Operation Manual
easyTymp

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Title: **easyTymp** – Operation Manual

Date of issue/last revision: 15/11/2016

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Compliance

MAICO Diagnostics is an ISO 13485 certified corporation.

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

1 Introduction

1.1 General

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

The easyTymp is designed and manufactured to meet all quality and safety requirements. When designing the easyTymp, 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 user manual is meant to make it as easy as possible for the operator to become familiar with the operation and functions of the easyTymp when performing Impedance tests. If you have questions or suggestions for further improvements, please, do not hesitate to contact MAICO.

This operation manual provides instruction about different versions of the easyTymp. Please, confirm your version for relevant sections to your purchased device.

1.2 Intended Use

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

1.3 Indications for Use

The easyTymp is an electroAcoustic test instrument that produces controlled levels of test tones and signals intended for use in conduction diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders. It features Tympanometry and acoustics reflex.

1.4 Contraindications of Use

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.

1.5 Essential Performance

The following is considered essential performance:

To generate and present stimulus signals in the audio and pressure ranges as specified in the applicable IEC 60645/ANSI S3.39 series in normal condition.

It is intended to be used by audiologists, ENTs, hearing healthcare professionals, or other trained technicians in a hospital, clinic, healthcare facility or other suitable quiet environment as defined in standard ISO 8253-1.

The easyTymp can be used on patients in the age range of infants, children and adults.

1.6 Features and Benefits of the easyTymp

The purpose of the easyTymp test system is to provide a rapid Tympanometry and Acoustic reflex measurements to measure the middle ear status where a pass or refer notation is identified. easyTymp provides an optional 1 kHz probe tone for testing newborns. Factory defined protocols allow for simple screening measurements, and different versions are available that provide diagnostic testing functions. As with any type of hearing screening, a “pass” result should not overrule any additional concerns regarding middle ear function. A referral to physician should be administered if concerns about middle ear function persists.

The easyTymp cradle serves as a docking and recharging station for the handheld device and can include an integrated printer or opening for placement of the eartip box.

Using the included Software, the handheld unit will transfer data to a PC via USB-connection while in the docking station, or it can also transfer data directly via USB cable when no docking station is available.

The easyTymp comes in multiple versions and configurations dependent on the country and service partner. Each version provides specific testing functionalities dependent upon the user needs.

easyTymp (as Standard Version)

- Rapid Tympanometry measurement
- Ipsilateral Acoustic Reflexes at several frequencies
- 1 kHz probe tone (option)

easyTymp Pro Version (Contra probe required)

- Rapid Tympanometrymeasurement
- Ipsilateral Acoustic Reflexes at several frequencies
- Contralateral Acoustic reflex measurements at several frequencies
- Acoustic Reflex Decay (Ipsilateral and Contralateral)
- Eustachian Tube Function
- 1 kHz probe tone (option)

1.7 Description

1.7.1 General

Dependent on the configuration the easyTymp offers the following Impedance measurements:

- Tympanometry
- Acoustic Reflex
- Contralateral Acoustic Reflex
- Acoustic Reflex Decay
- Eustachian Tube Function Test

Further information on the different tests are given in sections 1.7.2 to 1.7.6.

1.7.2 Tympanometry

Tympanometryis 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).

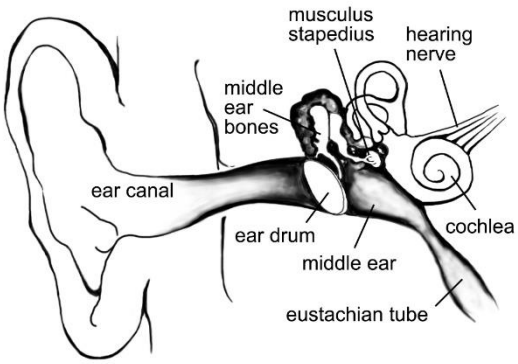


Figure 1

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: 1.02 mmH_2O = 1.0 daPa.

[1] Compliance is measured with respect to an equivalent volume of air, with the scientific quantity milliliter (ml).

[2] Air pressure is measured in deca-Pascals (daPa).

1.7.3 Acoustic Reflex

An Acoustic Reflex, or contraction of the 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, and in graphical form.

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

1.7.4 Contralateral Acoustic Reflex

A Contralateral Acoustic Reflex is available with the easyTymp Pro Version. When the stimulus presentation and measurement are made in the different ears by means of the Contra Probe.

1.7.5 Acoustic Reflex Decay

An Acoustic Reflex Decay is available with the easyTymp Pro. Acoustic reflex decay, also known as adaptation, is the measurement of the Acoustic reflex response during sustained stimulus presentation. Ipsilateral and Contralateral Reflex Decay can be performed.

1.7.6 Eustachian Tube Function Test

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 with an intact tympanic membrane or in patients who have a perforated TM or pressure equalization tubes.

2 For your Safety

2.1 How to read this Operation Manual

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

READ THIS ENTIRE MANUAL BEFORE ATTEMPTING TO USE THIS SYSTEM!

Use this device only as described in this manual.

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 instrument, 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).

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

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 sevices
	Do not reuse
REP	EU authorized representative
CE	Conforms to European Medical Device Directive 93/42/EEC
	Non-ionizing electromagnetic radiation
	ETL listed mark
MAICO	Logo

2.5 General Precautions

Before measurement make sure, that the device works properly.

Do not immerse the unit in any fluids. For cleaning and disinfection see section 3.3.

Use and store the instrument indoors only. For operation, storage and transport conditions see table in section 6.2.

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

No modification of this equipment is allowed.

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

Calibration of the instrument: The audiometer and the headphone complement each other and share the same serial number (i.e. 7663252). Therefore, the instrument shall not be used with any other headphone prior to recalibration. Recalibration also needs to be conducted, when a defected headphone is replaced.

Uncalibrated instruments may lead to faulty measurements and sometimes even damage the hearing of the examinee.

2.6 Electrical Safety and Measuring Security

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

The protection class of the system depends on the used power supply.

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

In Case of Emergency

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

In Case of Emergency

Do not position the instrument 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 instrument if the mains cable and/or the outlet is damaged.

Safety against electrical hazard is guaranteed only when the connected notebook computer is powered by batteries respectively the computer´s power supply accords to the IEC 60601-1 or IEC 60950-1 safety regulations.

To transfer data to a PC, establishing a PC-connection via USB is required. See section 4.2.3 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 instrument is connect to a PC (IT equipment forming a system) ensure not to touch the patient while operating the PC.

If the instrument 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 instrument is not intended for operation in areas with an explosion hazard.

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 instrument.

In order to maintain a high level of safety and to ensure the instrument works properly, it is necessary to have the instrument 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 please 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 bend or buckled.

Remove batteries both in the hand held unit and the cradle if the instrument will not be used for some time.

2.7 Device Control

The user of the instrument should perform a subjective instrument check once a week according ISO 8253-1. For annual calibration please see section 3.2.

See section 4.2.2 Test cavities for volume check.

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.

The instrument 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 6.2.

3 Warranty, Maintenance and After-Sales Service

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 instrument 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 instrument to the original purchaser.

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

WARNING

No modification of this equipment is allowed.

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

3.2 Maintenance

In order to ensure that the instrument works properly, it has to be checked and calibrated at least once a year.

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

When returning the instrument 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 instrument.

3.3 Cleaning and Disinfection Recommendations

3.3.1 General

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

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

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

- Before cleaning always switch off and disconnect the device from power supply.
- For cleaning use a lightly dampened cloth with soap water solution.
- Disinfect the plastic housing of the easyTymp 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
- Disinfect computer, keyboard, transport trolley etc. with Sani-Cloth® Active wipes:
    - once a week
    - after contamination
    - when polluted

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

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

Should the user suspect fluids have 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 3.3.3.

3.3.2 Cleaning the Case and Cables

CAUTION

Use caution while cleaning.

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

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.

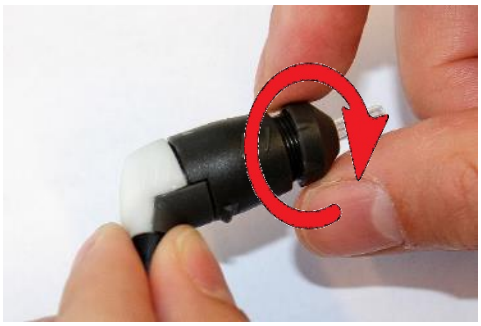
Follow the instructions on the disinfection product.

3.3.3 Cleaning the probe tip

In order to secure correct impedance 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.

Never clean the probe tip while the tip is still attached to the probe (Figure 50).

Figure 50



1. Unscrew the probe cap by turning it in a counter clockwise direction (Figure 51).

Figure 51

2. Take the plastic probe tip out of the probe (Figure 52).

Figure 52

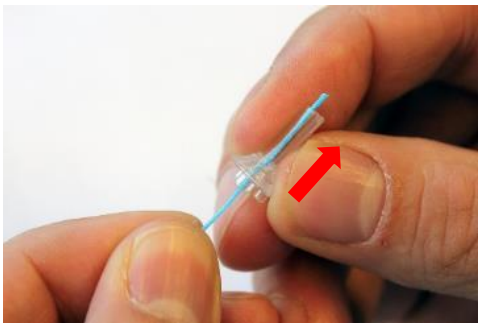


Figure 53

3. 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 53).

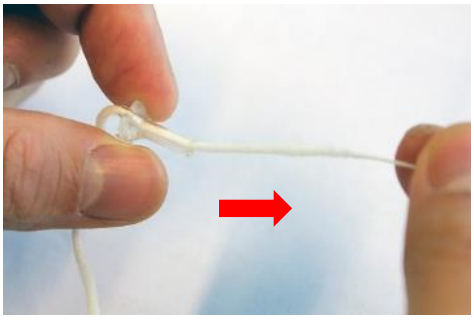


Figure 54

4. Proceed in the same way with all 4 probe channels. Use the floss only once (Figure 54).

Figure 55

5. Place the probe tip back onto the probe. Make sure that the plastic pegs are inserted into the appropriate corresponding cavities (Figure 55).

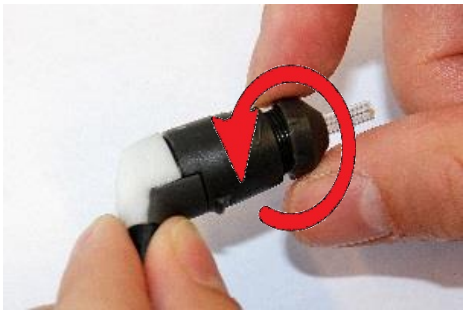


Figure 56

6. Screw the probe cap back on the probe (Figure 56). 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:

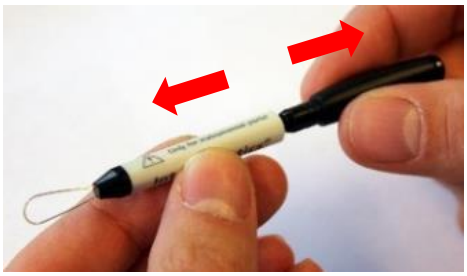


Figure 57

Use the cleaning set from the eartip box (Figure 57): Take the cleaning tool apart to find the thin brush and thin rigid plastic cord (Figure 58).

Figure 58

Figure 59

Use the plastic cord or brush to push debris out of the probe tip (Figure 59). Always enter the probe tip from the rear to avoid accumulation of debris inside the vents (Figure 60).

Figure 60

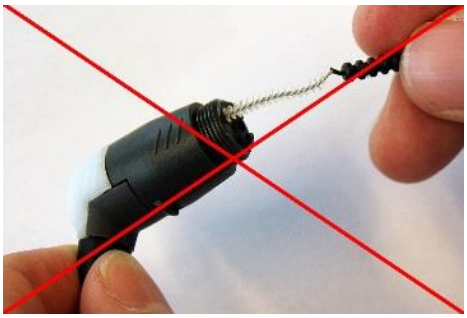


Figure 61

CAUTION

This procedure destroys the probe (Figure 61).

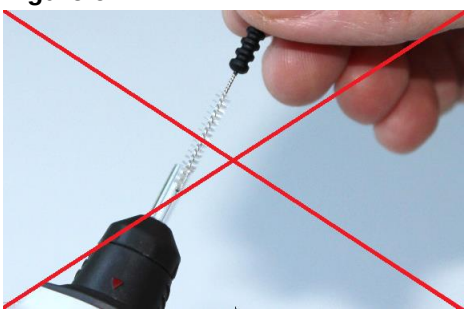


Figure 62

CAUTION

This procedure destroys the probe (Figure 62).

3.3.4 Disposables

Figure 2

Operating the easyTymp will require the use of ear tips – either mushroom shaped (1) or umbrella (2) ear tips (Figure 2).

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

WARNING

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

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

3.3.5 Components/Replacement Parts

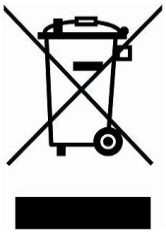
Some reusable components are subject to wear with use over time. MAICO recommends that you keep theses replacement parts available (as appropriate for your easyTymp device configuration).

3.4 Troubleshooting

ISSUE	SOLUTION
White Screen	If the device shows white screen after turning on, make sure battery is fully charged.
Frozen Display	If the display freezes try ○ to restart the unit ○ to shut off the system and change the battery **NOTE:** Please do not take out the battery before turn off. Always turn off the device and then take out the battery.
Battery cavity	- Please check that the battery is properly inserted into the compartment. - Please check that the battery connector (spring contacts) inside the compartment is clean and working properly.
Probe	Make sure the probe tip is inserted correctly into the probe. Otherwise, follow the suggestions in Probe tip.
Probe tip	1. Please 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. 3. Change the complete probe and check if the system is running.

ISSUE	SOLUTION
Extension cable	If the device shows leaking, please 1. Follow the suggestions for probe tip/ Probe. 2. If step 1 is not helpful, please change the extension cable. If the problem persists follow the suggestions for Probe tip/Probe.
Battery slot	1. If the spare battery is not charging, please, check if the battery is properly inserted and the terminals are in contact (springs in cradle). 2. Please make sure the battery contacts are clean in the case.
Connection in cradle	1. Make sure the handheld is properly inserted after the test. Improper docking may lead to no connection between device and the cradle. 2. Please make sure battery contacts are clean in the case.
Printer problem	1. Please check if the cradle is connected with power supply. 2. Please check if the printer function is activated in the device. 3. Please check if the printer paper is properly inserted. 4. Properly place the handheld on the cradle. 5. When during printing process the 2nd battery is charged also, take the 2nd battery out of cradle and try again.
PC Connections	1. Make sure the Patient database and the printer is deactivated from handheld. 2. Handheld: a. Please check the USB connection in the PC and the system. b. Use another USB cable. 3. Cradle: a. Make sure the device is properly placed into the Cradle. b. Make sure the Cradle is powered while transferring the result to PC. 4. Make sure the easyTymp option is selected in the PC software (for detail contact your distributor). 5. Try to reinstall the PC software. Check the device manager in the PC. If the easyTymp does not appear in the list install the driver again using the installation CD.

3.5 Recycling and Disposal



Within the European Union it is illegal to dispose of electric and electronic waste as unsorted municipal waste. According to this, all MAICO products sold after August 13, 2005, are marked with a crossed-out wheeled bin. Within the limits of Article (9) of DIRECTIVE 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.

Batteries may explode or cause burns, if disassembled, crushed or exposed to fire or high temperatures.

4 Unpacking and Installation

4.1 Unpacking the system

Check Box and Contents for Damage

- It is recommended that you unpack your easyTymp 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 instrument 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 instrument can be properly packed if it needs to be returned for service or calibration (see section 3.2).

Components

(1) easyTymp Handheld Unit
(1) Probe
(1) Cradle Kit based on configuration
(1) Power supply unit for easyTymp handheld unit based on configuration
(1) DC USB adapter for easyTymp handheld unit based on configuration
(1) Rechargeable Battery
(1) Eartip box (configuration see below)
(1) Test Cavity
(1) Software Kit MAICO Impedance Software
(1) Operation Manual
(1) Quick Guide
(1) Probe cleaning kit

Standard Configuration of Eartip Box:

(10) Eartip flanged 3-5 mm (red)
(10) Eartip mushroom 7 mm (blue)
(10) Eartip mushroom 9 mm (green)
(10) Eartip mushroom 11 mm (blue)
(10) Eartip mushroom 13 mm (green)
(5) Eartip mushroom 15 mm (blue)
(5) Eartip mushroom 19 mm (yellow)
(5) Eartip umbrella 15 mm (red)
(5) Eartip umbrella 19 mm (blue)
(2) Probe Tip (replacement)
(1) MAICO cleaning tool for probe tip
(1) MAICO eartip removal tool
(1) Allen key SW: s = 2 mm (See chapter 4.2.1.5 Adjust the cradle)

Cradle Kit

(1) Cradle with or without printer
(1) USB cable
(1) Power supply
(1) Rechargeable battery
(1) Roll of paper (with printer cradle)

Configuration dependent components for all easyTymp Versions:

- External Probe (35cm)
- Wall Mount Kit for cradle with integrated eartip box, power supply unit and additional rechargeable battery
- Carrying case

Configuration dependent components for easyTymp Pro Version:

- Contra Probe (140 cm)
- CIR55 (Contralateral Earphone)
- Insert Phones (Contralateral Earphone)
- DD45C (Contralateral Headset)
- Quick Guide (Pro Version)

Licenses:

- License for high frequency probe tone of 1 kHz
- License for Pro Version: Acoustic Reflexes Contra, Decay and ETF

NOTE: License for Pro Version: An upgrade to the device version is required.

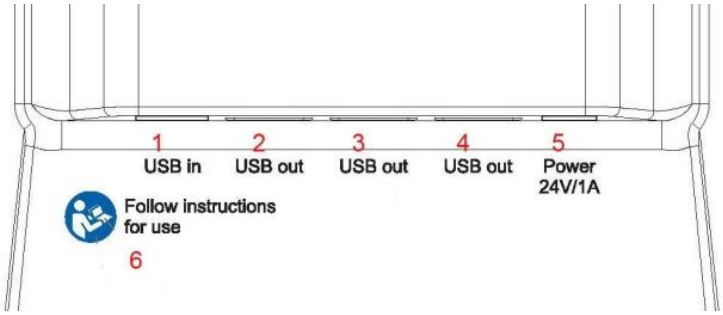
Consumable Material:

- Printer paper
- Replacement eartips
- Probe tip
- Cleaning floss

4.2 System Installation

4.2.1 Hardware Installation

4.2.1.1 Installing the Cradle



1 = USB in;

2 = USB out;

3 = USB out;

4 = USB out;

5 = Power;

6 = Follow the instructions for use

Figure 1

Put the enclosed mains cable into the power connection socket #5 and the mains plug into a power socket.

4.2.1.2 Cradle Indication Lights

Depending on the version (with or without printer) the cradle has up to three indication lights (Figure 2).

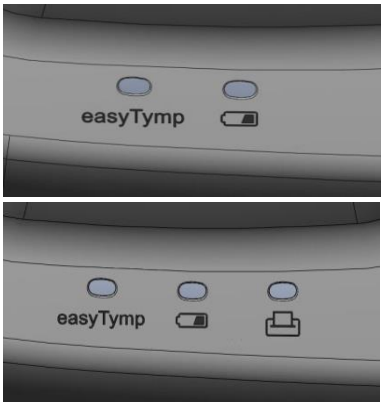


Figure 2

- easyTymp LED shows solid blue when it is placed inside the cradle. The battery will be charged automatically and will be fully charged after approximately three hours. The current battery state of charge may be seen on the easyTymp display.
- Battery LED shows solid blue when the spare battery in the cradle is fully charged. The LED will flash while the battery is charging.
- Printer LED is red when a printer problem occurs.

4.2.1.3 Installing Paper in the Thermal Printer

Figure 3

Step 1 – Push button to open the printer cover (Figure 3).

Figure 4

Step 2 – Pull the blue lever upwards (Figure 4).

Figure 5

Step 3 – Insert paper roll into the compartment with its loose end to the front of the printer. Position the loose end into the printer roll and raise it by rotating the printer roll with your finger (Figure 5).

Figure 6

Step 4 – Push the blue lever down (Figure 6).

Step 5 – Close the printer cover (Figure 7).

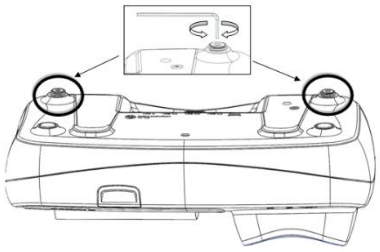
Figure 7

4.2.1.4 Mounting the Cradle on the Wall (optional accessory)

In order to mount the cradle on the wall, an optional wall mount kit is available (Figure 8).

Figure 8

4.2.1.5 Adjust the Cradle



Use the allen key to adjust the cradle on the table (Figure 8.1).

Figure 8.1

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 cradle.

Please ensure that the Allen key is only used to adjust the setting of the adjustable feet on the cradle and that this tool is not used for any other purpose on the easyTymp unit.

4.2.1.6 Installing the easyTymp Battery

The battery compartment is opened by gently pressing the indentation and pushing the cover downwards (Figure 9).

Figure 9

Place the battery inside the compartment (Figure 10).

Figure 10

Figure 10.1

Make sure the battery contacts are aligned before pushing the battery into place (1) and the removal-tab is easy to reach (2).

Figure 11

The removal-tab, attached to the back of the battery case, should be wrapped around the battery to remove it easily (11).

Figure 12

Replace the lid on the easyTymp and push it upwards to close the battery compartment (Figure 12).

It is recommended that the battery is removed from the instrument when it is not in use for extended time periods.

4.2.1.7 Charging the Battery

Figure 13

NOTE: Please note that the battery needs to be charged for a minimum period of approximately 6 hours prior to first use of the easyTymp hand-held Tympanometer (Figure 13). To charge the battery please place the easyTymp into the cradle and connect the cradle to the mains power with the use of the easyTymp power supply provided.

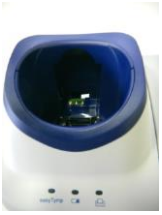


Figure 14

The spare battery is stored and charged in the back of the cradle (Figure 14). Battery LED will show solid blue when the spare battery in the cradle is fully charged. The LED will flash as long as the battery is charging.

WARNING

Observe the following precautions at any times:

- Keep the battery fully charged.
- Do not place the battery in fire or apply heat to the battery.
- Do not damage the battery or use a damaged battery.
- Do not expose the battery to water.
- Do not short circuit the battery or reverse the polarity.
- Use only the charger provided with the easyTymp
- Please see the following section for estimated charging times.

4.2.1.8 Battery Life

The following table gives an estimate of the charging time (CT) in hours for the battery. Be aware that negative numbers mean that the battery is discharging. Charge times are the same for the spare battery in the cradle and the battery in the cradled easyTymp.

	CT through cradle up to 80 %	CT through USB (PC) up to 80 %	CT through cradle up to 100 %	CT through USB (PC) up to 80 %
Off	1.5	3.8	2.3	5.7
On (pump off)	2.8	-32	4.1	-47

4.2.1.9 Changing Probes

Figure 15

To release the probe, press the circular button on the back of the instrument and pull the probe out (Figure 15).

NOTE: Do not pull on the extension cable as this can damage the tubing connection!

Figure 16

Connect the probe to the easyTymp by lining up the red triangles and pushing the probe into the unit (Figure 16).

Figure 17

The probe can be attached to the extension cable by correctly lining up the pins and clicking the probe into the end of the extension cable (Figure 17).

4.2.1.10 easyTymp Pro Version: Connecting the Contralateral Headphone or Insert Phone

Figure 18

To measure Contralateral reflexes it is necessary to connect the Contra Probe to the easyTymp as described previously.

Find the jack labeled “Contra” on the Contra Probe. Insert the Contralateral transducer into this jack (Figure 18).

The Contra Probe must be calibrated to the selected Contralateral transducer type. This calibration is already completed if the Contra Probe and transducer are purchased at the same time. Otherwise the Contra Probe and transducer need to be sent to an authorized service center to perform the calibration.

NOTE: Three different Contra phones can be purchased for use with the easyTymp. The Contra phones need to be calibrated to the Contra Probe before use. If a new Contra phone should be used a recalibration of the Contra Probe is necessary. We strongly advise against using an uncalibrated Contra Phone! Uncalibrated instruments may lead to faulty measurements and possibly damage the patient’s hearing.

4.2.2 Test cavities

The easyTymp comes with a separate test cavity which can be used to quickly check the probe calibration validity. The test cavity includes 0.2 ml, 0.5 ml, 2.0 ml and 5.0 ml cylinders.

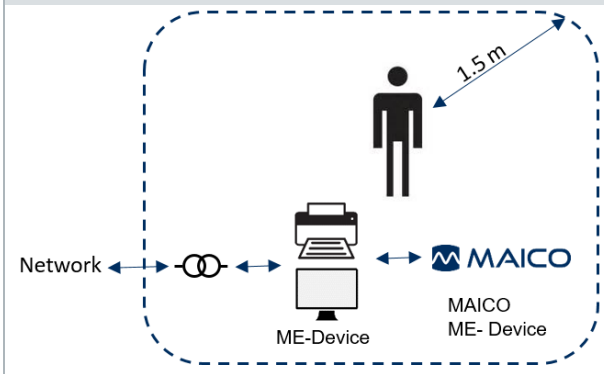
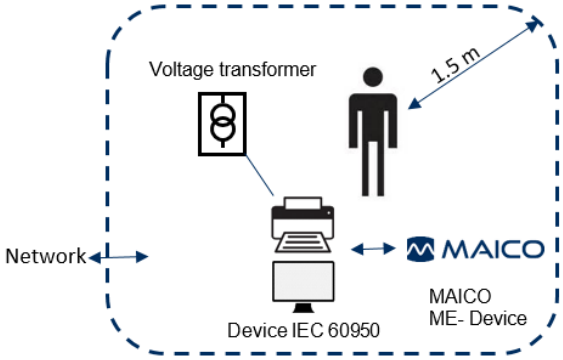
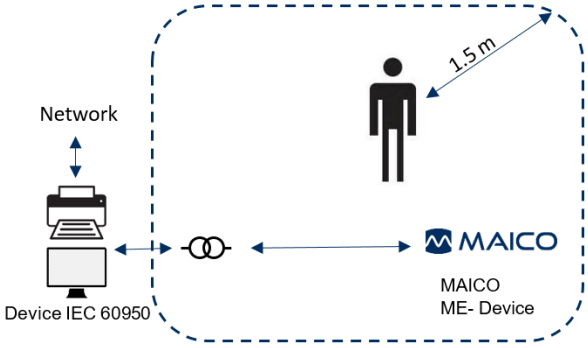
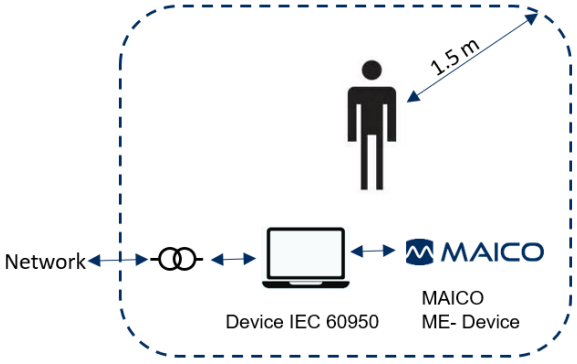
We strongly recommend calibrating each probe at least once a year. If a probe is handled roughly (e.g. has fallen onto a hard surface) it might need to be calibrated again. Calibration values of the probe are stored in the probe itself. Therefore probes can be exchanged at all times.

4.2.3 Establishing a PC-Connection

To transfer data to a PC, establishing a PC-connection via USB is required. If the easyTymp is used with office equipment that is not a medical device itself (see Table 2, PC-Connection 1), make sure to establish the PC-connection in one of the following ways (see Table 2, PC Connection 2, 3 or 4).

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 2 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)
	

4.2.4 Storage

When the easyTymp is not in use, store it in the optional carry case or 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 6.2.

4.3 Software

You can view and store all measurements with the MAICO Impedance Software Module.

NOTE: For installation and functions see the software operation manual. For transferring data to the PC see section 5.6.

5 Operating the Device

5.1 Preparing for Testing

5.1.1 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.

Keep in mind the indication and contraindications of use given in sections 1.3 and 1.4.

5.1.2 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.

5.1.3 Impedance Measurements

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

- An ear tip 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.

5.1.4 Handling the Eartips

Choose the proper size of ear tips based on your inspection of the size of the patient’s ear canals.

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

Figure 19

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

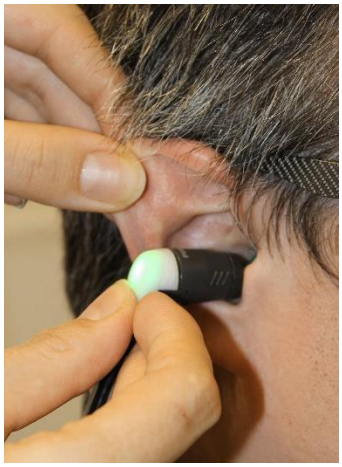


Figure 20

Insert the probe with ear tip 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 ear tip into the ear canal. The fit of the ear tip should be secure; not superficial (Figure). Release the earlobe. When testing infants, gently pull the Pinna down and back to straighten the ear canal.

WARNING

Each ear tip should only be used once. For more detailed information see section 3.3.4.

Figure 21

In order to remove the ear tip, grasp the ear tip at the base using the ear tip removal tool and pull it smoothly straight off the probe tube (21).

NOTE: If the probe tip becomes dirty or clogged, it must be cleaned (see section 3.3.3) or replaced.

5.1.5 easyTymp Pro Version: Placing and Using the Contra Probe

Figure 22

A clip is located on the back of the Contra Probe which can be attached to the patient's clothing (Figure 22). For most patients it is easiest to clip the Contra Probe to the patient. When a child is being held by a parent, clip the Contra Probe to the parent's clothing.

Figure 23

Press the button on the Contra Probe to start or stop/pause the current measurement or switch between right and left when the probe is not inserted to the ear (Figure 23).

5.1.6 easyTymp Pro Version: Placement of Contralateral Phones

Multiple transducers are available for purchase to perform Contralateral measurements.

Figure 24

If the CIR55 or IP30 insert phone is used, place the proper eartip on the insert before inserting the phone into the non test-ear (Figure 24 and Figure 24.1).

Figure 24.1

Figure 25

If the DD45C is used, place the head band over the patient's head. The audiometric headphone is placed over the non test-ear (or Contralateral reflex ear) (Figure 25).

5.2 Operating Panel

Figure 26

Function Keys (Figure 26):

Top buttons: Function of the keys is related to the functions indicated in the display above the individual function key. (e.g. Select Test, Patient, Stop …)

Arrow Keys: Turn on easyTymp by pressing the right or left arrow key.

Turn off easyTymp by pressing both keys at the same time.

Selection of the right or left ear to be tested.

Up and down buttons: Scroll through the different easyTymp settings menu, test protocols or scroll up and down on the display.

5.3 Start the Test

To get started, removing the easyTymp from the cradle will turn the device on automatically.

If you don't store the easyTymp in the cradle, press either the red or blue arrow key to switch the device on.

To switch easyTymp off, press both red and blue arrow keys together and hold for one second.

The easyTymp will always start within the test screen, ready to start a measurement. It will always default to the same protocol as previously used.

5.4 Probe Status Indication

If you use the optional external probe the light at the back of the probe indicates the probe status with the following colors (Figure 27):

Figure 27

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.

Yellow – Probe is in the ear and blocked or leaking.

White – The probe has just been attached. Probe status is unknown. The probe status stays white in hand held use if the easyTymp is not monitoring the probe status. If the

probe light stays white in any other situation easyTymp might need to be switched off and on again to regain proper probe status.

Flashing color – easyTymp is pausing during a protocol and waits for you to press continue. The color in which the probe light is flashing indicates the probe status like above.

Flashing green to red/blue – easyTymp just finished the protocol.

5.5 Testing

5.5.1 General

Operating the easyTymp is very intuitive. After switching the instrument on, it will usually start in the Test Screen and is ready to test the same protocol as was used last. After disconnecting easyTymp from a PC it will start in the Select Protocol screen and the desired protocol should be selected.

The battery status bar will show the current battery power status. If the battery is empty, you will be warned, the measurement will be stopped and all recorded data will be stored. If this occurs shut down the instrument and change the battery to continue testing. The measurement data will be recovered when you start up again, so the measurement can continue without restarting the test.

NOTE: If a white screen appears and the easyTymp does not proceed with the next screen, the battery is almost empty. Please change the battery to proceed.

The following paragraphs describe the precise operation of the different screens you will observe during the use of easyTymp.

5.5.2 Test

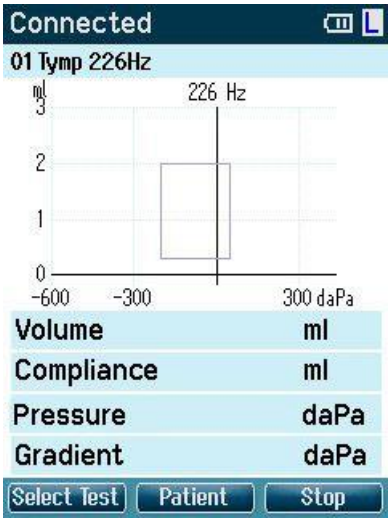


Figure 28

Usually the easyTymp starts with the Test Screen. When deleting or saving data after a measurement, you will also return to this screen (Figure 28).

The graphics of the ongoing test will also be displayed. The box indicates the normative area where the peak of the tympanogram is expected to fall. The measured curve will be directly shown in the graphic while the measurement is being taken. Below the graphic the measured values (Volume, Pressure, Compliance and Gradient) are shown following the measurement.

The header shows the status of the probe. It might show **Ready, In Ear, Leaking** or **Blocked**.

- In the upper right corner the battery status is indicated  . When the easyTymp is placed in the cradle, it will charge the battery and a flashing battery icon will be shown.
- In the upper right corner an icon indicates if the easyTymp is testing the left ear  or right ear  .

- 

When entering the **Test** screen, the second line shows the name of the protocol which is in use. As soon as the easyTymp detects that the probe is in the ear, the second line will show which test of the protocol is running.

Operating from this screen:

Putting the probe in the ear and obtaining a seal will automatically start the test.

- 

: The top left button will bring you to the **Select Test** screen where you can select a different test protocol.
- 

: The top middle button will bring you to the **Patient** screen where patient data can be viewed or changed and earlier sessions can be reviewed and/or printed. This function is only displayed if the patient management is activated.
- 

: Top right button will interrupt the test and **Done!** will appear in the upper left hand corner of the screen. When the measurement is stopped the top buttons will change to give the option to print or delete.
-  arrows will select respectively right or left ear for testing.
- If data on one or both ears is still available, the up and down buttons will bring you back to the **Done!** screen and allow you scroll through the measurement results.

When the probe is in an ear the button will interrupt the testing and bring you to the **Done!** screen. To return to the **Test** screen, press print, save or delete results.

If a protocol includes an instruction message, pressing the Contra Probe button results in continuing the protocol, no matter what the probe status indicates.

5.5.3 Select Test Screen

Figure 29

To change the selected protocol press "**Select**" (Right Top Button). The following measurements are available in the standard easyTymp (Figure 29):

01 Tymp 226 Hz

03 Tymp 226 Hz + Auto Reflex

04 Tymp 226 Hz + Reflex 90dB

NOTE: Protocol list is based on version and licensing. Not active protocols are ghosted.

Operating from this screen:

- easyTymp takes you to the Setup screen.
- Select selects the highlighted protocol and returns to the **Test** screen.
- buttons will bring you to the top or bottom of the protocol list respectively.
- buttons allow scrolling up or down to select one protocol.

5.5.4 Done

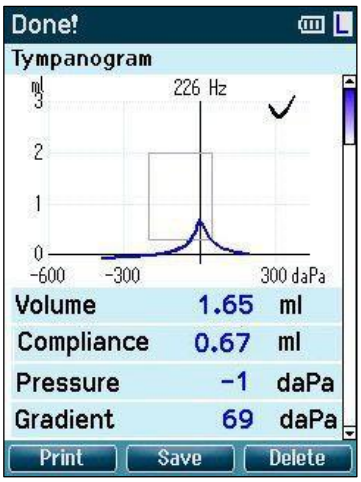


Figure 30

easyTymp will automatically go to the **Done!** screen when it has finished testing (Figure 30).

From here, measurements of both ears can be reviewed, printed and/or saved. Of course, you can also directly start a new measurement in the Test screen from here.

Operating from this screen:

- Print**:** Top left button will print the test results of the left and right ear. Note that there should be a connection to the printer by placing the easyTymp in the cradle.
- Save**:** Top middle button will save the measurement of both ears.

- Delete: Top right button will present a popup message saying “Delete current or both ears?” the top left button will cancel the process. The top middle button will delete the data of the currently selected ear and bring you back to the **Test** screen. The top right button will delete data for both ears and bring you back to the **Test** screen.

- buttons will select respectively right or left ear for testing and bring you back to the **Test** screen. The existing data of the selected ear will only be deleted after the probe detects that it is in the ear with a proper seal.

- buttons make you scroll through the different test results. When viewing the first or last test of an ear, pressing up or down respectively will bring you to the test results of the other ear.

5.5.5 Advanced Testing: easyTymp Pro Version

Acoustic Reflex Testing (Ipsi and Contra)

Before performing Ipsilateral and Contralateral reflex testing Tympanometry will be performed (Figure 31).

NOTE: Deflection of reflexes can be positive or negative and is selected within the setup menu.

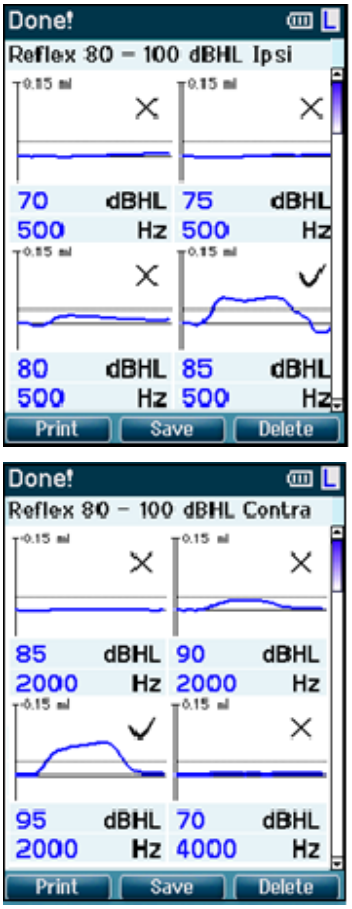
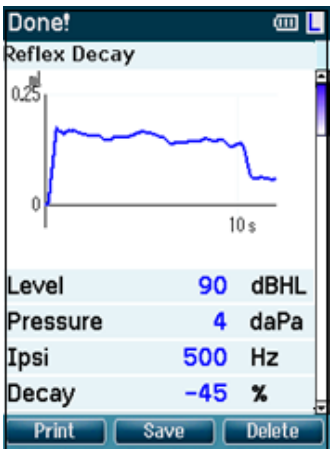


Figure 31

5.5.6 Advanced Testing: easyTymp Pro Version

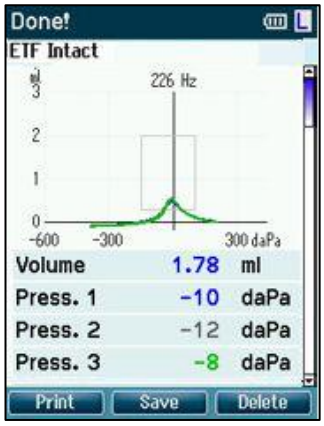
Acoustic Reflex Decay



Ipsilateral and Contralateral Reflex Decay Testing can be performed (Figure 32).

Figure 32

ETF Testing Intact



Instructions for testing will be displayed at the top of the screen (Figure 33).

(1) Red or Blue: represents test ear

(2) Grey: represents “Swallow”

(3) Green: represents “Valsalvation”

Figure 33

Perforated

Instruct patient to swallow.

Measurement of changing pressure indicates status of Eustachian tube (Figure 34).

Figure 34

5.5.7 Select Patient & Save

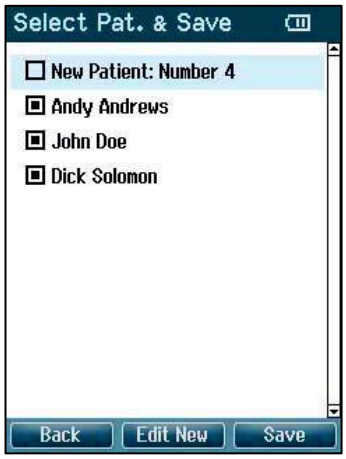


Figure 35

Patient From this screen you can either save data to an existing patient or save data to a new client (Figure 35). New patient will always get the name “New Patient: Number #”, where # is always the next available number.

Operating from this screen:

- Back will bring you back to the **Done!** screen without saving and without deleting data.
- Edit New opens a screen for editing new patient details.
- Save will save the data to the selected client. After saving, all data is deleted and easyTymp returns in the **Test** screen, ready for testing.
- buttons will bring you to the top or bottom of the client list respectively.
- buttons scroll up or down as one client’s information is viewed.

5.5.8 Edit New

Figure 36

With this screen you can input data for a new client before saving the measurement (Figure 36).

Operating from this screen:

- Save saves the patient details and brings you back to Select Patient & Save.
- Select will select the highlighted field. Backspace is an arrow in the top right corner. Space is a bar underneath the keyboard
- Next will select the next details for editing.

- arrows buttons will move the selection of the keyboard one character to the left or right.
- buttons will move the selection of the keyboard one character up or down. When editing the birth date the up and down button will change the numerical value.

5.5.9 View Patients

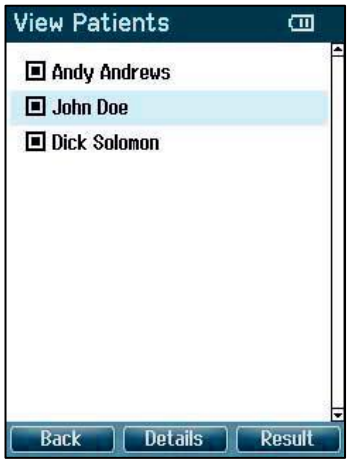


Figure 37

This screen shows a list of clients (Figure 37).

When one or more sessions are stored, the square in front of the patient's name is filled. If a session is not stored yet, this square will be empty.

Operating from this screen:

- Back brings you back to the **Test** screen.
- Details brings you to the **View Details** screen where the data of the selected client is shown.
- Result will bring you to the **View Sessions** screen where the available sessions of the selected client can be reviewed and printed.
- will bring you to the top or bottom of the client list respectively.
- buttons scroll up or down as one client's information is viewed.

5.5.10 View Details

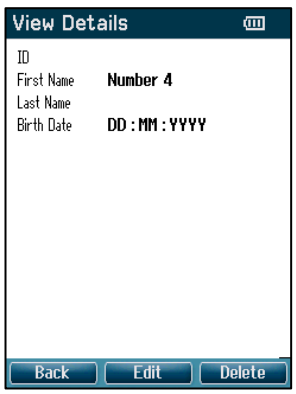


Figure 38

This screen shows demographics of the selected client (Figure 38).

From here you can either use Back to go back to the **View Client** screen or Edit to edit the client details in the **Edit Details** screen.

Delete button will delete either this patient, or all patients.

5.5.11 Edit Details

Figure 39

This screen shows the client ID, First Name, Last Name and Birth Date (Figure 39).

Operating from this screen:

- Back brings you back to the **View Details** screen.
- Select will select the highlighted character and put it where the cursor is placed. Backspace is an arrow in the top right corner. Space is a bar underneath the keyboard
- Next will select the next details for editing.
- ◀ ▶ will move the selection of the keyboard one character to the left or right.
- ▲▼ buttons will move the selection of the keyboard one character up or down. When editing the birth date the up and down button will change the numerical value.

5.5.12 View Results

View Results – select session

Figure 40

For the selected client, the screen shows a list of available sessions (Figure 40).

Operating from this screen:

- Back button brings you back to the **View Patient** screen.
- Delete will prompt you and ask for confirmation before it deletes the selected session or all sessions.
- View will show the selected session in the **View Results** screen (see Figure 39).
- ◀ ▶ buttons will bring you respectively to the top or bottom of the result list.
- ▲▼ buttons scroll up or down one session

View Results – show results

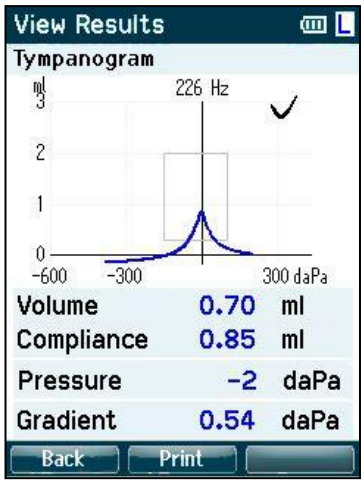


Figure 41

In this screen the test recordings of the selected session are shown (Figure 41).

Operating from this screen:

- Back brings you back to the **View Results** screen.
- Print button will print all results which are stored in the selected session.
- The top right button has no function.
- buttons will show the recordings of the right or left ears respectively, if available.
- buttons scroll through the different tests which are included in the selected session.

5.5.13 Setup

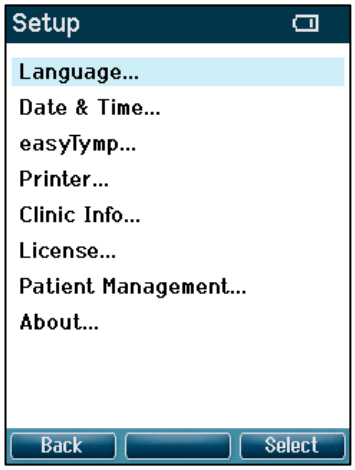


Figure 42

To change the Setup of the easyTymp navigate from Test screen to Select test and then to easyTymp (Figure 42).

Operating from this screen:

- Back brings you back to the **Select** test screen.
- The top middle button has no function.
- Select selects the highlighted setting to be viewed.
- buttons have no function.
- buttons scroll up and down to the next item.

5.5.14 Setup Language

Figure 43

Use right and left arrow keys to adjust language (Figure 43). Available languages are English, German, Spanish, French, Italian, Chinese, Russian, Japanese and Polish.

5.5.15 Setup Date & Time

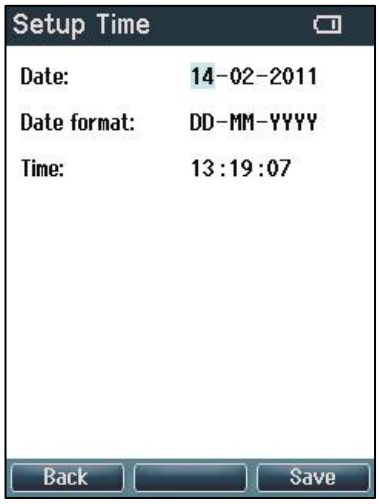


Figure 44

arrow keys will scroll through the options (Figure 44).

buttons adjust Date, Date format and Time.

5.5.16 Setup easyTymp

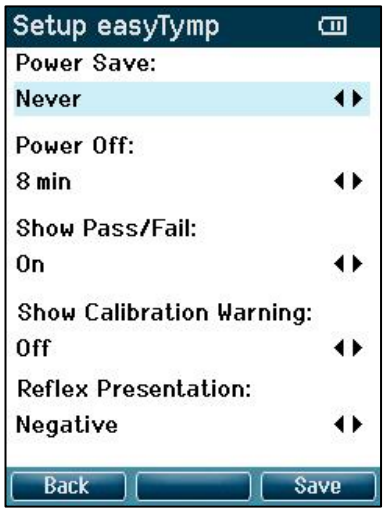


Figure 45

will scroll through the options. buttons to adjust selection (Figure 45).

The **Power Save** can be set to ”Never” or 1, 2, 3, 4 or 5 minutes.

The **Power Off** can be set to “Never” or from 1 to 10 minutes.

Show Pass/Fail: If “On” the test result will display with a Pass / Fail symbol depending on Normative Values defined internally

Show Calibration Warning: When “On”, calibration reminder will display on device, when turned on

Reflex Presentation: Negative or Positive deflection in the graphs

5.5.17 Setup Printer

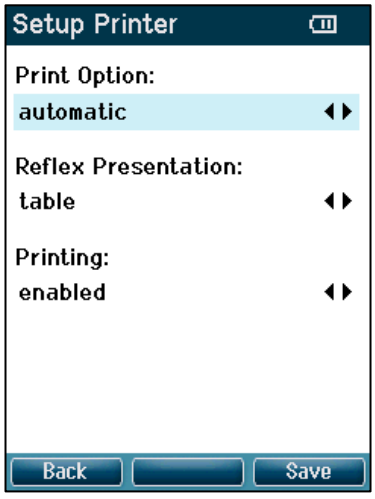


Figure 46

buttons will scroll through the options (Figure 46). buttons to adjust selection.

Print Options: automatic or manual.

Reflex Presentation: table or graph.

Printing: enabled or disabled.

5.5.18 Setup Clinic Info

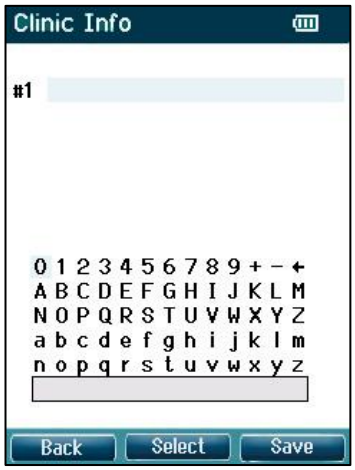


Figure 47

Use Up, Down, Right and Left arrow keys to move the cursor over the keyboard (Figure 47).

Select to select the highlighted character. Backspace is an arrow in the top right corner. Space is a bar underneath the keyboard.

Next to select the next details for editing.

Save to save and return to the **Setup** screen.

5.5.19 Setup License

Figure 48

Option to buy licenses to unlock further measurements (Figure 48):

Select**:** By pressing the Top right button you can select the module to view, add or change the license key.

NOTE: License should be modified by the licensed distributor only.

Figure 49

Use Left, Right, Up and Down arrow keys to move the cursor over the keyboard (Figure 49).

Select**:** The top middle button will select the highlighted character. Backspace is an arrow in the top right corner. Space is a bar underneath the keyboard.

Save**:** The top left button will save and return to the **Setup** screen

5.5.20 Setup Patient Management

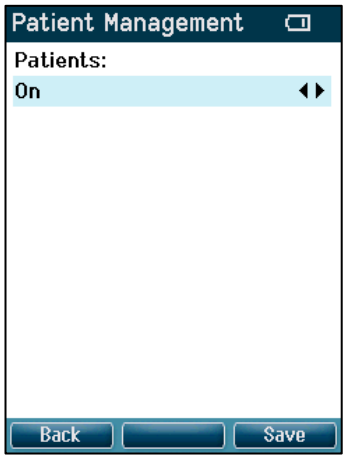


Figure 50

Turns the internal patient data management “on” or “off” (Figure 50).

NOTE: When changing from “On” to “Off”, all measured and/or stored data will be deleted.

5.5.21 About

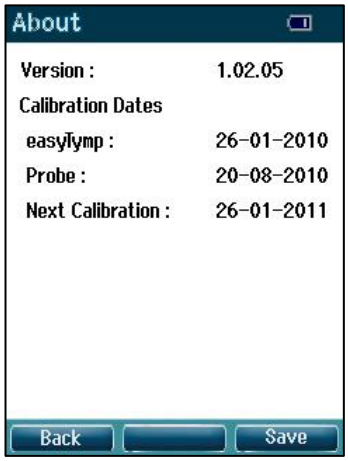


Figure 51

About displays the firmware version and calibration dates (Figure 51).

5.5.22 easyTymp Pro Version: Contra Probe Button

The Contra Probe button will change ears as long as the probe detects it is not in the ear.

When the probe is in an ear it will interrupt the testing and bring you to the **Done!** Screen, and from there also back to the Test screen with a second press of the button. If a protocol includes an instruction message, pressing the Contra Probe button results in continuing the protocol, no matter what the probe status.

5.6 Managing Test Results

5.6.1 General

Dependent on the configuration there are different possibilities to manage test results. It is possible to delete test results, print the session directly with the thermal printer or transfer the data to a PC for further processing.

5.6.2 Deleting Test Results

The procedure of deleting test results depends on whether patient management is active or not.

Deleting Test Results Directly After Testing

Deleting a measurement is possible by pressing the Delete button directly after having finished a measurement and the **Done!** screen is shown. It is possible to delete measurements of one or both ears. See section 5.5.4 for more information.

NOTE: Making a measurement on the same ear without having saved the previous measurement will overwrite the previous test result.

Deleting Test Results in the Patient Management

Using the patient management it is possible to delete either single or all results of a client or one or all clients including test results. See section 5.5.12 on how to delete single or all test results of a client. See section 5.5.10 on how to delete a single or all clients including test results.

NOTE: If the management system is getting activated or deactivated, a message box warns that all measurement data will be deleted. Press Yes to change the setting and delete the data or Back to keep the settings. See also section 5.5.20.

5.6.3 Printing Test Results with the Thermal Printer

Print directly from the **Done!** screen (see section 5.5.4) or after **viewing results** via patient management (see section 5.5.12) by placing the device in the cradle and pressing Print.

If the **Print Option** in the **Setup Printer** is set to **automatic**, the print process starts automatically as soon as the device is placed in the cradle (see section 5.5.17).

5.6.4 Data Transfer Between easyTymp and Impedance Software Module

NOTE: Data transfer between the easyTymp and the Impedance Software Module is only possible, if the patient management system is deactivated. See section 5.5.20 on how to deactivate the patient management system.

It is not possible to transfer data from the patient management system to PC.

To transfer data between easyTymp and the Impedance Software Module, complete the measurement and connect the easyTymp to the PC. Connection is made via the USB cable inserted directly into the USB port on the device or placement of easyTymp in a connected cradle. The transfer process will start automatically.

NOTE: The easyTymp cannot make a measurement if it is connected to the running Impedance Software Module.

See the Software Operation Manual of the Impedance Software Module for more information.

6 Technical Specifications

6.1 Classification according EEC

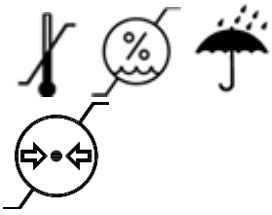
CE 0123

The device is graded as active diagnostic medical product in class IIa, see also rule 10 of the 93/42/EEC (Appendix IX).

6.2 Technical Data

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

Approval of the quality system is made by TÜV – identification no 0123.

Standards:	Safety:	IEC 60601-1, Class II, Type B
	EMC:	IEC 60601-1-2
	Impedance:	IEC 60645-5/ANSI S3.39, Type 2
	Normative Box:	e.g. Appendix A
Power, UE24WCP-240100SPA	Consumption:	0.6 A
	Mains voltages and fuses:	100 – 240 VAC, 50 – 60 Hz
Power, easyTymp	Fuses:	3 A (5 V)
Power, Cradle	Fuses:	3 A (24V)
Environment Conditions: 	Operation	+15 °C … +35 °C / +59 °F … +95 °F Humidity: 30 % … 90 %, non-condensing Air pressure 98 kPa … 104 kPa[1] Maximum altitude: 2000 m / 6561 ft above sea level
	Storage	0 °C … +50 °C / +32 °F … +122 °F Humidity: 10 % … 95 %, non-condensing
	Transport	-20 °C … +50 °C / -4 °F … +122 °F Humidity: 10 % … 95 %, non-condensing

[1] Environment 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.

Dimension and weight	Dimension	W x D x H: 80 x 300 x 70 mm / 3.15” x 11.81” x 2.76”
	Weight	427 g / 1 lb
Warm-up time		less than 10 minutes
Impedance Measuring System		
Probe tone:	Frequency:	226 Hz, 1000 Hz
	Level:	69 dB HL with AGC, assuring constant level at different ear canal volumes.
Air pressure:	Control:	Automatic.
	Indicator:	Measured value is displayed on the graphical display.
	Range:	-400 to +200 daPa.
	Pressure limitation:	-750 daPa and +550 daPa.
Compliance:	Range:	0.1 to 8.0 ml at 226 Hz probe tone (Ear volume: 0.1 to 8.0 ml) and 0.1 to 15 mmho at 1000 Hz probe tone.
Test types:	Tympanometry	Automatic.
Indicators:	Graphical display	Compliance is indicated as ml for 226 Hz and as mmho for 1000 Hz and pressure as daPa. Stimulus level is indicated as dB Hearing Level.
Memory:	Tympanometry:	1 curve per ear, per Tympanometry test. And theoretically an infinite number of tests per protocol.
Reflex Functions		
Signal sources:	Tone - Ipsi, Reflex:	500, 1000, 2000, 4000 Hz, max. 100 dB $_{HL}$.
	Noise - Ipsi, Reflex:	Broad-band noise (BBN)
	Tone - Contra, Reflex:	500, 1000, 2000, 4000 Hz, max. 100 dB $_{HL}$.
	Noise - Contra, Reflex:	Broad-band noise (BBN)
Outputs:	Ipsi Earphone:	Probe earphone incorporated in the probe system for Reflex measurements.
	Contra Earphone:	Probe earphone incorporated in the probe system for Reflex measurements.

	Air:	Connection of the air system to the probe.
Test types:	Automated Reflex	Automatic reflexes: Single intensities Single reflex auto search

Reflex Decay Functions

Test method	Ipsi- and Contralateral	
Test signals:	Pure Tones:	500 Hz, 1000 Hz, 2000 Hz, 4000 Hz each with ± 2%
Test level:	Ipsilateral:	70 to 110 dB HL
	Contralateral:	70 to 120 dB HL
Control Acoustic Reflexes:	Automatic	Single intensities Reflex growth
Time range:	0 to 12 s	
Volume Range:	-0.05 to 0.25 ml	
Graphical display:	y-axis: Volume in ml x-axis:Time in s Level in dB HL	
Ipsi earphone:	Earphone integrated in probe	

ETF – Intact

Same specification as Tympanometry, expect only one test signal (226 Hz).

ETF - perforated

Test signals:	Pure tone: 226 Hz with ± 1 %	
Test level:	85 dB SPL ±1.5 dB measured in an IEC 60318-5 Acoustic coupler. The level is constant for all volumes in the measurement range.	
Distortion:	Max 5 % THD	
Control Tympanometry:	Automatic	
Time range:	0 to 30 sec. (settings)	
Pressure range:	0 to 400 daPa	
Accuracy:	Compliance:	±5% or ±10 daPa, whichever is greater
	Pressure:	±5% or ±0.1 ml, whichever is greater
Graphical display:	x-axis: Time in sec. y-axis: Pressure in daPa	

General

PC connection	USB:	Input/output for computer

		communication.
Memory:		Stores test results for up to 499 patients. The easyTymp hand held unit is delivered with a 8 GB memory card.

Calibration properties

Calibrated transducers:	Probe system:	Ipsilateral and Contralateral Earphone: is integrated in the probe system. Probe frequency transmitter and receiver and pressure transducer is integrated in the probe system.
Accuracy:	General	Generally the instrument is made and calibrated to be within and better than the tolerances required in the specified standards:
	Reflex Frequencies:	±3%
	Ipsilateral Reflex Tone Levels:	±5 dB for 500 to 2000Hz and +5/-10 dB for 3000 to 4000Hz
	Contralateral Reflex Tone Levels:	±5 dB for 500 to 2000Hz and +5/-10 dB for 3000 to 4000Hz
	Pressure measurement:	±5% or ±10 daPa, whichever is greater
	Compliance measurement:	±5% or ±0.1 ml, whichever is greater
Impedance calibration properties		
Probe tone	Frequencies:	226 Hz ± 1%, 1000 Hz ± 1%
	Level:	85 dB SPL ±1.5 dB measured in an IEC 60318-5 Acoustic coupler. The level is constant for all volumes in the measurement range.
	Distortion:	Max 5% THD
Compliance	Range:	0.1 to 8.0 ml
	Temperature dependence:	-0.003 ml/°C
	Pressure dependence:	-0.00020 ml/daPa
	Reflex sensitivity:	0.001 ml is the lowest detectable volume change
	Temporal reflex characteristics:	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%
Pressure	Range:	- 400 to +200 daPa.
	Safety limits:	-750 daPa and +550 daPa, ±50 daPa

Reflex calibration standards and spectral properties:

General	Specifications for stimulus signals are made to follow IEC 60645-5	
Ipsi- and Contra-	Pure tone:	±3 dB
lateral Earphone	Broad-band noise (BBN):	MAICO Standard
	Spectral properties:	As “Broad-band noise” specified in IEC 60645-5, but with 500 Hz as lower cut-off frequency.
	General about levels:	The actual sound pressure level at the eardrum will depend on the volume of the ear.

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

6.3 Connections and Pin Assignment

Inputs	Connector Type	Pin Assignment	
USB	USB Type „B“	USB port for communication	
power	Mains cable	DC socket 24 V/1 A	
Outputs	**Connector Type**	**Pin Assignment**	
USB	USB Type „B“	USB port for communication	
Probe connector	Probe connector, 12-pole	CH1 out CH1 GND DGND GND Microphone Microphone – input / Analog balanced in Microphone + input / Analog balanced in Power supply +3/+5V CH2 out CH2 GND I2C CLK I2C DATA I2C Interrupt	
Data connector	Data connector, 30-pole	STAT2_HH Cradle+5V Cradle+5V Cradle+5V DGND DGND DGND USB+5V USBDP USBDN Temp.bat PRT_BUSY IC33-NO2 PRT_ACK/U2RX TP116 IC33-NO1	TRIGGER-OUT2 RESET# TRIGGER-IN2 KEY_DOWN / POWER ON Vbat PRT_ACK/U2RX Strobe# DATA0 DATA1 DATA2 DATA3 DATA4 DATA5 DATA6 DATA7

6.4 Reference values for stimulus calibration

Table 3

COUPLER TYPES USED BY CALIBRATION

IOW Probe (probe system):	Calibrated using a IEC 60380-5 (2cc) Acoustic coupler made in accordance to MAICO Standard Values
IP30/CIR55 :	Calibrated using a IEC 60380-5 (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

Table 4 Reference Values for Stimulus Calibration

REFERENCE VALUES FOR STIMULUS CALIBRATION			
Frequency [Hz]	**Reference equivalent threshold sound pressure level [RETSPL, dB re. 20 µPa]**		
	IP30/CIR55 ISO 389-2	**DD45 C MAICO Standard Values**	**IOW Probe MAICO Standard Values**
125	26.0	47.5*	41.0*
250	14.0	27.0*	24.5*
500	5.5	13.0*	9.5*
750	2.0	6.5*	9.0*
1000	0.0	6.0*	6.5*
1500	2.0	8.0*	5.0*
2000	3.0	8.0*	12.0*
3000	3.5	8.0*	11.0*
4000	5.5	9.0*	3.5*
6000	2.0	20.5*	3.0*
8000	0.0	12.0*	-5.0*
WB	**-5.0**	**-8.0***	**-5.0***

*All values marked with at star are MAICO Standard Values.

Table 5 Frequencies and Intensity Ranges for Impedance

FREQUENCIES AND MAXIMUM VALUES FOR IMPEDANCE				
Center Frequency [Hz]	**Intensities [dB HL]**			
	IP30	**CIR55**	**DD45 C**	**IOW Probe**
	Tone	**Tone**	**Tone**	**Tone**
125	100	85	80	70
250	110	100	100	85
500	115	110	115	100
750	120	110	120	100
1000	120	115	120	105
1500	120	115	115	110
2000	120	115	115	105
3000	120	115	125	95
4000	120	110	115	100
6000	105	95	110	85
8000	90	80	105	80

6.5 Electromagnetic Compatibility

The device fulfils the relevant EMC requirements. Precautions should be taken to 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.

Portable and mobile RF communications equipment can affect the easyTymp. Install and operate the device according to the EMC information presented in this chapter.

The device has been tested for EMC emissions and immunity as a standalone device. Do not use the device 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 delivered from MAICO, 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 easyTymp is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device 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 device 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 easyTymp.			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device 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 easyTymp is intended for use in the electromagnetic environment specified below. The customer or the user of the device is 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 IEC 61000-4-4	+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 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70% UT (30 % dip in UT) for 25 cycles <5 % UT	Mains power quality should be that of a typical commercial or residential environment. In case of a power failure the device will automatically shut down within 10 s. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device 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: UT is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The easyTymp is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any parts of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device. [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. ANSI/AAMI ES/IEC/EN 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety
2. CAN/CSA-C22.2 No. 60601-1: Medical Electrical Equipment, Part 1 General Requirements for Safety Electrical Equipment for Laboratory Use
3. UL/IEC/EN 60950-1: Information Technology Equipment - Safety - Part 1: General Requirements
4. IEC/EN 60601-1-1 General requirements for safety; Collateral standard: Safety requirements for medical electrical systems
5. IEC/EN 60601-1-2: 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 - Application of risk management to medical devices
7. Essential Requirements of the current European Union Medical Device Directive 93/42/EEC
8. RoHS (Restriction of the use of certain Hazardous Substance)
9. WEEE (Waste Electrical & Electronic Equipment) Legislation

6.7 Test Protocols

NOTE: Test protocols are configuration dependent.

01 226Hz	Tympanometry, Frequency: 226 Hz Earside: Ipsilateral
02 1kHz	Tympanometry, Frequency: 1 kHz Earside: Ipsilateral
03 226Hz + Ipsi Reflex Auto	Tympanometry, Frequency: 226 Hz Number of Reflexes tested = 4, Frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity Reflex Min (Intensity in dB HL) = 70 Intensity Reflex Max (Intensity in dB HL) = 100 Earside: Ipsilateral
04 226Hz + Ipsi Reflex 90dB	Tympanometry, Frequency: 226 Hz Number of Reflexes tested = 4, Frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity Reflex (Intensity in dB HL) = 90 Earside: Ipsilateral
05 1kHz + Ipsi Reflex Auto	Tympanometry, Frequency: 1 kHz Number of Reflexes tested = 4, Frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity Reflex Min (Intensity in dB HL) = 70 Intensity Reflex Max (Intensity in dB HL) = 100 Earside: Ipsilateral
06 1kHz + Ipsi Reflex 80dB BB	Tympanometry, Frequency: 1 kHz Number of Reflexes tested = 1, Test signal: Broad-band noise Intensity Reflex (Intensity in dB HL) = 80 dB Earside: Ipsilateral
07 226Hz + Ipsi-Contra Auto	Tympanometry, Frequency: 226 Hz Number of Reflexes tested = 8, Frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity Reflex Min (Intensity in dB HL) = 70 Intensity Reflex Max (Intensity in dB HL) = 100 Frequency during Reflexes: 226 Hz Earside: Ipsi- and Contralateral

08 226Hz + Ipsi-Contra 90 dB	Tympanometry, Frequency: 226 Hz Number of Reflexes tested = 8, Frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity Reflex (Intensity in dB HL) = 90 Earside: Ipsi- and Contralateral
09 1kHz + Ipsi-Contra Auto	Tympanometry, Frequency: 1 kHz Number of Reflexes tested = 8, Frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity Reflex Min (Intensity in dB HL) = 70 Intensity Reflex Max (Intensity in dB HL) = 100 Earside: Ipsi- and Contralateral
10 1kHz + Ipsi-Contra 80dB BB	Tympanometry, Frequency: 1 kHz Number of Reflexes tested = 2, Test signal: 80 Broad-band noise Intensity Reflex (Intensity in dB HL) = 80 dB Earside: Ipsi- and Contralateral
11 Decay Ipsi	Number of Reflexes tested = 4, Frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity Reflex Min (Intensity in dB HL) = 70 Intensity Reflex Max (Intensity in dB HL) = 100 Duration of Signal: 10 s Earside: Ipsilateral
12 Decay Contra	Number of Reflexes tested = 4, Frequencies: 0.5, 1.0, 2.0, 4.0 kHz Intensity Reflex Min (Intensity in dB HL) = 70 Intensity Reflex Max (Intensity in dB HL) = 100 Duration of Signal: 10 s Earside: Contralateral
13 ETF Intact	Tympanometry, Frequency: 226 Hz Number of Measurements = 3 Earside: Ipsilateral
14 ETF Perforated	Frequency during Testing: 226 Hz Duration of Signal: 30 s Earside: Ipsilateral

7 Appendix

Literature

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