

touchTymp

MI 24 and MI 34 Version



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Title: Operation Manual touchTymp – MI 24 and MI 34 Version

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Compliance

MAICO Diagnostics GmbH is an ISO 13485 certified corporation.

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

1 Introduction

This section offers you important information about:

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

1.1 General

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

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

This operation manual is for the touchTymp MI 24 and MI 34 versions. If sections or parts of sections of this operation manual apply only to certain versions of the device, they are marked with "MI 24" or "MI 34 ". This operation manual is meant to make it as easy as possible for the operator to become familiar with the operation and functions of the touchTymp when performing Immittance tests. If you have questions or suggestions for further improvements, please, do not hesitate to contact MAICO.

1.2 Intended Use Statement

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

Indications of Use Statement

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

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

1.3 Contraindications of Use

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

- Recent stapedectomy or other middle ear surgery
- Discharging ear
- Acute external auditory canal trauma
- Discomfort (e.g. severe otitis externa)

- Occlusion of the external auditory canal
- Presence of tinnitus, hyperacusis or other sensitivity to loud sounds may contraindicate testing when high intensity stimuli are used

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

1.4 Essential Performance

There is no essential performance as defined in IEC 60601-1.

1.5 Features and Benefits of the touchTymp

1.5.1 General Information About the touchTymp

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

- Full touchscreen operation
- Screening Immittance test battery – MI 24 version (i.e. Tympanometry, Acoustic Reflex Tests)
- Diagnostic Immittance test battery – MI 34 version (i.e. Tympanometry, Acoustic Reflex, Reflex Decay, Eustachian Tube Function)
- Optional high frequency probe tone
- Optional RaceCar animation
- Multiple transducer options for contralateral reflex testing
- Automatic test function in Immittance modules
- Included test cavities for quick and easy calibration verification
- Print directly from device with built-in printer
- Automatic printing cability with placement of probe in holder

1.5.2 Licenses

The touchTymp comes with some optional measurements which can be activated by entering a license key. In the settings (see section 5.6.16) this key can be added.

The following functions are available:

- ***Tympanometry 1000 Hz*** (all versions)
- ***Acoustic Reflexes Contra*** (MI 24 version only, included in MI 34 version)
- ***RaceCar*** (all versions)

It might appear that the touchTymp already contains licenses due to the version you ordered (e.g. if ordered touchTymp MI 24 version comes with a probe tone of 1000 Hz for ***Tympanometry*** and ***Acoustic Reflexes***).

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

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

1.5.3 Printing Options

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

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

1.6 Description

1.6.1 General

The touchTymp is designed for Immittance testing as ***Tympanometry*** and ***Acoustic Reflex*** (i.e. ***Ipsilateral*** and ***Contralateral***) testing (and MI 34 version).

MI 34 version also includes ***Reflex Decay*** and ***Eustachian Tube Function (ETF)*** tests.

The functions are described in detail in the following sections.

1.6.2 Tympanometry

Tympanometry is the objective measurement of middle ear mobility (compliance[1]) and pressure[2] within the middle ear system (Figure 1). During the test, a low-pitched probe tone (226 Hz) is presented to the ear canal by means of the hand-held probe. This tone is used to measure the change in compliance in the middle ear system while the air pressure is varied automatically from a positive value (i.e. +200 daPa) to a negative value (i.e. -400 daPa max).

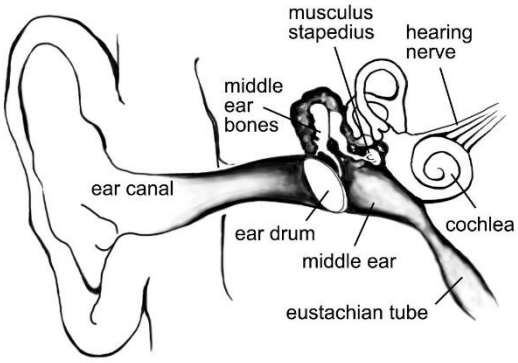


Figure 1

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

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

[1] 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).

1.6.3 Acoustic Reflex

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

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

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

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

1.6.4 Acoustic Reflex Decay (MI 34 Version Only)

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

1.6.5 Eustachian Tube Dysfunction (ETF) (MI 34 Version Only)

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

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

2 For Your Safety

This section offers you important information about:

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

2.1 How to Read this Operation Manual

This Operation Manual contains information pertinent to the use of the MAICO device system including safety information as well as maintenance and cleaning recommendations.

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

Use this device only as described in this manual.

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

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

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

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

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

2.2 Customer Responsibility

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

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

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

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

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

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

2.3 Manufacturer's Liability

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

2.4 Regulatory Symbols

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

Table 1 Regulatory Symbols

REGULATORY SYMBOLS SYMBOL	DESCRIPTION
SN	Serial number
	Date of manufacture
	Manufacturer
	Caution, consult accompanying documents
	Warning, consult accompanying documents
	Return to authorized representative, special disposal required
REF	Reference number
	Patient applied part type B according to IEC 60601-1
	Refer to instruction manual (mandatory)
	Keep away from rain
	Transport and storage temperature range
	Transport and storage humidity limitations
	Transport and storage atmospheric pressure limitations
	Voltage transformer
	Electrostatic sensitive devices
	Do not reuse
CE	Conforms to European Medical Device Directive 93/42/EEC
	Non-ionizing electromagnetic radiation
ETL CLASSIFIED Intertek	ETL listed mark
MAICO	Logo

2.5 General Precautions

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

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

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

No modification of this equipment is allowed.

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

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

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

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

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

2.6 Electrical Safety and Measuring Security

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

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

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

In Case of Emergency

In Case of Emergency

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

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

Do not use the device if the mains cable and/or the 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 device/non-medical device) or to a battery-driven laptop.

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

If the device is connect 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.

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

Never short-circuit the terminals

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

CAUTION

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

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

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

2.7 Device Control

The user of the device should perform a subjective device check once a week according ISO 8253-1.

For annual calibration see section 2.5 and 3.2.

2.8 Electromagnetic Compatibility (EMC)

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

To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.

WARNING

The device fulfills the relevant EMC requirements. Avoid unnecessary exposure to electromagnetic fields, e.g. from mobile phones etc. If the device is used adjacent to other equipment it must be observed that no mutual disturbance appears.

Please also refer to EMC consideration in section 6.5.

3 Warranty, Maintenance and After-Sales Service

This section offers you important information about:

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

3.1 Warranty

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

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

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

No modification of this equipment is allowed.

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

3.2 Maintenance

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

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

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

3.3 Cleaning and Disinfection Recommendations

3.3.1 General

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

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

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

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

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

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

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

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

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

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

3.3.2 Cleaning the Touch Screen

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

3.3.3 Cleaning the Case and Cables

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

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

CAUTION

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

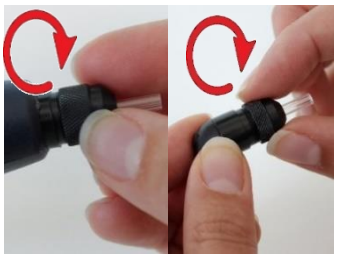


Figure 2

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

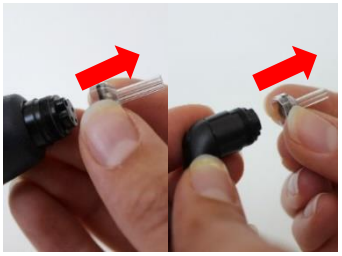


Figure 3

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

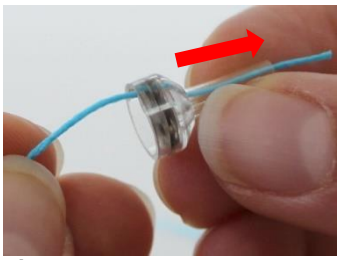


Figure 4

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

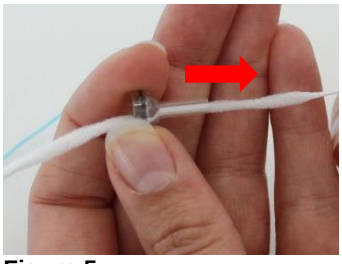


Figure 5

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

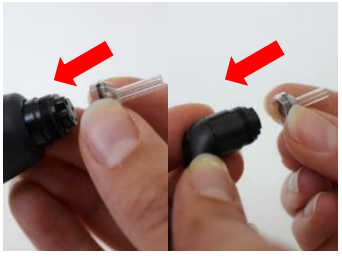


Figure 6

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

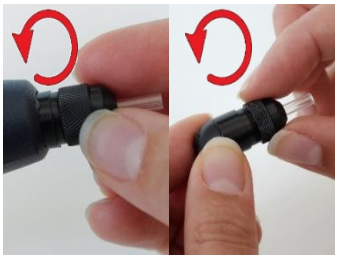


Figure 7

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

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

Cleaning alternative

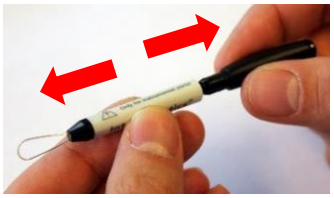


Figure 8

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

Figure 9

Figure 10

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

Figure 11

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

Figure 12

CAUTION

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

Figure 13

CAUTION

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

3.4 Disposables

Figure 14

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

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

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

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

3.5 Components/Replacement Parts

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

3.6 Troubleshooting

Table 2 Troubleshooting

Problem	Reason	Suggestion
No start of measurement	Probe	Make sure the probe is connected to the back of the device correctly and the brackets are closed. Otherwise, follow the suggestions in Probe tip.
No start of measurement	Probe tip	1. Clean the probe tip as described in the manual. If the system still does not run proceed with step 2. 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 ***Front key*** button for 10 seconds in order to shut-off the device. Restart.
Probe light stays white		Turn off the device. Confirm/reconnect the probe before restarting.
Transfer to PC not possible	Connection to PC	Make sure the USB/PC-connection is established, the PC module is opened and the device and the connection icon is displayed green. If the connection icon is not displayed green, check if the right device is selected in the Software Module (see Operation Manual of the Software Module).
Buttons are greyed out	No license Missing transducer calibration Combinations of settings not allowed	Purchase license if wanted. Calibrate transducer. Verify settings are correct.

NOTE: If there are any problems that you cannot solve yourself, please, contact your customer service. It will be helpful to use the function ***Export error log*** (see section 5.6.17) to send the customer service the data needed for solving the problem.

3.7 Recycling and Disposal

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

Non-European countries

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

4 Unpacking and Installation

This section provides information on:

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

4.1 Unpacking the System

Check Box and Contents for Damage

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

Reporting Imperfections

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

Report Immediately any Faults

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

Keep Packaging for Future Shipment

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

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

Components
General components
Base Unit (with or without Printer)
MAICO USB Flash Drive Kit
Power Supply 24V 60W UE60-240250SPAx
Country-Specific Mainscable
USB Cable
Thermal Paper Rolls***
EarTip Kit
Probe Floss Kit
Cleaning Cloth
Touch Pen
MAICO Software Module Bundle
Operation Manual
Quick Guide
Components for Testing Tympanometry and Acoustic Reflexes
Pen Probe**
Shoulder Box**
Shoulder Box Adapter Kit*
Shoulder Box Attachment Kit*
IP30 (6.3 mm Plug)**
IP30 (3.5 mm Plug)**
CIR22 (6.3 mm Plug)**
CIR55 (3.5 mm Plug)**
DD45C (6.3 mm Plug)**
DD45C (3.5 mm Plug)**

*Only if sold with Shoulder box
**Applied parts according to IEC 60601-1
***Only if sold with base unit with printer

MI 24 Licenses

Standard Licenses
Tympanometry 226 Hz
Acoustic Reflexes Ipsi

Extra Licenses
Tympanometry 1000 Hz
Acoustic Reflexes Contra*
RaceCar

*Additional transducer required

MI 34 Licenses

Standard Licenses
Tympanometry 226, 678 and 800 Hz
Acoustic Reflexes Ipsi and Contra
Reflex Decay Ipsi and Contra
ETF

Extra Licenses
Tympanometry 1000 Hz
RaceCar

Disposables Supplied

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

Eartip Box
Sanibel Blue, 7 mm Mushroom, Silicone Eartips (10 pcs.)
Sanibel Green, 9 mm Mushroom, Silicone Eartips (10 pcs.)
Sanibel Red, 3-5 mm Flanged, Silicone Eartips (10 pcs.)
Sanibel Blue, 11 mm Mushroom, Silicone Eartips (10 pcs.)
Sanibel Green, 13 mm Mushroom, Silicone Eartips (10 pcs.)
Sanibel Blue, 15 mm Mushroom, Silicone Eartips (5 pcs.)
Sanibel Red, 15 mm Umbrella, Silicone Eartips (5 pcs.)
Sanibel Yellow, 19 mm Mushroom, Silicone Eartips (5 pcs.)
Sanibel Blue, 19 mm Umbrella, Silicone Eartips (5 pcs.)
Probe Tip (1 pc.)
Probe Cleaning Tool (1 pc.)
Eartip Removal Tool (1 pc.)

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

4.2 Hardware and Accessories

4.2.1 Display

Figure 15

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

4.2.2 Connections for Accessories, Power Supply and USB-Devices

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

CAUTION

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

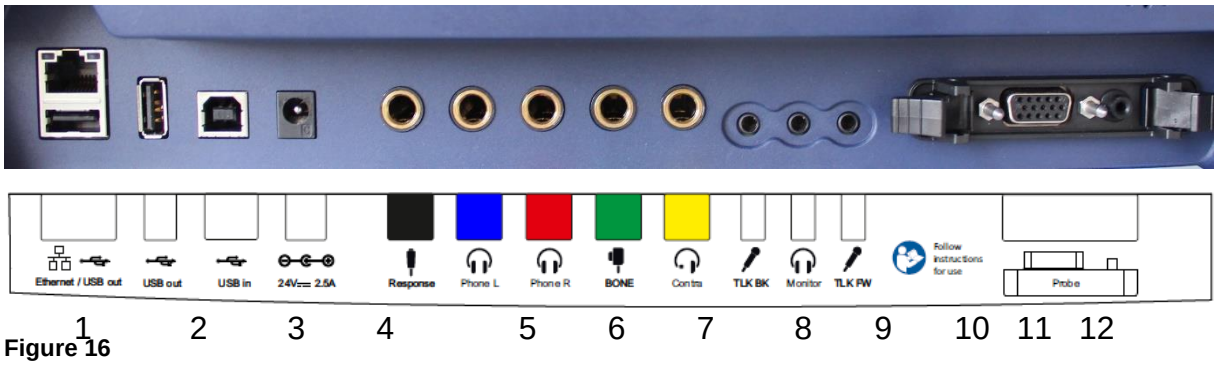


Figure 16

Table 3 Connections on Backside of Device

CONNECTIONS		
1	**Ethernet / USB out**	Dual connector: Ethernet – no function in actual touchTymp version / USB A-connection for connection of USB flash drive
2	**USB out**	USB A-connection for connection of USB flash drive
3	**USB in**	USB B-connection for data transfer to PC
4	⊖—⊂—⊕ **24 V/2,5 A**	Power socket for power supply Item no. 8101895
5	**Response**	Connection for the Patient Response Switch
6	**Phone L**	Connection for Headphones Left
7	**Phone R**	Connection for Headphones Right
8	**Bone**	No function in MI 24/MI 34 versions
9	**Contra**	Connection of Contralateral headphone
10	**TLK BK**	No function in MI 24/MI 34 versions
11	**Monitor**	No function in MI 24/MI 34 versions
12	**TLK FW**	No function in MI 24/MI 34 versions
13	**Probe**	Connection for probe

See section 6.3 for more information on the pin assignment.

4.2.3 Connecting the Probe System

Connect and disconnect the probe as follows:

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

Figure 17

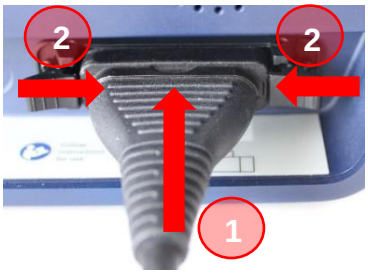


Figure 18

Figure 19

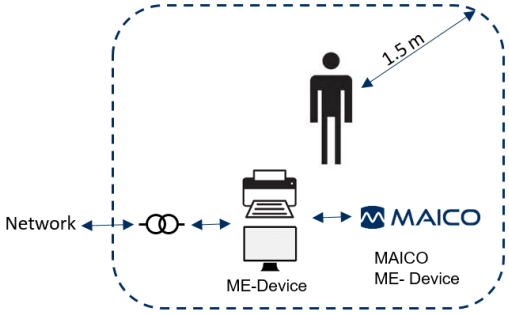
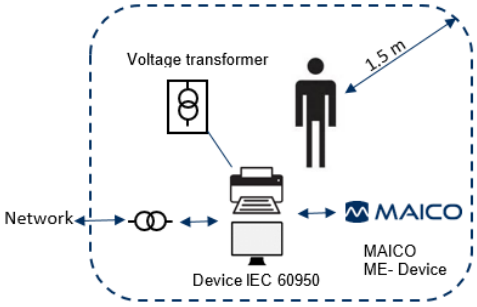
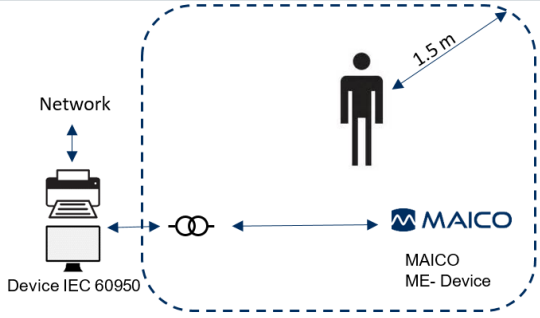
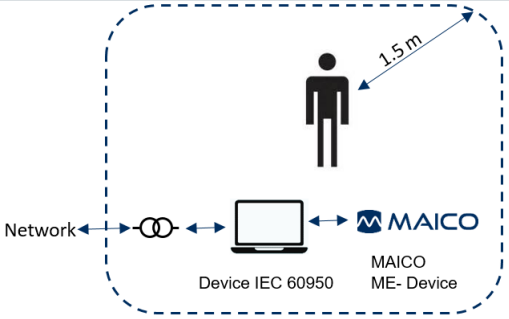
4.2.4 Establishing a PC-Connection

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

WARNING

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

Table 4 PC-Connections

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

4.2.5 Storage

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

4.2.6 The Probes

There are two probes available for the touchTymp, Pen Probe and Shoulder Box. The main functionalities are the same. The Pen Probe is most suitable for screening since you can fit it on the patient with high sensitivity and is standard with MI 24 versions. The Shoulder Box allows hands free work while performing diagnostic measurements and is the standard probe for MI 34 versions. Additionally, the Shoulder Box has a 3.5 mm jack for the Contralateral headphone (Figure 22). Both, the Pen Probe (Figure 20) and the Shoulder Box (Figure 21) are connected to the device in plug 13 (Figure 16).

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

Table 5 Probe design

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

The Pen Probe

Figure 20

CAUTION

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

The Shoulder Box

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

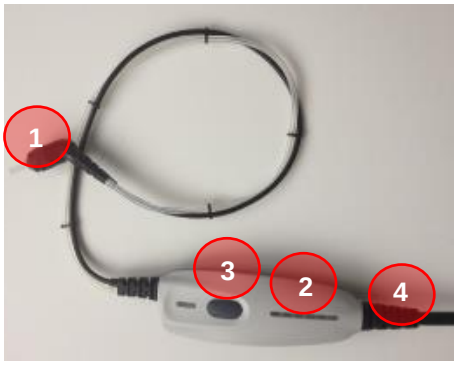


Figure 21

Figure 22

Figure 23

Contralateral headphone with the Shoulder Box

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

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

The Indication Light

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

Table 6 Indication Light

PROBE	COLOR	EXPLANATION
	Red	Right ear is selected. Probe is out of ear.
	Blue	Left ear is selected. Probe is out of ear.
	Green	Probe is in the ear and is sealing, test is running or done.
	Yellow	Probe is in the ear and blocked or leaking. If the indicator remains “yellow” (sealing), the screener must improve the position of the probe in the ear: 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.
	White	An error has occurred. Confirm connection of probe and/or restart the device.

The Light Bar

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

Table 7 Light Bar Functions 1

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

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

Table 8 Light Bar Functions 2

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

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

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

4.2.7 The Built-In Printer

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

In order to change paper rolls:

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

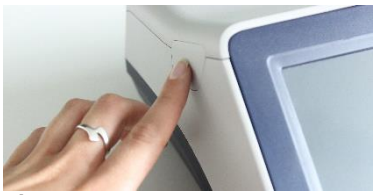


Figure 24

Figure 25

Figure 26

4.2.8 Test Cavities

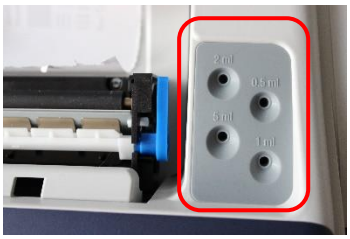


Figure 27

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

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

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

4.2.9 Adjusting the Feet Height

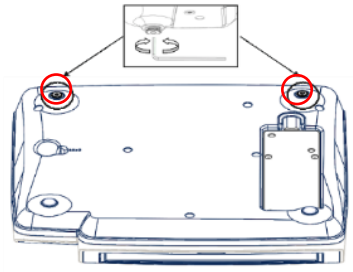


Figure 28

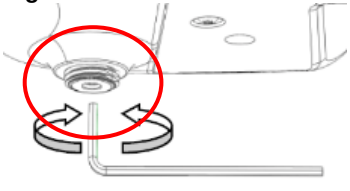


Figure 29

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

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

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

5 Operating the Device

This section offers you information about:

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

5.1 Getting Started with the touchTymp

5.1.1 Use of Equipment After Transport and Storage

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

5.1.3 Switching On the Device

Figure 30

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

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

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

Figure 31

Calibration Reminder: If a detected transducer is within one month of expiration of the calibration date, a reminder message (Figure 31) will appear (once per day). See section 5.6.17.

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

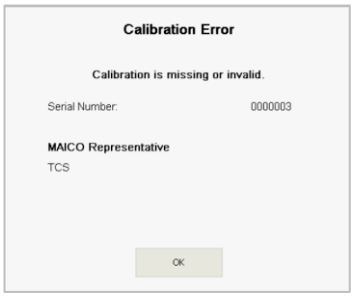


Figure 32

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

5.1.4 Switching Off the Device

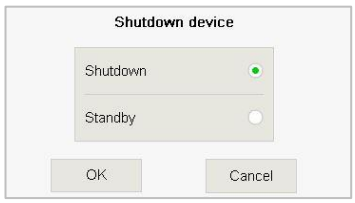


Figure 33

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

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

5.2 Power-Saving Mode and Automatic Power-Off

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

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

5.3 The Home Screen

The ***Home*** screen displays the buttons controlling entry into the major functions of the touchTymp. These functions include the specific test selection for MI 24 version (Figure 34) and MI 34 version (Figure 35).

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

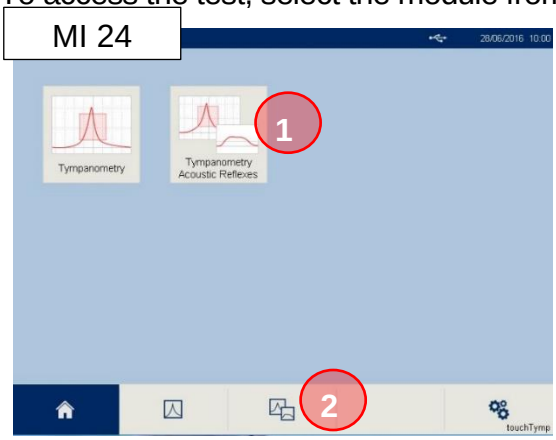


Figure 34

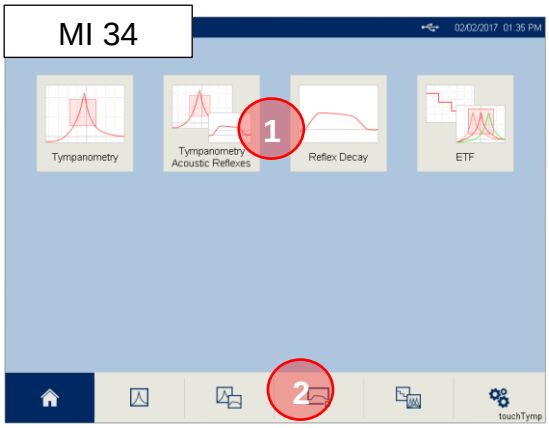


Figure 35

5.4 Immittance Testing

5.4.1 General

The following sections 5.4.2 to 5.4.5 offer information about the modules ***Tympanometry***, ***Tympanometry and Acoustic Reflexes*** (MI 24 and MI 34 version)***,*** ***Reflex Decay***, and ***Eustachian Tube Function*** (MI 34 version only***)***.

5.4.2 The Screen Format

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

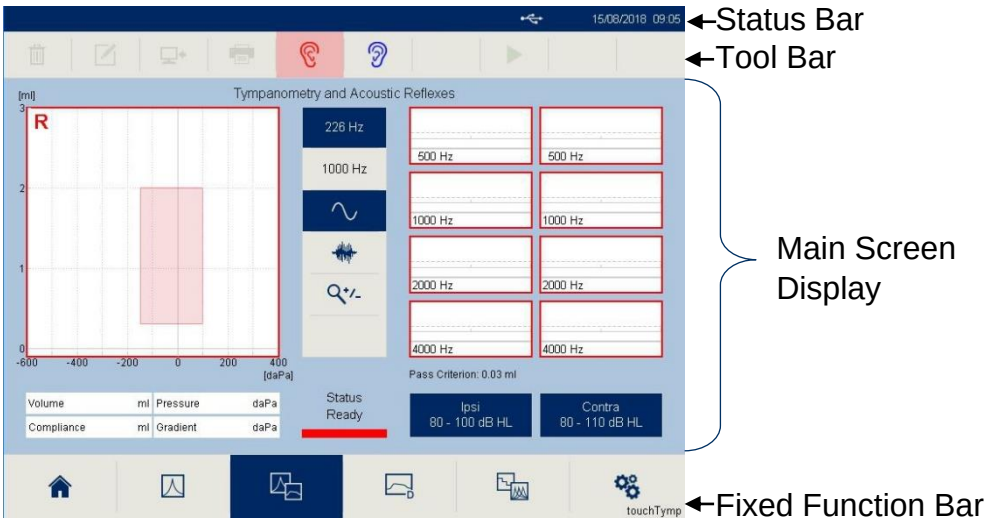


Figure 36

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

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

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

Table 9 Icons in the Tool Bar

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

NOTE: An active button is displayed in blue.

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

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

Table 10 Icons in the Fixed Function Bar

ICON	FUNCTION	EXPLANATION
	Home	***Home:*** to return to the ***Home*** screen for test selection.
	Tympanometry	***Tympanometry:*** to open the ***Tympanometry*** module.
	Tympanometry & Acoustic Reflexes	***Tympanometry & Acoustic Reflexes***: to open the ***Tympanometry and Acoustic Reflex*** module.
	Settings	***Settings:*** to access a list of all the device settings.
Additional icons for MI 34 Version:		
	Reflex Decay	***Reflex Decay***: to open the ***Reflex Decay*** module
	ETF	***ETF:*** to open the ***ETF*** module for ***intact*** or ***perforated ETF*** testing.

5.4.3 Preparing for Testing

5.4.3.1 Preparing the Patient

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


WARNING

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

5.4.3.2 Visual Inspection of the Ear Canal

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

5.4.3.3 Immittance Measurements

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

- An eartip is placed on the tip of the probe and inserted into the ear canal. A seal must be achieved for the test to progress.
- Coughing, talking and swallowing will disturb test results.
- The aim of ***Tympanometry*** is to test the mobility of the eardrum and the condition of the middle ear.
  - A small amount of air will flow through the probe to move the eardrum; it produces a sensation equal to pressing a finger slightly into the ear canal.
  - One or more tones will be heard during the test. No participation is expected from the patient.

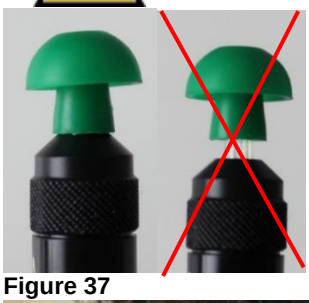
- The aim of ***Acoustic Reflexes*** is to test the condition of the Musculus stapedius.
  - One or more louder tones will be heard during the test. No participation is expected from the patient.
- The aim of ***Reflex Decay*** is test the integrity of the CN VIII.
  - One tone is presented above the acoustic reflex threshold measurement for a minimum period of 10 seconds.
- The aim of ***ETF*** is to test the condition of the Eustachian tube.
  - ***ETF Intact***: three tympanograms are completed while the patient performs a manueaver between each tympanogram.
  - ***ETF Perforated***: pressure level is obtained in the ear canal and the patient swallows to measure change of pressure.

5.4.3.4 Handling the Eartips

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

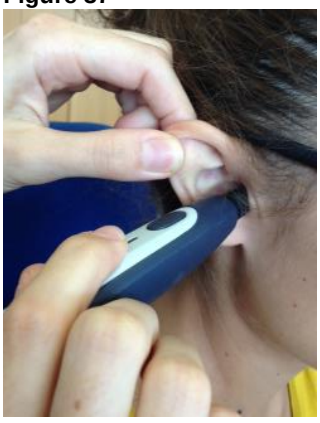
WARNING

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



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

Figure 37

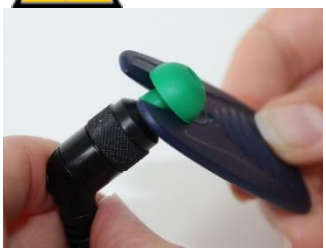


Insert the probe with eartip attached into the patient's ear. For children and adults, pull gently up and back on the outer ear (i.e. Pinna) during insertion to straighten the ear canal. Hold the adapter and aim and twist (gently) the eartip into the ear canal. The fit of the eartip should be secure;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

Figure 38

WARNING

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



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

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

Figure 39

5.4.3.5 Status Indicator

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 11).

Table 11 Test Status Indication

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

5.4.4 Testing

5.4.4.1 Performance and Evaluation of Tympanometry Test

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

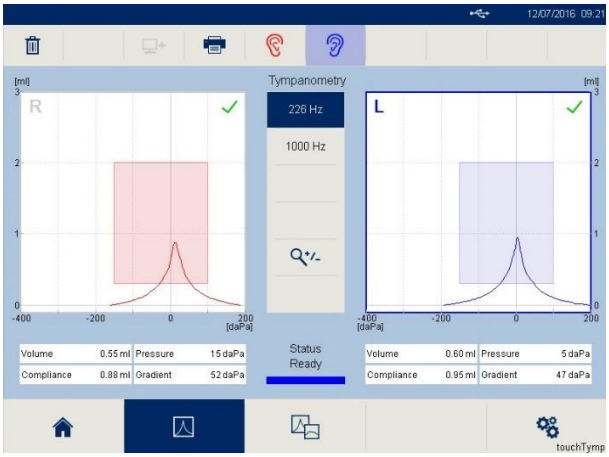


Figure 41

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

Performing a measurement

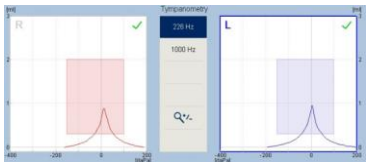


Figure 42

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

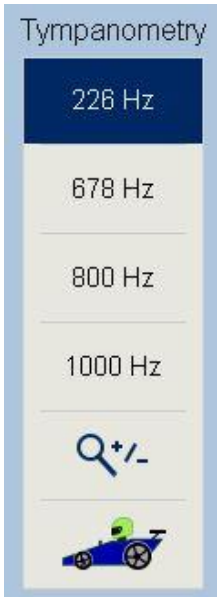


Figure 43

Choose the test frequency by pressing on the corresponding button.

- ***226 Hz***: Test frequency of 226 Hz is always preselected as default. A 226 Hz testing is recommended for adults and children older than ½ year.
- ***678 Hz***: Test frequency of 678 Hz (MI 34 version only).
- ***800 Hz***: Test frequency of 800 Hz (MI 34 version only).
- ***1000 Hz***: Licensed function, to be chosen if patient is younger than half a year.
- Press to increase or decrease the intercepts of the graphs.
- **RaceCar** : Licensed function, to display ***RaceCar*** animation during testing. See section 5.4.4.3 for more information (Figure 43).

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

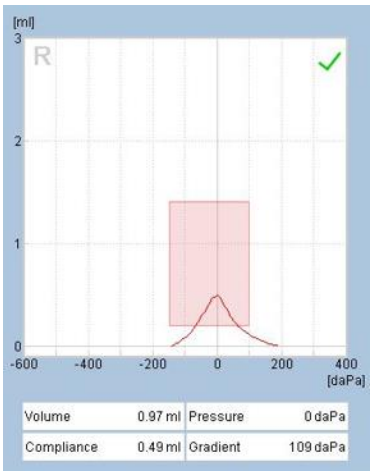
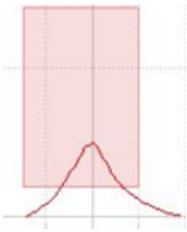


Figure 44

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

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



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

Figure 45

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

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

Normative Data / Pass and No Response Criteria

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

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

5.4.4.2 Performance and Evaluation of the Acoustic Reflex Test

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

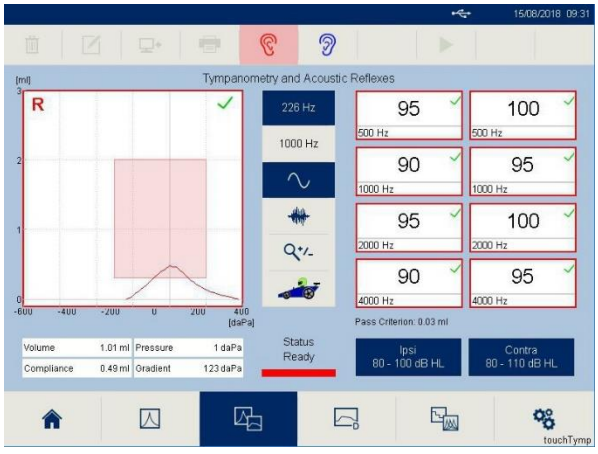


Figure 46

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

Performing a measurement

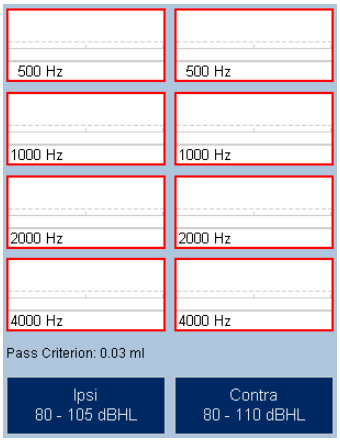


Figure 47

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.

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

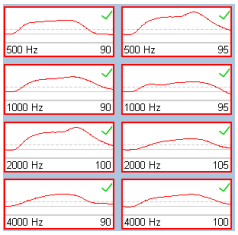


Figure 48

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

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

Figure 49

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

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

Noise stimuli (MI 34 Version Only)

Figure 50

The MI 34 version includes pure tone and noise stimuli for ***Acoustic Reflex*** testing.

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

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

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

Edit Acoustic Reflex

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

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

Figure 51

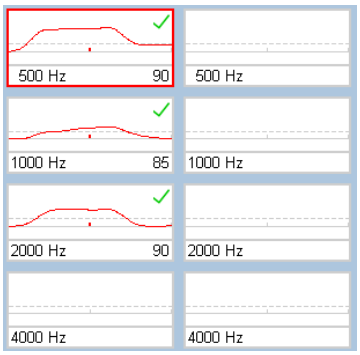


Figure 52

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

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

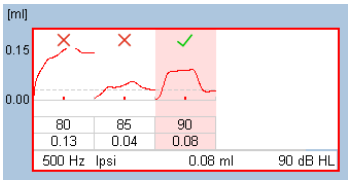


Figure 53

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

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

Editing the displayed reflex

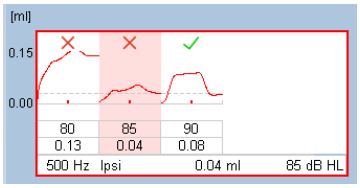


Figure 54

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

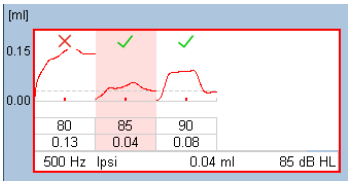


Figure 55

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

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

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

5.4.4.3 RaceCar Operation (Extra License)

Figure 56

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

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

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

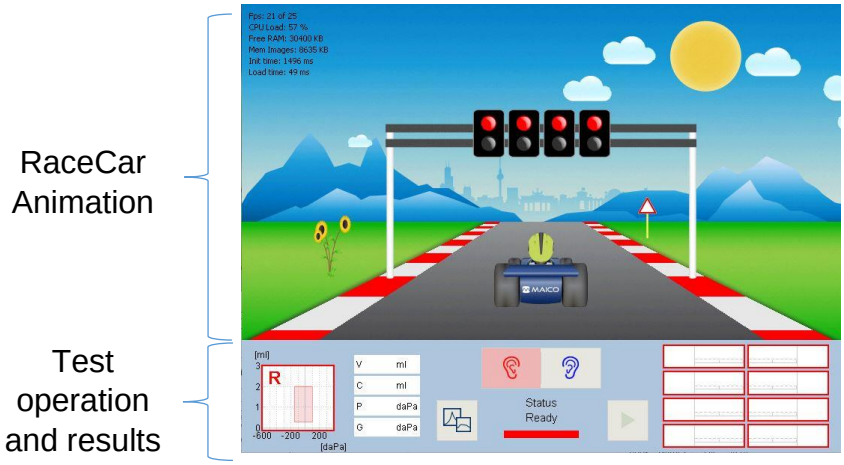


Figure 57

RaceCar Test Sequence

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

Active Buttons within the RaceCar screen are:

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

5.4.4.4 Performance and Evaluation of Reflex Decay Test – MI 34 Version

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

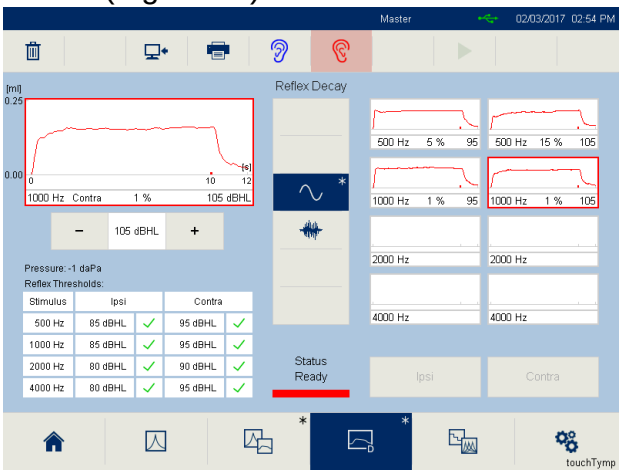


Figure 58

Performing a measurement

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

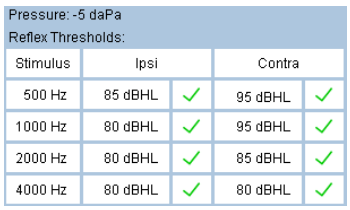


Figure 59

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

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

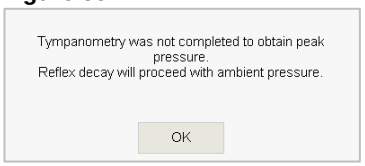


Figure 60

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

Figure 61

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

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

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

Figure 62

Figure 63

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

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

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

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

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

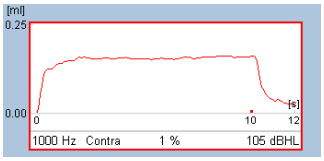


Figure 64

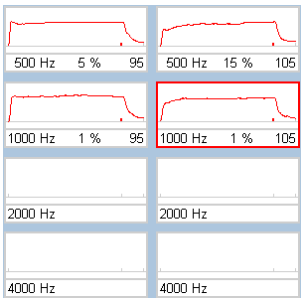


Figure 65

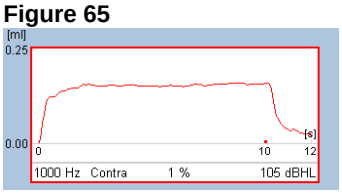


Figure 66

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

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

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

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

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

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

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

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

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

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

5.4.4.5 Performance and Evaluation of Eustachian Tube Function (ETF) – MI 34 Version

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

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

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

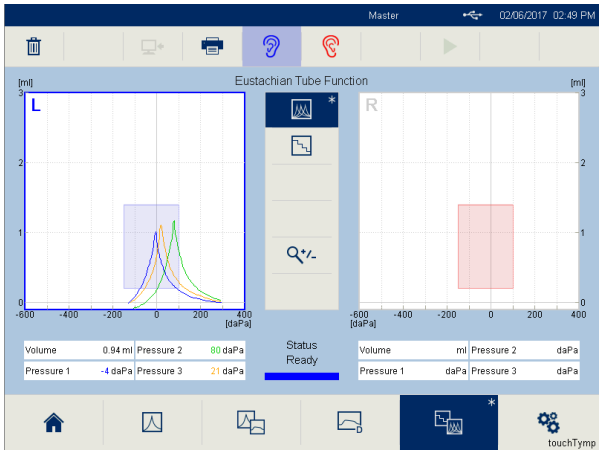


Figure 67

Performing a Measurement

Figure 68

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

Performing an ETF Intact Measurement

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

Volume	ml	Pressure 2	daPa
Pressure 1	daPa	Pressure 3	daPa

Figure 69

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

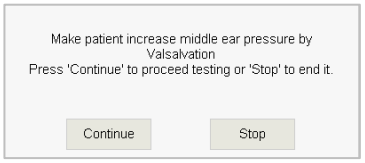


Figure 70

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

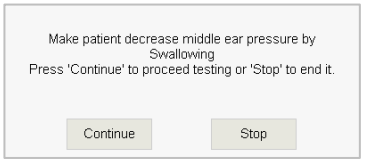


Figure 71

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

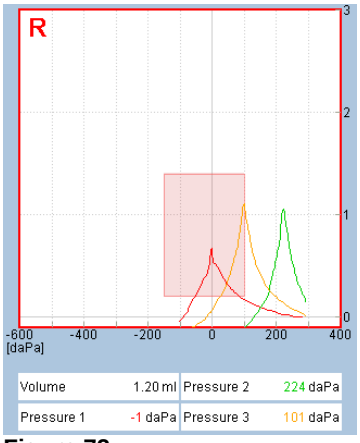


Figure 72

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

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

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

Performing an ETF Perforated Measurement

Figure 73

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

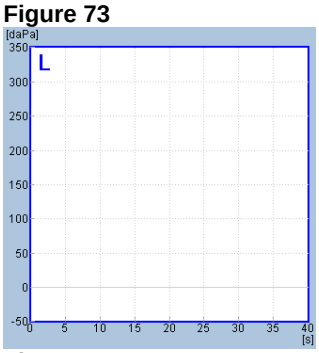


Figure 74

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

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

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

Figure 75

Pressure will increase to the predetermined setting.

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

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

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

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

5.4.5 Managing Test Results

5.4.5.1 General

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

5.4.5.2 Completed Results

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

5.4.5.3 Deleting Test Results

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

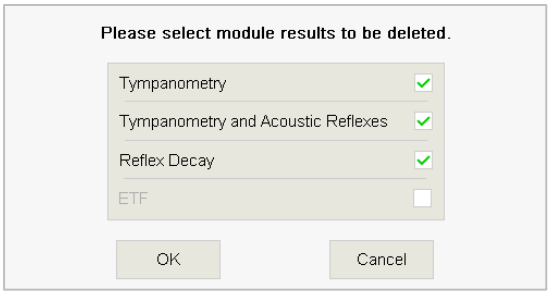


Figure 76

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

5.4.5.4 Printing Test Results with the Built-in Printer

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

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

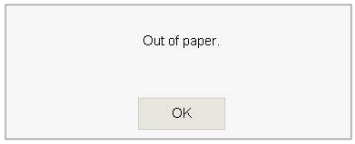


Figure 77

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

Figure 78

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

Figure 79

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

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

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

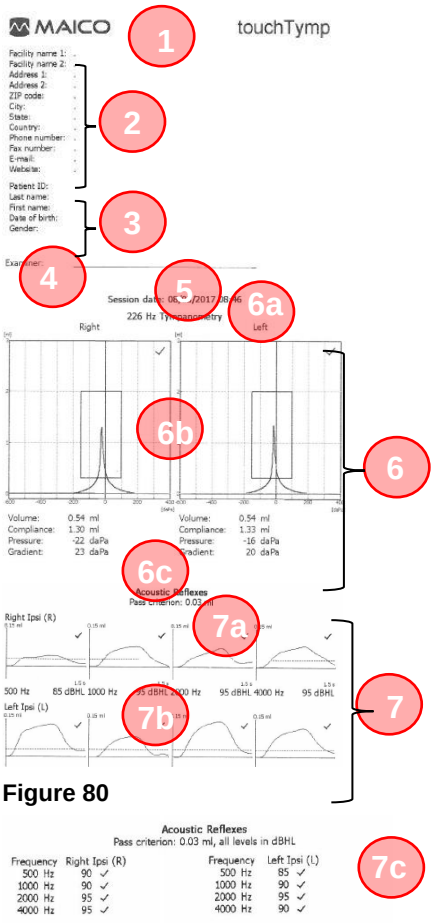


Figure 80

Figure 81

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

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

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

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

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

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

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

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

5.4.5.6 Transferring Test Results to PC

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

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

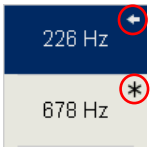


Figure 82

Figure 83

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

5.6 Settings

5.6.1 General

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

Select the ***Settings*** button in the ***Fixed Function Bar*** to access the list of setting menus. MI 34 version offers two additional menus: ***Reflex Decay*** and ***ETF*** (MI 24 – Figure 84, MI 34 – Figure 85).

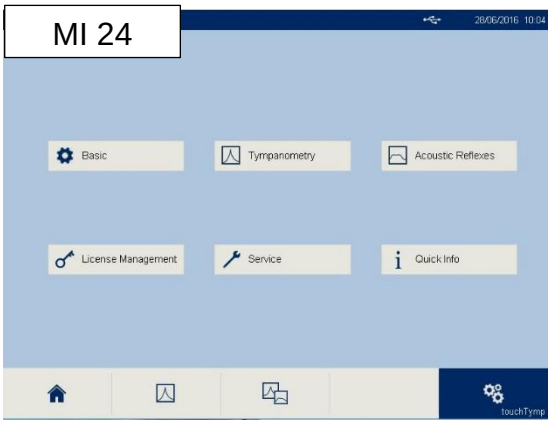


Figure 84

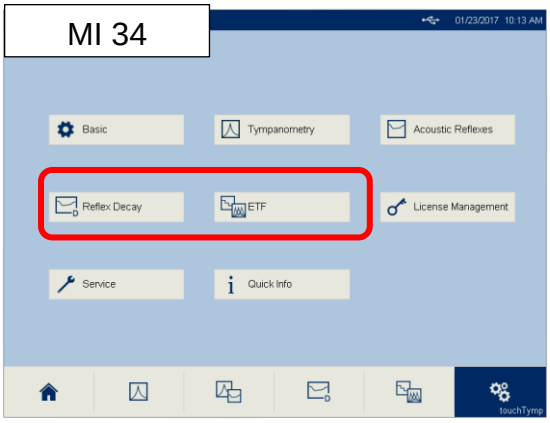


Figure 85

Each menu consists of one or more tabs. Each tab contains one or more settings (Figure 86). When a tab is greyed out, it is not available due to a license must be purchased.

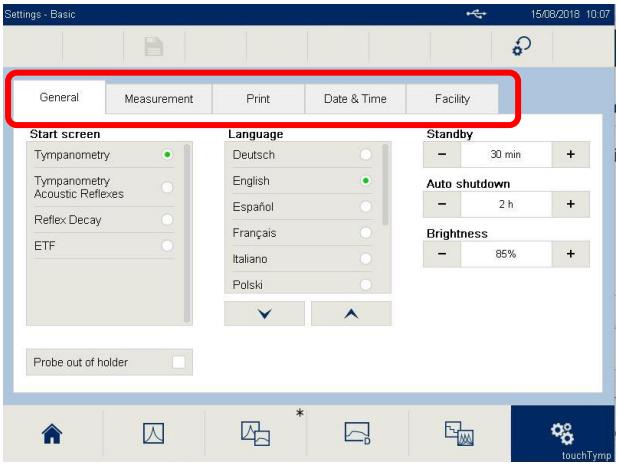


Figure 86

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 87

Start Screen: Adjust the start screen to your needs. Choose ***Tympanometry*** or ***Tympanometry and Acoustic Reflexes*** for upon boot-up the chosen screen is automatically entered (Figure 87).

NOTE: MI 34 Version will offer ***Reflex Decay*** and ***ETF*** within this menu setting.

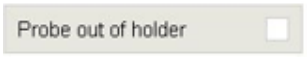


Figure 88

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 88). Setting is inactive if ***Audiometry*** is selected as ***Start*** Screen (Figure 87).

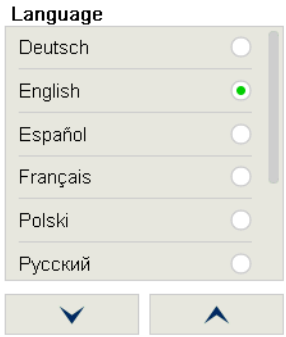


Figure 89

Language: Choose one of the supported languages incorporated in the device (Figure 89).

Figure 90

Standby: Set the period of inactivity, after which the display will turn off. Pressing the screen or the ***Front key*** will awaken the device (Figure 90).

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

Figure 91

Auto shutdown: After a period of inactivity (greater than the ***Standby Mode*** setting) the device will turn off automatically (Figure 91).

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

Figure 92

Brightness*:* Set the maximum brightness of the display (Figure 92).

5.6.3 Settings – Basic – Measurement

Figure 93

Start measurement : 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 93).

Figure 94

Start ear: Defines which ear is the default upon entering the test modules (Figure 94).

Figure 95

Display: Defines on which side of the screen the button and graph for the left and the right ear shall be displayed (Figure 95).

Figure 96

Light bar: Activates or deactivates the light bar function on the probe (Figure 96).

5.6.4 Settings – Basic – Print

Figure 97

Automatic printout (Immittance): An automatic printout is directly generated upon the return of the probe into the probe holder when ***Probe into holder*** is selected (Figure 97).

Figure 98

Info on printout: Select or deselect if the printout shall show the ***Facility*** and ***Patient*** fields (Figure 98).

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

5.6.5 Settings – Basic – Date & Time

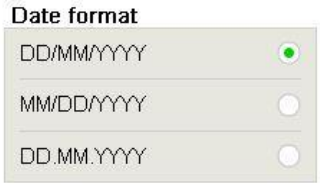


Figure 99

Date format: Select the preferred date format to be displayed in the ***Status Bar*** and printout (Figure 99).

Figure 100

Set date: Set the current date using the date control (Figure 100).

Figure 101

Time format: Select the preferred clock, using the 12 or 24 hour time format (Figure 101).

Figure 102

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 102).

5.6.6 Settings – Basic – Facility

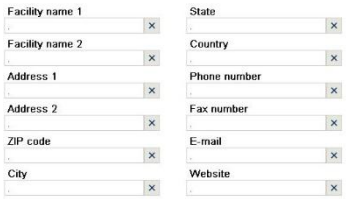


Figure 103

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 103).

Also see section **Fehler! Verweisquelle konnte nicht gefunden werden.**.

5.6.7 Settings – Tympanometry – General

Figure 104

Pump speed: Selection of pump speed determines how precisely and quickly the test will proceed (Figure 104).

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 105

Auto stop: will automatically stop measurement when hitting the zero line to lessen the test time without affecting results (Figure 105).

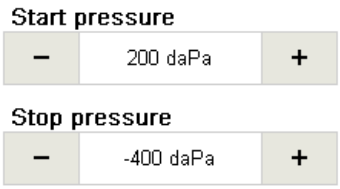


Figure 106

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

Stop pressure*:* the end pressure of the tympanometry measurement (Figure 106).

NOTE: MI 24 version, the start pressure must be a higher value than the stop pressure. MI 34 version, the start pressure can be higher or lower than the stop pressure. This way, ***Tympanometric*** measurements can be performed with decreasing or ascending pressure.

5.6.8 Settings – Tympanometry – Probe Tone 226 Hz/1000 Hz (MI 34 Version Only: 678 Hz/800 Hz)

The following explanations are for the tabs Probe tone 226 Hz (Figure 107) as well as Probe tone 1000 Hz (Figure 108).

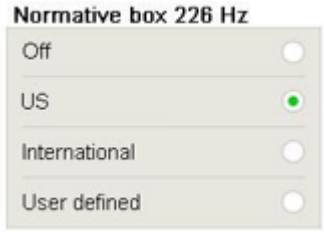


Figure 107

Figure 108

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

Normative Box options include:

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

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

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

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

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

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

Figure 109

678 Hz and 800 Hz allows for a ***User defined*** normative box only (MI 34 version only) (Figure 109).

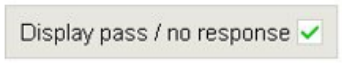


Figure 110

Display pass / no response: Activates a ***Pass*** ✓ or ***No Response*** ✗ to be displayed after the completion of a measurement (Figure 110).

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 111

Presentation: Defines the ***Acoustic Reflex*** screen to start in graphical or table format (Figure 111).

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

Figure 112

Axis: Defines the reflex deflection is displayed negative or positive on the graphical display (Figure 112). The selection here will also define the graphical presentation on the print-out and **Reflex Decay** display for MI 34 version.

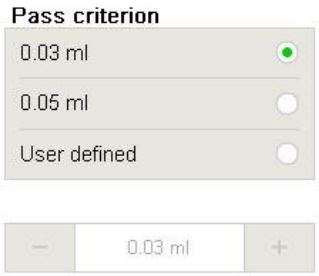


Figure 113

Pass criterion: Defines the deflection value that must be measured for the reflex to be considered an accepted measurement (Figure 113). 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.

Figure 114

Display pass / no response: If active the result (***Pass*** ✓ ***No Response*** ✗) will be displayed (Figure 114).

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

Figure 115

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 115).

Figure 116

AGC (Automatic gain control): If ***AGC*** is selected (Figure 116), the stimulus level will be reduced for small ear canal volumes (< 2 ml) correspondingly to the values in Table 14.

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

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

Table 14: AGC Active, Relative SPL Level Corrections

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

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

5.6.10 Settings – Acoustic Reflexes – Level

Figure 117

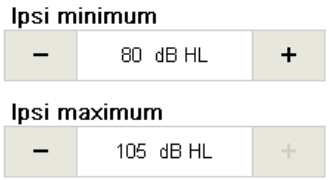


Figure 118

Figure 119

Figure 120

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

- ***Automatic***: touchTymp starts ***Acoustic Reflex*** test at the minimum level and increases in 5 dB steps automatically until a reflex is registered or the maximum level is reached (Figure 117).
- 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 118).
- ***Fixed*****:** The measurement is performed at one level as defined in the ***Settings*** (Figure 119 and Figure 120).

5.6.11 Settings – Acoustic Reflexes – Stimulus

Figure 121

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 121).

NOTE: Stimuli for MI 24 version are frequencies ***500 Hz, 1000 Hz, 2000 Hz, 4000 Hz***. Stimulus options

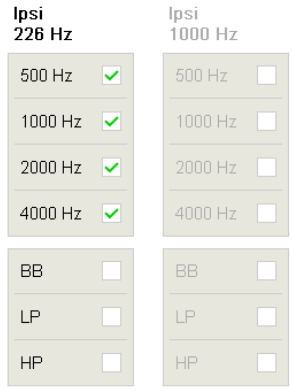


Figure 122

for MI 34 version also include noise stimuli (***BB*** – Broadband, ***HP*** – High Pass, ***LP*** – Low Pass).

When options are greyed out in the settings screen, the license is not active (Figure 122).

5.6.12 Settings – Decay – General (MI 34 Version)

Figure 123

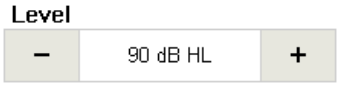


Figure 124

Duration: Defines the length the tone will be presented to the patient (Figure 123). ***Duration*** can be configured in by 5 second increments from 10 s to 30 s.

Level: Defines the default intensity of the stimulus upon entering the screen (Figure 124). You can adjust the level in 5 dB steps.

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

5.6.13 Settings – ETF – Intact (MI 34 Version)

Figure 125

First Test: Defines the message while the test is in progression. The end user can select which maneuver will be displayed first, ***Swallow*** *or* ***Valsalva*** (Figure 125).

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

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

Figure 126

Pump speed: Selection of pump speed determines how precisely and quickly the test will proceed (Figure 126).

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 127

Auto stop: will automatically stop measurement when hitting the zero line to lessen the test time without affecting results (Figure 127).

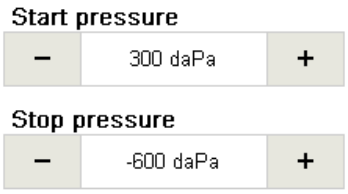


Figure 128

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

Stop pressure: the end pressure of the ***ETF – Intact*** measurement (Figure 128).

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

5.6.14 Settings – ETF – Perforated (MI 34 Version)

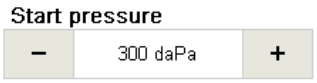


Figure 129

Start pressure: the pressure that is first introduced when performing ***ETF – Perforated*** measurement (Figure 129). This is a default setting and can be configured within the test screen.

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

Figure 130

Test duration: Defines the length the time the test will be conducted (Figure 130). Test duration can be configured in 5 s increments from 30 s to 100 s.

5.6.16 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.

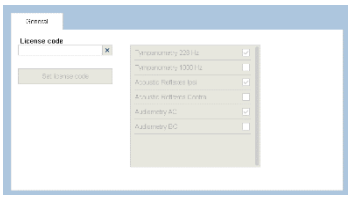


Figure 131

The tab ***General*** contains a field to enter a new license code in order to activate the license on the device. In the middle, all available licenses are shown. The checkboxes are activated automatically as soon as a license is activated (Figure 131).

Figure 132

To enter a new license code, activate the keyboard by pressing into the field ***License code*** and type in the code (Figure 132).

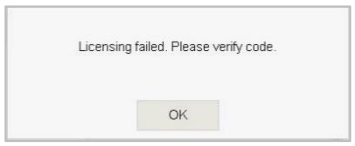


Figure 133

If the code entered is invalid a message box will be shown telling you to verify the code (Figure 133).

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

5.6.17 Settings – Service – General

Figure 134

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

Select or deselect this item to enable or disable a reminder that will display daily. The reminder starts 1 month prior to the expiration of the calibration date for your acoustic transducer(s) (Figure 134).

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

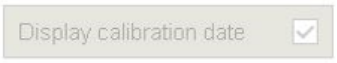


Figure 135

Display calibration date: Only for service (Figure 135).

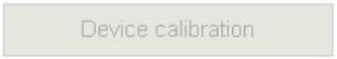


Figure 136

Device calibration: Only for service (Figure 136).

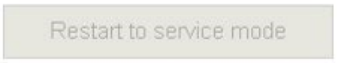


Figure 137

Restart to service mode: Only for MAICO Technical customer support (Figure 137).

Figure 138

Screen calibration: Only for Service (Figure 138).

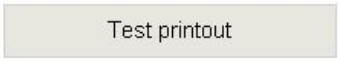


Figure 139

Test printout: prints a test printout (without a session result, Figure 139).

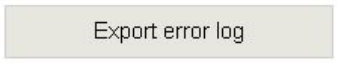


Figure 140

Export error log: If an error is occurring you can export the error log data onto a USB flash drive (Figure 140). If there is no USB flash drive connected the message box (Figure 141) will be shown with further information.

Figure 141

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

Figure 142

Application update: for updating via USB flash drive (Figure 142). A message box will be shown to ask you if you want to continue updating (Figure 143).

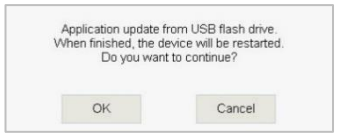


Figure 143

NOTE: The device will be restarted after application update.

Figure 144

Export Settings: Export file onto USB flash drive (Figure 144).

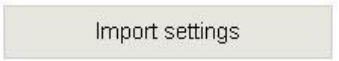


Figure 145

Import Settings: Import file from USB flash drive (Figure 145).

Figure 146

Reset Settings: Resets settings to default. Facility information will also be deleted (Figure 146).

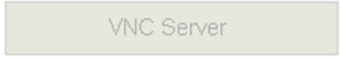


Figure 147

VNC Server: Only for service (Figure 147).

5.6.18 Settings – Service – About

On this screen the most important device information are presented. Additionally, the Qt License Agreement is shown (Figure 148).

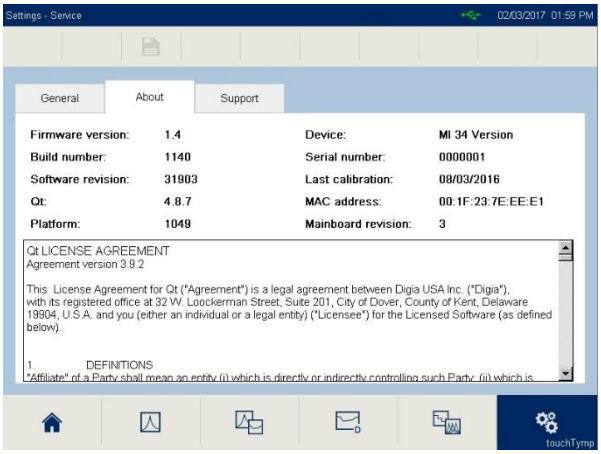


Figure 148

5.6.19 Settings –Service – Support

Figure 149

This menu is only for editing by service. The dealer can enter his contact information to display in the ***Quick Info*** screen (Figure 149).

5.6.20 Quick Info

Figure 150

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 150.

6 Technical Data

This section offers you important information about

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

6.1 touchTymp Hardware

CE 0123

The touchTymp is an active, diagnostic medical product according to the class IIa of the EU medical directive 93/42/EEC.

General Information About Specifications

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

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

STANDARDS	
Medical CE-mark	Yes
Safety Standards	IEC 60601-1, ES 60601-1/A2/ CAN/CSA-C22.2 No 60601-1 Class I, Type B applied parts
EMC Standards	IEC 60601-1-2
Audiometer Standards	Tone: IEC 60645-1 Type 3/ANSI S3.6 Type 3
Tympanometer Standards	IEC 60645-5, Type 2/ANSI S3.39, Type 2

DEVICE SPECIFICATIONS	
Power supply 24V 60W UE60-240250SPAx	Consumption: 1.5A rms. at 90 VAC input and maximum load Mains voltages and fuses: 100 VAC to 240 VAC ± 10 % 50 Hz to 60 Hz ±10 %
Mode of operation	Continuous

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 minutes (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 Diagnostic Probe:	104 mm x 36 mm x 24 mm 4.09 in x 1.42 in x 0.94 in	
Display:	10.4 in full color display with high bright white LED back-light	
User Interface:	Touch screen (resistive)	
User Feedback:	Integrated speaker	
Language Settings:	Chinese, English, French, German, Italian, Polish, Russian, Spanish, Turkish	
Connectors:	External / USB out, USB in, USB out, power socket, Contra headphone jack, probe connector	
Data interfaces:	USB 1.1 / Ethernet (not implemented)	
PC Connection:	USB; the system can not be operated from a PC. Using the MAICO 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 IEC 60645-1.
NOTE: Reference equivalent threshold sound pressure levels may differ significantly with ambient pressures outside the above range. Therefore recalibration around the normal ambient pressure at the site of the user should be undertaken in those circumstances where the calibration site and the user site do not share similar ambient conditions.

TYMPANOMETRY

Test signals:	Pure tone: 226 Hz, 1000 Hz each with ± 1 % Additional for MI 34: 678 Hz, 800 Hz each with 1 %	
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	
Air pressure:	**Control:**	Automatic
	Indicator:	Measured value shown in the display.
	Range:	-600 daPa to +400 daPa
	Pressure limitation:	-800 daPa and +600 daPa
	Pressure change rate:	Speed at compliance peak (change in settings): **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 seconds	
Accuracy:	**Pressure:**	±5 % or ±10 daPa, whichever is greater
	Compliance:	±5 % or ± 0.1 ml, whichever is greater
Graphical display:	x-axis: Pressure in daPa y-axis: Compliance in ml (226 Hz, 678 Hz, 800 Hz) and mmho (1000 Hz)	
Test types:	Tympanometry	Automatic, where the start and stop pressure can be user-programmed in the setup function.
	Eustachian tube function 1 – Intact eardrum	Williams test
	Eustachian tube function 2 – Perforated eardrum	Toynbee test

[4] THD = Total Harmonic Distortion

ACOUSTIC REFLEXES

Test methods:	Ipsilateral and Contralateral	
Test signals:	**Pure Tones:**	500 Hz, 1000 Hz, 2000 Hz, 4000 Hz each with ±1 %
	Noise (MI 34):	Broadband, High Pass, Low Pass
Test level:	Ipsilateral: 70 dB HL to 105 dB HL Contralateral: 70 dB HL to 120 dB HL	
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 dBSPL	
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 headphones:	**Insert earphone:**	IP30 CIR22/CIR55
	Headphone:	DD45 C
Test types:	**Automated Reflex:**	Automatic/Fixed
	Reflex Decay:	Manual, 10 dB above threshold and stimulus durations of 10 seconds.

IMMITTANCE CALIBRATION PROPERTIES

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

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 CIR22/CIR55.
The risk of artifacts at higher stimulus levels in reflex measurements are minor and will not activate the reflex detection system.		

6.2 Connections

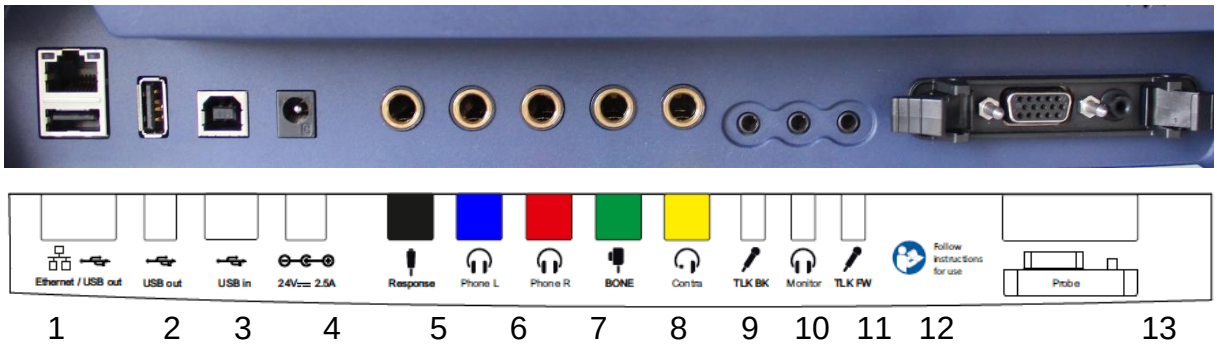


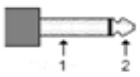
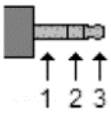
Figure 151

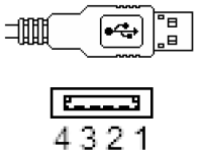
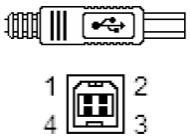
Table 15 Connections on Backside of Device

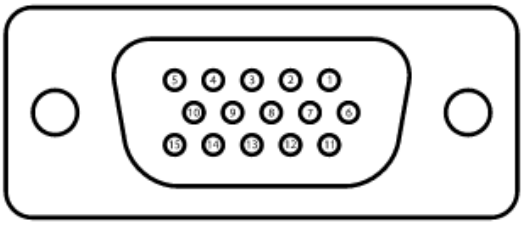
CONNECTIONS		
No.	Connection socket	Specification
1	**Ethernet**	Not applicable in actual version
1/2	**USB out**	2 x USB 1.1
3	**USB in**	USB 1.1
4	⊖—C—⊕ **24 V/2,5 A**	24V DC, 2.5A, Part. No. Power Supply UE60-240250SPAx 8101895
5	**Response**	RI = 2000 Ω
6	**Phone L**	ZA =10 Ω, UA = 3 V_{eff}
7	**Phone R**	ZA =10 Ω, UA = 3 V_{eff}
8	**Bone**	ZA= 10 Ω, UA= 3 V_{eff}
9	**Contra**	ZA =10 Ω, UA = 3 V_{eff}
10	**TLK BK**	Z_I= 1 kΩ, U_I= 0.38 - 500 mV_{eff}
11	**Monitor**	Z_A= 250 Ω, U_A= 3 V_{eff}
12	**TLK FW**	Z_I= 1 kΩ, U_I= 0.38 - 500 mV_{eff}
13	**Probe**	See Table 16 below.

6.3 Pin Assignment

Table 16 Pin Assignment

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

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

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

6.4 Calibration Values

COUPLER TYPES USED BY CALIBRATION	
IOW Probe (probe system):	Calibrated using a IEC 60318-5 (2cc) acoustic coupler made in accordance to MAICO Standard Values
IP30 CIR22/CIR55 :	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 MAICO Standard Values

REFERENCE VALUES FOR STIMULUS CALIBRATION				
Fre-quency [Hz]	**Reference equivalent threshold sound pressure level [RETSPL, dB re. 20 µPa]**			
	IP30/CIR22/CIR55 ISO 389-2	**DD45 C**		**IOW Probe MAICO Standard Values**
		MAICO 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 MAICO Standard Values.				

FREQUENCIES AND MAXIMUM VALUES FOR IMMITTANCE				
Center Frequency [Hz]	**Intensities [dB HL]**			
	IP30	**CIR22/CIR55**	**DD45 C**	**IOW Probe**
	Tone/Noise	**Tone/Noise**	**Tone/Noise**	**Tone/Noise**
500	110	110	120	100
1000	120	115	120	105
2000	120	115	120	105
4000	120	110	120	100
BB	115	115	120	95
LP	120	115	120	100
HP	120	115	120	95

6.5 Electromagnetic Compatibility (EMC)

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

Guidance and manufacturer's declaration - electromagnetic emissions		
The touchTymp is intended for use in the electromagnetic environment specified below. The customer or the user of the touchTymp should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions 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.
RF emissions CISPR 11	Class B	The touchTymp is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Complies Class A Category	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the 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 2.5 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	+6 kV contact +8 kV air	+6 kV contact +8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines +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 differential mode +2 kV common mode	+1 kV differential mode +2 kV common mode	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% *U*T (>95% dip in *U*T) for 0.5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T (>95% dip in *U*T) for 5 sec	< 5% *U*T (>95% dip in *U*T) for 0.5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T	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	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The touchTymp is intended for use in the electromagnetic environment specified below. The customer or the user of the touchTymp should assure that it is used in such an environment,			
Immunity test	IEC / EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC / EN 61000-4-6 Radiated RF IEC / EN 61000-4-3	3 Vrms 150kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	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 $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 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: 
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

1. IEC 60601-1:2012/ ANSI/AAMI ES 60601-1: 2005 / A2:2010: Medical Electrical Equipment, Part 1 General Requirements for Safety
2. CAN/CSA-C22.2 No. 60601-1:2008: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
3. UL/IEC/EN 60950-1:2005: Information Technology Equipment - Safety - Part 1: General Requirements
4. IEC 60601-1-1:2000: General requirements for safety; Collateral standard: Safety requirements for medical electrical systems
5. 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
6. DIN/EN/ISO 14971:2012 - Application of risk management to medical devices
7. Essential Requirements of the current European Union Medical Device Directive 93/42/EEC
8. DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2)
9. Directive 2002/96/EC on waste electrical and electronic equipment (WEEE)

Appendix A Literature

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Specifications are subject to change without notice.

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