

Operation Manual

Impedance Audiometer AT235



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Introduction

Intended Use

The AT235 is an automatic impedance audiometer suited for clinics performing screening, as well as diagnostic work. The test battery includes tympanometry, acoustic reflex testing, ipsilateral and contralateral reflex decay testing, Eustachian tube function test and AC audiometry.

The AT235 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 airtight 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 - When conducting audiometry using Eartone insert phones – do not insert or in anyway try to conduct measurements without proper foam tip 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.

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 AT235 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 AT235 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 -

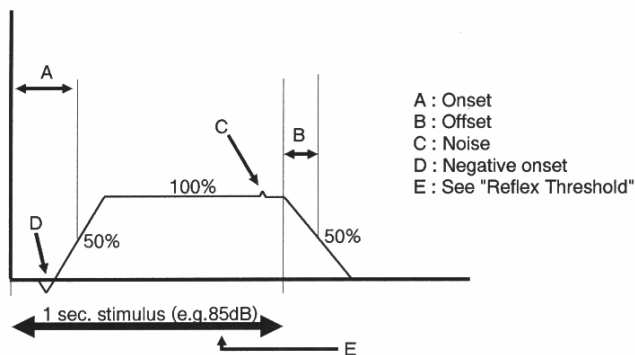
Peak Pressure			
Negative Pressure:	Normal Pressure:	Positive Pressure:	Absence of Pressure Peak:
<ol style="list-style-type: none"> 1) Blocked Eustachian tube 2) Serous otitis media 	<ol style="list-style-type: none"> 1) Ossicular bone fixation 2) Adhesive fixation 3) Ossicular discontinuity 4) Middle 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

Figure 1:



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:

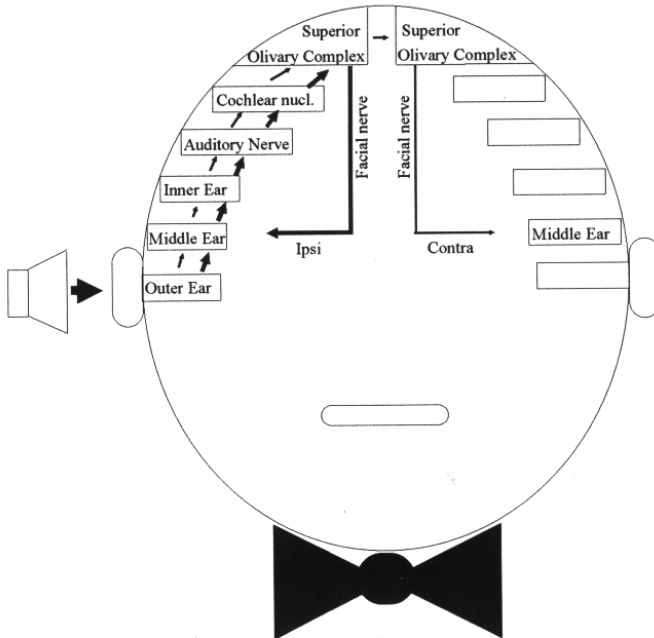
For a given stimulus the lowest level that elicits a detectable reflex. This is not an absolute measurement as no exhausting norm exists defining stimuli and related reflex characteristics. Therefore, differences in test setups and reflex evaluation will produce somewhat different results. It is not 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

Figure 2:



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:

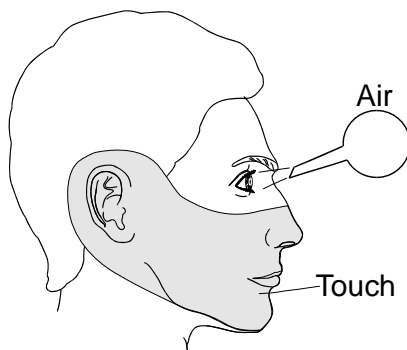
- Is the reflex absent or present?
- If present, is it present both contralateral and ipsilateral?
- What is the threshold of the reflex?

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.

Non Acoustic Stimulation:

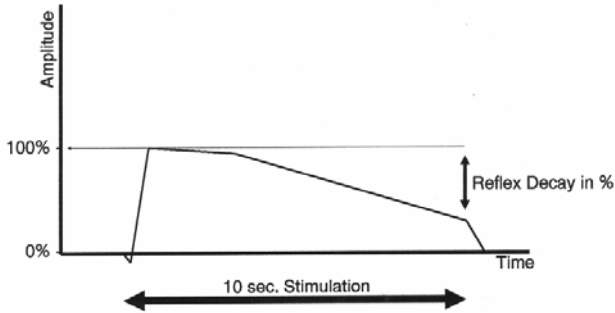
The Tensor Tympany muscle of the middle ear can produce a reflex elicited by a non acoustic stimulus or by an acoustic stimulation loud enough to have a startling effect on the patient. As the tensor reflex is a startle response, it will decrease and disappear after a few equal stimulations. Even though the tensor reflex is regarded late and unstable compared to the Stapedius reflex, it may be useful in testing deaf or hard of hearing patients. Below is shown the tactile sensitive area of the face to be stimulated with e.g. a piece of wool. Stimulation may also be a blow of air into the eye region of the patient.

Figure 3:



Reflex Decay Interpretation

Figure 4:



Reflex Decay:

Reflex decay is calculated as the reduction of size of the acoustic reflex during the first 10 seconds of muscular contraction. Most normal ears will be able to maintain a Stapedius contraction for 10 seconds or longer for frequencies below 1000Hz, at a level 10dB above reflex threshold. A high reflex decay score could indicate VIIIth nerve disorders. Another way of stating the reflex decay is by finding the number of seconds it takes before the Stapedius contraction falls to 50% of its initial maximum.

Note: If a decay score is obtained, you should assure that it is not due to an improper seal, which might produce an artefact similar to a decaying curve. See the chapter “Preparing the Test” for details of fitting the probe.

The fact that the light band of the probe goes off, and the test starts is not an absolutely certain indication of a fit good enough to produce valid decay test results. This is due to the prolonged test time and the high sensitivity of the test.

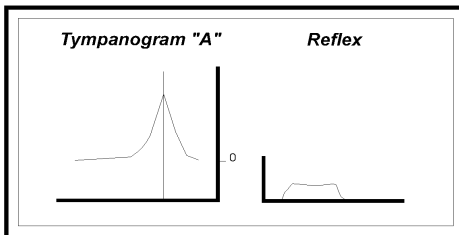
Also great care should be taken to have the probe kept in a very fixed position relative to the ear during testing.

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.

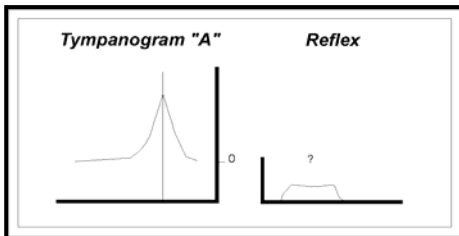
A combination of variables always has to be taken into consideration. E.g. the combination of a stiff middle ear system and a floppy eardrum may result in a tympanogram falling within the normal category. The interpretations stated here are generalised examples taken from the currently available literature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



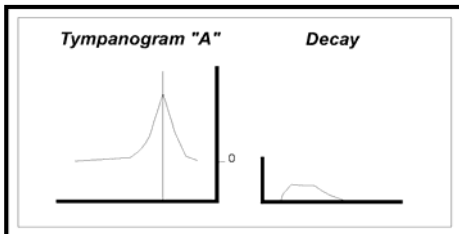
Pathology : Normal ear.

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



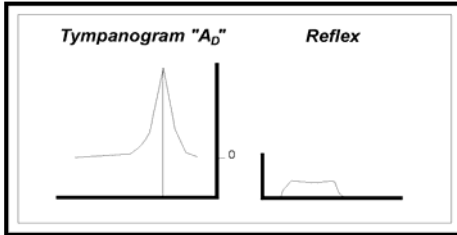
Pathology : Cochlea lesion.

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



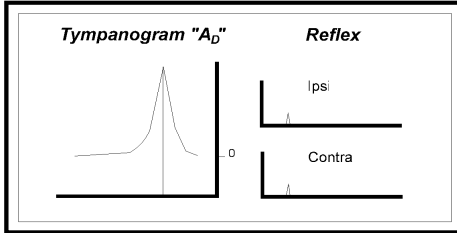
Pathology : Retrocochlear lesion.

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



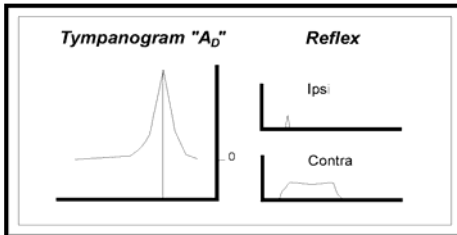
Pathology : **Supranormal eardrum (floppy) or atrophic/scarred eardrum.**

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



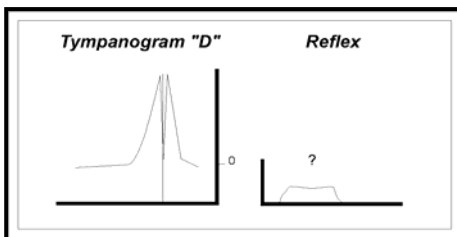
Pathology : **Disrupted ossicular chain peripheral to stapes muscle attachment.**

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



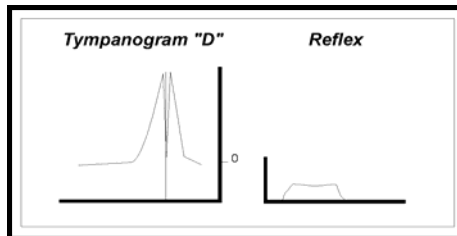
Pathology : **Disrupted ossicular chain medial to stapes muscle attachment.**

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



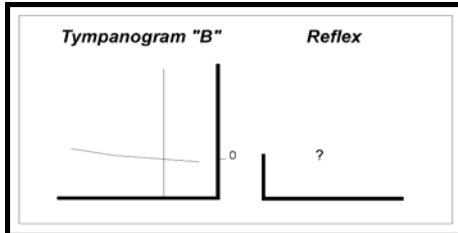
Pathology : **Disruption of ossicular chain with bones fixated to the tympanic membrane, resonating. Supranormal eardrum (floppy).**

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



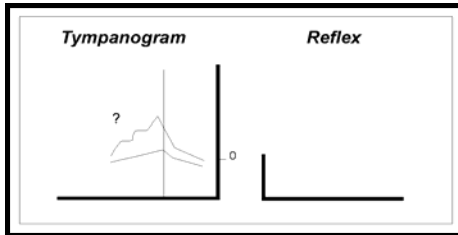
Pathology : **Scarred and healed (abnormal) eardrum.**

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



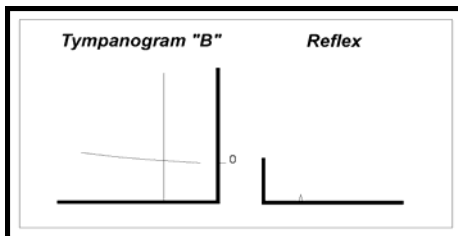
Pathology : Fluid in the middle ear, or serous otitis media.

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



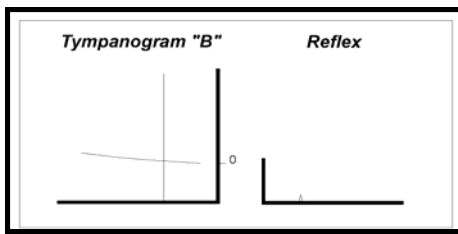
Pathology : Ear wax in the external ear canal (Obturing cerumen).

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



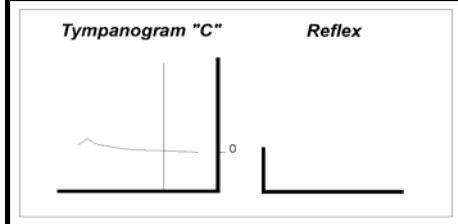
Pathology : Perforated tympanic membrane - defect or ventilated tympanotomy. Traumatic rupture.

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



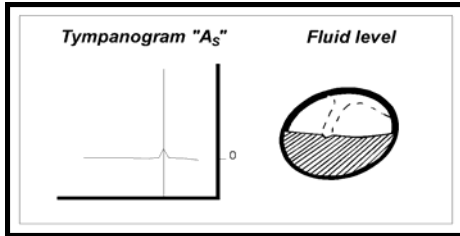
Pathology : Otosclerosis or stapes fixation.

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



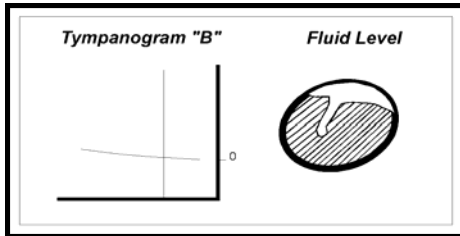
Pathology : Adhesive otitis media. Adhesive ossicular fixation (glue ear).

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



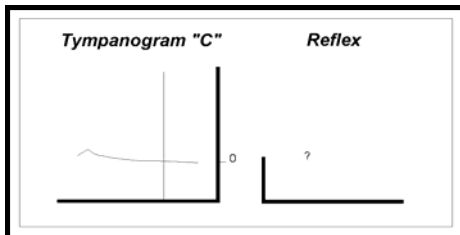
Pathology : Moderate fluid in the middle ear.

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.

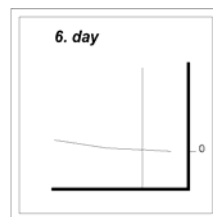
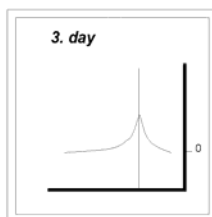
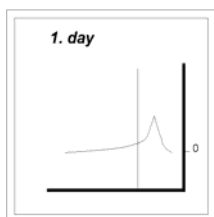
Volume : Normal.
 Pressure : Negative.
 Ventilation : Absent or poor
 Reflex : Absent or elevated (rare).
 Audiogram : Mild to moderate conductive loss.

Pathology: Acute Serous

Otitis Media:

Positive middle ear pressure is rarely observed in typanometry. 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.

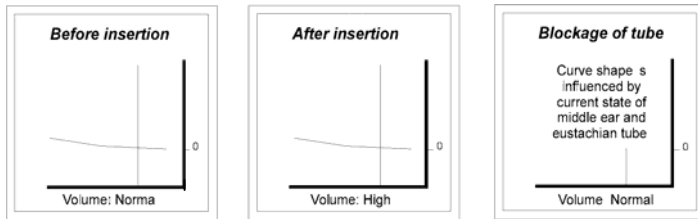
A typical acute serous otitis media may develop according to the typanograms outlined below:



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.



Basic Functions

Preparing the Test

AT235 must warm up:

After approximately 10 minutes the AT235 will reach operation temperature. At this time it will automatically calibrate itself to actual ambient barometric pressure. Tests carried out before this automatic calibration has been performed by the AT235, may show slightly wrong pressure results.

If the AT235 has been subject to very high or low temperatures e.g. from being kept in a hot or cold car, the temperature of the AT235 must be normalised to between 15 and 35 °C / 60 and 95 °F before accurate result 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 probe to the patient and then explain the following:

- That the aim of the test is to test the mobility of the eardrum.
- That the tip of the probe will be inserted into the ear canal, and that it has to make a perfect seal.
- That a small amount of air will flow through the probe to move the eardrum; this will produce a sensation equal to pressing a finger slightly into the ear canal.
- That one or more tones 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 with 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 be mistaken for a fluid filled middle ear.

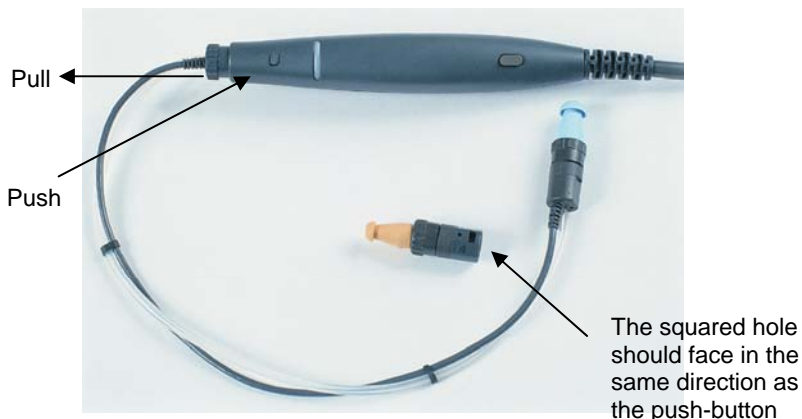
Ear Tip Selection:

The probe shall be fitted with an ear tip of suitable size before testing. Be sure to insert the probe tip completely into the ear tip.

Transforming the Probe from Handheld to Clinical and Reverse:

The probes are easily exchanged by pressing the button and pulling the probe.

Picture 1:



The other probe is then pushed into the socket until a distinct "click" is heard. **Note!** The squared hole in the probe connection should face in the same direction as the push-button.

Fitting the Clinical Headset – see picture 2

- A) Place the head band over the patient's head. The audiometric headphone TDH39 is placed over the non test-ear (or contralateral reflex ear).
- B) Slide the transducer house downwards in the head band holder. Try to position the transducer holder slightly behind the ear. This will ensure free space for inserting the probe tip with the ear tip into the ear canal.

Note: A shoulder strap is also available for performing clinical tympanometry. See this shoulder strap in picture 3.

Picture 2:



Picture 3:



- C) Press "Pause" (9) in order to prevent the instrument from automatically starting the test as soon as an airtight fit is obtained.
- D) Insert the probe tip into the ear canal until you have an airtight fit. Pull the transducer house upwards again, until the probe in the ear is hanging by the tubes from the transducer.

Pause

The pause function operated from "Pause" (9) has been built into AT235 to prevent the instrument from automatically starting the test as soon as an airtight fit has been obtained. The pause function is mainly used when using the clinical headset or shoulder strap on the patient.

When the pause function is activated it can be released from the remote switch on the probe or from the "Pause" key (9) on the instrument. A red or a blue light symbolising the right or the left ear will be blinking on the probe when the pause function is on standby mode ready to be activated by the operator. Also, the "Pause" key (9) will be blinking.

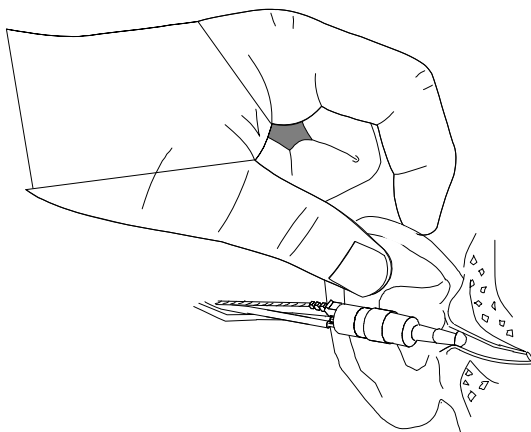
The various functions of the remote switch are defined in the Common Setup Menu. If the pause function is wanted as a

default setting, this can be selected in the Common Setup Menu, too.

Making a Good Probe 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 probe as indicated in figure 5.

Figure 5:



Hair coming out of the ear canal may make an airtight fit difficult to obtain. Therefore, ideally, excessive hair should be removed prior to testing. Also, a clinical 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.

For the decay test an absolutely airtight fit is needed to avoid test results indicating decay, where the test result is actually just an artefact caused by a poor fit.

Test Procedure

Before every test is performed it is recommended to delete all stored patient data from the instrument. This is done by holding down “shift”

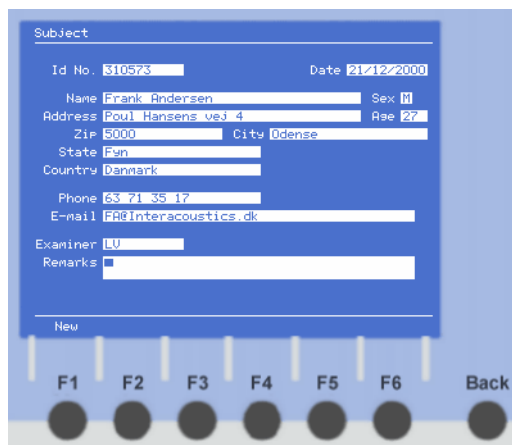
(17) while pressing “new subject” (9). After this action the following message will appear on the screen:

Figure 6:



If AT235 has a keyboard connected and the Common Setup Menu parameter “Keyboard Connected” is set to “Yes” the below “Subject Screen” in figure 7 will appear:

Figure 7:



Press F1 “New” to delete all stored data from the previous patient and use the keyboard to type in new patient data.

Finally, press “Back” (7) to return to the test screens.

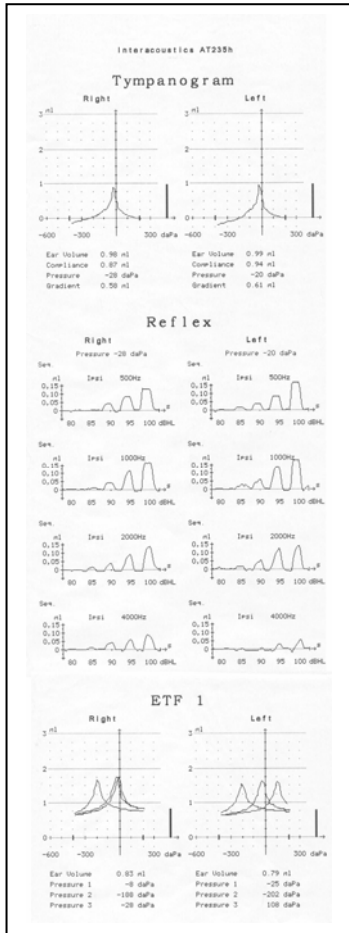
Printing Test Results

To print test results obtained by the AT235 press "Print" (8) and the internal thermal printer will start printing. It is possible to print the

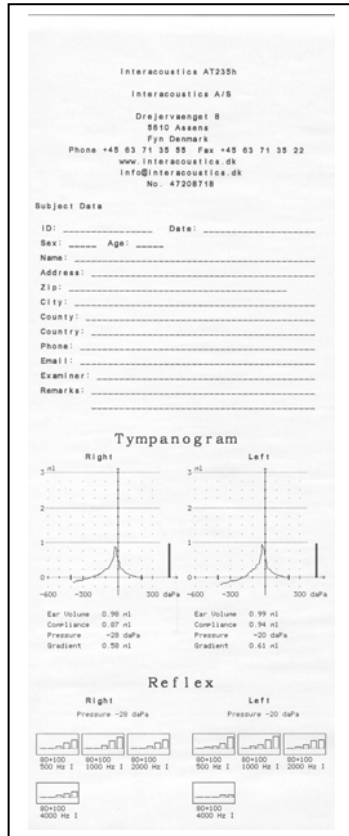
present screen only by holding down "shift" (17) while pressing "print screen" (8).

Please see below some typical examples of printouts from the internal printer:

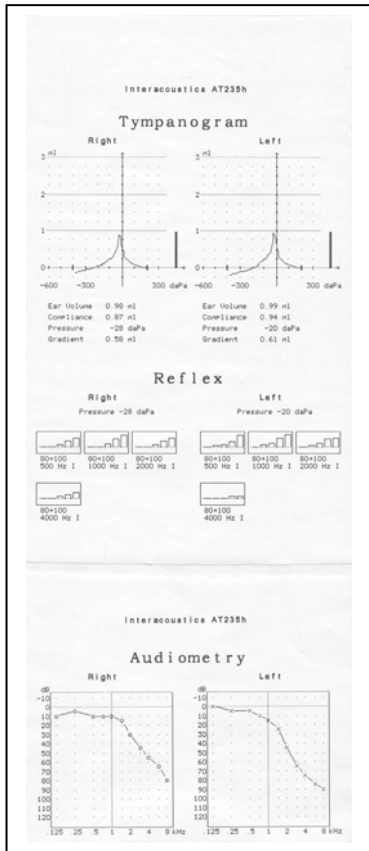
Printout 1:



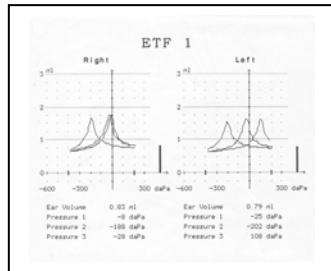
Printout 2:



Printout 3:



Printout 4:



Printout 1:

Printout 1 contains the following:

- Tympanogram.
- Reflexes (sequence method with individual reflexes starting at 80 dB at 4 different frequencies).
- ETF 1 test (Eustachian Tube Function test).

Printout 2:

Printout 2 contains the following:

- Tympanogram.

- Reflexes (sequence method with 5 individual reflexes starting at 80 dB at 4 different frequencies). Unlike the reflexes from printout 1, the reflexes from printout 2 have been printed with the special paper saving function. This function is activated by holding down “shift” while pressing “Print” (8).
- In the top of the printout “Clinic” data and “Subject” data have been printed.

Printout 3:

Printout 3 contains the following:

- Tympanogram.
- Reflexes (sequence method with 5 individual reflexes starting at 80 dB at 4 different frequencies).
- Audiogram with stored threshold for right and left ear.

Printout 4:

Printout 4 contains the following:

- ETF 1 test (Eustachian Tube Function test).

Connection to PC

The data from AT235 can be transferred to a PC by means of a USB cable. The software needed for AT235 for transferring data to a PC is one of the following Windows compatible software:

- OtoAccess™ Database Program + diagnostics modules minimum version 1.25
- PrintView for PC monitoring and printing minimum version 1.15
- IA-NOAH-Imp Module interfacing to NOAH minimum version 1.12
- IA-NOAH-Aud Module interfacing to NOAH minimum version 1.23

In the software open the “Instrument Setup”:

- Select the com port number, see appendix B
- The Baud Rate in the PC software must be set to USB.
- For OtoAccess, set the Group to IAP
- Select the Instrument ID, choose “AA22X.100 if you want to transfer Audiometer data

Select the Instrument ID, choose "AT235.100 if you want to transfer Tympanometry data.

Installing Printer Paper

1. Open the plastic cover of the paper compartment of AT235.
2. Place the new paper roll in the paper compartment in such a way that the paper ascends from the lower part of the paper roll. With a pair of scissors cut two triangles of paper away. This will make the feeding of the paper easier – see picture 7.

Picture 7:



Picture 8:



3. Pull the blue lever (picture 8) in the direction of the instrument in order to open the pathway of paper travel.
4. Gently insert the paper between the lower part of the black rubber platen and the black plastic – see picture 8.

Picture 9:



Picture 10:



5. When the paper appears between the upper part of the rubber platen and the paper cutter, pull out an extra 10 to 15 centimetres of paper and return the small blue lever to its original position. Make sure that the paper is aligned correctly – see picture 9 and 10.
6. Now guide the paper through the slot of the cover of the paper compartment.
7. Close the plastic cover of the paper compartment again. AT235 is now ready to print.

Reflex and Tympanometry

When the instrument is switched on it automatically powers-up in

1) Reflex and Tympanometry Test mode

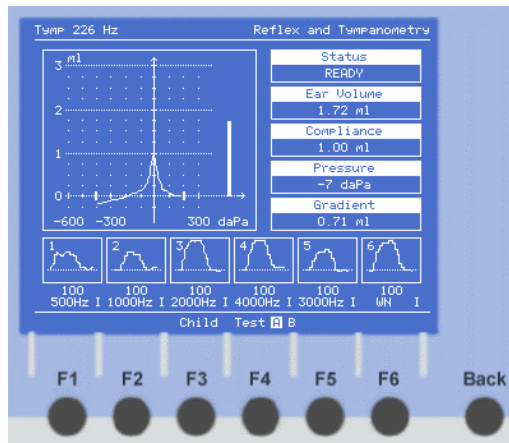
or

2) Tympanometry mode

(depending on the Power-up setting selected in the Common Setup Menu).

In order to choose between Tympanometry Test, Reflex Test and Reflex and Tympanometry Test, browse with the “Tymp/Reflex” key (10). Figure 8 shows the Reflex and Tympanometry Test Screen:

Figure 8:



In the Reflex and Tympanometry mode both indication lights of the “Tymp/Reflex” key (10) will be active.

1. Select test ear by means of “Right” (20) or “Left”(21).
2. Select the wanted reflex test “Test A” or “Test B” with (F4).

Note: In the Setup Menu of AT235 it is possible to pre-program two separate reflex tests "Test A" and "Test B". When starting a test procedure "Test A" is always default. Therefore if "Test B" is wanted press F4 "Test A B".

3. Place the probe in the test ear.

The probe will have an airtight fit when the indication light on the probe is green. When the status "Leaking" or "Blocked" is displayed in the upper right hand corner of the screen under the Status Bar, the indication light on the probe will be yellow. This indicates a bad fitting or a blocked ear tip.

When a correct fit has been obtained a tympanometric test is automatically performed on the first ear. By means of the tympanometric test, AT235 establishes the correct pressure in the ear canal for the subsequent reflex test.

3a) If clinical headset is used:

When using the clinical headset, select "Pause" (9) in order to prevent the instrument from automatically starting the test as soon as an airtight fit has been obtained.

Now, place the clinical headset over the patient's head or use the shoulder strap and insert the probe tip into the ear canal. When an airtight fit has been obtained the tympanometric test is ready to be performed. To start the test, select "Pause" (9) once again and the test will be carried out automatically.

Note: From the Common Setup Menu it is possible to set up "Pause" key (9) to be controlled from the Remote Switch of the probe.

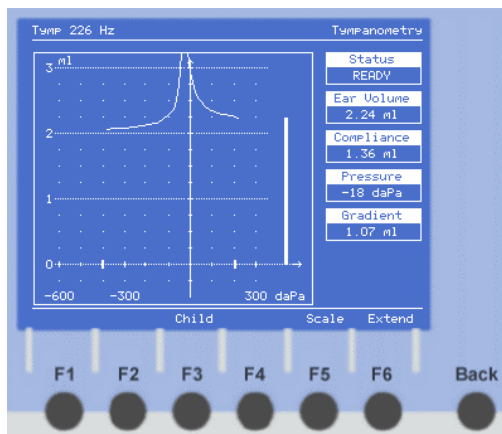
On the screen the tymp test can be followed on-line. When the tymp curve has been drawn, the AT235 will automatically continue with the selected reflex test "Test A" or "Test B".

4. Remove the probe from the first ear when the test sequence has finished. Select the other ear "Right" (20) or "Left" (21) and move the probe to the second ear and repeat the test sequence once again.
5. To print out the test result, simply press "Print" (8).

Changing Scale:

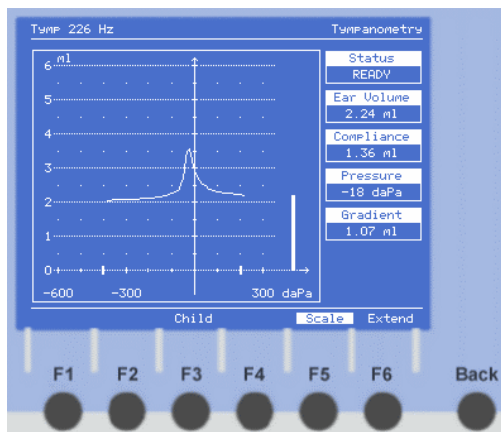
When performing Tympanometry situations might occur where the compliance peak will exceed the standard 3 ml tympanogram. When the compliance peak exceeds the 3 ml scale like in the below figure 9 AT235 will give the operator the possibility to change the 3 ml scale to a 6 ml scale.

Figure 9:



When the tympanogram with the 6 ml scale is activated the 6 ml scale will be present for both right and left ear:

Figure 10:



Modifying Reflex Test A and B

Before starting the test procedure the selected reflex Test A or B can be modified in order to meet the exact demands which are needed for the individual patient:

To modify reflex “Test A or B” press (F6):

Figure 11:

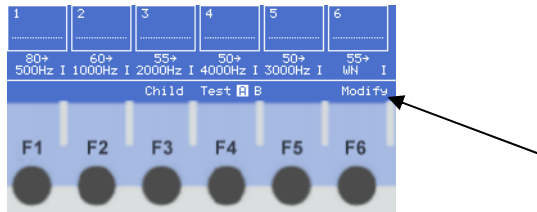
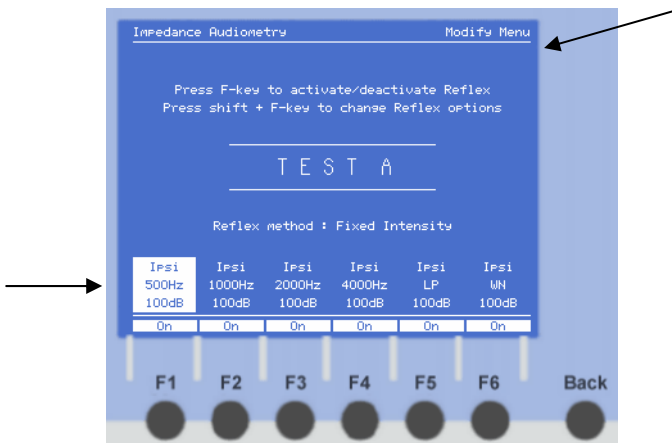


Figure 12 shows the Modify Menu for Reflex Test A – it is similar for Reflex Test B:

Figure 12:



In order to modify the individual reflex settings of Test A or B hold down “shift” (17) while pressing F1 to F6 depending on which reflex that needs to be modified.

When highlighted, it is possible to select between “Ipsi” (18) and “Contra” (19). The frequency can be changed by means of the “Frequency Decr / Incr” keys (14 and 15). The intensity can be change by means of the “Intensity Decr / Incr” keys (23 and 24). Finally it is possible to switch on or off the highlighted reflex by pressing the F-key underneath the highlighted reflex.

When the individual reflex for Test A or B has been modified to the special personal needs, hold down “shift” (10) while pressing the F-key underneath the highlighted reflex once again.

In the same way all the reflexes for Test A or B can be modified. Finally, press “Back” (7) to return to the test screen.

Ipsilateral and Contralateral reflexes

AT235 is capable of performing ipsilateral as well as contralateral reflexes.

In the Setup Menu for Reflex A or B it is possible to set up a reflex test procedure to perform either ipsilateral or contralateral reflexes only. Alternatively AT235 can be set up to perform ipsilateral and contralateral in the same test procedure.

By pressing “Ipsi” (18) or “Contra” (19) it is possible to switch on or off the ipsilateral or contralateral reflexes. This means that it is possible to manually overrule (meaning switch off) e.g. a contralateral reflex that was selected as default for Reflex Test A or B simply by pressing “Contra” (19).

The idea is that light indication in the “Ipsi” (18) and “Contra” (19) keys indicates whether or not the ipsilateral and / or contralateral reflexes will be performed in a preceding test session.

Tympanometry - only

When the instrument is switched on it automatically powers-up in

1) Reflex and Tympanometry Test mode

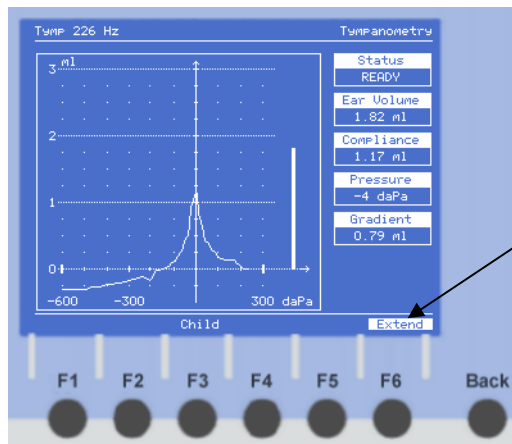
or

2) Tympanometry mode

(depending on the Power-up setting selected in the Common Setup Menu).

In order to choose between 1) Tympanometry Test, 2) Reflex Test and 3) Reflex and Tympanometry Test, browse with the “Tymp/Reflex” key (10). Figure 13 shows the Tympanometry Test Screen:

Figure 13:



In the Tympanometry mode the left indication light only on the “Tymp/Reflex” key (10) will be active.

1. Select test ear by means of “Right” (20) or “Left” (21).
2. Place the probe in the test ear.

The probe will have an airtight fit when the indication light on the probe is green. When the status “Leaking” or “Blocked” is displayed in the upper right hand side of the screen the indication light on the probe will be yellow. This indicates a bad fitting or a blocked ear tip.

When a correct fit has been obtained a tympanometric test is automatically performed on the first ear.

2a) If clinical headset is used:

When using the clinical headset select "Pause" (9) in order to prevent the instrument from automatically starting the test as soon as an airtight fit has been obtained.

Now place the clinical headset over the patient's head or use the shoulder strap and insert the probe tip into the ear canal. When an airtight fit has been obtained the tympanometric test is ready to be performed. To start the test, select "Pause" (9) once again and the test will be carried out automatically.

Note: From the Common Setup Menu it is possible to set up the "Pause" key (9) to be controlled from the Remote Switch of the probe.

On the screen the tymp test can be followed on-line.

3. Remove the probe from the first ear when the test sequence has finished. Select the other ear "Right" (20) or "Left" (21) and move the probe to the second ear and repeat the test sequence once again.

Extend Function

When being in the Tympanometry mode it is possible to extend the pressure range to go from +300 daPa to -600 daPa by pressing F6. When the Extend Function is active "Extend" in lower right hand corner of the screen is highlighted. The pressure range is indicated by two small, bold, vertical lines on the horizontal 0 ml line. To go back to the standard pressure range press F6 once again.

The standard pressure range is set up in the Tympanometry Setup Menu where Start Pressure and Stop Pressure are defined.

<h2>Automatic Reflex Test - only</h2>

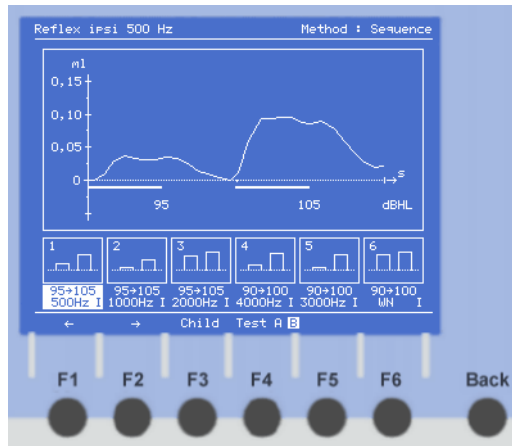
When the instrument is switched on it automatically powers-up in 1) the Reflex and Tympanometry Test mode or in 2) the Tympanometry

mode (depending on the Power-up setting selected in the Common Setup Menu).

To choose between 1) Tympanometry Test, 2) Reflex Test and 3) Reflex and Tympanometry Test browse with the “Tymp/Reflex” key (10).

Figure 14 shows the Reflex Test Screen:

Figure 14:



In the Reflex Test mode the right indication light only on the “Tymp/Reflex” key (10) will be active.

Note: It is recommended always to make a preceding tympanometry test in order to establish the correct middle ear pressure which is the optimal basis for precise reflex test.

If a reflex test is performed without first making a tympanometry curve, the reflex will be performed at 0 daPa and not at the correct middle ear pressure.

1. Select test ear by means of “Right” (20) or “Left” (21).
2. Place the probe in the test ear.

The probe will have an airtight fit when the indication light on the probe is green. When the status “Leaking” or “Blocked” is displayed in

the upper right hand side of the screen the indication light on the probe will be yellow. This indicates a bad fitting or a blocked ear tip. When a correct fit has been obtained the reflex test will begin.

2a) If clinical headset is used:

When using the clinical headset select "Pause" (9) to prevent the instrument from automatically starting the test as soon as an airtight fit has been obtained.

Place the clinical headset over the patient's head or use the shoulder strap and insert the probe tip into the ear canal. When an airtight fit has been obtained the reflex test is ready to be performed. To start the test, select "Pause" (9) once again and the test will be carried out automatically.

Note: From the Common Setup Menu it is possible to set up the "Pause" key (9) to be controlled from the Remote Switch of the probe.

On the screen the reflex test can be followed on-line.

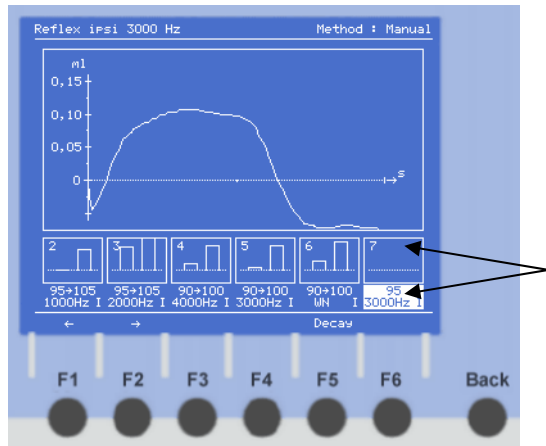
3. Remove the probe from the first ear when the test sequence has finished. Select the other ear "Right" (20) or "Left" (21), move the probe to the second ear and repeat the test sequence once again.

Manual Reflexes

With AT235 there are two different ways to perform manual reflexes. Manual reflexes can be performed subsequently to an automatic test session or on their own.

After an automatic session where a number of reflexes have been recorded, there might be a need for making one or more manual reflexes. This can be performed by pressing "Man" (13). An empty reflex box will appear and below it the default intensity and frequency will be highlighted like in figure 15. With the "Frequency Decr / Incr" buttons (14 and 15) and the "Intensity Decr / Incr" buttons (23 and 24) it is possible to change the parameters for the manual reflex.

Figure 15:



When ready, press the “Tone Switch” (22) and the manual reflex will be performed and appear on the display. The parameters for the manual reflex can be changed once again if the result is not satisfactory. When satisfied, press “Store” (16) to store the manual reflex next to the automatic reflexes in the lower right hand corner of the screen and AT235 will automatically prepare for performing another manual reflex.

The number of manual reflexes available depends on the number of automatic reflexes recorded. 18 reflex boxes per ear can be stored. If for instance 6 automatic reflexes are stored there are 12 manual reflexes available and if for instance 12 automatic reflexes are stored there are 6 manual reflexes available.

Editing Automatic and Manual Reflexes

After a session of automatically or manually recorded reflexes you have the following possibilities to edit and work with the reflexes:

- Browsing between the reflexes.
- Repeating reflexes.
- Deleting reflexes

The idea of browsing between the automatically recorded reflexes is to see the individual reflex not only in the small reflex boxes, but also on the full screen. After the automatic test procedure press “Man” (13) and an empty reflex box will appear and below it the default intensity and frequency will be highlighted like in figure 16.

Figure 16:

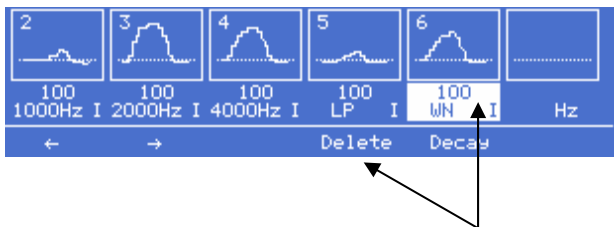


Just above the F1 and F2 keys there are two small arrows pointing to the left and the right hand respectively. By pressing the F1 and F2 keys it is possible to browse between the recorded reflexes.

Repeating and Deleting reflexes

When browsing between the recorded reflexes it is possible to manually repeat the reflexes which have been recorded previously. This is done simply by pressing the “Tone Switch” (22). Now the reflex is repeated at the same frequency and intensity as the previously recorded reflex. This action can be repeated several times. When satisfied press “Store” (16) to store the reflex.

Figure 17:



When repeating a reflex, it is possible to change the frequency by pressing “Frequency Decr / Incr” (14 and 15) and intensity by pressing “Intensity Decr / Incr” (23 and 24). This action can be repeated several times. When satisfied press “Store” (16) to store the reflex.

Note: If you do not press “Store” (16) the original automatically recorded reflex will come back.

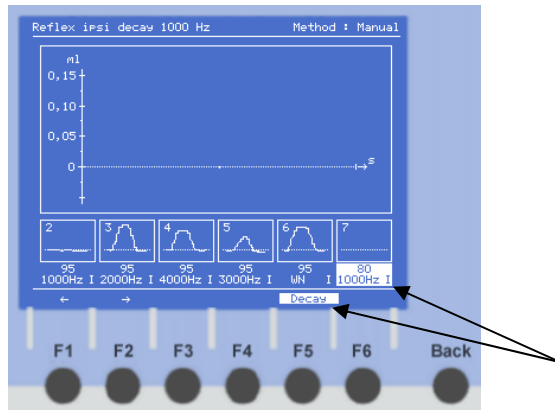
To delete a reflex use the F1 and F2 key to go to the reflex which needs to be deleted. When the selected reflex is highlighted, simply press F4 “Delete” to delete this reflex.

Manual Reflex Decay

There are two different ways to perform reflex decay tests with AT235. Reflex decay tests can be performed subsequently to an automatic test session or on their own.

After an automatic session where a number of reflexes have been recorded, there might be a need for making one or more manual reflex decay tests. This can be performed by pressing “Man” (13). Now an empty and highlighted reflex box will appear and below it the default intensity and frequency will be highlighted like in figure 18. Also “Decay” above the F5-key will be highlighted.

Figure 18:

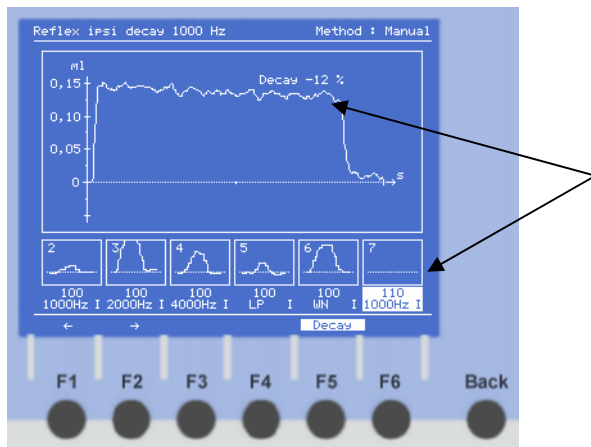


Note: To ensure the right basis for performing a reflex decay test it is necessary to find the reflex threshold for the frequency to be tested. When the reflex threshold has been found 10 dB must be added to this threshold to get the correct starting point.

When ready, press the “Tone Switch” (22) and the manual reflex decay will be performed and appear on the screen. The parameters for the manual reflex can be changed by pressing the “Frequency Decr / Incr” keys (14 and 15) and the “Intensity Decr / Incr” keys (23 and 24). Press “Store” (16) to store the manual reflex decay. AT235 automatically prepares for performing another manual reflex decay.

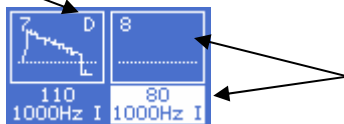
In Figure 19 an example of the decay test result can be seen. The decay result is expressed graphically and numerically in percent (%).

Figure 19:



When a reflex decay test has been accepted and stored it will be put into one of the small reflex boxes. A small “D” (see figure 20) will indicate that a Decay test has been performed.

Figure 20:



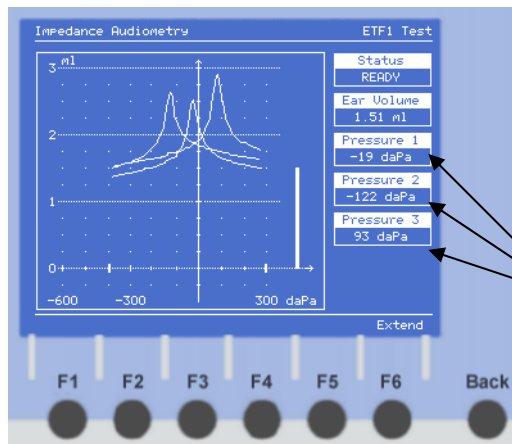
By storing the test result the instrument automatically prepares for performing another manual reflex or reflex decay test.

Eustachian Tube Function

With AT235 it is possible to perform a Eustachian Tube Function test for non-perforated ear drums, the so-called Williams Test. With AT235 the test is semi automatic and will suggest the operator how to operate the instrument and how to instruct the patient.

To choose the Eustachian Tube Function test press the “ETF” key (11)

Figure 21:



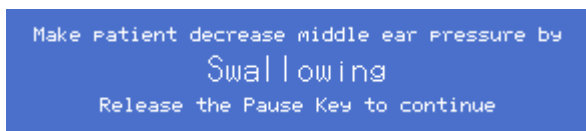
In the Eustachian Tube Function test mode the indication light on the “ETF” key (11) will be active and at the same time the indication light on the “Pause” key (9) will start blinking in order to tell the operator that his/hers action is now needed.

1. Select test ear by means of “Right” (20) or “Left” (21).
2. Place the probe in the test ear.

The probe will have an airtight fit, when the indication light on the probe is green. When the status “Leaking” or “Blocked” is displayed in the upper right hand side of the screen the indication light on the probe will be yellow. This indicates a bad fitting or a blocked ear tip.

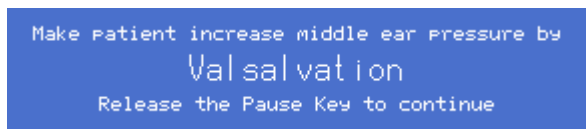
To perform the test the operator will have to press the blinking “Pause” key (9) to make a tympanometric curve.

After the first sweep an information window appears on the screen:



Follow this instruction. To decrease the middle ear pressure (create a negative middle ear pressure) make the patient swallow while closing his/hers nose with two fingers.

Now press the blinking "Pause" (9) key once again and the test will make its second sweep. When the second sweep has been carried out another information window will appear on the screen:



Follow this instruction. To increase the middle ear pressure (create a neutral middle ear pressure) make the patient blow softly with the mouth closed while also closing his/hers nose with two fingers.

Press the blinking "Pause" (9) key once again as told in the information window and the test will make its final and third sweep.

Now three tympanometric curves can be viewed in the screen where a change in peak pressure graphically will indicate the function of the Eustachian tube.

To the right of the tympanogram under Pressure 1, Pressure 2 and Pressure 3 the peak pressures of the three tympanometric curves are also expressed numerically in daPa.

If the three peak pressures are the same, it has not been possible for the patient to operate his Eustachian tube to change the middle ear pressure. This means that the Eustachian tube is temporarily or permanently out of function.

Note: From the Common Setup Menu it is possible to set up the "Pause" key (9) to be controlled from the Remote Switch of the probe.

Automatic and Manual Audiometry

When the instrument is switched on it automatically powers-up in

1) the Reflex and Tympanometry Test mode

or

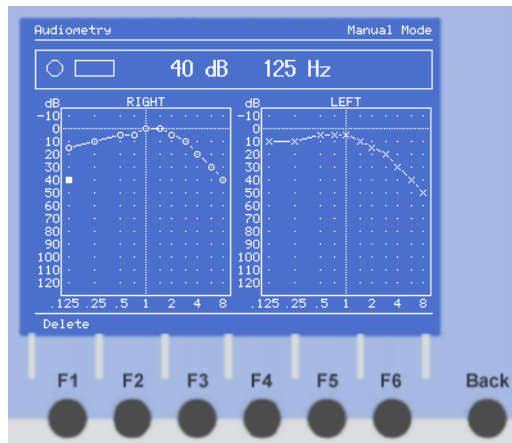
2) the Tympanometry mode

(depending on power-up setting selected in Common Setup Menu).

To select automatic tone audiometry, press the “Audiometry” key (12). The automatic audiometry threshold test is according to the Hughson Westlake (HW) test procedure. The HW test procedure is defined as 2 out of 3 correct responses at a certain level in a 5 dB increase and 10 dB decrease test procedure.

Figure 22 shows the Automatic Audiometry Test Screen for the HW test:

Figure 22:



In the Automatic Audiometry Test mode the indication light of the “Audiometry” key (10) will be active and the indication light of the “Pause” key (9) will be blinking.

Test Procedure:

Instruct the patient that he will hear tones with different frequencies and that he is supposed to push the patient response button whenever a tone is audible to him.

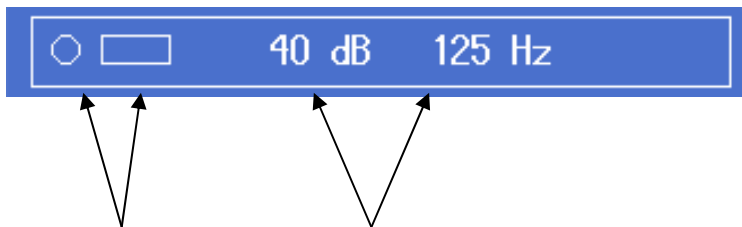
1. Select desired test ear “Right” (20) or “Left”(21).
2. Select “Famili” to familiarise the patient with the HW procedure. When the familiarisation procedure is succeeded the HW test will start automatically. If the familiarisation procedure is not needed simply press “Pause” (9) to start the HW test.

When the audiogram for the first test ear has been completed the test will automatically continue testing the other ear.

In the horizontal bar above the right and the left audiogram it is possible to follow the test procedure see figure 23. To the left there is a small circle, which is highlighted whenever a tone is audible to the patient. Next to the circle there is a small rectangle, which is highlighted whenever the patient presses the patient response button.

Finally, the present dB value and frequency is expressed numerically.

Figure 23:

**Manual Audiometry:**

To perform manual audiometry first select “Audiometry” (12) and then press “Man” (13). Now manual audiometry can be performed. Select frequency by pressing “Frequency Decr / Incr” (14 and 15) and intensity by pressing “Intensity Decr / Incr” (23 and 24). To store thresholds for the audiogram press “Store” (16).

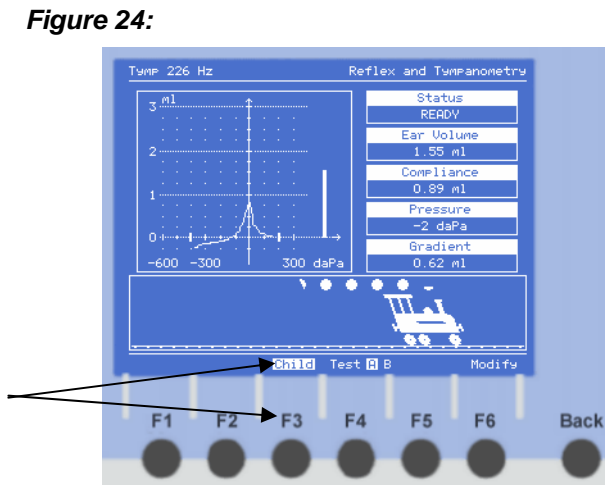
"Child" Function

AT235 has been equipped with a special Child Function. The intention of this function is to help the operator keeping the child concentrated for the short while it takes to perform the test.

The Child Function is available from the 1) Tympanometry Test, 2) Reflex Test and 3) Reflex and Tympanometry Test.

To activate the Child Function press F3.

Figure 24 shows the Reflex and Tympanometry Test with the Child Function activated:



The train will continue moving until the selected reflex test session has finished. When the test session has finished the train will automatically disappear.

Handling of Ear Tips

Cleaning of Ear Tips

We recommend 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.

Cleaning of 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 instruction on how to remove e.g. cerumen from the small acoustic and air pressure channels of probe tip.

For AT235 two different probe systems exist; the AT235-ATP Standard Probe System and the AT235h-ATP Clinical Probe System.

The two different probe systems can be seen in the below picture 11:

Picture 11:



To clean the small acoustic and air pressure channels of probe tip unscrew the small ribbed plastic nut that holds the probe tip:

Picture 12:



After unscrewing the small ribbed plastic nut it is possible to detach the small probe tip with the small acoustic and air pressure channels from the transducer house:

Picture 13:



Ribbed Plastic Nut

Transducer House

Probe Tip with the small acoustic
and air pressure channels

The cleaning of the acoustic and air pressure channels of the probe tip must be performed by means of the cleaning wire (nylon wire) which can be found in the Ear tips Assortment provided with the AT235.

When cleaning the acoustic and air pressure channels of the probe tip the cleaning wire must be inserted from the back of the probe tip according to picture 14:

Picture 14:



After cleaning all the acoustic and air pressure channels of the probe tip it can be reassembled. Make sure that the Probe Tip is connected correctly onto the Transducer Housing – a small flange will ensure correct positioning - before the plastic nut is gently tightened.

Picture 15:



Functions of Buttons

The numbers below refer to the drawing in the back of this manual.

- 1-6) F1 – F6** The six Function Keys hold functions displayed in the screen right above the individual F-key.
- 7) F7 - Back** Will always take you back one level.
- 8) Print** Prints out the obtained test data.
- Shift + print screen*** *Prints out the present screen.*
- 9) Pause** Selects pause function when clinical headset is used.
- Shift + new subject*** *Deletes test results and if a keyboard is installed new patient data can be typed.*
- 10) Tymp/Reflex** Selects:
1) Tympanometry.
2) Reflex and Tympanometry.
3) Reflexometry.
- 11) ETF** Selects Eustachian Tube Function test.
- 12) Audiometry** Selects Audiometry.
- 13) Man** Activates manual testing.
- 14) Frequency Decr** Browses between the different frequency options in manual reflexometry and manual audiometry.
- 15) Frequency Incr** Browses between the different frequencies options in manual reflexometry and manual audiometry.

- 16) Store** Stores manually obtained data.
- 17) Shift** *The shift key activates the sub functions of the other keys (9 – 24) written in italic.*
- 18) Ipsi** Activates and deactivates the ipsilateral reflex stimulus, which is presented through the probe.
- 19) Contra** Activates and deactivates the contralateral reflex stimulus, which is presented through the TDH39.
- 20) Right** Selects right test ear.
- 21) Left** Selects left test ear.
- 22) Tone Switch** Stimulus presentation switch for manual audiometry and manual reflex mode.
- 23) Intensity Decr** Decreases the intensity chosen for manual reflex testing or manual audiometry.
- 24) Intensity Incr** Increases the intensity chosen for manual reflex testing or manual audiometry.

Technical Specifications

Standards:

Safety	:	EN60601-1, Class 1, Type B
EMC	:	EN60601-1-2
Impedance	:	EN61027/ANSI S3.39, Type 2
Audiometer	:	EN60645-1/ANSI S3.6, Type 4 Tone Audiometer

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.

Power, UPS400

Consumption	:	15VA
Mains voltage/fuses:	:	100-240V AC, 50-60Hz, 40VA

Operation Environment:

Temperature	:	15 – 35 °C / 65 – 95 °F
Rel. Humidity	:	30 – 90%

Temperatures below 0 °C and above 50 °C may cause permanent damage on the instrument and its accessories.

Warm up time	:	10min at room temperature (20 °C)
--------------	---	-----------------------------------

Printer (Optional)

Type	:	Thermal printer with recording paper in rolls.
Printing Time	:	Depending on the test printed.

Paper Rolls:

Width	:	112 (+/- 0.5) mm
Diameter	:	45 (+2.0) mm
Basis weight	:	58.5 +/- 3g/m ²
Thickness	:	62 +/- 3 u
Tensile	:	Min. 3.2 kN/m

Impedance Measuring system

Probe tone:

Frequency : 226 Hz.
Level : 85 dB SPL with AGC, assuring constant level at different volumes.

Air Pressure

Control : Automatic.
Indicator : Measured value is displayed on the graphical display.
Range : -600 to +300 daPa.
Pressure Limitations: -800 daPa and +600 daPa.
Pressure Change Rate: Minimum (50 daPa/s), medium, maximum or automatic with minimum speed at compliance peak. Selectable in the setup.

Compliance

Range : 0.1 to 6.0 ml (Ear volume: 0.1 to 8.0 ml).

Types

Tympanometry : Automatic, where the start and stop pressure can be user-programmed from the setup menu.
Eustachian Tube Function: Williams test (automatic function).

Indicators

Graphical display : Compliance is indicated as ml and pressure as daPa. Stimulus level is indicated as dB Hearing Level.

Memory

Tympanometry : 1 curve per ear.
Eustachian Tube Function: 3 curves per ear.

Reflex and Audiometer Functions

Signal Sources

Tone – Contra, Reflex: 250, 500, 1000, 2000, 3000, 4000, 6000 and 8000Hz.

Tone – Contra, Audiometry: 125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000 and 8000Hz.

Tone – Ipsi, Reflex: 500, 1000, 2000, 3000 and 4000Hz.

Noise – Contra, Reflex: Wide Band, High Pass, Low Pass

Noise – Ipsi, Reflex: Wide Band, High Pass, Low Pass.

Inputs

Patient Response : Connection for patient response switch.

Output

Contra Earphone : TDH39, earphone for reflex and audiometry measurements.

Ipsi Earphone : Probe earphone incorporated in probe system for reflex measurements.

Air : Connection for air system to the probe.

USB : Input/output for PC connection. An external PC can be setup to both monitor and control the instrument. The control actions can be followed on the display and the operation panel. Online communication can be selected, where the measured data will be sent to an external PC.

Keyboard : Connection for external keyboard, standard PC type.

Attenuator

Range : 0 to 130 dB in 1 or 5 dB steps. Typical range is –10 to 120 dB HL. Range is individual for different modes – see below table.

Test Types

Manual Audiometry:	Manual control of all functions.
Automatic Audiometry:	Auto threshold according to ISO 8253-1 (Patient controlled Hughson Westlake). The threshold is determined by the activation of the patient response.
Manual Reflex :	Manual control of all functions.
Reflex Decay :	Manually controlled with stimulus duration of 10 seconds.

Memory

6 ipsilateral and 6 contralateral graphs / curves. Each of them can hold up to 6 pulses. There is an additional capacity for 6 manual tests.

Table 1: Frequencies and intensity ranges

Frequency	Reflex				Audiometry	
	Contralateral		Ipsilateral		TDH39	
	Min	Max*	Min	Max*	Min	Max
Hz	dB HL	dB HL	dB HL	DB HL	dB HL	dB HL
250	10	110	-	-	-10	110
500	10	120	10	105	-10	120
1000	10	120	10	110	-10	120
2000	10	120	10	105	-10	120
3000	10	120	10	100	-10	120
4000	10	120	10	100	-10	120
6000	10	120	-	-	-10	120
8000	10	110	-	-	-10	110
WB noise	10	120	10	105		
LP noise	10	120	10	105		
HP noise	10	110	10	105		

Parts

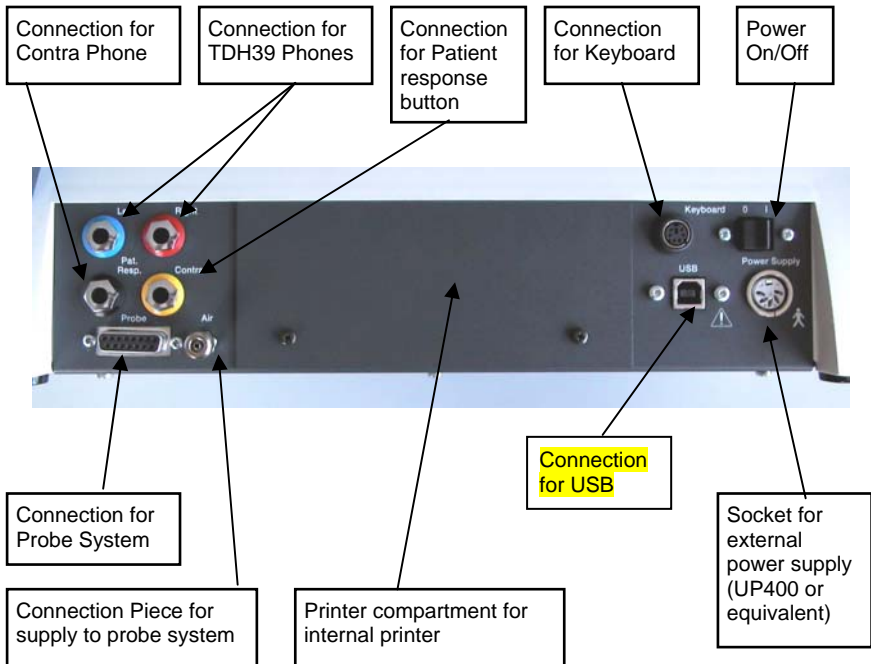
Included Parts:

ATP-AT235u Universal probe system with shoulder strap and wrist strap
TSH39 Single contralateral headset
UPS400 external switch mode power supply
Power cable
BET50 Box of 65 assorted ear tips
TPR26 3 rolls of recording paper
PCR-AT235 dust cover
Operation Manual
Multilingual CE instructions for use

Additional Parts:

TDH39 audiometric headset
ACC226 Carrying Case
EARtone 5A Audiometric Insert Phones
ACC25 carrying case
CIR22 contralateral insert phone
APS2 patient signal
CAT40 calibration unit 0.2-0.5-2.0-5.0 ml
CAT227 calibration unit 0.2-0.5-1-2-3-4-5 ml
IES impedance ear simulator
USB cable 2m black

Connection Panel



To maintain the validity of the CE-mark of the AT235 the power supply must be CE-medical approved.

Unpacking / Inspection

Check box and contents for damage:

When the instrument has been 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.

Store carton for future shipment

The AT235 comes in its own shipping carton, which is specially designed for the AT235. Please store 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

When AT235 is delivered as a standard unit the case contains the following:

Quantity	Item	Order No.
1	Instrument	AT235
1	Universal Probe System	ATP-AT235U
1	Single Contralateral Earphone	TDH39
1	External Switch Mode Power Supply	UPS400
1	Power Cable	
1	Box of 65 Assorted Ear tips	BET50
3	Rolls of Recording Paper	TRP35
1	Dust Cover	PCR-AT235
1	Operation manual	
1	CE-manual	

Check numbers on AT235 and Manual:

The identification label on the connection panel holds the

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

Write down serial number:

To maintain the validity of the CE-mark of the AT235, the power supply must be CE-medical approved. When AT235 is supplied with the external power supply model UPS400 write down serial number located on the bottom plate.

Reporting Imperfections

Inspect before connection:

Prior to connecting AT235 to the Power Supply 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. Therefore using the Return Report will be of great help to us and at the same time it is your best guarantee that the correction of the problem will be to your satisfaction.

Care and Maintenance

The performance and reliability of AT235 is prolonged if the following recommendations for care and maintenance are adhered to:

Using an External power Supply e.g. UP400 - turn off at the mains socket.

Great care when handling the transducers:

Great care should be exercised when handling the transducers of AT235 as dropping them may alter the calibration.

Annual calibration:

The AT235 has been designed to provide many years of reliable service, but annual calibration is recommended due to possible impact on transducers.

We do also recommend to calibrate the AT235 if something drastic happens to a part of it (e.g. if headset or bone conductor is dropped on a hard surface).

Trouble Shooting

AT235 does not turn on:

The power cable from the mains to the power supply and from the power supply to the instrument must be correctly connected.

The mains switch must be "on" and the power switch on the rear panel of the AT235 must also be "on".

If still nothing happens a fuse may be blown in the power supply. The power supply for AT235 is designed with two changeable fuses.

Data is not transmitted to the computer:

The correct COM port must be selected in the computer, and this COM port must be chosen in the computer program.

The baud rate in the computer program must be set to USB.

The USB driver must be installed on the PC. Please refer to "Appendix B" of this manual for instructions.

No Tymp curves are drawn:

The probe system has to make a perfect seal to the ear canal. This has not been obtained if the display shows "Leaking" or "Blocked" and the indication light on the probe is yellow. A perfect seal is indicated with a green light on the probe.

Check if the transducer / probe system is connected on the connection panel of AT235.

Also the small rubber tube of the probe cable must be connected on the connection panel of AT235.

"Blocked" is displayed in Tymp mode:

The probe is blocked at the ear tip, either by wrong insertion into the ear canal, or by cerumen. Any accumulated cerumen at the probe tip opening should be removed very carefully. Please refer to the chapter "Cleaning Probe and Ear tips" of this manual for details.

Test starts despite a blocked ear tip:

The instrument must warm up for 10 minutes for calibration to be accurate.

If the problem is still present a calibration of this feature by means of a 0.2ml cavity calibrator is needed to match the altitude related air pressure of the installation site. This is a job for a technician.

Printer does not respond:

The printer might be out of paper!

Please refer to “Installing Printer Paper” in order to see how to change the paper roll.

Maybe the printer is set to “Off” in the Common Set Up under Printer.

Printer responds, but nothing is printed on the paper:

The printer paper has been installed incorrectly meaning that the backside of the paper is facing the printer head.

Simply turn around paper roll. Please refer to the chapter “Installing Printer Paper”.

Display is too bright or too dark:

From the Main Menu it is possible to adjust the brightness by means of “LCD-“ and “LCD+” (F5 and F6).

Frequently Asked Questions

My Reflex Test (A or B) is pre-programmed to ipsilateral reflexes. Is it possible also to have contralateral reflexes in the same session or simply contralateral reflexes only?

Yes and yes!

In the Reflex and Tympanometry test menu the indication lights of the “Ipsi” key (18) and the “Contra” key (19) will inform you which reflex method is selected, Ipsilateral and / or contralateral.

Normally, only the indication light of the “Ipsi” key (18) will be active informing that only the ipsilateral reflex test will be performed during the subsequent test procedure. Press the “Contra” key (19) to activate also the contralateral reflex test for the subsequent.

In case only contralateral reflexes are wanted, press the “Ipsi” key (18) to switch off the indication light in the “Ipsi” key and deactivate the ipsilateral reflexes.

Sometimes I would like to temporarily change the pre-programmed reflex setup. How can I do that?

It is always possible to modify the pre-programmed reflex test A or B in the Reflex and Tympanometry test menu. All previous data must be deleted by pressing “new subject” (9) while holding “shift” (17).

In the lower right hand corner of the display it is now possible to activate the Modify Menu by pressing “Modify” (F6). In the Modify Menu the selected Reflex Method (Fixed, Screening, Auto or Sequence) can now be modified to personal need. It is possible to select between ipsilateral or contralateral reflexes, frequency and intensity can be changed and finally reflexes can be switched on or off according to the number of reflexes needed.

It is important to know that the modifications carried out in the Modify Menu are current only until all previous data have been deleted by pressing “new subject” (9) while holding down “shift” (17).

Why is the light on the probe sometimes yellow?

When the light on the probe is yellow this indicates that the probe tip is blocked e.g. against the wall of the ear canal or that an airtight fit of the ear tip cannot be obtained.

Why does the test not start automatically?

Please check if the indication light on the “Pause” key (9) is blinking!

AT235 is designed with a Pause Function, which is very convenient especially in connection with the use of the clinical probe.

The Pause Function can be chosen as power-up under “Pause” in the Common Setup Menu or it can be selected from the operation panel when needed when simply by pressing the “Pause” key (9).

When the Pause Function is selected either manually or as power-up the indication light will be active on the “Pause” key (9).

The Remote Switch on the probe does not allow me to change between right and left ear:

The function of the remote switch on the probe is defined under Remote Switch in the Common Setup Menu of AT235. It is possible to set up the remote switch to:

- a. “L/R” – in this way you can select between left and right ear.
- b. “Pause” – in this way the Pause Function can be controlled.
- c. “L/R or Pause” – in this way you can select between left and right ear, when the probe with the ear tip is out of the ear. And the Pause Function can be controlled when the probe with the ear tip is inside the ear.
- d. The remote switch is set to “Off”.

The Remote Switch on the probe does not allow me to control the Pause Function:

See previous paragraph!

The instrument only performs Tympanometry:

This is probably because of the fact “Tymp” has been selected in Power-up under the Common Setup Menu instead of “Reflex and Tymp”.

Can I review recorded reflexes?

Yes!

After a test session it is possible to review the recorded reflexes. All recorded reflexes can be viewed in the small reflex boxes in the lower part of the display. However, by pressing “Man” (13) two small arrows “←” and “→” (F1 and F2) makes it possible to browse between all recorded reflexes from the small reflexes. When a specific reflex is viewed in the small reflex box, the numerical data for the reflex test is highlight and the graphical data of the reflex test is shown in a large window above the reflex box.

What is Gradient?

Gradient is explained in the chapter “Tympanometry Setup Menu” of this manual.

My AT235 only displays 4 reflexes boxes. I need 6 reflex boxes:

In the Common Setup Menu under Reflex Icon Boxes it is possible to select between either 4 or 6 reflex boxes. Make sure that you select the right number of reflex boxes according to personal preferences.

I find the sensitivity of the reflex recording unsuitable! Can it be modified?

Yes!

In the following Reflex Methods: Screening, Auto and Sequence (Sequence only when Test Stop Criteria is set to Automatic) it is possible to set the Reflex Sensitivity to Sensitive, Normal or Robust.

In the chapter “Reflex Methods” in this manual, the three settings are explained in detail.

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Stratton 1981)

Dictionary

Acoustic Admittance:

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

Acoustic Compliance:

Another term for Acoustic Admittance.

Acoustic Immittance:

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 Immittance.

Dynamic Acoustic Immittance:

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 Immittance.

Peak Static Acoustic Immittance:

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

Probe:

A coupling device that is inserted into the external auditory canal, to connect it to the acoustic immittance 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 immittance.

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 Immittance:

The acoustic immittance 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 Immittance:

- 1) The acoustic immittance 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^3 .

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:

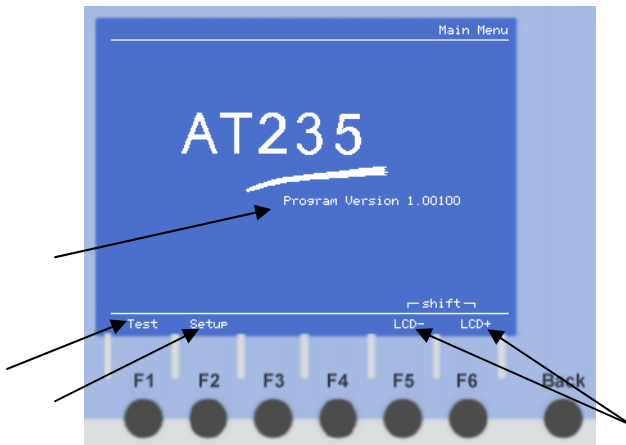
Test designed to determine the function of the Eustachian tube in ears with non-perforated eardrums.

Appendix A: Main Menu and Setup

When the instrument is switched on it automatically powers-up in the Reflex and Tympanometry Test mode or Tympanometry Test mode.

To go to AT235's Main Menu press "Back" (7) one or more times, or simply hold down "shift" (17) while pressing "Back" (7) – the latter will bring you to the Main Menu from wherever you are in the instrument. Figure 25 shows the Main Menu:

Figure 25:



From the main menu it is possible to adjust the contrast of the display by means of "LCD-" (F5) and "LCD+" (F6). The instrument will always remember the last setting.

When holding down "shift" (17) the writing above F5 and F6 changes to "LED-" and "(LED+)". Now the brightness of the LEDs (indication lights) of the instrument keys can be adjusted. Also here the instrument will remember the last setting.

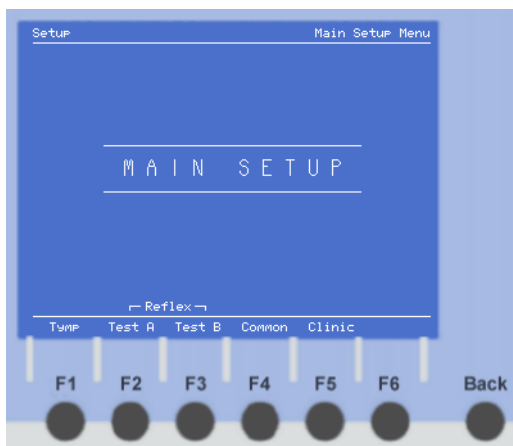
Pressing "Test" (F1) will bring you back to the Test Screens.
Pressing "Setup" (F2) will bring you to the Main Setup Menu

The program version of AT235 is written in the middle of the screen.

Main Setup Menu

The internal Main Setup Menu of AT235 is reached from the Main Menu by pressing “Setup” (F2). Figure 26 shows the Main Setup Menu:

Figure 26:



From the Main Setup Menu it is possible to enter the following Setup Menus by pressing F1 to F5:

- Tympanometry Setup
- Setup for Reflex Test A and B
- Common Setup
- Clinic Setup

In the individual setup menus navigation through the setup points and changing parameters in the individual setup points is very simple. With the F-keys (F2 to F5) representing arrow keys “↓, ↑, ←, →” it is possible to browse through the different setup points. Parameters can be changed with “Change” (F1) when it is highlighted.

To leave the individual setup menu press “Back” (7). This key will always take you back one level. If one or more parameters have been changed the following message will appear on the screen:

Save Changes ?

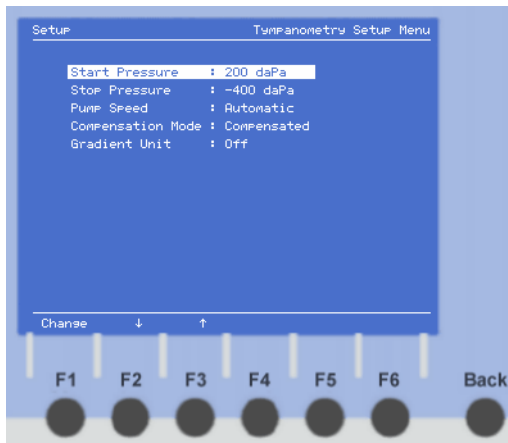
If you want to confirm the changes press F1 for “Yes”. If the changes should not be confirmed press F6 for “No”.

Tympanometry Setup Menu

The Tympanometry Setup Menu is reached from the Main Menu by pressing “Setup” (F2). In the Main Setup Menu press “Tymp” (F1) to enter the Tympanometry Setup Menu:

Figure 27 shows the Tympanometry Setup Menu:

Figure 27:



Start Pressure:

Start pressure indicates the pressure that will be established as the starting point for the pressure sweep for the tympanometric curve. The range of Start Pressure goes from 25 daPa to 300 daPa.

Stop Pressure:

Stop Pressure indicates at what pressure the sweep for the tympanometric curve will stop.

Pump Speed:

With AT235 there are four different pump speed settings:

- Minimum (17 daPa/sec).
- Medium (50 daPa/sec).
- Maximum (>150 daPa/sec).
- Automatic (see below).

A slow speed will be more time consuming, but may give more detailed information. The horizontal displacement of the tympanometric curve's peak in the sweeping direction caused by inherent hysteresis of the system and the middle ear itself will be smaller with lower speed.

With the Automatic setting speed and precision is combined in the tympanometric sweep. At the start of the sweep the pump speed will be at maximum due to the fact that the information derived from the first part of the sweep only contains little information of diagnostic value.

The speed will gradually be reduced to minimum speed when coming closer to the peak. Just before and just after the peak the pump speed will be at minimum since this part of the sweep diagnostically is the most important part. At the final part of the sweep the speed will gradually increase again to reach maximum at the end of the sweep.

Compensated Mode:

AT235 can be set to either Compensated Mode or Non Compensated Mode. Compensated Mode is used when you want the tympanometric curve to be displayed at the floor of the co-ordinate system of the tympanogram. See figure 28.

Non Compensated Mode is used when you want the tympanometric curve to be displayed including the ear canal volume. See figure 29.

Figure 28: Compensated

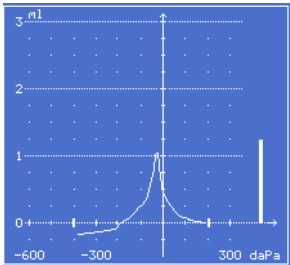
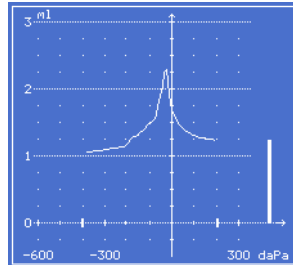


Figure 29: Non-Compensated



Gradient Unit:

The Gradient unit is an expression of the shape of the tympanometric curve. Narrow or wide.

It is possible to select between daPa or ml.

If ml is selected the gradient will be calculated the following way: The program will go 50 daPa to each side from compliance value and save the two ml values. The gradient is the average of the two ml values subtracted from the compliance value.

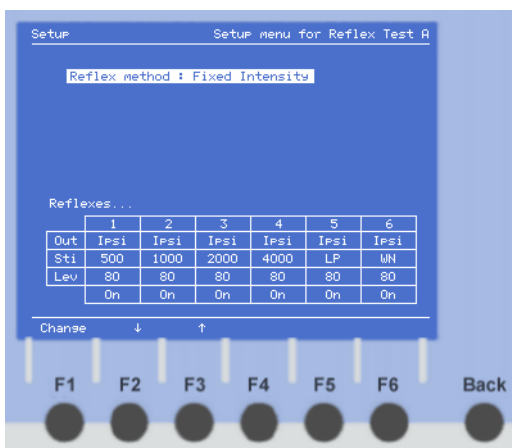
If daPa is selected the gradient will be calculated the following way: The program searches from each end of the tymp curve and stores the pressure at the point where the tymp curve is equal to compliance value divided by 2. Gradient is equal to the two stored pressures subtracted from one another.

Setup Menu for Reflex Test A and B

The Setup Menu for Reflex Test A and B is reached from the Main Menu by pressing “Setup” (F2). In the Main Setup menu press “Test A” (F2) or “Test B” (F3) to enter the Setup Menu for Reflex Test A and B:

Figure 30 shows the Setup Menu for Reflex Test A (for Test B it is identical).

Figure 30:

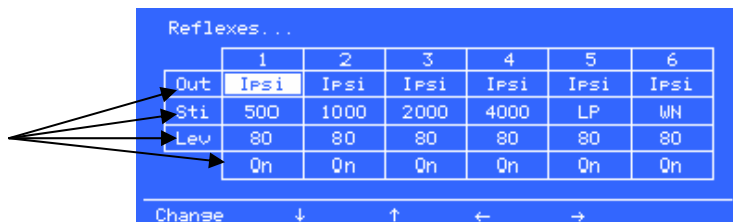


It is possible to choose between four different Reflex Methods:

- Fixed Intensity
- Screening (10 dB Steps)
- Auto (5 dB Steps)
- Sequence

Each Reflex Method can hold up to six individually pre-programmed reflexes. In the below figure 31 the starting conditions for each of the four Reflex Methods can be set up to personal needs:

Figure 31:



With the four arrow keys (F2 to F5) it is possible to browse between the parameters of the individual reflex. Each reflex parameter can be changed by pressing "Change" (F1) or by pressing the dedicated keys "frequency Decr / Incr" (14 and 15) and the "Intensity Decr /

Incr" (24 and 25). The changeable parameters are pointed out in figure 29 and will be described below:

Output:

It is possible to select between ipsilateral and contralateral reflexes as output.

Stimuli Frequency:

For ipsilateral reflexes the stimuli frequency options are the following:

500, 1000, 2000, 3000 and 4000 Hz. Including also the noise stimuli WN, LP and HP.

For contralateral reflexes the stimuli frequency options are the following:

125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000 and 8000 Hz. Including also the noise stimuli WN, LP, and HP.

Level:

The intensity level for the reflexes goes from 60 dB to maximum. Maximum depends on the selected frequency and the selected transducer.

In the final line of the table it is possible to switch on or off the reflexes according to the number of reflexes needed.

Note: Because of the possibilities of the Modify Function it might be relevant to set reflexes which are only rarely used to "off". When used now and then these reflexes can be turned "on" via the Modify Menu.

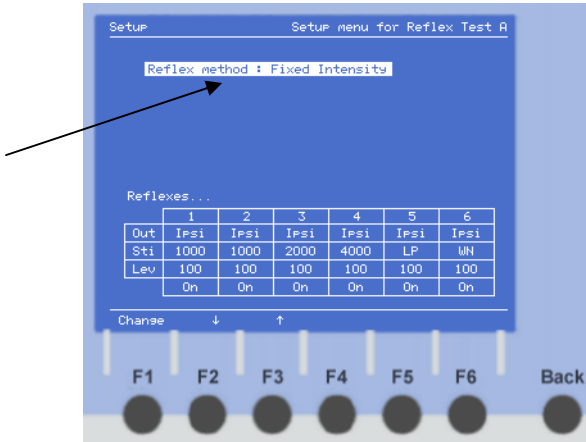
<h2>Reflex Methods</h2>

There are four different reflex methods to choose from in the Setup Menu for Reflex Test A and B. In the following these reflex methods will be described in details:

Fixed Intensity Method:

Figure 32 shows the screen for setting up the Fixed Intensity Reflex Method:

Figure 32:



With the Fixed Intensity Method the parameters of the individual reflex (frequency and intensity) are fixed.

Reflex Sensitivity:

To fully understand the reflex search procedure of the three Reflex Methods it is important to know the Reflex Sensitivity idea. Reflex Sensitivity appears under the Reflex Method line when Screening, Auto or Sequence Method is selected.

The software of AT235 uses an algorithm to determine if a reflex is acceptable or not. There is a selection of three different algorithms to choose from, each representing its individual level of Reflex Sensitivity. These three Reflex Sensitivities are referred to as Sensitive, Normal and Robust and they are expressed in ml.

When searching for the reflex with the following three Reflex Methods the algorithms in the software will continue to search for the reflex until the intensity has reached the maximum level for the selected transducer at the given frequency.

Therefore, a reflex can be accepted in two ways:

1. The reflex does not touch the pass box (the pass box is normally invisibly). Concerning “Pass Box” see figure 33 to 35
2. Intensity is at maximum level.

To understand what is meant by pass box see the three figures below. The pass box is the dotted rectangle in the middle of the 4 figures.

Figure 33: Sensitive (0.03 ml)

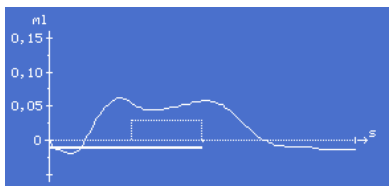


Figure 34: Normal (0.05 ml)

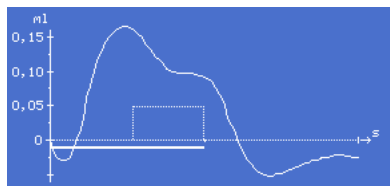


Figure 35: Robust (0.08 ml)

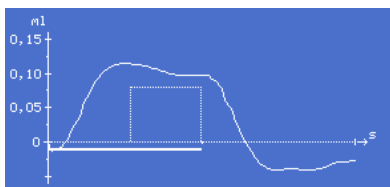


Figure 36: Robust (0.08 ml)

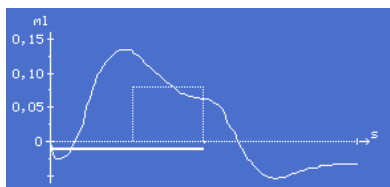


Figure 33 to 35 show examples of how the Reflex Sensitivity system functions. The first three reflexes are all examples of reflexes that have been accepted according to the different algorithms (sensitive, normal and robust). They are accepted due to the fact that they do not touch the pass box.

However, figure 36 shows an example of a reflex that is not accepted according to the chosen algorithm. The reflex is not accepted because it goes through the pass box.

Sensitive makes the search algorithm accept small reflexes, elicited by a relatively low stimulus intensity. Unfortunately, the test is easily disturbed by noise and movements of the probe.

Robust needs more compliance change for the initial search function to trigger - this will ensure a test which can be carried out with a less than perfect test situation, but will also run relatively high in intensity and provide similarly larger reflexes.

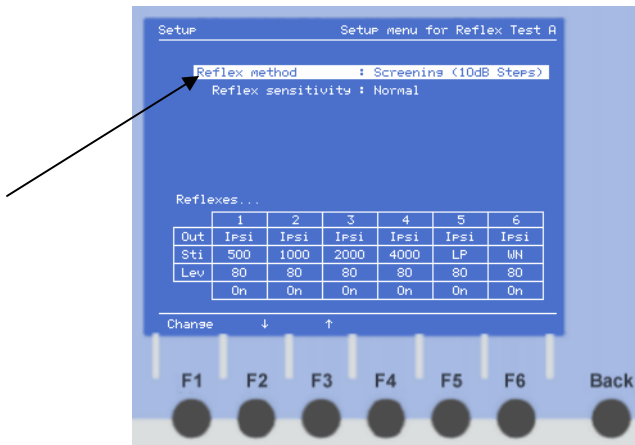
Normal is a compromise suitable for most applications - it is relatively forgiving for the accuracy of the test procedure, and still does not run excessively loud in intensities.

Note: The pass box is not shown in the screen of AT235 but serves as an example of what sensitivity is and how it is used.

Screening (10 dB steps):

Figure 37 shows the screen for setting up the Screening (10 dB steps) Reflex Method.

Figure 37:



The Screening Method is an automatic test for detecting reflexes. The reflex parameters in the Screening Method can be set up to personal needs from the reflex table in the lower part of the screen.

The Screening Method starts with the selected Output, Stimuli Level and Intensity Level from the parameter table in figure35 as starting point for the reflex test. It will automatically search

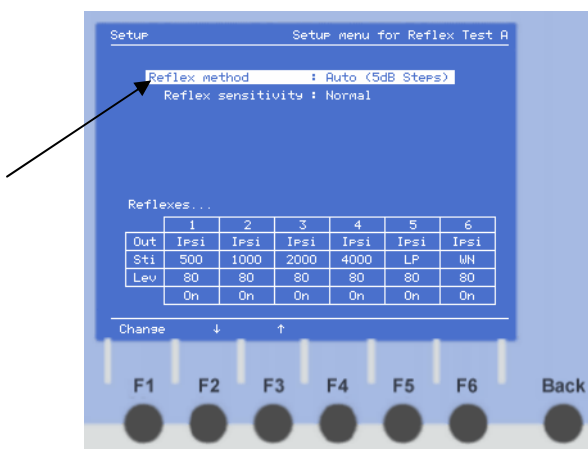
for the reflex in steps of 10 dB according to the selected Reflex Sensitivity. If the reflex is above the above mentioned pass box it will be accepted and drawn on the screen. The test will then automatically proceed to the next reflex.

If the reflex goes through the pass box it is not accepted. The intensity level automatically increases with 10 dB for another reflex. This procedure continues until the reflex is above the selected pass box or the maximum intensity level is reached.

Auto (5 dB steps):

Figure 38 shows the Auto (5 dB steps) Reflex Method screen:

Figure 38:



The Auto test is used for testing when only one reflex per frequency is needed, but a reflex of a certain size is preferred (see “Reflex sensitivity” above). The Auto test then searches for suitable stimulus intensity before each reflex is tested.

The automatic procedure for determining which intensity to use for the reflex test follows these guidelines:

- 1) A stimulus where the intensity quickly increases is presented to the ear. Simultaneously the instrument monitors at which intensity a change of compliance

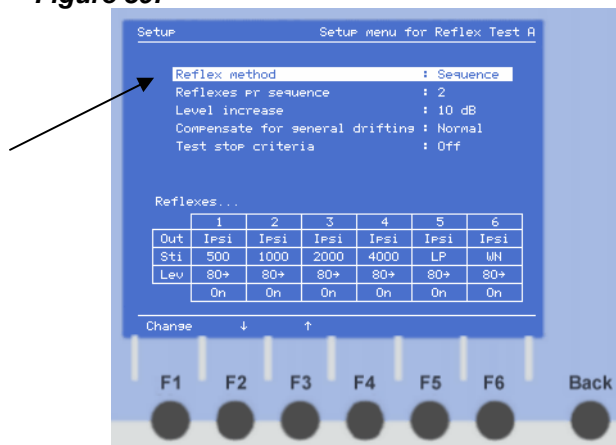
(typically caused by the reaction of the Stapedius muscle) occurs.

- 2) Now the actual reflex test will be performed, using the intensity found in 1).
- 3) The recorded reflex will be checked automatically to ensure that it meets the criteria (see “Reflex sensitivity” above). If it does, the test at this frequency is completed.
- 4) If the reflex does not pass the criteria, automatically 1) 2) and 3) is repeated.
- 5) If the reflex found the second time also does not meet the pass criteria, a new reflex is recorded at 5dB higher intensity. Consecutively higher intensities are then used until a reflex is accepted. (If a pass cannot be obtained, the reflex recorded at maximum intensity will be displayed as the test result for the test).

Sequence:

Figure 39 shows the screen for the Sequence Reflex Method:

Figure 39:



With the Sequence Method it is possible to have up to six single reflexes in one reflex window. The reflex parameters in the Sequence Method can be set up to the personal needs

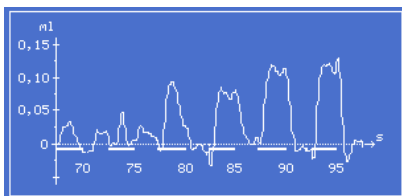
from the reflex table in the lower part of the screen. In the Sequence Method the intensity levels are marked with small arrows pointing right indicating that a number of reflexes are expected to come at a pre-selected increasing intensity.

Reflex pr. Sequence:

It is possible to choose between 2,3,4,5 or 6 reflexes per sequence. Please note that the higher number of reflexes selected per sequence the less detailed the graphic in the small reflex windows will be.

Figure 40 shows an example of a sequence with six reflexes starting from 70 dB with 5dB intensity increases per reflex:

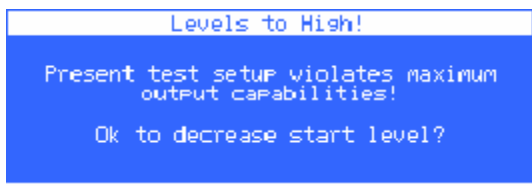
Figure 40:



Level Increase:

Selects how many dB the intensity will be increased between each single reflex. It is possible to choose between 5, 6, 8, 9, or 10.

Note: A warning pops up when too high a Level Increase has been chosen together with too high a start intensity level. This will violate the maximum output capabilities of AT235.



Compensate for General Drifting:

When searching for reflexes with the Sequence Method the compliance may drift a little. When the instrument is set to

“Normal” in the setup parameter Compensated for General Drifting, the drifting will mathematically be compensated for. This is illustrated in figure 42:

Figure 41: Off

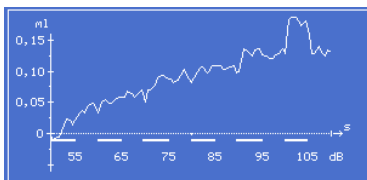


Figure 42: Normal

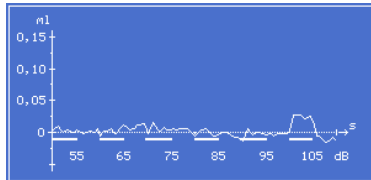


Figure 41 illustrates what may happen in situations where the setup parameter Compensated for General Drifting is set to “Off”.

Test Stop Criteria:

When Test Stop Criteria is set to “Off” the Sequence test will continue recording reflexes even after a reflex has been identified and accepted.

When the Test Stop Criteria is set to “Automatic” the Sequence test will automatically stop as soon as a reflex has been identified and accepted.

Reflex Sensitivity (appears when Test Stop Criteria is set to Automatic):

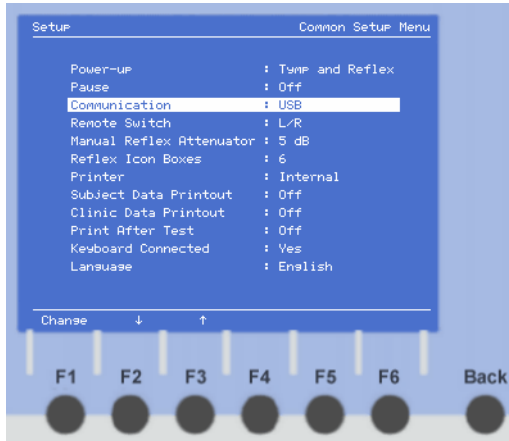
Reflex Sensitivity appears in the line just below Test Stop Criteria when Automatic is selected. Reflex Sensitivity functions in the same way as in the Screening and Auto Reflex Methods.

The Reflex Sensitivity can be set to “Sensitive”, “Normal” or “Robust”.

Common Setup Menu

The Common Setup Menu is reached from the Main Menu by pressing “Setup” (F2). When being in the Main Setup Main press “Common” (F4) to enter the Common Setup Menu:

Figure 43:



Power-up:

It is possible to select between “Tym” or “Tym and Reflex” as Power-up.

Pause:

If “On” is selected the “Pause” key (9) is pre-selected as default for 1) the Tympanometry Test, 2) the Reflex Test and 3) the Reflex and Tympanometry Test.

When “Off “ is selected the Pause Function must be switched on manually. The Pause Function can be activated from for 1) the Tympanometry Test, 2) the Reflex Test and 3) the Reflex and Tympanometry Test.

Communication:

The setting is USB. It cannot be changed.

Remote Switch:

Selects the function of the Remote Switch of the probe. Select between “Off”, “L/R”, “Pause” and “L/R or Pause”.

1. When “Off” is selected the Remote Switch is out of function.
2. When “L/R” is selected it is possible to shift between left and right ear with the Remote Switch.
3. When “Pause” is selected it is possible to control the “Pause” key (9) from the Remote Switch.
4. When “L/R or Pause” is selected the “Pause” key (9) can be controlled from the Remote Switch of the probe when the probe tip is in the ear canal, and the “Right” (20) and “Left” (21) keys can be controlled when the probe tips is not in the ear canal.

Manual Reflex Attenuator:

Selects the intensity increase and decrease levels for manual reflexes when pressing the “Intensity Decr / Incr” keys (23 and 24). It is possible to choose between 1, 2 and 5 dB.

Reflex Icon Boxes

With Reflex Icon Boxes it is possible to select between 4 or 6 reflex. See the appearance of the two possibilities below:

Figure 44: 4 Reflex Boxes

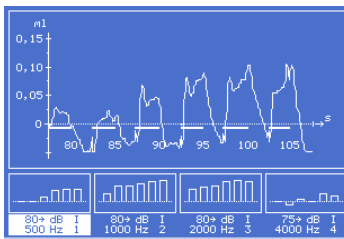
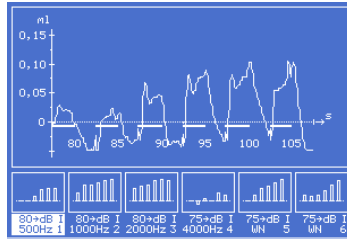


Figure 45: 6 Reflex Boxes



Printer:

There are two different “Printer” settings; “Off” and “Internal”.

1. “Off” means that there will be no printing possibilities.

2. "Internal" means that the internal printer of AT235 is activated and can be used, if an internal printer is installed.

Subject Data Printout (appears only when "Printer" is set to "Internal"):

Subject Data Printout can be set to either "On" or "Off". When set to "On" the Subject Screen in figure 46 appears when holding down "shift" (17) while pressing "new subject" (9).

Figure 46:

The screenshot shows a blue window titled "Subject" with the following fields and values:

Id No.	310573	Date	21/12/2000
Name	Frank Andersen	Sex	M
Address	Poul Hansens vej 4	Age	27
Zip	5000	City	Odense
State	Fyn		
Country	Danmark		
Phone	63 71 35 17		
E-mail	FA@Interacoustics.dk		
Examiner	LU		
Remarks			

At the bottom of the window, there is a "New" button.

To enter the above Subject Screen, a keyboard must be connected to the AT235 and the "Keyboard Connected" point in the Common Setup Menu must be set to "Yes".

Clinic Data Printout:

If "On" is selected the Clinic data will be printed.

To enter the individual clinic data go to the Main Setup Menu and press F5 "Clinic". See Clinic Screen in figure 47.

To be able to enter the above Clinic screen a keyboard must be connected to the AT235 and the "Keyboard Connected" point in the Common Setup Menu must be set to "Yes"

Figure 47:

Clinic

Name Interacoustics A/S

Address Drejervaenset 8

Zip 5610 City Assens

State Fun

Country Denmark

Phone +45 63 71 35 55

Fax +45 63 71 35 22

Web www.interacoustics.dk

E-mail info@interacoustics.dk

No. 47208718

New Edit

To enter your own Clinic data press F1 “Edit”. The Clinic data is edited by pressing F2.

Print After Test:

Print After Test can be set to either “On” or “Off”.

When set to “On” the test result will be printed automatically when both right and left ear have been tested. This automatic printing possibility is directly related to the “Power-up” chosen – “Tymp” or “Reflex and Tymp”.

When set to “Off” the print function must be addressed manually.

Keyboard Connected:

It is possible to connect a keyboard to AT235.

If a keyboard is connected “Keyboard Connected” must be set to “Yes”. When a keyboard is connected it is possible to fill in data in the “Clinic” and “Subject” screens.

When no keyboard is connected “Keyboard Connected” should be left “Off”.

Language:

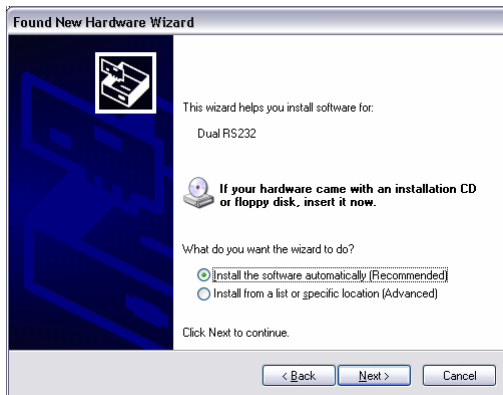
It is possible to select between “English” and “German”.

Appendix B: Installing the USB Driver on the PC

Connect the Instrument to the PC with a USB cable and turn on the instrument, the following window should appear. The Driver is available from Windows Update if the PC is connected to the internet or it can be found on the CD with the operation manual.



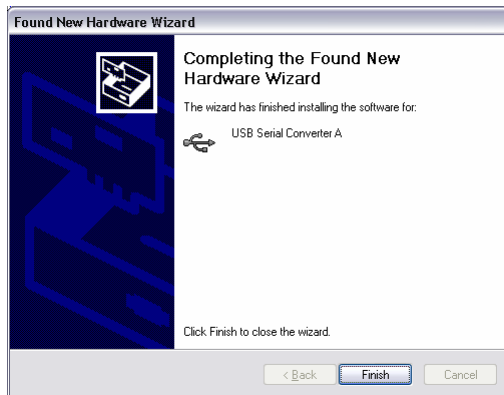
Click Next and the following window should appear.



Insert the CD, if the PC is not connected to the internet, click Next.

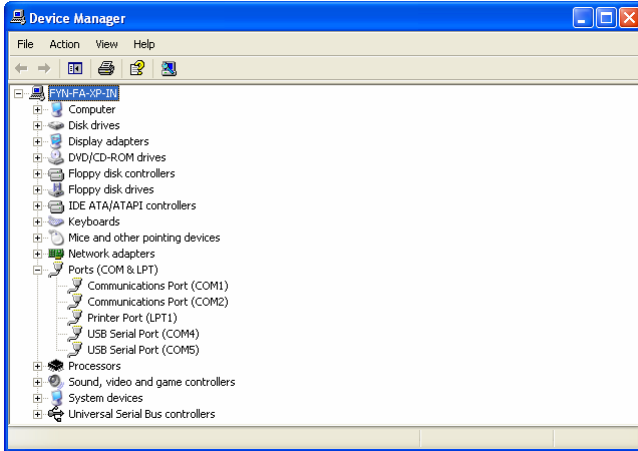


When the Driver is found the following window appears:

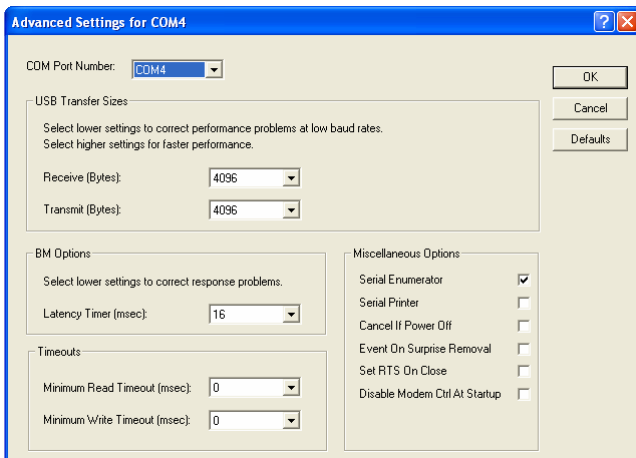


Click Finish, the Found New Hardware Wizard now starts over again because a driver for Serial Converter B needs to be installed, follow the directions above.

The Driver for the USB Serial Converter is now installed, to find out which COM port to use when communicating with the instrument start the Device Manager (Click Start, My Computer -> properties, Hardware -> Device Manager). The Port is recognized as "USB Serial Port" use the one with the lowest number.



If the COM port number is higher than it is possible to set in the PC application, it is possible to change the number by selecting properties for the USB Serial Port, then Click Hardware and Advanced, the following window should appear:



Change the COM port number in the drop down box.

Appendix C: 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
Drejervaenget 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.

Drawing of Front Plate

