MAICO Diagnostic GmbH

Operating Instructions easyTymp

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Operating Manual
easyTymp

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1 Introduction

Thank you for selecting one of our quality products from the MAICO family range. The easyTymp is designed and manufactured to meet all quality and safety requirements, and has been certified with the CE-symbol according to Medical Directive.

Particular attention has been taken during the designing phase of the easyTymp to ensure its user-friendliness, meaning that its operation is simple, easy to learn and to understand. As all the functions are software-controlled, upgrading the software and/or adding additional functions at a later date will be simple and cost-effective. By purchasing the easyTymp, you have made a decision towards long-term investment.

This operating manual aims to make learning and understanding the different easyTymp functions as quick and as easy as possible. Should you encounter any problems or have ideas for any further improvements, we are only a phone call away. Please do not hesitate to contact us.

Your MAICO-Team

Note:

Although upmost attention has been given to ensure the accuracy of the operating manual, some minor errors may still exist. We do apologize for any inconvenience this may cause.

1.1 Description

The easyTymp is an automatic impedance audiometer, well suited to perform tympanometry and screen acoustic reflexes on people of all ages.

The easyTymp is intended to be used by hearing healthcare professionals (i.e. ENT doctors, audiologists), trained technicians as well as neonatal nurses and school nurses in a quiet environment.

The handheld unit also enables the transfer of data to a PC via USB-connection.

The easyTymp cradle serves as a docking station and recharger. It is available as a version with ear tip box or integrated printer.

1.2 Safety Notes

The easyTymp should always be operated in a quiet room with minimal magnetic influence, to ensure that examinations are not disturbed by external noise.

Electro-medical instruments that emit strong electromagnetic fields (e.g. microwaves, radiotherapy devices) can affect the operation of the easyTymp.

Therefore, the operation of these instruments in close proximity to the easyTymp should be avoided at all times.

The examination room should have a normal temperature between 15˚C/ 59˚F and 35˚C/ 95˚F. If the instrument has cooled down during transportation, please wait for it to warm up to room temperature before operation.

MAICO easyTymp is specified according to EN 60 601-1.
Protection against electrical hazard is guaranteed only when the instrument is connected to a grounded safety. Please note that during operation, the instrument should always be connected to a battery-operated or mains-operated notebook computer that complies with EN 60 601-1 or EN 60 950-1. In the event that a main cable, connector or wall socket is damaged, please do not use the instrument under any circumstance.

Allen key for adjustable feet on the cradle unit:

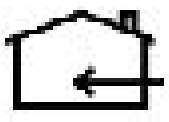
An Allen key is enclosed in the packaging of the ear tip box to enable adjustment of the pair of adjustable feet located on the bottom of the cradle.

Please ensure that the Allen key is not permanently stored in the ear tip box, 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.

Attention
PLEASE READ THE ENTIRE MANUAL CAREFULLY BEFORE OPERATING THIS INSTRUMENT.

Please only use this instrument as described in the manual.

Please familiarize yourself with the instrument and its operation before using.



Should defects or damages be suspected, please do not, under any circumstances, use or attempt to fix the instrument yourself.

To guarantee that the tympanometer works properly, the instrument has to be checked and calibrated at least once a year.

The service and calibration must be performed by an authorized service centre. In accordance with the regulations of the EU medical directive we will drop our liability if these checks are not done.

The use of non-calibrated tympanometers is not allowed.

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

Take note to ensure that all the accessories have been properly connected.

To avoid person-to-person cross contamination of communicable diseases, parts that come in direct contact with the patient (i.e. eartips) should only be used one time.

In accordance with the Electronic Equipment Act for disposal of electronic equipment, the customer is obliged to dispose of the used consumables, according to appropriate regulation at own cost.

2 Impedance measurements

2.1 Tympanometry

Tympanometry is the objective measurement of middle ear mobility (compliance) and pressure within the middle ear system. 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 (+200 daPa) to a negative value (-400 daPa max.).

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 "limits" box is available on both the display and printout to aid in diagnosis.

Compliance is measured with respect to an equivalent volume of air, with the scientific quantity milliliter (ml) for 226 Hz and mmho for 1000 Hz. Air is measured in deca-Pascals (daPa).

NOTE: 1.02 mmH2O = 1.0 daPa.

2.2 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.

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, 1000, 2000 or 4000 Hz are presented as short bursts. If a change in compliance greater than 0.03 ml 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).

3 Getting started

3.1 PC system requirements

Processor: Intel Pentium 4 / Celeron 1.4 GHz
Memory: 1 GB RAM
Graphic display: 1024 x 768
Operating system: Windows XP Professional (SP3), Windows 7, Professional or Ultimate Version for 32 und 64 Bit Computer
Connection: USB 1.1 or higher

3.1.1 Supported Software

MAICO Impedance Software, BDT/GDT, NOAH3

3.2 Unpacking and inspecting

Check the packaging and content for damage

Thoroughly inspect the exterior of the shipping for any sign of damage or tempering. Should any damage be noted, please notify the carrier immediately.

If the content box has been damaged during transportation, the instrument should be checked for any electrical or mechanical defects. Should any defects be identified, please contact the responsible dealer. Keep all original packaging to facilitate any insurance claims against the damages.

Keep the original packaging for future shipment!

The easyTymp is packaged in a specially-designed box. Please keep the box as it will be useful for sending the instrument for the annual instrument check-up, as required by law.

Please contact your nearest responsible dealer should the annual instrument check-up be needed.

Please check that all accessories listed below are received in good condition. If any accessories are missing or damaged, immediately notify your MAICO Special Instrument Distributor

Standard Accessories

easyTymp handheld unit
Probe
Probe Tip (replacement)
1 Rechargeable battery
Power supply unit for easyTymp handheld unit (only when operating without cradle)
Eartip box (configuration see below)
Calibration cavity
Carrying case
Operating manual
Short user guide

Standard probe configuration in Ear tip box:

Eartip flanged 3-5 mm / 10 pieces (red)
Eartip mushroom 7 mm / 10 pieces (blue)
Eartip mushroom 9 mm / 10 pieces (green)
Eartip mushroom 11 mm / 10 pieces (blue)
Eartip mushroom 13 mm / 10 pieces (green)
Eartip mushroom 15 mm / 5 pieces (blue)
Eartip mushroom 19 mm / 5 pieces (yellow)
Eartip umbrella 15 mm / 5 pieces (red)
Eartip umbrella 19 mm / 5 pieces (blue)
MAICO cleaning tool for probe

Additional accessories for easyTymp:

External probe (35cm)
Wall Mount Kit for cradle
License for high frequency probe tone of 1 kHz
Cradle with integrated ear tip box, power supply unit and additional rechargeable battery
Cradle with integrated printer, power supply unit and additional rechargeable battery
Software Kit MAICO Impedance Software

Consumption material

Printer paper

3.2 System installation

3.2.1 Hardware installation

3.2.1.1 Installing the cradle

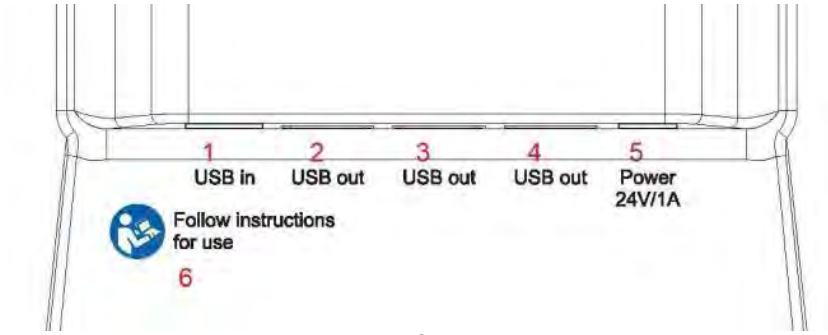


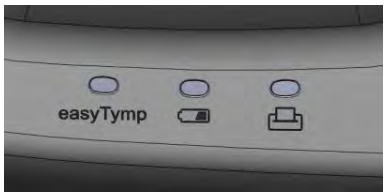
Figure 1 Connectors at the rear bottom of the cradle

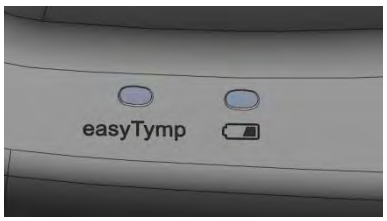
1 = USB in; **2** = USB out; **3** USB out; **4** USB out
5 Power; **6** = Follow the instructions for use

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

3.2.1.2 Cradle indication lights

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





easyTymp LED shows solid blue when the easyTymp is placed inside the cradle and the battery is fully charged. The LED will flash as long as the battery is charging.

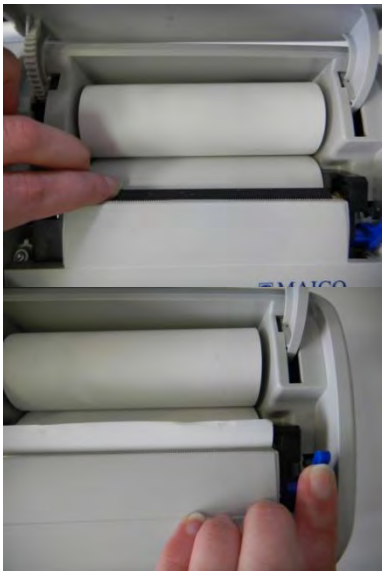
Battery LED shows solid blue when the spare battery in the cradle is fully charged. The LED will flash as long as the battery is charging.

Printer LED is red when a printer problem occurs.

3.2.1.3 Installing paper in the thermal printer

Step 1 - Push button to open the printer cover

Step 2 – Pull blue lever upwards



Insert paper roll in the compartment with its loose end to the front of the printer. Position the loose end into the printer roll and hoist it by rotating the printer roll with your finger

Push blue lever down

Close printer cover

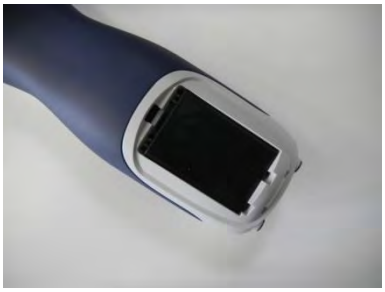
3.2.1.4 Mounting the cradle on the wall

To mount the cradle on the wall is an optional wall mount kit available.

3.2.1.5 Installing the easyTymp

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.

The battery compartment is opened by gently pressing the indentation and pulling the cover downwards.

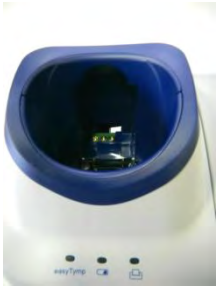


Place the battery inside the compartment. Make sure the battery contacts are correctly placed.

Replace the lid on the easyTymp and push it upwards to close the battery compartment.

If not in operation for longer periods it is recommended to remove the battery from the instrument.

3.2.1.6 Charging the battery



The spare battery is stored in the charger in the back of the cradle. Battery LED shows solid blue when the spare battery in the cradle is fully charged. The LED will flash as long as the battery is charging

Please observe the following precautions
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.

3.2.1.7 Battery lifetime

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

	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 100%
Off	1,5	3,8	2,3	5,7
On (pump off)	2,8	-32	4,1	-47

3.2.1.8 Changing probes

To release the probe press the button at the back and pull the probe out.
Do not pull the cord of the extension cord as this can damage the tubing connections!

Place the probe to the easyTymp by lining up the red triangles and pushing the probe into the unit.

The probe can be attached to the extension cord by lining it up correctly and clicking the probe into the end of the extension cord.

3.2.1.9 Calibration cavities

The easyTymp comes with a separate cavity which can be used for a quick check of the validity of the probe calibration. You can use 0.2 ml, 0.5 ml, 2.0 ml and 5.0 ml cylinders for more extended checks.

To perform this check, select a protocol which measures a tympanogram.

Do not use an ear tip! Place the probe tip completely into the cavity. Perform the measurement. Check the volume which was measured.

The allowed tolerance in the volume measurement is ± 0.1 ml for cavities up to 2 ml and ± 5% for bigger cavities. These tolerances count for all probe tone frequencies.

We strongly recommended calibrating each probe at least once a year. If a probe is handled roughly (e.g. 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.

3.2.2 Optional Software

You can view and store all your measurements also with the MAICO Impedance Software Module.
For installation and functions see the software manual.

3.3 Preparing the test

3.3.1 Patient Instruction

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

The aim of the test is to test the mobility of the eardrum.

The tip of the probe will be inserted into the ear canal, and that it has to make a perfect seal.

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.

Coughing, talking and swallowing will disturb test results.

3.3.2 Visual inspection of the ear canal

Check the external ear canal for wax with an otoscope and remove excessive wax to prevent the probe opening from clogging which will inhibit testing. Excessive hairs may have to be cut.

3.3.3 Handling the eartips

Choose an ear tip of the appropriate size from the ear tip set, depending on the size and shape of the ear canal and ear. Put the ear tip tightly on the probe tip.

Always use eartips from MAICO or Sanibel. Each eartip should only be used one time.

3.4 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 follow the below illustrated instructions on how to remove e.g. cerumen from the small acoustic and air pressure channels of probe tip.

Never clean the probe tip while the tip is still fitted on the probe.

Unscrew the probe cap of the probe by turning counter clock direction.

Take the probe tip out of the probe.

Take the cleaning tool apart to find the thin brush and thin rigid plastic cord.

Use the plastic cord or brush to push contamination out of the probe tip. Always enter the probe tip from the rear to avoid accumulation of contamination inside the vents.

Place the probe tip back onto the probe. Make sure that the different holes fit in the corresponding cavities.

Screw the probe cap back on the probe. Finger force 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.

4 Operating easyTymp

4.1 Operating Panel

Function Keys:
- 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.

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

4.2 Getting started

To get started, take the easyTymp out of the cradle. In default setting it will turn on automatically.

If you don't store the easyTymp in the cradle, press either 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.

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

4.3 Probe status indication

If you use the optional external probe the indication the light at the back of the probe indicates the probe status with following colors:

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 to off – 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.

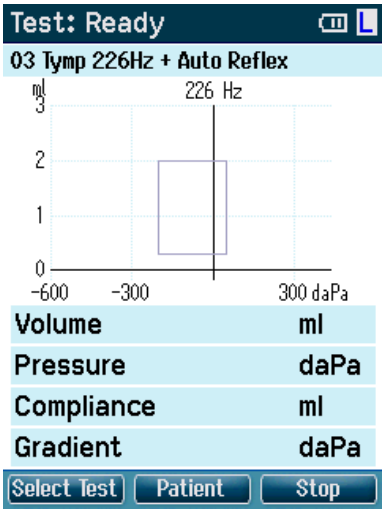
4.4 Operating easyTymp

Operating the easyTymp is very intuitive. After switching on the instrument, 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 you have to select which protocol should be used.

The battery status bar will show, if the battery power runs down. If the battery is empty, you will be warned and the measurement will be stopped and all recorded data will be stored. You will have to shut down and change the battery. The measurement data will be recovered after you start up again. In that way you can continue measurement without retesting.

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

4.4.1 Test



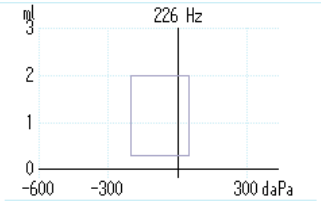
Usually the easyTymp starts with the Test Screen. When deleting or saving data after a measurement, you will also return to this screen. The following information can be viewed in the screen

Test: Ready The header shows the status of the probe, showing **Ready**, **in ear**, **leaking** or **blocked.**

In the top at the right you find status of the battery . When the easyTymp is placed in the cradle, it will charge the battery and it will show a moving, charging battery icon.

In the upper right corner an icon shows if the easyTymp is testing either left ear L or right ear R.

03 Tymp 226Hz + Auto Reflex When entering the Test screen, the second line shows the name of the protocol which is used. As soon as easyTymp detects that the probe is in the ear, the second line will show which test of the protocol is running.



Here you find the graphics of the ongoing test. The box indicates the normative area where the peak of the tympanogram is expected under normal conditions.

Display of the determined measurements:

Volume	ml
Pressure	daPa
Compliance	ml
Gradient	daPa

Operating from this screen:
Putting the probe in an ear will automatically start the test.

Top left button will bring you into the **Select Test** screen from where you can select a different test protocol.

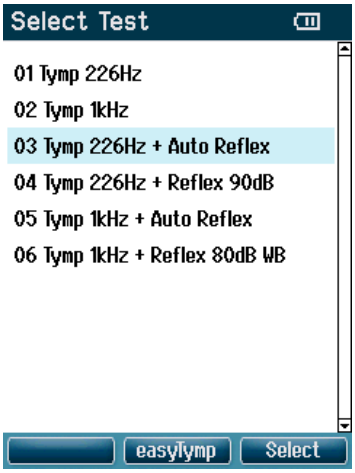
Top middle button will bring you to the **Patient** screen from where patient data can be viewed and changed and earlier sessions can be reviewed and/or printed. This finction is only displayed if the patient management is activated.

Top right button will interrupt the test (**Stop**) and bring you to the Done! screen.

Right and Left buttons 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.

4.4.2 Select Test Screen



Opens screen with available test protocols:

Preset Tymp 226Hz + Auto Reflex

Option: Extra software license for high frequency probe tone of 1kHz.

easyTymp: Leads to the easyTymp Setup
Select: Select a test protocol and return to the test screen

Keyboard operation from this screen:

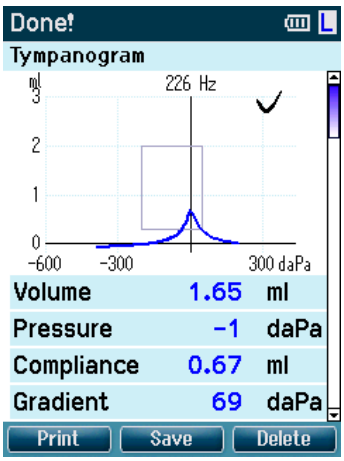
Top middle button brings you to the Setup screen.

Top right button selects the protocol of your choice and brings you to the Test screen.

Right and Left buttons will bring you to respectively the top or bottom of the protocol list.

Up and Down buttons make you move up or down one protocol.

4.4.3 Done



easyTymp will automatically go to the Done screen when it has finished testing.
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 result in printing 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.

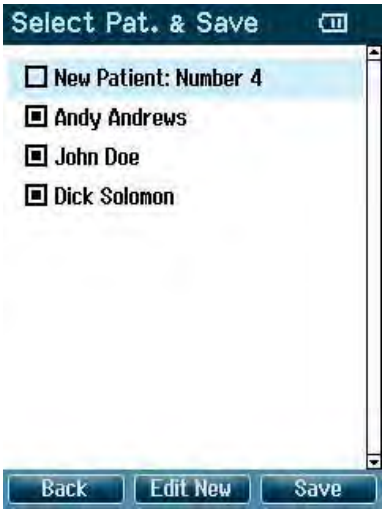
Save: Top middle button will save the measurement of both ears.

Delete: Top right button will pop up a 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 on both ears and bring you back to the Test screen.

Right and Left buttons will select respectively right or left ear for testing and brings you back to the Test screen. The existing data of chosen ear will only be deleted after the probe is detected to be in the ear with a proper seal.

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

4.4.4 Select Patient & Save



From this screen you can either save data to an existing patient who could have been uploaded from your database or save data to a new client. New patient will always get the name "New Patient: Number #", where # stands for the next available number.

Operating from this screen:
Top left button will bring you back to the Done screen without saving and without deleting data.

Top middle button opens a screen for editing new patient details.

Top right button will save the data to the selected client. After saving all data is deleted and easyTymp returns in the Test screen, ready for testing.

Right and Left buttons will bring you to respectively the top or bottom of the client list.

Up and Down buttons make you move up or down one client.

4.4.5 Edit New

With this screen you can put in data to a new client before saving the measurement.

Operating from this screen:

Top left button saves the patients details and brings you back to the Select Patient & Save.

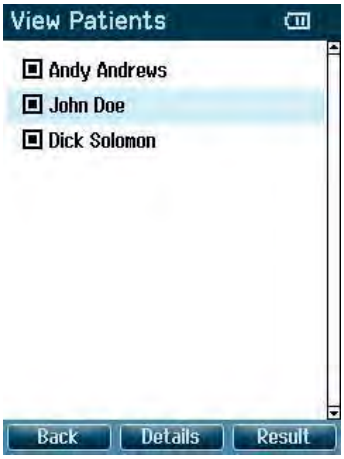
Top middle button will select the highlighted character and put it where the cursor is placed. Backspace is found as an arrow in the top right corner. Space is found as a bar underneath the keyboard

Top right button will select the next details for editing.

Right and Left buttons will move the selection of the keyboard one character to the left or right.

Up and Down 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.

4.4.6 View Patients



This screen shows a list of clients.
Some of the clients might be uploaded from your database. When one or more sessions are stored, the square in front of the patients name is filled. If there is not session stored yet, this square shows empty.

Operating from this screen:
Top left button brings you back to the Test screen.

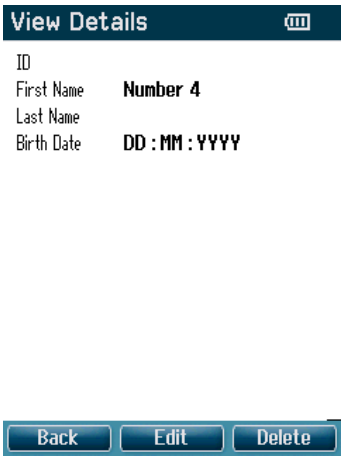
Top middle button brings you to the View Details screen where the data of the selected client are shown.

Top right button will bring you to the View Sessions screen from where the available sessions of the selected client can be reviewed and printed.

Right and Left buttons will bring you to respectively the top or bottom of the client list.

Up and Down buttons make you move up or down one client.

4.4.7 View Details

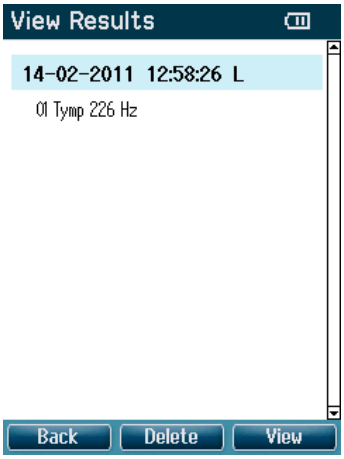


This screen shows some demographics of the selected client.
From here you can either use the Top left button to go back to the View Client screen or use the Top middle button to edit the client details in the Edit Details screen.
With the Top right button you can delete either this patient, or all patients.

4.4.8 Edit Details

This screen shows the client ID, First Name, Last Name and Birth Date.
Top left button brings you back to the View Details screen.
Top middle button will select the highlighted character and put it where the cursor is placed. Backspace is found as an arrow in the top right corner. Space is found as a bar underneath the keyboard. Top right button will select the next details for editing.
Right and Left buttons will move the selection of the keyboard one character to the left or right.
Up and Down 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.

4.4.9 View Results

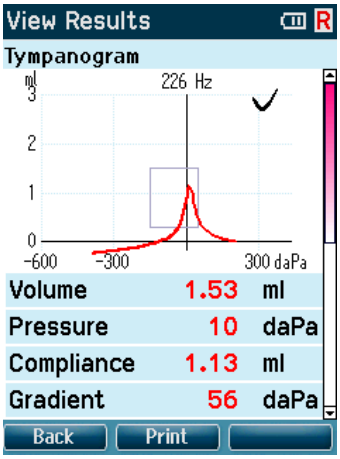


For the selected client, the screen shows a list of available sessions.

Operating from this screen:

Top left brings you back to the View Patient screen.
Top middle button will prompt you and ask for confirmation before it deletes the selected session or all sessions.
Top right button will show the selected session in the View Results screen.
Right and Left buttons will bring you to respectively the top or bottom of the result list.
Up and Down buttons move you up or down one session

4.4.10 View Results

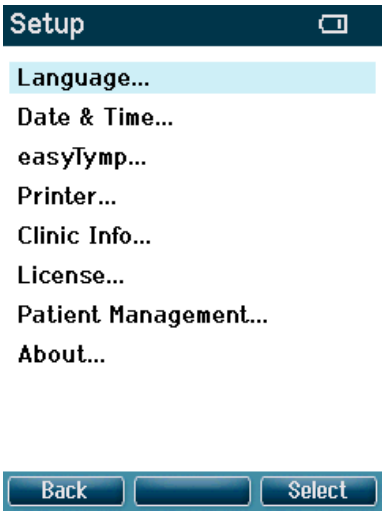


In this screen the test recordings of the selected session are shown

Operating from this screen:

Top left brings you back to the View Results screen.
Top middle button will print all results which are stored in the selected session.
Top right button has no function.
Right and Left buttons will show the recordings of respectively the right or left ear, if available.
Up and Down buttons make you scroll through the different tests which are included in the selected session.

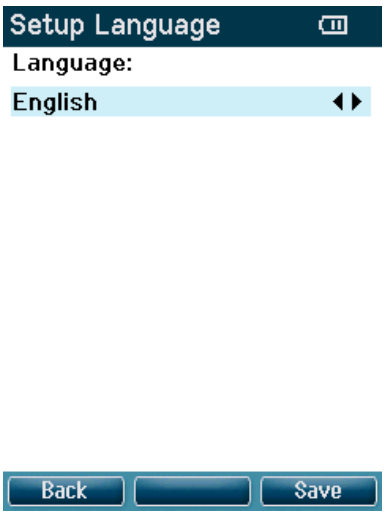
4.5 Setup



To change the Setup of the easyTymp navigate from **Test screen** to **Select test** and then to **easyTymp**.

Operating from this screen:
Top left brings you back to the Select test screen. Top middle button has no function. Top right button selects the highlighted setting to be viewed.
Right and Left buttons have no function.
Up and Down buttons make you move up and down to the next item.

4.5.1 Setup Language

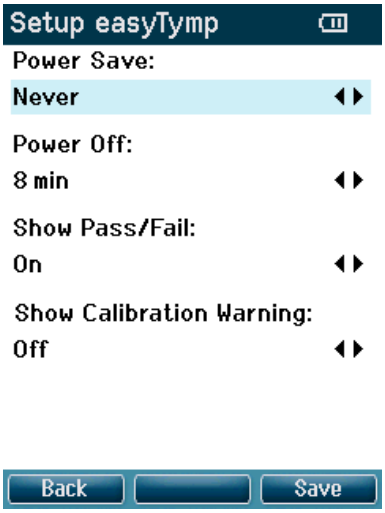


Use right and left arrow keys to adjust language. Available languages are English, German, Spanish, French and Italian.

4.5.2 Setup Date & Time

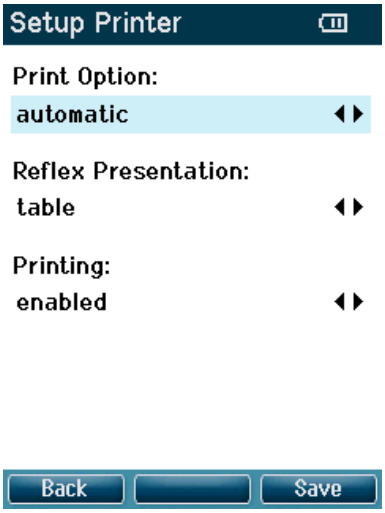
Use right and left arrow keys to go to the next or previous item.
Use Up and Down to adjust Date, Date format and time.

4.5.3 Setup easyTymp



Use Up and Down to go to the next and previous item. Use right and left arrow keys to go to adjust.
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 result with a Pass / Fail symbol
Show Calibration Warning: On - you will be reminded in calibrating the device

4.5.4 Setup Printer

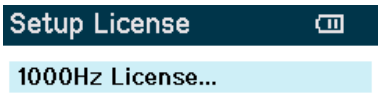


Use Up and Down to go to the next and previous item. Use right and left arrow keys to go to adjust.
Print Options: automatic or manual.
Reflex Presentation table or graph.
Printing: enabled or disabled.

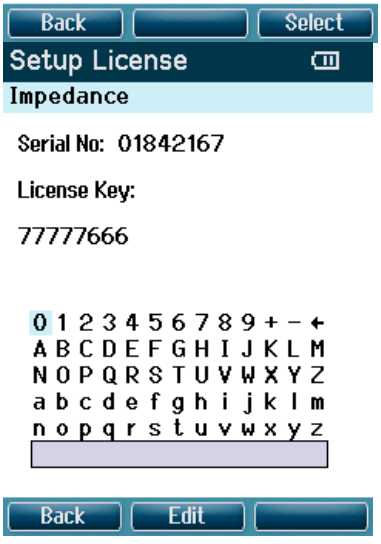
4.5.5 Setup Clinic Info

Use Up, Down, Right and Left arrow keys to move the cursor over the keyboard.
Top middle button will select the highlighted character and put it where the cursor is placed. Backspace is found as an arrow in the top right corner. Space is found as a bar underneath the keyboard. Top right button will select the next details for editing. Top left button to save and return to the Setup screen.

4.5.6 Setup License

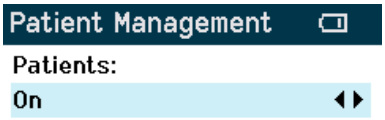


Option: Extra software license for high frequency probe tone of 1 kHz
By pressing the Top right button you can select the module you want to view or change the license key.



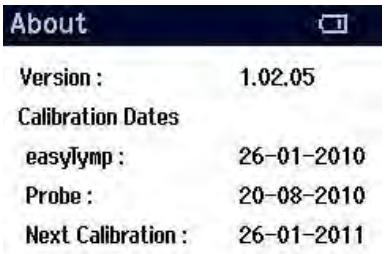
Use Left, Right, Up and Down arrow keys to move the cursor over the keyboard. Top middle button will select the highlighted character and put it where the cursor is placed. Backspace is found as an arrow in the top right corner. Space is found as a bar underneath the keyboard. Top right button will select the next details for editing. Top left button to save and return to the Setup screen

4.5.7 Setup Patient Management



Turns the internal patient data management "on" or "off".
Off will delete all measured data.

4.5.8 About



Here you find information about firmware version and calibration dates.

5 Warranty, Maintenance and Service

The easyTymp is guaranteed for 1 year. 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 one year from date of delivery of the instrument to the original purchaser.

The tympanometer may be repaired only by your dealer or by a service centre recommended by your dealer. We urgently advise you against attempting to rectify any faults yourself or commissioning non-experts to do so.

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

In order to ensure that your instrument works properly the tympanometer should be checked and calibrated at least once a year. This check has to be carried out by your dealer.

When returning the instrument for repairs it is essential to also send the probe and all other accessories.

Send the device to your dealer or to a service centre authorized by your dealer.

Please also include a detailed description of the faults.

In order to prevent damage in transit, please use the original packing if possible when returning the instrument.

6 Disinfection

It is recommended that parts which are in direct contact with the patient are subjected to standard disinfecting procedure between patients. This includes physically cleaning and use of a recognized disinfectant. Individual manufacturer's instruction should be followed for use of this disinfecting agent to provide an appropriated level of cleanliness.

To avoid person-to-person cross contamination of communicable diseases eartips should only be used one time.

7 Safety Regulations

7.1 Electrical safety

The instrument is not to be used in environments dealing with explosive material or equipment. The easyTymp is constructed to comply with protection class I!, Type B of the international standard IEC 601-1 (EN 60601-1).

Protection from an electric shock is ensured even without the system earth connection. The instruments are not intended for operation in areas with an explosion hazard.

7.2 Measurement Safety

To guarantee that the tympanometer works properly, the instrument has to be checked and calibrated at least once a year. The service and calibration must be performed by an authorized service centre. In accordance with the regulations of the EU medical directive we will drop our liability if these checks are not done.

The use of non-calibrated tympanometers is not allowed

7.3 Instrument Handling

The instrument should be checked once a week.

7.4 Operation

The instrument should only be handled and operated by trained personnel (audiologists, ENT doctors or personnel with similar qualifications).

7.5 Patient Safety

Warning: Do not take a test while charging the device via USB cable.

External equipment intended for connection to signal input, signal output or other connector, shall comply with relevant IEC standard (e.g. IEC 60950 for IT equipment and the IEC 60601 series for medical electrical equipment). In addition, all such combinations - systems - shall comply with the standard 60601-1-1, Safety requirements for medical electrical systems. Equipment not complying with IEC 60601 shall be kept outside patient environment, as defined in the standard (at least 1.5 m from the patient).

Any person who connects external equipment to signal input, signal output or other connectors has created a system and is therefore responsible for the system complying with the requirements of IEC 60601-1-1. If in doubt, contact your service technician or local representative for help.

The cradle connection provides power for the thermal printer.
In order to maintain a high level of safety it is necessary to have the instrument and its power supply checked according to the medical electrical safety standard IEC 60601-1 on a yearly basis by a qualified service technician.

8 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.

Medical CE-mark		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 1
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)
Operation environment:	**Temperature:**	15 – 35 °C
	Rel. Humidity:	30 – 90%
Storing/handling:		Temperatures below 0°C and above 50°C may cause permanent damage on the instrument and its accessories.
Transport:	**Temperature:**	-20 – 50 °C
	Rel. Humidity:	10 – 95%
Dimension and weight	**Dimension**	W x D x H: 80 x 300 x 70 mm
	Weight	427 g

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:	Wide Band,
Outputs:	**Ipsi 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

General

PC connection	**USB:**	Input/output for computer communication.
Memory:		Theoretically an infinite amount of test results can be stored on the PC. The easyTymp hand held unit is delivered with a 2 Gb memory card, enough for storing more than a quarter of a million tests.

Specification of output connections

Outputs:

Transducer	proprietary, 12-pole	Pin 1:	CH1 out
		Pin 2:	CH1 GND
		Pin 3:	DGND
		Pin 4:	GND A / GND Microphone
		Pin 5:	Microphone – input / Analog balanced in
		Pin 6:	Microphone + input / Analog balanced in
		Pin 7:	Power supply +3/+5V
		Pin 8:	CH2 out
		Pin 9:	CH2 GND
		Pin 10:	I2C CLK
		Pin 11:	I2C DATA
		Pin 12:	I2C Interrupt
USB	USB type"B"	USB port for communication	

Calibration properties

Calibrated Transducers:	Probe system:	Ipsilateral 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
	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	
Ipsilateral Earphone	Pure tone:	MAICO Standard.
	Wide Band noise (WB):	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. See Table 2 for details.

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

Table 2: Reference values for stimulus calibration

Freq.	Reference values for stimulus calibration [dB re. 20 µPa]		Variation of Ipsi stimulus levels for different volumes of the ear canal Relative to the calibration performed on an IEC 126 coupler [dB]	
	ISO 389-2	**ISO 389-4 (ISO 8798)**	**0.5 ml**	**1 ml**
[Hz]	**IPSI** CIR55	**IPSI** CIR55**I**		
125	26			
250	14			
500	5.5		9.7	5.3
1000	0		9.7	5.3
1500	2.0			
2000	3.0		11.7	3.9
3000	3.5		-0.8	-0.5
4000	5.5		-1.6	-0.8
6000	2.0			
8000	0			
WB		-5.0	7.5	3.2

Coupler types used by calibration

Probe tone is calibrated using a 2cc acoustic coupler made in accordance to IEC 60318-5

Specifications are subject to change

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