

Operation Manual

Hand Held Impedance Audiometer MT10



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Introduction

Intended Use

The MT10 is a handheld tympanometer offering tympanometry, Ipsilateral reflex testing and a simple screener for audiometry. The MT10 allows storing of data by printing (optional printer) or by transferring data to a computer (optional software module).

The MT10 tympanometer is intended to be used by an audiologist, hearing healthcare professional, or trained technician in a quiet environment (tympanometry and reflexes) and extremely quiet environment (Audiometry). Careful handling of instrument whenever in contact with patient should be of high priority. Calm and stable positioning while testing is preferred for optimal accuracy. It is recommended that the instrument be operated within an ambient temperature range of 15-35 degree Celsius (59-95 degrees Fahrenheit).

Precautions

Notice - Be sure to insert the probe tip in a way which will assure an air tight fit without causing any harm to the patient. Using a proper and clean ear tip is mandatory.

Notice - We recommend using a new ear tip for each patient. If the clinician rinses the ear tips they should be subjected to standard disinfecting procedure between patients. This includes physically cleaning the ear tip and use of a recognised disinfectant. Individual manufacturer's instruction should be followed for use of this disinfecting agent to provide an appropriated level of cleanliness.

Notice - Be sure to use only stimulation intensities acceptable for the patient.

Notice - The transducers (headphones, bone conductor, etc.) supplied with the instrument are calibrated to this instrument - exchange of transducers requires a re-calibration.



If this apparatus is connected to one or more other devices with medical CE marking, to make up a system or pack, the CE marking is only valid also for the combination if the supplier has issued a declaration stating that the requirements in the Medical Device Directive article 12 are fulfilled for the combination.

Notice - Never clean the transducer housing with water or insertion instruments.

Notice - Do not insert or in any way try to conduct measurements without proper probe eartip in place.

Notice - Although the instrument 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.



Notice - Within the European Union it is illegal to dispose electric and electronic waste as unsorted municipal waste. Electric and electronic waste may contain hazardous substances and therefore has to be collected separately. Such products will be marked with the crossed-out wheeled bin shown below. The cooperation of the user is important in order to ensure a high level of reuse and recycling of electric and electronic waste. Failing to recycle such waste products in an appropriate way may endanger the environment and consequently the health of human beings.

Disposal of batteries must be made according to national regulations.

General Theory of Impedance Measurements

To understand impedance measuring from a popular point of view it is sufficient to know that a sound of 226 Hz, presented into a cavity like the human ear will produce different SPLs depending on the volume of the cavity. By measuring changes in the SPL, equivalent volume changes can be established.

Presenting a high positive or negative air pressure to the outer ear canal will stiffen the tympanic membrane, thus creating a cavity acoustically consisting of only the outer ear canal. In this way the equivalent volume of the outer ear canal can be established.

By gradually varying the air pressure from a positive pressure to a negative the tympanic membrane and the attached ossicular chain will gradually become more and more mobile, showing more compliance to the sound pressure waves. The sound passage to the middle ear will then be less and less reduced or impeded by the tympanic membrane, and the impedance is said to be lower. The lowest impedance will be obtained when the air pressure is equal on both sides of the tympanic membrane, thus showing the highest compliance to the sound waves. In this state, the cavity responding to the introduced sound will be comprised of the outer ear canal as well as the middle ear. This will reveal the total equivalent volume of the outer- and middle ear.

The equivalent volume of the middle ear, also called the compliance, is easily derived by subtracting the two volume measurements above. This is done automatically on the MT10 and the result is presented as "Compliance", measured in ml.

The impedance curve, drawn by a gradual sweep across a wide pressure range, can reveal a great deal of information about the state of the middle ear, the tympanic membrane, and the ossicular chain.

The above principle for measuring the stiffness of the tympanic membrane can also be used to detect tympanic membrane stiffness, caused by contraction of the middle ear muscles. This is usually

referred to as the "Stapedius Reflex". The normal ear will, when subjected to loud signals, reflexively contract the Stapedius muscle (and in some cases the tensor tympani muscle). This will immobilise the tympanic membrane somewhat and this change of impedance is detectable as explained above and a reflex recording of the impedance change can be presented. Such a reflex is called a Stapedius reflex, as the Stapedius muscle contraction is the dominant factor in creating this impedance change. Reflex measurements are normally carried out with air pressure in the outer ear canal set for maximum compliance.

This Stapedius reflex can be elicited both ipsilateral and contralateral, and has great diagnostic value. Together with the impedance curve measurement the integrity of the complete middle ear system can be evaluated.

Understanding Tympanograms

General Considerations:

A given curve drawn in a co-ordinate system will always have its shape dictated by the vertical and horizontal graduations. The printout of the MT10 complies with the international standards in this respect, and therefore may not produce tympanogram shapes directly comparable to other instruments if these do not meet the standard requirements.

The Peak:

The peak of the tympanogram will horizontally be placed at the air pressure of the middle ear, as equal pressures on both sides of the tympanic membrane produces the highest compliance of the system. A slight deviation of the peak in the direction of the air pressure sweep may be experienced, due to an inherent hysteresis of the middle ear and the test equipment. A slower sweep speed may diminish the offset.

The Height:

The height of the tympanogram from its more or less horizontal bottom line (measurements made from start

pressure) to the top shows the difference in compliance between stiffened tympanic membrane and max. compliance. This difference is referred to as "compliance" and is a measure for the equivalent volume of the middle ear.

Equivalent Volume:

The term "Equivalent Volume", in which compliance is measured, should be understood clearly in order to avoid misinterpretation of test results. The unit of measurement is cm^3 (or ml.) but this does not mean that e.g. the middle ear has this exact internal volume. It means that the middle ear, as seen from the outer surface of the tympanic membrane, reacts the same way as a hard walled cavity of this exact volume would react.

Compared to a hard walled cavity a normal middle ear incorporates at least three major differences. One is friction due to the ligaments connected to the ossicles (resistance). The second is stiffness caused by the elastic qualities of the eardrum and the enclosed air and by a fluid pressure from the inner ear exerted on the stapes (stiffness reactance). The third is the mass of the eardrum and the ossicles (mass reactance).

At 226 Hz the stiffness component is by far the most dominant factor and is therefore the subject of measurement.

The Shape:

The shape of the tymp curve will change when the stiffness of the system is changed (e.g. by ossicular chain disruption, otitis media, etc.), and this is a primary reason for the diagnostic value of this measurement. However, normal ears show a great variety of tymp shapes so this should never be taken as the only basis for making a diagnosis. Furthermore, two different abnormalities may have opposing effects, resulting in a normal shape of the tymp curve.

Classification of Tympanograms

Tympanograms can be classified according to compliance (height, measured in ml. or cm^3), pressure at compliance maximum (measured in daPa), rate of compliance change (gradient in %), and shape. Please refer to the chapter "Examples of Interpretations" in this manual for illustrations of the classic curve categories, and the names given to them by Liden and Jerger. On the following pages a more detailed description of each category is presented.

Type "A" characteristics:

The tymp curve shows a clear compliance peak within the pressure range of ± 50 daPa for adults. For children the middle ear pressure may be considered normal down to -150 daPa negative pressure.

Normal ears often show type "A" tympanograms.

Type "A_D" characteristics:

The type A_D tympanogram is essentially a type A tympanogram in which the curve is very high and may be outside the range of the instrument / recording chart. Peak is within the pressure range of type A of ± 50 daPa. The very mobile eardrum can reproduce various curves.

It can represent ossicular discontinuity, flaccid eardrum or a combination of both. Peaking and notching outside the test range is possible. **Note:** The type A_D curve may reveal itself as being a type D curve, if a higher probe tone, e.g. 800 Hz, is used.

Type "A_s" characteristics:

The type A_s tympanogram is essentially a type A tympanogram in which the curve is much shallower than usual. Peak is within the pressure range of type A of ± 50 daPa. For children the middle ear pressure may be acceptable down to -150 daPa negative pressure. The pathology could be immobile stapes due to otosclerosis (no reflexes), some form of otitis media, thick or scarred eardrum, or just a normal variant. Infants' ears may show this small compliance.

Type "B" characteristics:

Low compliance without peak identification. Middle ear pressure is unknown, probably negative. The type "B" is flat, going slightly upwards by negative pressure. It may be associated with ears having extremely stiffened middle ear systems. Indication of fluid (serous or adhesive otitis media), retracted eardrum, blockage of the external ear canal, or perforated eardrum e.g. with drainage tube. **Note:** Ears with type B tympanograms should be tested for peak identification down to -600 daPa.

Type "C" characteristics:

Normal compliance peak with peak identification in the negative pressure range, e.g. below -50 daPa for adults (Bluestone), and below -150 daPa for infants (Liden). The type C curve shows all the characteristics of normal type A, A_D and A_S curves.

The type C curve indicates poor Eustachian tube function with possible developing or resolving middle ear effusion.

Type "D" characteristics:

Depicted by a deep curve with a small notch at the peak. Middle ear pressure ± 100 daPa. This curve does not necessarily indicate a pathological ear. Healed perforation of tympanic membrane, fixation of parts of the bones after ossicular discontinuity, flaccid eardrum with ear wax, or maybe a ventilation tube blocked with ear wax and healed middle ear, can cause peaking and notching, resulting in many shapes at the top of the maximum compliance curve. The curve could also be a narrow type E (W shaped) tympanogram. **Note:** May be better detected with an 800 Hz probe tone.

Type "E" characteristics:

Depicted by a broad, deep, often multiple notching. "W" shaped. This tympanogram is usually caused by ossicular discontinuity, but may also indicate restored ossicular chain one year or more after stapedectomy. **Note:** May be better detected with an 800 Hz probe.

Interpretation of Test Results

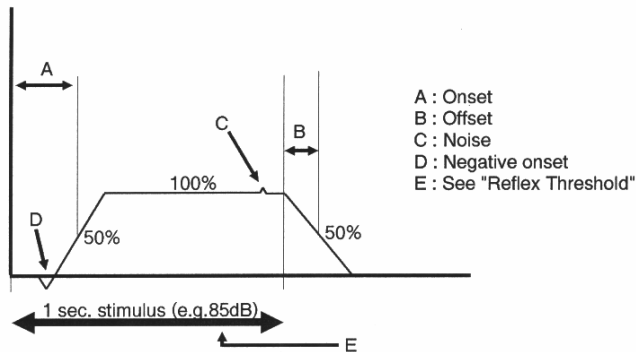
Tympanometric Curves And Pathologies - According to Feldmann -

Peak Pressure			
Negative Pressure:	Normal Pressure:	Positive Pressure:	Absence of Pressure Peak:
<ol style="list-style-type: none"> 1) Blocked Eustachian tube 2) Serous otitis media 	<ol style="list-style-type: none"> 1) Ossicular bone fixation 2) Adhesive fixation 3) Ossicular discontinuity 4) Middle ear tumour 5) Eardrum abnormality 	<ol style="list-style-type: none"> 1) Early acute otitis media 	<ol style="list-style-type: none"> 1) Middle ear effusion 2) Open tympanic membrane 3) Artifact

Amplitude		
Increased Amplitude:	Decreased Amplitude:	Unchanged Amplitude:
<ol style="list-style-type: none"> 1) Eardrum abnormality 2) Ossicular discontinuity 	<ol style="list-style-type: none"> 1) Ossicular fixation bony or adhesive 2) Serous otitis media 3) Cholesteatoma, polyps, granuloma 4) Glomus tumours 	<ol style="list-style-type: none"> 1) Blocked Eustachian tube 2) Early acute otitis media

Shape		
.....Slopes.....		Smoothness:
Decreased / Flattened slope:	Increased slope:	Altered smoothness:
<ol style="list-style-type: none"> 1) Serous otitis 2) Ossicular fixation 3) Tumours of middle ear 	<ol style="list-style-type: none"> 1) Eardrum abnormality 2) Ossicular discontinuity 	<ol style="list-style-type: none"> 1) Eardrum abnormality 2) Ossicular discontinuity 3) Vascular tumours 4) Patulous Eustachian tube

Reflex Interpretation



Onset and Offset:

As judged on the normal reflex these measurements have little or no diagnostic value (See Decay Test). The attention should be drawn to the fact that instrument variation exists in these parameters. Roughly, it can be said that the more steep the onset and offset slopes, the faster is the instrument. Especially older instruments had rather flat slopes.

Noise:

Acoustical signals showing up in the reflex recording, yet irrelevant to the Stapedius reflex. As the reflex measurements are based on observing the change in sound intensity of a 226 Hz tone, as explained in "Popular Introduction to Impedance", it is possible that environmental noise of this frequency entering the ear will show up as part of the test result. This is a problem inherent to the measuring method and therefore common to all normal impedance meters. Heart beat, talking and external noises are common causes of noise peaks seen on the reflex curve.

A negative reflex may occur due to the following interference of noise: Prior to recording the reflex activity an acoustic reference level is measured in the ear canal without any Stapedius activity. The difference between this

reference level and the level present when the Stapedius muscle is active is recorded as a reflex. If, however, external noise was entering the ear only during reference level measurement, and not during reflex measurement, the level may actually be lower during the reflex, thus resulting in a negative reflex. This is of course not a valid measurement. The negative reflex is an extreme situation, but noise will always distort the measurements to a certain degree and should therefore be avoided.

Negative Onset:

It is quite common to see reflexes start out with a small negative deflecting dip. In ears with stapedial otosclerosis this dip with an additional dip at the end of the stimulation can be the only reaction left from the contraction of the Stapedius muscle. Some tumour ears have been reported to give only the negative onset, but no further reaction.

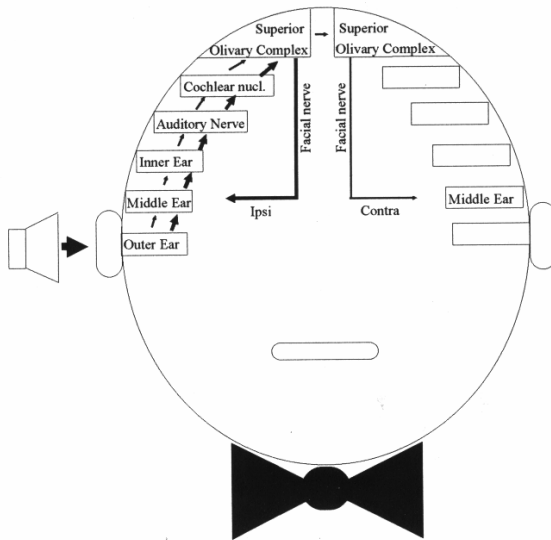
Reflex Threshold:

For a given stimulus the lowest level that elicits a detectable reflex. This is not an absolute measurement as no exhausting norm exists defining stimuli and related reflex characteristics. Therefore, differences in test setups and reflex evaluation will produce somewhat different results. It is not uncommon to report the reflex threshold as the intensity which produces a 1% or 2% change in equivalent volume (Test "A" with 2% sensitivity).

It should be noted that a visual examining of reflex test might reveal some Stapedius muscle action, also at slightly lower stimulus intensities. This procedure (see "Example of Popular Fixed Intensity Reflex Test") is recommended for establishing the absolute reflex threshold.

Generally, noise stimuli elicit reflexes at lower levels than pure tones do.

Pathways For The Stapedius Reflexes



The Nature of the Reflex:

The Stapedius muscle reflex is elicited binaurally via monaural stimulation (Ipsilateral stimulation via the impedance probe - contralateral stimulation via the headphone). The average reflex threshold is 85 dB HL (70 dB - 100 dB) for normal ears of 20 year old patients when pure tones are used as stimulus.

Noise as stimulus produces a threshold approx. 10-20 dB lower as noise is made out of many simultaneous tones together carrying more energy. Increased stimulation level will produce a stronger reflex. Cochlear and retrocochlear pathology may show less rapid growth of reflex amplitude versus stimulation amplitude.

Primarily, a reflex test shall answer these questions:

- Is the reflex absent or present?
- If present, is it present both contralateral and ipsilateral?
- What is the threshold of the reflex?

If the test shows normal reflex thresholds and a normal tympanogram is present, the middle ear will usually be classified as healthy. One exception, though, is the early stage of otosclerosis.

Eustachian Tube Test Interpretation

MiniTym

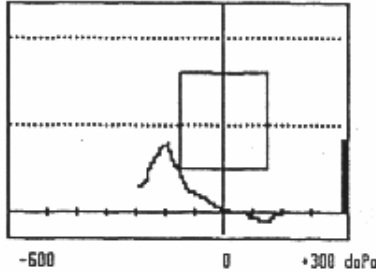
Date

No. 14

Name _____

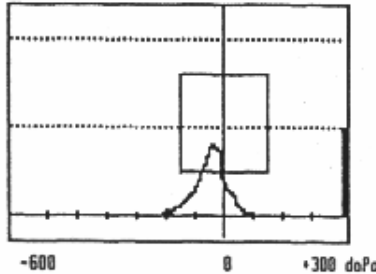
TYMPANOGRAM

RIGHT



C 0.81 ml
 V 0.86 ml
 G 0.30 ml
 P -190 daPa

LEFT



C 0.80 ml
 V 1.03 ml
 G 0.30 ml
 P -46 daPa

If it is possible for the patient to press air through the Eustachian tube a new tympanogram recorded will be located at a different horizontal place in the co-ordinate system of the tympanometry test. This indicates a functioning Eustachian tube.

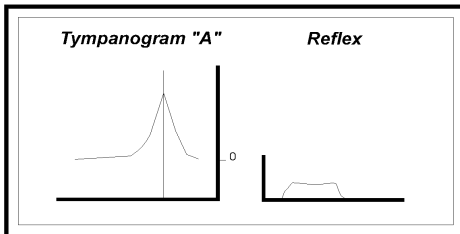
In the above example it has been possible for the patient to change his middle ear pressure between the two tests, indicating function of the Eustachian tube.

Examples Of Interpretation

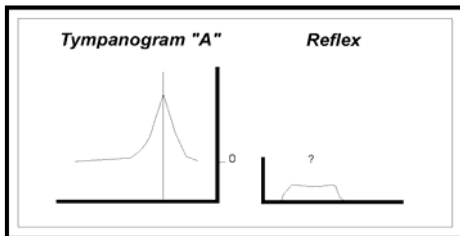
In the following, some typical compliance curves, reflex curves and the possibly associated pathology are shown. The curves are idealised and only one expected pathology is described for each combination of tympanogram and reflex.

A combination of variables always has to be taken into consideration. E.g. the combination of a stiff middle ear system and a floppy eardrum may result in a tympanogram falling within the normal category. The interpretations stated here are generalised examples taken from the currently available literature and they can, of course, vary with each individual case.

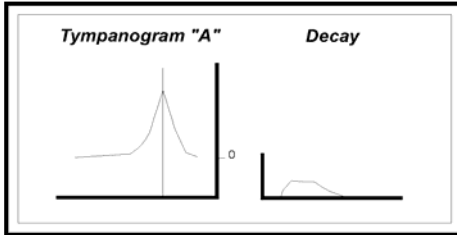
The diagnostic value of tympanograms showing a "D" or "E" shape is reduced today. A probe tone higher than 226 Hz has been preferred for these particular tympanograms.



Pathology : Normal ear.
Volume : Normal.
Pressure : -100 daPa to +100 daPa.
Ventilation : Present.
Reflex : Present.
Audiogram : No hearing loss.

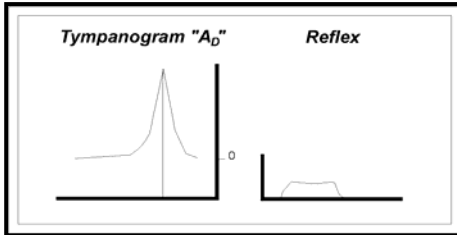


Pathology : Cochlea lesion.
Volume : Normal.
Pressure : -100 daPa to +100 daPa.
Ventilation : Present.
Reflex : Present or absent.
Audiogram : Sensory neural hearing loss.



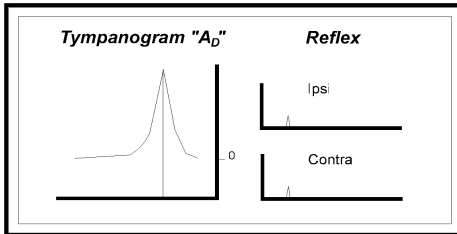
Pathology : Retrocochlear lesion.

Volume : Normal.
 Pressure : -100 daPa to +100 daPa.
 Ventilation : Present.
 Reflex : (Abnormal Decay.)
 Audiogram : Sensory neural hearing loss (May be unilateral).



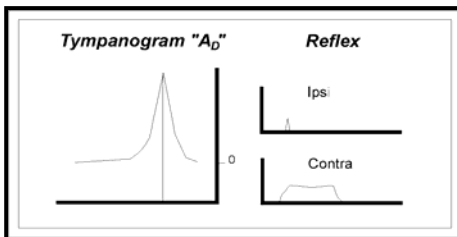
Pathology : Supranormal eardrum (floppy) or atrophic / scarred eardrum.

Volume : Normal.
 Pressure : -100 daPa to +100 daPa.
 Ventilation : Present.
 Reflex : Present.
 Audiogram : Normal.



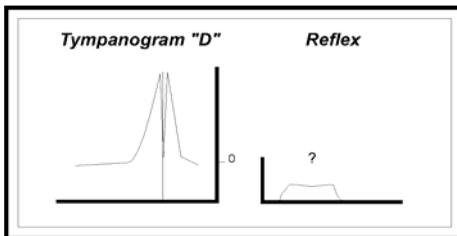
Pathology : Disrupted ossicular chain peripheral to stapes muscle attachment.

Volume : Normal.
 Pressure : -100 daPa to +100 daPa.
 Ventilation : Present.
 Reflex : Absent.
 Audiogram : Conductive loss.



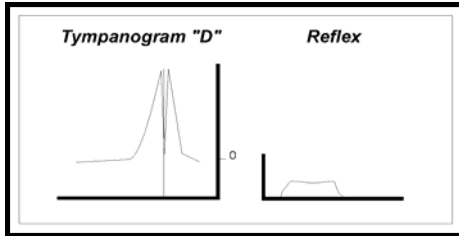
Pathology : Disrupted ossicular chain medial to stapes muscle attachment.

Volume : Normal.
 Pressure : -100 daPa to +100 daPa.
 Ventilation : Present.
 Reflex : Absent (Present by contralateral stimulation).
 Audiogram : Conductive loss.



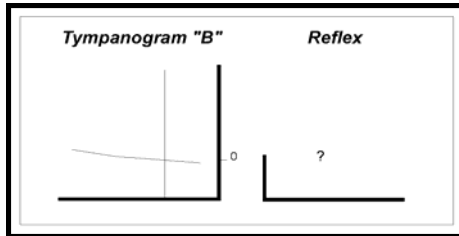
Pathology : Disruption of ossicular chain with bones fixated to the tympanic membrane, resonating. Supranormal eardrum (floppy).

Volume : Normal.
 Pressure : -100 daPa to +100 daPa.
 Ventilation : Present.
 Reflex : Absent / Present.
 Audiogram : Conductive loss.



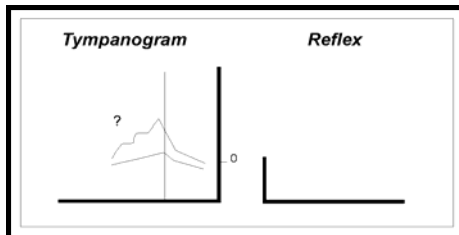
Pathology : Scarred and healed (abnormal) eardrum.

Volume : Normal.
 Pressure : -100 daPa to +100 daPa.
 Ventilation : Present.
 Reflex : Present.
 Audiogram : Normal.



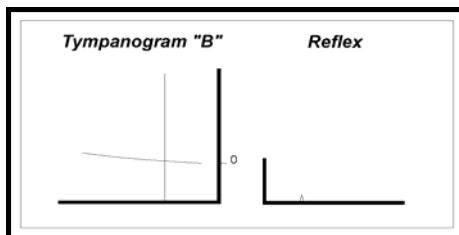
Pathology : Fluid in the middle ear, or serous otitis media.

Volume : Normal.
 Pressure : Peak not obtainable.
 Ventilation : -
 Reflex : Absent or elevated (rare).
 Audiogram : Mild to moderate conductive loss.



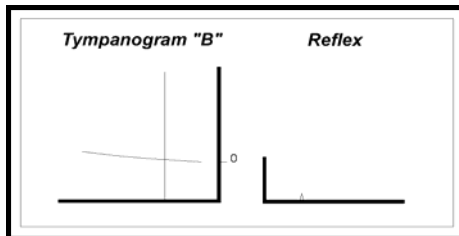
Pathology : Ear wax in the external ear canal (Obturing cerumen).

Volume : Low
 Pressure : Normal.
 Ventilation : -
 Reflex : Absent.
 Audiogram : Mild to moderate conductive loss.



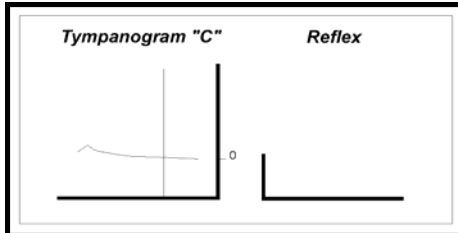
Pathology : Perforated tympanic membrane - defect or ventilated tympanotomy. Traumatic rupture.

Volume : Normal / High
 Pressure : Not obtainable.
 Ventilation : -
 Reflex : Absent (peaks).
 Audiogram : Mild to moderate conductive loss (20 dB).



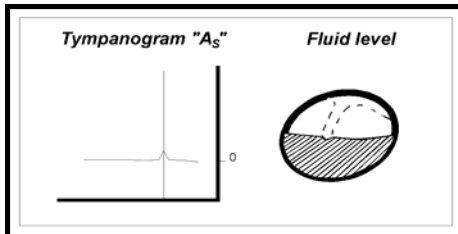
Pathology : Otosclerosis or stapes fixation.

Volume : Normal.
 Pressure : -100 daPa to +100 daPa.
 Ventilation : Present.
 Reflex : Absent or elevated (rare).
 Audiogram : Moderate conductive loss.



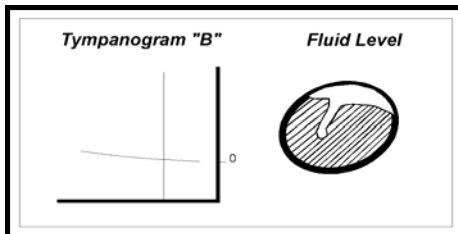
Pathology : **Adhesive otitis media. Adhesive ossicular fixation (glue ear).**

Volume : Normal.
 Pressure : Negative / moderate.
 Ventilation : -
 Reflex : Absent.
 Audiogram : Moderate conductive loss.



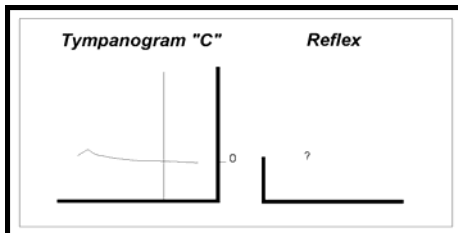
Pathology : **Moderate fluid in the middle ear.**

Volume : Normal.
 Pressure : Negative / negative.
 Ventilation : -
 Reflex : -
 Audiogram : Mild conductive loss.



Pathology : **Impact fluid in the middle ear.**

Volume : Normal.
 Pressure : Not obtainable.
 Ventilation : -
 Reflex : Absent.
 Audiogram : Moderate conductive loss.



Pathology : **Blockage of Eustachian tube; fluid in the middle ear may be present.**

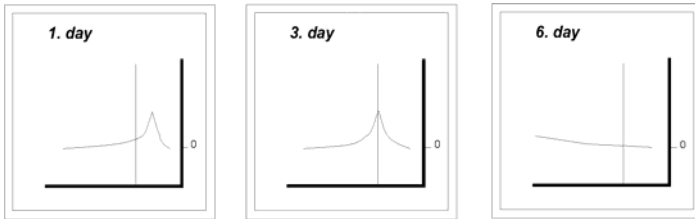
Volume : Normal.
 Pressure : Negative.
 Ventilation : Absent or poor
 Reflex : Absent or elevated (rare).
 Audiogram : Mild to moderate conductive loss.

Pathology: Acute Serous Otitis Media:

Positive middle ear pressure is rarely observed in tympanometry. Usually it is a consequence of sneezing or valsalvation.

One pathological condition that may cause positive pressure in the middle ear is acute serous otitis media in the early stage.

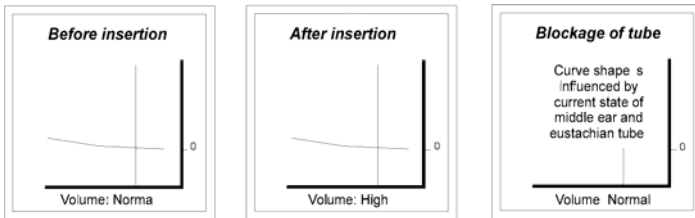
A typical acute serous otitis media may develop according to the tympanograms outlined below:



Status of middle ear drainage tubes:

Otoscopic or "visual" inspection of the drainage tube is difficult, as it can easily be blocked from the inside.

All three situations below will result in a mild conductive loss.



Preparing The Test

Charging before operation for the first time:

Before the MT10 is taken into use for the very first time its batteries should be charged twice. First, insert the batteries into the MT10 and place the instrument in the desk unit or in the printer unit MTP10. After three hours of charging the MT10 should be lifted from the desk unit or MTP10 and be put back again after app. 2-3 sec in order to start another charging period of three hours. After a total charging time of 6 hours the instrument is ready for use.

When new rechargeable batteries are inserted into the MT10 the above procedure should be repeated. When the MT10 is charging a red LED-light lights up next to the golden contacts in the bottom of MT10.

Normal operation temperature:

If the MT10 has been subjected to very high or low temperatures e.g. from being kept in a hot or cold car, the temperature of the MT10 must be normalised to between 15 and 35 degrees Celsius/60 and 95 degrees Fahrenheit before accurate results can be assured.

Patient Instruction:

Place the patient in a comfortable chair or on an examining table if necessary. Small children may feel more comfortable sitting on a parent's or nurse's lap. Show the MT10 to the patient and then explain the following:

- that the aim of the test is to test the mobility of the eardrum.
- that the ear tip will be inserted into the ear canal, and that it has to make a perfect seal.
- that through the ear tip a small amount of air will flow to move the eardrum; this will produce a sensation equal to pressing a finger slightly into the ear canal.
- that a tone will be heard during the test.
- that no participation is expected from the patient.

- that coughing, talking and swallowing will ruin test results.

Visual Inspection:

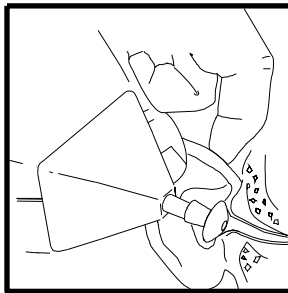
- Check the external ear canal for wax by the use of an otoscope and remove excessive wax to prevent probe opening from clogging, which will inhibit testing.
- Excessive hairs may have to be cut.
- Also check for a perforated eardrum as this may give a tympanometry curve which may accidentally be mistaken for a fluid filled middle ear.

Ear Tip Selection:

The probe must be fitted with an ear tip of suitable size before testing. Be sure to insert the ear tip as far as it will go on the probe tip of the MT10.

Making a Good Seal:

Most ear canals are more or less curved. To get a good fit of the ear tip, pull back the pinna to straighten out the ear canal during insertion of the ear tip into the ear canal opening.



Hair coming out of the ear canal may make an air tight fit difficult to obtain. An ear tip covered with vaseline may be helpful. Make sure the ear tip does not have its opening closed by the wall of the ear canal or clogged by vaseline or cerumen.

Maintaining a Stable Position:

As movements of the MT10 relative to the ear canal will

introduce irregularities in obtained test results (especially for reflex measurements), a fixed position should be assured.

Resting one or two fingers of the hand holding the MT10 against the cheek of the patient is often a good way to obtain the needed fixation.

Using Detached Probe Tip:

The probe tip can be removed from the main housing for a more convenient and stable positioning of the ear tip in the ear canal when testing e.g. infants or scared children.

Loosen the fitting screw with a few turns



Gently pull out the probe tip



Test Procedures

Normal Tympanometry

1. Apply a suitable ear tip.
2. Access the “Tympanometry” screen.
3. Select test ear.
4. Position the ear tip against the ear canal opening.
5. Wait for the test to finish.
6. Select the other ear.
7. Repeat the test.

Extended Tympanometry

The procedure equals that outlined above for Normal Tympanometry, except that you run the test with the “Extended Tymp” screen opened.

Note: In order not to apply unnecessary stress to the patient, it is advised to use extended tympanometry only when needed, and not as a standard screening procedure.

Reflex Testing

1. Apply a suitable ear tip.
2. Access the “Tymp + Reflex” screen.
3. Select test ear.
4. Position the ear tip against the ear canal opening.

5. Wait for the test to finish.
6. Select the other ear.
7. Repeat the test.

Eustachian Tube Function Test

The MT10 is capable of testing and printing 2 tympanograms (usually one for each ear) for each patient. Of course it is possible to make these 2 tympanograms on the same ear separated by e.g. a valsalvation procedure. In this way the Eustachian tube function may be evaluated.

1. Conduct a tymp test on the ear under test. (Please refer to the chapter on tympanometry tests for details).
2. Select the contralateral ear.
3. Make the patient swallow while he is closing his nose. (Another procedure would be to have the patient blow with mouth and nose closed.)
4. Make another tymp test on the ear under test.

The two curves may be reviewed on the screen by toggling between them with the “L/R” button. A change of peak pressure indicates the function of the Eustachian tube.

Note: The Left / Right indications make of course no sense in this test, as both tymp curves are made on the same ear. It is recommended that printouts are corrected by handwriting.

Audiometry

Prior to performing the audiometry test, show the MT10 to the patient and then explain the following:

- that the aim of the test is to check his ability to hear faint whistling tones.
- that the ear tip will be inserted into the ear canal.
- that each time he hears a faint whistling tone he should give a brief signal by raising his hand.
- that tones of different pitches may be presented.

1. Apply a suitable ear tip.
2. Access the “Audiometry” screen.
3. Select test ear.
4. Position the ear tip against the ear canal opening.
5. Select “Start”.
6. At each response from the patient, press “Store”.
7. The test is finished when the audiogram is complete.
8. Select the other ear and repeat the test if desired.

Printing Test Results

Printing on MTP10 Thermal Printer

1. Place the MT10 in the MTP10.
2. Turn on the MT10.
3. Press "Print" on the MT10

Note: The printout will only hold the test results stored under the ID number on the display on the MT10.

If you have additional test results stored under other ID numbers, you must change ID on the MT10 and print test results for each of these ID numbers separately. (Changing to other ID numbers is possible by holding down "L/R" for 2 seconds).

The correct printer language (MTP10v2) must be selected in the Main Setup.

Printing on External Printer

1. Place the MT10 in the MTI desk unit.
2. Turn on the MT10.
3. Press "PRINT" on the MT10.

Note: The correct printer language must be selected in the Main Setup. Select between IBM mode, HP PCL 3 and MTP10v2.

Printing By Use Of Computer

When using a computer for printing (or data storing) all actions are handled from the computer. Test results will be transmitted only for the ID present on the display of the MT10.

Dedicated software program is necessary for operation with MT10. laBasell and PrintView are examples of such dedicated programs.

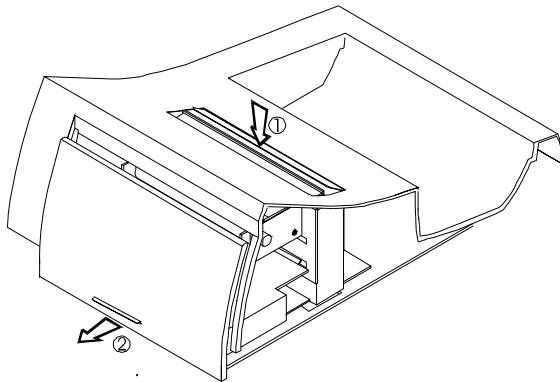
The MT10 may connect to the PC in three different ways:

- Using the MTS10 Desk-unit (built-in RS232 connector).
- Using the MTP10 Desk-unit (built-in RS232 connector and thermal printer).
- Using the supplied IFA10 cable which connects directly to the gold sockets of the MT10

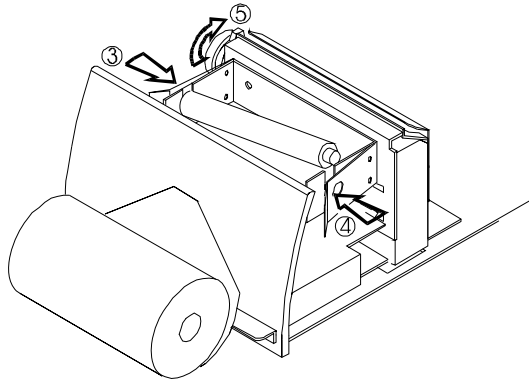
Changing Paper in the MTP10 Printer

The illustrations will step by step explain how the thermal paper is changed in the MTP10.

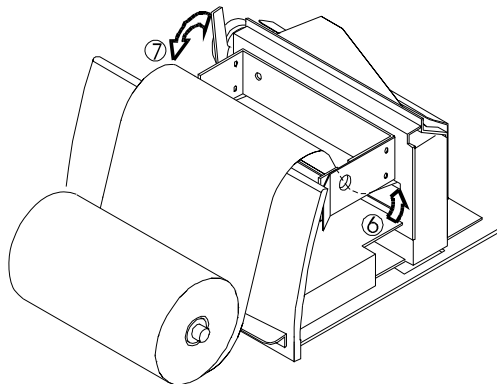
First, pull out the slide (2) where the printer is mounted while gently pressing the black paper cutter(1).



To loosen the axle that holds the paper roll, gently press the two flat springs (3 and 4). Now raise the small blue handle (5) to vertical position in order to loosen the rubber platen so the paper can be inserted. Fold the paper as shown on the illustration to make insertion of the paper easier.



After folding the paper it must be inserted into the narrow, vertical opening (6). When the paper appears from below the paper cutter pull out an extra 5 to 10 centimetres of paper and return the small blue handle (7) to horizontal position and tear off the paper by means of the paper cutter. Put the axle through the paper roll and reposition it in the paper holder device. Push the slide back again and MTP10 is ready for printing.



Power Supply

Charging Using MTP10 and MTS10

When the MT10 is run on rechargeable batteries, these are automatically charged when the MT10 rests in the MTP10 or MTS10, provided that these are connected to the supplied UPS400 power supply.

The charging will not start before the screen of the MT10 has shut off. Charging of the MT10 will be indicated by a red LED light next to the golden contacts at the bottom of the MT10. This lamp may not be easy to see, but charging is a fully automatic procedure, and the lighting sequence of the lamp is intended for evaluation by technical personnel only.

Please note that only rechargeable batteries must be charged.

Charging Through IFA10 Cable

The IFA10 cable may be used to charge the MT10 directly. Attach the cable to the MT10 and connect the other end of the cable to the supply cable coming from the supplied power supply. Charging is automatic.

The charging will not start before the screen of the MT10 has shut off. Charging of the MT10 will be indicated by a red LED light next to the golden contacts at bottom of the MT10. This lamp may not be easy to see, but charging is a fully automatic procedure, and the lighting sequence of the lamp is intended for evaluation by technical personnel only.

Please note that only rechargeable batteries must be charged.

Please also note that the supply from the IFA10 cable is not sufficient for testing, as it is only intended for charging.

Rechargeable And Regular Batteries

MT10 can operate using both regular AA batteries and rechargeable batteries.

When using normal batteries no charging must take place. Therefore, the power to MTP10 and MTS10 must be disconnected when the MT10 rests here.

If you experience problems using regular AA batteries, try a different brand as sufficiently high current drain is not available from all types.

Batteries

Usable battery AA types:

3 pieces of NiMH 1200 mAh; 1100 mAh or
3 pieces of NiCa 750 mAh

Note!

Only rechargeable batteries must be charged.

Many different types of AA batteries exist. Not all batteries are equally qualified for use in the MT10. Battery capacity depends on the load. The battery manufacturers describe the battery capacity matching a load on 0.2C, which is different to the one at MT10. Please remember always to replace all three batteries at same time.

Recommended rechargeable batteries:

VARTA NiMH 1200 AA
Multiplex NiMH 1200 AA
TOSHIBA NiMH AA TS-1200

VARTA NiCa 750 mAh (battery with memory)

Note! It is recommended to discharge NiCa batteries totally at intervals of 2-3 weeks.

Handling of Ear Tips

We recommended using a new ear tip for each patient. If the clinician rinses the ear tips they should be subjected to standard disinfection procedure between patients. This includes physically cleaning the ear tip 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 Dismount the Probe Tip

Loosen the fitting screw with a few turns

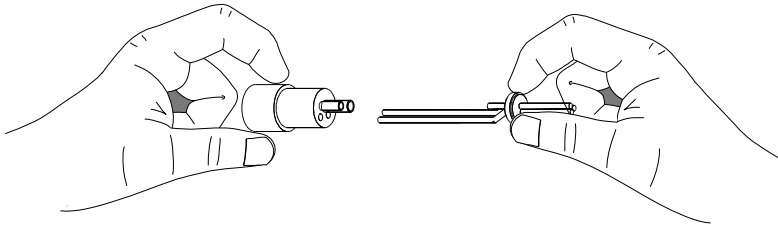


Gently pull out the probe tip

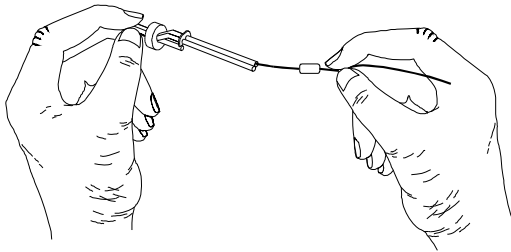


Cleaning the Probe Tubes

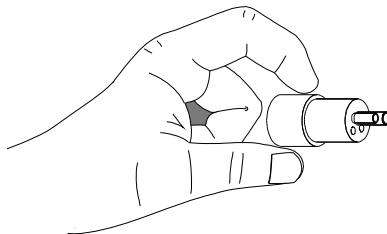
The three small tubes can be pulled out of the transducer housing. See the below illustration. Be careful not to bend the delicate metal tubes. Renew the short silicone tube ("A") if it is unable to make an air tight fit when reassembled.



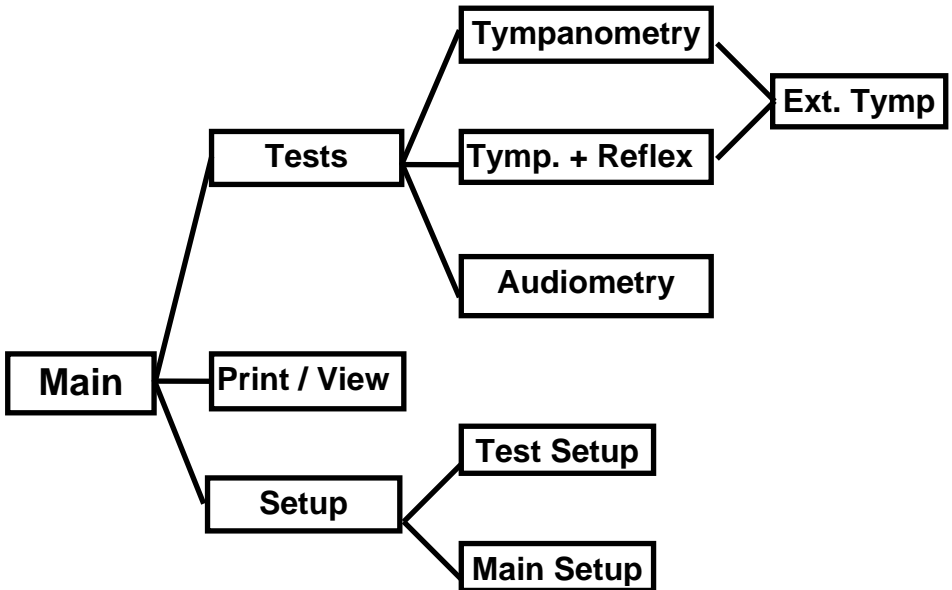
Now the small metal tubes can be cleaned with the cleaning wire ("A") type CLW and hot water. The probe seal ring ("B") may be lubricated with Vaseline to assure the necessary air tight fit when reassembled.



Warning: Never clean the transducer housing (See below illustration) with water or insertion instruments.



Short Instructions MT10



Turn on the MT10 by selecting any button.

1. Apply a suitable ear tip for airtight fit.
2. Select desired test screen.
3. Position MT10 with the ear tip in airtight position in the ear canal.
4. Wait for the test to be finished.

Turn off MT10 by selecting button 1 and button 4 simultaneously.

Change ID number (for storing more than one patient in memory):

Hold down the "L/R" button for 2 seconds.

Printing (with MTP10):

1. Place MT10 in MTP10.
2. If desired you may preview the test results by "L/R" and "Files".
3. If desired, change ID by holding down "L/R" for 2 seconds.
4. Select "Prnt" (prints complete test results of selected ID).

Transferring data to PC:

The Procedure is handled from the PC. Only stored test results of displayed ID are transmitted.

Shortcut Functions

With MT10 a selection of different short cut functions are available. Those functions can be viewed in the table below:

Mode	Key down	Action
Main	F1- ID	Patient ID number will increase
Tymp. + Reflex	F2 - L/R	Patient ID menu will pop up
Tympanometry	F2 - L/R	Patient ID menu will pop up
Ext. Tympanometry	F2 - L/R	Patient ID menu will pop up
Audiometry	F2 - L/R	Patient ID menu will pop up
PRNT	F2 - L/R	Patient ID menu will pop up
PRNT	F3 - View	Print MTP10 program version
PRNT	F4 - Print	Paper Feed
Patient Id menu	F3 - (-)	Patient ID number will decrease
Patient Id menu	F4 - (+)	Patient ID number will increase
Tymp. Test Setup	F3	The setup parameter will increase
Reflex Test Setup	F3	The setup parameter will increase

Technical Specifications

Standards:

Impedance: EN61027, ANSI S3.39, type 2.
Audiometer: EN60645-1/ANSI S3.6, Type 5
Safety: EN60601-1, Class 1, type B.
EMC: EN60601-1-2

Medical CE Mark:



The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. TÜV Product Service, Identification No. 0123, has approved the quality system.

Impedance:

Probe Tone Frequency : 226 Hz +/-3%.
Probe Tone Intensity : 85 dB SPL +/-3dB.
Pressure Range : Norm. range +200 to -300 daPa
Ext. range +300 to -600 daPa
Accuracy : +/-10% or 10 daPa
Compliance Range : 0.0-5 ml.
Compliance Accuracy : +/-5% or 0.1 ml.
Pump speed : 250-350 daPa/sec.

Reflex:

Automatic testing with 4 stimuli to each ear.
Auto Reflex Detection.
Multiple Reflex stimuli.
Stimulus Duration : 1.0 sec.
Intensity (Max.) : 110 dBHL. - at 3-4 KHz 100 dB HL.

Audiometer:

Screening Audiometry
Intensity: 10 dBHL to 50 dBHL.
Frequency: 0.5kHz, 1kHz, 2kHz, 3kHz and 4kHz.

Tests:

Tympanometry : Automatic.
Reflex Test : Automatic.

- Audiometry* : Automatic Audiometry test in five frequencies at one adjustable level.
- Eustachian Tube* : Semi Automatic function test based on tympanometry.

Calibration:

Impedance: EN61027/ANSI S3.39
Calibration is performed via the instrument's front panel and is stored in a permanent memory.

Construction:

Plastic cabinet.

Power supply:

115, 230VAC, 50 - 60 Hz., 25 VA maximum.

Dimensions:

L x W x H: 25 x 10 x 13 cm / 9.8 x 3.9 x 5.1 inches.
Weight: 0.5 kg / 1.1 lbs.

Parts

Included Parts MT10/MTS10:

MT10
MTS10 Desk unit (charger and RS232C)
EPS11 Power supply
RCB10 3 NiMH rechargeable batteries
BET50 set of ear tips
Operation Manual.
Multilingual CE instructions for use

Included Parts MT10/MTP10:

MT10
MTP10 Base station with built-in high speed thermal printer, charger and interfacing to PC
TPR10 3 rolls of thermal paper
EPS11 Power supply
RCB10 3 NiMH rechargeable batteries
BET50 set of ear tips

Operation Manual.
Multilingual CE instructions for use

Additional Parts:

IFC69 cable for PC connection (9 pins)
IFC59 cable for PC connection (25 pins)
ACC10 carrying case for MT10+MTP10
TPR10 3 rolls of thermal paper
BET50 set of ear tips
PrintView
IaBasell and Diagnostic Modules
Ia-NOAH-Imp module

Unpacking and Inspection

Check box and contents for damage:

When the instrument is received please check the shipping box for rough handling and damage. If the box is damaged it should be kept until the contents of the shipment have been checked mechanically and electrically. If the instrument is faulty please contact the nearest service office. Keep the shipping material for the carrier's inspection and insurance claim.

Keep carton for future shipment:

The MT10 comes in its own shipping carton, which is specially designed for the MT10. Please keep this carton. It will be needed if the instrument has to be returned for service. If service is required please contact your nearest sales and service office.

Contents of Shipment

As standard the MT10/MTS10/MTP10 is delivered with the following:

Quantity	Item	Order No.
1	Instrument	MT10
1	Power supply	EPS11
3	NIMH rechargeable batteries	RCB10
1	Set of ear tips	BET50
1	Operation Manual	
1	CE Manual	
MTS10 is also delivered with:		
1	Desk unit (charger and RS232C)	MTS10
MTP10 is also delivered with:		
1	Base station with built-in high speed thermal printer, charger and interfacing to PC	MTP10
3	Rolls of thermal paper	TPR10

Check numbers on MT10 and Manual:

The identification label holds the serial number. This should be checked with the manual number and written down for later service claims.

To maintain the validity of the CE-mark of the MT10 the power supply must be CE-medical approved.

Reporting Imperfections

Inspect before connection:

Prior to connecting the MT10 to the mains it should once more be inspected for damage. All of the cabinet and the accessories should be checked visually for scratches and missing parts.

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. In the back of this manual you will find a "Return Report" where you can describe the problem.

Please use "Return Report":

Please realise that if the service engineer does not know what problem to look for he may not find it, so using the Return Record will be of great help to us and is your best guarantee that the correction of the problem will be to your satisfaction.

Trouble Shooting

MT10 does not turn on:

There must be three AA batteries inserted in the instrument.
The batteries must be fully charged.

MT10 turns off automatically:

The instrument has an automatic function that will shut down the instrument automatically when the instrument has not been used for 1, 2, 3, 4 or 5 minutes. The time interval can be changed in the internal main setup. This function has been included for power saving reasons.

MT10 generates noise:

From time to time the MT10 might generate a minor high frequency mechanical noise emerging from the display. This noise is without importance for the tympanometry and reflex test.

Charging LED seems to flicker on and off :

This indicates that the batteries are fully charged. Constant red light indicates that the batteries of the MT10 are currently being charged.

Data is not transmitted to the computer:

The correct COM port must be selected in the PC software program.

The right connection cable must be used - not all RS232C cables are the same!! The Interacoustics cable used to connect the MTS10 or MTP10 to a computer must be either IFC59 (25 pins) or IFC69 (9 pins), depending on your computer.

The Baud rate set on MT10 and the computer must be the same.

Your computer may not be able to handle the Baud rate chosen. Try a lower Baud rate in the computer as well as in the MT10.

When selecting "Instrument ID" in PrintView, laBasell or the IA Noah software modules the following instruments must be chosen to ensure communication between the PC and the instrument:

Instrument Table Stand for MT10 Instrument ID

MT10	MTS10	→	MT10
MT10	MTP10	→	MTP10

No Tymp curves are drawn:

The probe system has to make a perfect seal with the ear canal before a Tymp curve is measured and drawn in the display.

Alternatively TYMP may be disabled in the MAIN SETUP.

No Reflex curves are drawn:

If no reflex curves are drawn in the display of MT10 it might be possible that only Tympanometry has been chosen and not Tymp + Reflex.

Tests cannot be performed:

If T + R, TYMP, EX. TYMP or AUD cannot be performed with MT10 those tests might be "DISABLED" in the main setup. To perform the above tests these must be "ENABLED".

MTP10 cannot print:

First of all check if the power is on.

If the printer cannot print it is recommended that the power supply (UPS400) is switched off the mains for approximately 2-3 minutes.

There is also the possibility that the small red handle on the printer has not been put back to the horizontal position after a paper change. To print, the small red handle must be in the horizontal position.

The correct printer language must be selected in the Main Setup (MTP10v2).

Thermal paper:

The thermal paper rolls used in the MTP10 printer must not be stored in direct sunlight.

The printouts from the MTP10 printer must not be stored in direct sunlight.

Printouts must not be filed in copy-safe pockets containing PVC as this provokes a chemical reaction which will make the printing disappear.

Recommended Literature

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13. 1974)
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(Arch Otolaryngol vol.79 1974).
- Liden, G.:**
Audiology (Almqvist & Wiksell. 1985) (Swedish language)
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Hearing Assessment with the Acoustic Reflex. (Grune &
Stratton 1981)

Dictionary

Acoustic Admittance:

The ease with which sound waves flow through a medium, as the eardrum membrane. See Acoustic Imittance.

Acoustic Compliance:

Another term for Acoustic Admittance.

Acoustic Imittance:

Refers collectively to acoustic impedance and / or acoustic admittance.

Compliance:

- 1) Ease with which air moves (e.g. influenced by the eardrum and middle ear mechanism).
- 2) Often used to indicate the equivalent volume of air in the middle ear.

Contra lateral Reflex:

The middle ear muscle reflex that occurs in the ear, contra lateral to the stimulus ear.

Dynamic Acoustic Compliance:

See Dynamic Acoustic Imittance.

Dynamic Acoustic Imittance:

The acoustic Imittance as observed with a continuous change in air pressure (tympanometry) and/or during the activation of the middle ear muscle(s) (reflex measurements)

Ear Tip: A cuff which is used to seal the probe into the external auditory canal.

ETF: (Eustachian Tube Function). This function is tested by trying to force air through the Eustachian tube and then by tympanogram recordings checking if the expected change of middle ear pressure has occurred.

Ipsilateral Reflex:

The middle ear muscle reflex which occurs in the stimulus ear.

Myringoplasty:

Surgical repair of the eardrum membrane.

Myringotomy:

(Tympanotomy) A small incision made in the eardrum membrane to remove fluid from the middle ear.

Non Acoustic Reflex:

A middle ear muscle reflex elicited by a non-acoustic stimulus.

Ossicular Chain Disruption:

(Ossicular chain interruption, discontinuity or disarticulation) A break in the three connected bones (ossicles) in the middle ear.

Pascal (Pa):

A unit of pressure or stress, equal to one Newton per m².

Static Acoustic Compliance:

See Static Acoustic Immitance.

Peak Static Acoustic Immitance:

The static acoustic Immitance obtained with a specific air pressure in the external auditory canal as adjusted to produce an extreme in the measured acoustic Immitance.

Probe: A coupling device that is inserted into the external auditory canal, to connect it to the acoustic Immitance meter.

Probe Ear:

The ear into which the probe is inserted.

Probe Signal:

An acoustic signal that is emitted into the external auditory canal by means of a probe. The signal is used to measure acoustic Immitance.

Probe Tip:

The upper part of the probe tip on which the ear tip, a cuff which is used to seal the probe into the external auditory canal, is placed.

Reflex Activated Acoustic Immitance:

The acoustic Immitance measured with the middle ear muscle reflex activated by a defined stimulus at a specified air pressure and with a constant tonus of the middle ear muscle.

Static Acoustic Immitance:

- 1) The acoustic Immitance as observed at a constant specified air pressure and with a constant tonus of the middle ear muscles.
- 2) The volume of air that is equivalent in acoustic compliance to that of the middle ear. Measured in millilitres or cm^2 .

Stimulus Ear:

The ear to which the reflex activating stimulus is presented in order to elicit a middle ear muscle reflex. **Note:** If a bone vibrator or a loudspeaker is used to deliver an acoustic reflex it may not be possible to define the stimulus ear.

Toynbee Test:

Test designed to determine the function of the Eustachian tube in ears with perforated eardrums.

Toynbee's Manoeuvre:

See Valsalvation.

Tympanogram:

A chart of the results of tympanometry - compliance measurements at the eardrum.

Tympanometry:

The measurement of the ability of the eardrum and ossicular chain to transmit sound pressure waves. An intact eardrum is subjected to air pressure changes to determine its stiffness (impedance) and compliance (admittance).

Valsalvation:

Swallowing with the mouth and nose closed to draw air out of the middle ear. Syn.: Toynbee's manoeuvre.

Valsalva's Manoeuvre:

Blowing forcibly to open Eustachian tube by holding nose and closing mouth. Named for its originator, Antonio Valsalva. Sometimes called Valsalva's experiment.

Williams Test:

Test designed to determine the function of the Eustachian tube in ears with non-perforated eardrums.

Appendix A: Setup

Please refer to the Short Instruction Chapter for advice on how to open the various setup screens mentioned below.

Main Setup

In the Main Setup screen you will find the following options:

Power up:

Select which screen to open automatically when you turn on the MT10.

Ear: Choose which ear to automatically be selected for the first testing.

All test screens (T+R, Tymp, ExT. and Aud.)

May be selected or deselected. A deselecting of test screens never used is advised, as this will make the instrument easier to learn to operate.

Auto Off:

Decide how many minutes the instrument should wait before it automatically shuts itself down. (This facility is included for power saving reasons.)

Display: Controls the brightness of the display.

Baud rate:

Communication speed for transmitting data to PC. The Baud rate must match that of the PC program used.

Printer: Select the required printing language.

Calibration:

Do not enter, as this is to be used by qualified service technician only.

Tympanometry Setup

In the Tympanometry Setup screen you have the following options:

Norm. Box : You may choose to deselect the normative box which indicates the Pass / Fail limits of the audiogram peak.

Max. and Min. Pressure and Compliance

Limits may be changed for the normative box displayed.

Grad. Unit: The gradient may be set up to be displayed in either ml. or daPa.

Reflex Setup

The MT10 may test reflexes in three different ways which may be selected individually:

- **Auto** is a search procedure in steps of 5 dB which will search for an intensity where a suitable size reflex is present.
- **Screen** - as Auto, but in steps of 10dB. This is also a more rugged test, as it incorporates a double check for the presence of a reflex before accepting the test intensity.
- **Fixed** intensities. The test of choice, if automatic tests are not acceptable.

The MT10 may test up to 4 reflexes per ear. For each reflex you may select frequencies of your own choice between 500Hz and 4000Hz. If you have selected "**Fixed**" intensities, you must select which intensity to use for each reflex test.

Audiometry Setup

Level: Sets the test level

Fam. Test: Selects whether or not the test shall be preceded by a four tone presentations at 1kHz to train the patient in responding correctly.

Appendix B: General Maintenance Procedures

The performance and safety of the instrument will be kept if the following recommendations for care and maintenance are observed:

- It is recommended to let the instrument go through at least one annual overhaul, to ensure that the acoustical, electrical and mechanical properties are correct. This should be made by an authorised workshop in order to guaranty proper service and repair.
- Before the connection to the mains network, be sure that the local mains voltage corresponds to the voltage labelled on the instrument. Always disconnect the power cord if the instrument is opened or by control / replacement of the mains fuses.
- Observe that no damage is present on the insulation of the mains cable or the connectors and that it is not exposed to any kind of mechanical load, which could involve damage.
- Consult the Operating Manual for the instrument in question to see how long time it takes from turning on the instrument until it is stabilised and ready to use.
- For maximum electrical safety, turn off the power from a mains powered instrument when it is left unused.
- Do not site the instrument next to a heat source of any kind, and allow sufficient space around the instrument to ensure proper ventilation.
- To ensure that the reliability of the instrument is kept, it is recommended that the operator at short intervals, for instance once a day, perform a test on a person with known data. This person could be the operator him/herself.
- A plastic cover can be provided to protect the instrument against the accumulation of dust. The cover should only be

used when the instrument is left unused with the power turned off.

- If the surface of the instrument or parts of it are contaminated, it can be cleaned using a soft cloth moistened with a mild solution of water and dish washing cleaner or similar. The use of organic solvents and aromatic oils must be avoided. Always disconnect the mains conductor during the cleaning process, and be careful that no fluid is entering the inside of the instrument or the accessories.

- After each examination of a patient, it should be ensured that there is no contamination on the parts in connection with the patient. General precautions must be observed in order to avoid that disease from one patient is conducted to others. If ear cushions or ear tips are contaminated, it is strongly recommended to remove them from the transducer before they are cleaned. By frequent cleaning water should be used, but by severe contamination it may be necessary to use a disinfectant. The use of organic solvents and aromatic oils must be avoided.

Great care should be exercised by the handling of earphones and other transducers, as mechanical shock may cause change of calibration.

Return Report – Form 001



Opr. dato: 2003-02-24 af: EC Rev. dato: 2006-11-13 af: HNI Rev. nr.: 4

Company: _____

Address: _____

Phone: _____

Fax or e-mail: _____

Contact person: _____ Date : _____

Address
Drejerveanget 8
5610 Assens
Denmark

Phone
(+45) 63713555

Fax
(+45) 63713522

E-mail
info@interacoustics.com

Following item is reported to be:

- returned to INTERACOUSTICS for: repair, exchange, other: _____
- defective as described below with request of assistance
- repaired locally as described below
- showing general problems as described below

Item: Type: _____ Quantity: _____

Serial No.: _____ Supplied by: _____

Included parts: _____

Important! - Accessories used together with the item must be included if returned (e.g. external power supply, headsets, transducers and couplers).

Description of problem or the performed local repair:

Returned according to agreement with: Interacoustics, Other : _____

Date : _____ Person : _____

Please provide e-mail address or fax No. to whom Interacoustics may confirm reception of the returned goods:

The above mentioned item is reported to be dangerous to patient or user ¹

In order to ensure instant and effective treatment of returned goods, it is important that this form is filled in and placed together with the item.

Please note that the goods must be carefully packed, preferably in original packing, in order to avoid damage during transport. (Packing material may be ordered from Interacoustics)

¹ EC Medical Device Directive rules require immediate report to be sent, if the device by malfunction deterioration of performance or characteristics and/or by inadequacy in labelling or instructions for use, has caused or could have caused death or serious deterioration of health to patient or user.