Amplivox Ltd
Otowave 302 Tympanometer
Operating Manual

(Applies from serial number 80000 onwards)

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For supply in US only

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

Indications for Use

The Otowave 302 Tympanometer is designed for use by trained operators (audiologists, general practitioners, hearing aid dispensers, and child health professionals) in hospitals, ENT clinics, and audiologist offices for the detection of possible otologic disorders in the general population associated with the functioning of the middle ear.

The instrument performs two types of measurement:

Tympanometry is used to measure the acoustic admittance (which is also known as “compliance”) of the tympanic membrane and middle ear at a fixed frequency over a range of pressures.

Reflex tests are used to measure stapedial reflexes. The Otowave 302 can measure both ipsilateral and contralateral reflexes and, when selected, reflex measurement is automatically carried out after a tympanogram is taken.

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1. Introduction

Thank you for purchasing the Amplivox Otowave 302, a desktop tympanometer incorporating an ergonomically-designed remote probe assembly that will give many years of reliable service if treated with care.

This operating manual applies to the Otowave 302 which is available as a standard option (with 226Hz probe tone) and as an H-option (with 226Hz and 1000Hz probe tones). Text that applies to 1000Hz operation only is marked [H].

1.1. Intended applications

The Amplivox Otowave 302 is designed for use by audiologists, general practitioners, hearing aid dispensers and child health professionals.

The instrument performs two types of measurement:

Tympanometry is used to measure the acoustic admittance (which is also known as “compliance”) of the tympanic membrane and middle ear at a fixed frequency over a range of pressures.

Reflex tests are used to measure stapedial reflexes. When selected, reflex measurement is automatically carried out after a tympanogram is taken.

1.2. Features

- Automatic measurement of ear canal volume, tympanic admittance peak and placement of the peak using either 226Hz or 1000Hz [H] probe tone with options for the display of tympanometric data
- Flexible meatus compensation settings
- Automatic detection of stapedial reflexes using a choice of ipsilateral and/or contralateral reflex stimulus
- Choice of frequency and level for reflex stimulus
- Up to 36, dual-ear patient tests can be stored in non-volatile memory
- An intuitive menu system for operation, setting test options and other user preferences, held in non-volatile memory
- Printout to a thermal printer
- Data transfer to computer via a USB connection for storage, viewing & printing using either the Amplivox “TympView” software or the NOAH application
- English, German, French, Spanish, Portuguese or Italian operating language (selectable by the user)

1.3. Unpacking

Please check the contents of the shipping carton against the delivery note to make sure that all items ordered have been included. If anything is missing, please contact the distributor who supplied the tympanometer or Amplivox if purchased directly.

Please retain the carton and packaging as the tympanometer will need calibrating on an annual basis and should be returned to Amplivox in its original shipping carton.

1.4. Standard contents

Otowave 302 Tympanometer
Mains adapter, see 2.3
Carrying case
Set of disposable ear-tips
Operating manual & TympView
Amplivox NOAH impedance module
Contralateral transducer
4 in 1 cavity assembly
USB cable
Calibration certificate
Warranty card

1.5. Optional accessories

Additional sets of ear tips
Portable thermal printer
Additional rolls of thermal paper
Additional probe tip

1.6. Warranty card (UK Customers only)

Please complete the enclosed warranty registration card and return it to Amplivox. This will enable us to register your purchase, help with your enquiries and provide technical support.

1.7. Guarantee

All Amplivox instruments are guaranteed against faulty materials and manufacture. The instrument will be repaired free of charge for a period of two years from the date of dispatch if returned, carriage paid, to the Amplivox service department. Return carriage is free of charge for customers in the UK and chargeable for overseas customers.

The following exceptions apply:

- The pressure pump and transducers may go out of calibration due to rough handling or impact (dropping)

- The lifetime of probe, probe seals and eartips is dependent upon conditions of use. These parts are only guaranteed against faulty materials or manufacture.

2. Important Safety Instructions

The Otowave 302 instrument must be used only by practitioners qualified to perform tympanometric tests. It is intended for transient use as a screening and diagnostic tool; however no surgical or medical procedure should be undertaken solely on the basis of results obtained from the instrument.

2.1. Precautions

READ THIS OPERATING MANUAL BEFORE ATTEMPTING TO USE THE INSTRUMENT

To comply with the standards IEC 60601-1 for safety and IEC 60601-1-2 for electromagnetic compatibility (EMC) the tympanometer is designed to be used only with the medically-approved mains adapter supplied, which is specified as part of the equipment. **Do not use any other type of mains adapter with this instrument. Refer to Section 15 for the stock number of the adapter.**

The tympanometer is for indoor use only and should be used only as described in this manual.

The transducers supplied with the tympanometer are specifically calibrated with it; if these transducers are changed recalibration will be required.

Before the first use of the instrument each day, or if suspect or inconsistent results are apparent, the checks specified in Section 10 must be carried out. If these do not give the results specified, the instrument must not be used.

Never insert the probe or the contralateral transducer into a patient's ear canal without a suitable ear tip fitted.

Use only the recommended disposable ear tips for the probe and the contralateral transducer (see Section 15 for details). These are for single use only - that is, each ear tip is intended to be used once only for a single ear for a single patient. Do not reuse ear tips as this will pose the risk of ear-to-ear or patient-to-patient cross-infection.

Do not immerse the unit in any fluids. See Section 11 of this manual for the proper cleaning procedure for the instrument and its accessories and the function of single-use parts.

Do not use the instrument in an oxygen-rich environment or in the presence of a flammable anaesthetic mixture or other flammable agents.

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

The instrument must be stored and used indoors within the specified temperature, pressure and humidity ranges, see Section 14.

As with all instruments of this nature the measurements taken will be influenced by significant changes in altitude & pressure. The Otowave 302 tympanometer must be re-calibrated if it is to be used at elevations greater than 800m above mean sea level.

Do not attempt to open, modify or service the instrument. Return the instrument to the manufacturer or distributor for all repair and servicing requirements. Opening the instrument will void the warranty.

2.2. Electromagnetic compatibility (EMC) considerations

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in Section 17. This provides guidance on the electromagnetic environment in which to operate the instrument.

Portable and mobile radio-frequency (RF) communications equipment can affect medical electrical equipment. The instrument should not be used adjacent to or stacked with other equipment; if this is necessary the instrument should be observed to verify normal operation.

2.3. Mains supply operation

The tympanometer is designed for continuous operation and is powered by a mains adapter which is supplied, and specified as part of the equipment. If a replacement is required, please contact your Amplivox distributor.

All other connections must be made **before** connecting the output lead from the adapter into the POWER input socket on the back of the tympanometer. Switch on the mains supply - the indicator on the adapter and the POWER indicator on the tympanometer will both illuminate green, showing that the instrument is ready for use.

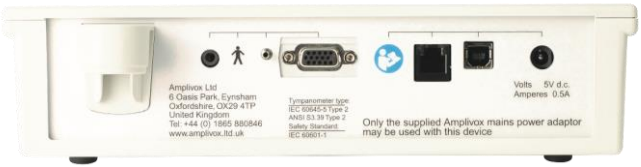
The output from the mains adapter is fitted with electronic circuit protection. In case of overload the adapter will shut down and the indicator will be extinguished. When the fault is cleared the adapter will operate as normal.

The input to the mains adapter is protected with a non-replaceable fuse. If this fails the adapter will not operate.

The mains adapter is the mains disconnect device and therefore the tympanometer should be positioned such that easy access to the mains adapter is possible.

2.4. Tympanometer connections

All connections are made to the rear panel of the tympanometer as shown below.



To ensure correct identification each connection is labelled on the top panel above each corresponding terminal as shown below.

Socket Label	Socket Type	Connected Part	Notes
CONTRA	3.5mm jack	Contralateral transducer *	
AIR	Push-fit connector	Remote probe (pressure) *	
PROBE	15-way D connector	Remote probe (electrical) *	
PRINTER	RJ12 socket (6-way)	Designated printer *	See 2.5
USB	USB Connector Type B	Computer (via USB port)	See 2.6
POWER	2.5mm power jack	Mains AC/DC Adapter *	

The relevant part numbers are indicated in Section 15.

For connected parts marked * only connect the accessories supplied with the instrument or supplied by Amplivox or an Amplivox distributor. These parts have been tested for use with the Amplivox Otowave 302 tympanometer for compliance with the standards IEC 60601-1 and IEC 60601-1-2. The use of accessories other than those specified may compromise compliance with these standards. For other sockets refer to Section 18.

2.5. Data transfer to a printer

Please refer to Section 18 for important information regarding the connection of non-medical electrical equipment to medical electrical equipment

The tympanometer can be upgraded with an option to allow connection via the supplied cable to a designated portable thermal printer for printing tympanometric test results (see Section 7). Upon receipt of the printer it must be initially charged for a minimum of 15 hours prior to use.

2.6. Data transfer to a computer

Please refer to Section 18 for important information regarding the connection of non-medical electrical equipment to medical electrical equipment

The tympanometer is supplied with software to allow connection to a computer for the transfer of test results (see Section 8). You must use the designated USB cable which is available from Amplivox (see Section 15).

3. Principles of Operation

Please note: This operating manual is not intended as a training manual for tympanometry. The reader should consult standard audiology texts for the theory and application of the tests provided by this instrument.

3.1. Admittance measurement

The Otowave 302 measures the admittance of the tympanic membrane and middle ear by playing a continuous tone into the ear canal at either 226Hz or 1000Hz [H]. The level of this tone is calibrated to give 85dB SPL (226Hz) or 79dB SPL (1000Hz [H]) into a 2ml cavity. The sound level this produces in the ear canal is measured using a microphone and the admittance calculated from the result. In line with normal audiometric practice admittance is displayed as an equivalent volume of air in ml (for 226Hz) or mmho/mʊ (for 1000Hz [H]). The residual Ear Canal Volume between the probe and the tympanic membrane is always displayed in ml; when using a 1000Hz [H] probe tone the measured value in mmho is converted to ml using a conversion factor of 226/1000.

3.2. Tympanogram

To record the tympanogram the admittance is measured while the air pressure in the ear canal is varied from +200daPa to -400daPa by means of a small pump. The admittance peaks when the air pressure is the same on both sides of the tympanic membrane. The change of admittance with pressure is displayed graphically.

3.3. Stapedial reflex measurement

Using the same principle it is also possible to establish whether a stapedial reflex is present. In this case, the 226Hz tone is used to measure the admittance of the ear, while a short tone at a different frequency is presented (the reflex stimulus). The level of this stimulus is increased in steps until the stapedial muscles respond causing the tympanic membrane to become stiffer, or a preset maximum level is reached. When the change in admittance exceeds a predetermined threshold this constitutes a reflex and the change in admittance at that level when the stimulus is applied is displayed as a plot against time.

The stapedial reflex is measured at the static ear canal pressure that produces the maximum membrane admittance, so reflex measurements are taken after the tympanogram is measured when the peak admittance pressure has been established.

The reflex stimulus may be produced in the ear being measured (ipsilateral mode), the opposite ear (contralateral mode) or in both ears (ipsilateral mode followed by contralateral mode). For contralateral stimulation the reflex tone is produced in a separate transducer supplied with the instrument.

The Otowave 302 can measure a stapedial reflex at 500Hz, 1000Hz, 2000Hz and 4000Hz; any combination of these frequencies may be selected for ipsilateral and contralateral mode. The maximum level for the reflex stimulus may be preset, along with the step size in dB between the three preceding lower levels of stimulus (see Section 5.6).

4. Using the Otowave

This instrument is equipped with a real-time clock. Before use, please set the date & time to local values in order to ensure that test data and calibration status are correctly identified. Refer to Section 12.2.

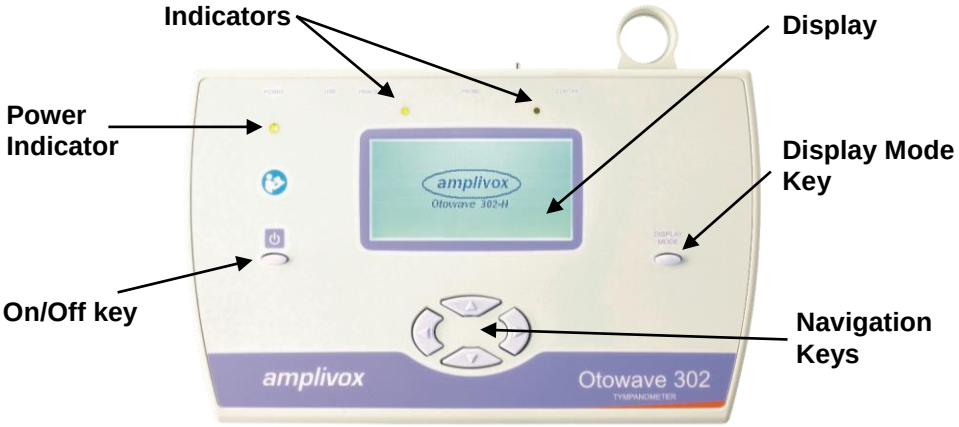
4.1. Operating language

To set the operating language (English, German, French, Spanish, Portuguese or Italian) use the SYSTEM SETTINGS options within the CONFIGURATION menu (see Section 12.2).

4.2. Controls and indicators (base unit)

Press the On/Off key momentarily to turn the Otowave 302 on (refer to the diagram below).

No warm-up time is required, although a short diagnostic routine will run for a few seconds. During this time the internal pump will operate. To switch off press the On/Off key and hold for 2 seconds.



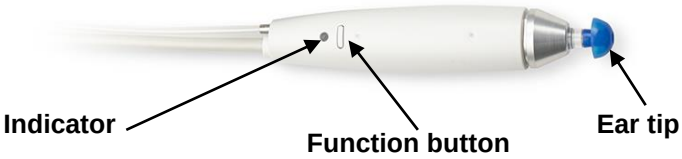
Press the up ▲ and down ▼ navigation keys to scroll through the menus or set values

Press the right navigation key ► to accept a menu choice or go to the next step.

Press the left navigation key ◄ to cancel an operation or go back to the previous step.

The function of the left and right keys is usually shown on the bottom line of the display.

4.3. Controls and indicators (probe)



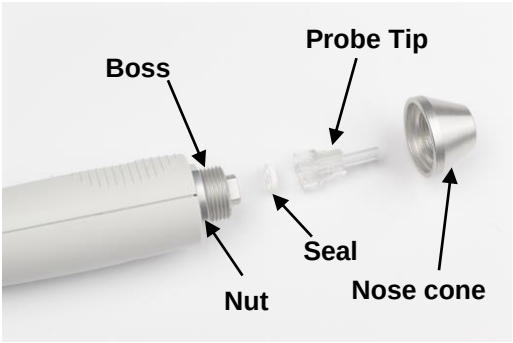
4.4. Indicators and system status

The indicators show the status of the system. Typical indications during a measurement sequence are as follows:

Base Unit Indicator (Green)	Base Unit Indicator (Yellow)	Probe Indicator (Green/Yellow)	Status
Off	Off	Off	Otowave turned off
On	Off	On (Green)	Idle, test completed or test cancelled
Fast flash	Fast flash	Alternating (Green/Yellow)	Insert probe or remove probe (refer to display for details)
Off	Slow flash	Slow flash (Yellow)	Ensure probe is held steady while an ear seal is obtained
Slow flash	Off	Slow flash (Green)	Testing - tympanogram and/or reflex measurement

For a full description of indicators used, messages displayed and possible error conditions refer to Section 13.

4.5. Probe components



The small holes through the Otowave probe tip must be kept clear. If these become blocked a warning message will be displayed. The probe tip must be removed and cleaned or replaced.

To remove the probe tip, unscrew the nose cone and remove the probe tip from the boss. A small seal will be found in the base of the probe tip. This should be examined and replaced if it is blocked or damaged. Do not remove the nut securing the boss to the probe body.

When replacing the probe tip, ensure that the seal is correctly located with the flat side aligned with the flat side within the base of the probe tip. Push the probe tip over the boss and replace the nose cone. Make sure that the nose cone is screwed home firmly but do not over-tighten. Do not use any tools to tighten the nose cone.

After replacing the tip a Daily Check should be carried out (see Section 10).

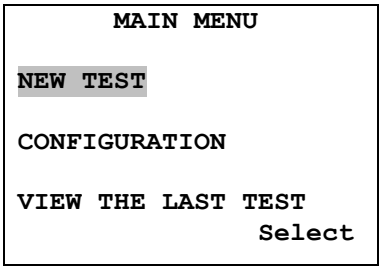
4.6. Contralateral transducer

This accessory is used when it is required to provide a reflex stimulus to the opposite ear to that being tested with the main probe assembly. For use it should be connected to the CONTRA socket on the base unit and fitted with a new eartip (see Section 5.3).

The contralateral probe tip may be replaced if necessary (e.g. if damaged). Refer to Section 15 for details of the replacement part. To remove the contralateral probe tip, carefully unscrew it from the body of the transducer. Carefully fit the replacement part and make sure that it is screwed home firmly but do not over-tighten. Do not use any tools to tighten the contralateral probe tip.

4.7. Start-up and menu displays

When the Otowave 302 is turned on the start-up screen is shown while internal tests are performed and the pump is initialised. When the start-up sequence is complete the MAIN MENU is displayed:



Use the navigation keys to scroll through & select options. The menus are summarised in Section 12.

4.8. Initial settings

Use the CONFIGURATION > SYSTEM SETTINGS menu (see Section 12.2) to select the following options as required (all settings will be retained until changed again):

- operating language
- display brightness & contrast for ease of viewing
- correct local date and time
- hospital/clinic name & department
- required date format (DD/MM/YY or MM/DD/YY)

5. Taking Measurements

Ensure that the appropriate settings have been made before carrying out a test. See below and the CONFIGURATION options in Section 12.2

To view the test settings ensure that the MAIN MENU is displayed and then press and hold the function button on the probe to display the TEST SETTINGS screen as shown below.

```
    TEST SETTINGS
Probe:    226 Hz
Reflexes: Ipsi+Contra
 500 1k 2k 4k Max dB
I: ✓ ✓  ✓  ✓  85/5
C: ✓ ✓  ✓  ✓  85/5
Probe #: 12345
Contra #: 6789
```

This indicates the probe frequency being used, the reflex source selected, and the selected frequencies, maximum level and step size of the reflex stimulus. Also displayed are the serial numbers of the probe and the contralateral transducer.

In the above example the probe frequency is 226Hz, all frequencies have been selected for both the ipsilateral and contralateral reflex stimuli, and the maximum level for both reflex stimuli is 85dBSPL with a step size of 5dB between the three preceding lower levels of stimulus. To change these settings see Section 12.

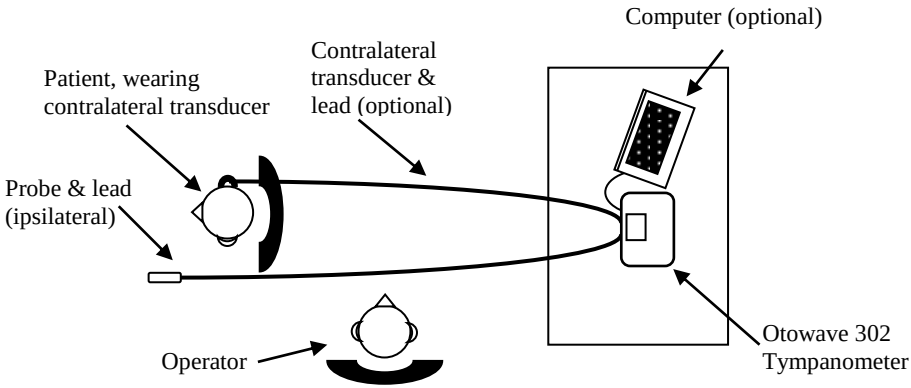
5.1. Prior to testing and ambient conditions

A suitably-qualified health care professional should perform a thorough otoscopic examination to establish that the condition of the ear is suitable for the test options selected and that no contraindications are present. The latter would include obstruction of the external ear canal due to excessive wax and/or hairs, both of which would need to be removed.

Tympanometric and reflex testing should always be performed in quiet conditions.

5.2. Test arrangement

The schematic diagram below shows a typical example of the use of audiometric test equipment. The Otowave 302 tympanometer is located on the desk of the operator as shown, and the operator is positioned (seated or standing) so as to be able to initiate a test by using the tympanometer controls and then apply the ipsilateral probe to the patient's ear.



The patient is seated in front of the desk as shown and is positioned relative to the operator such that the ipsilateral probe may subsequently be applied. If required, a contralateral transducer may be securely applied to the ear of the patient that is not under test. All necessary patient leads must be connected to the instrument prior to fitting to the patient.

No further action is required by the patient during the automatic test. However the patient must be advised to remain still and avoid speaking or swallowing while the probe is applied to the ear.

5.3. Ear tip(s)

These must be selected and fitted by a practitioner qualified to perform tympanometric tests.

The probe tip must be fitted with a new ear tip before it is presented to a patient's ear canal. The ear tip must be fitted completely to the probe tip and must not occlude any of the four holes in the probe tip. The ear tip size is chosen to suit the patient's ear and provide a comfortable pressure seal.

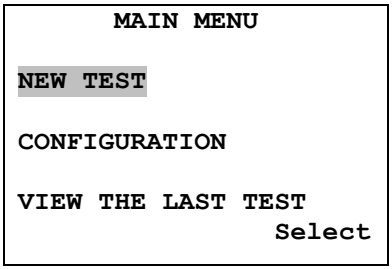
If a contralateral reflex stimulus is to be applied, fit a new ear tip to the contralateral transducer before presenting it to the patient's opposite ear canal.

Refer to Sections 2.1 and 11.2 regarding these single-use parts.

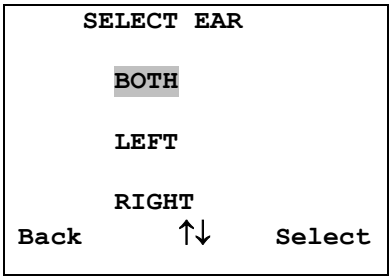
5.4. Performing a test

Having selected the required test settings a typical tympanogram measurement and reflex tests are carried out as follows.

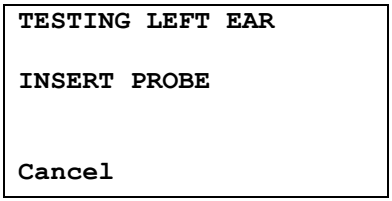
From the MAIN MENU select NEW TEST:



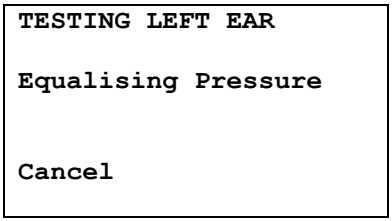
Select the ear(s) required for test (BOTH signifies LEFT followed by RIGHT):

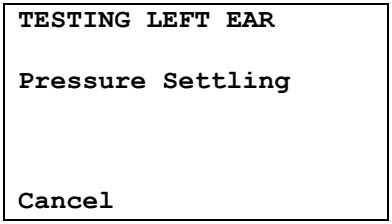


The message "Deleting last test" will be displayed momentarily and a message displayed to insert the probe into the ear to be tested:

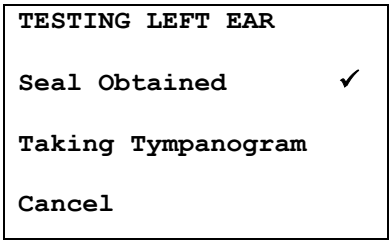


Present the ear tip to the ear and obtain a seal. If a good seal has been detected the following sequence of messages will be seen:





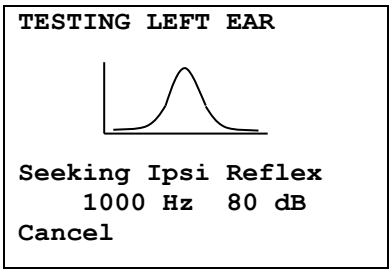
Press ◄ at any time to cancel the test and return to the ear selection menu.



Once an adequate seal is detected the tympanogram measurement is made. This takes about 3 seconds. It is important not to move the probe and to ask the patient to remain very still during the test.

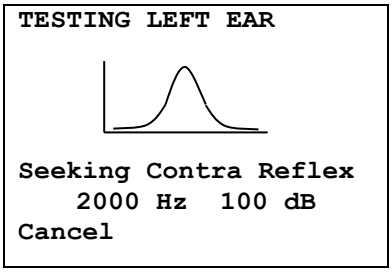
When the tympanogram is complete the instrument will perform the reflex test(s), if selected. By default this test is only performed if a peak is found in the tympanogram. This and other reflex test options may be changed in the CONFIGURATION menu, see Sections 12.2 and 5.6.

Before starting the reflex test the ear canal pressure will be set to the value that gave the peak admittance during the tympanogram test. The instrument will then step through the tone frequencies and levels set in the CONFIGURATION menu searching for a reflex response. If selected, an ipsilateral reflex is tested first:



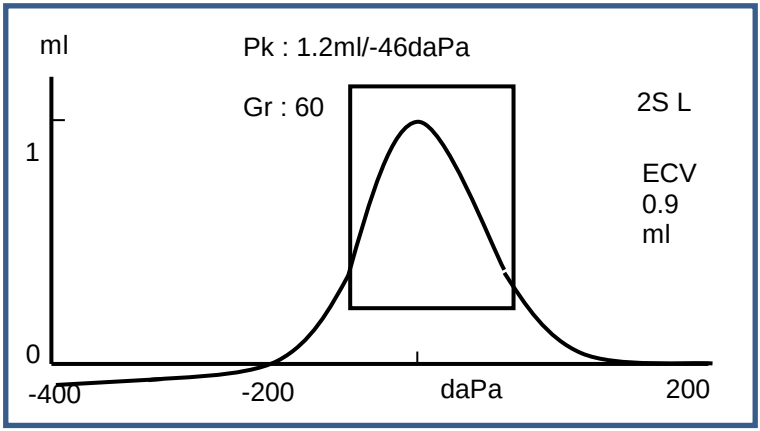
The display changes to show a small image of the measured tympanogram plus the reflex frequency and level being used, starting with the lowest frequency and level selected.

This will be followed by a contralateral reflex test if this has been selected, with the display showing the frequency and level being used:



When the measurement is complete the indicator on the probe changes from flashing green to steady green. The display confirms that the test has been completed along with the instruction WITHDRAW PROBE.

Remove the eartip from the patient and after a short period the tympanogram will be displayed. The following illustration is of a 226Hz tympanogram with the default baseline offset of +200daPa, signified by "2S" shown on the graph (refer to Section 5.5.3 for an explanation of this terminology). A letter indicating the ear under test, "L" or "R", is also shown.



The graph shows:

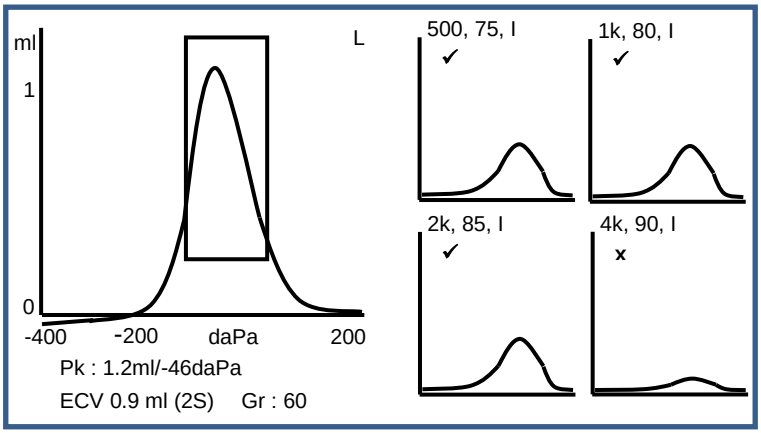
- The peak admittance in ml (Pk)
- The pressure at which the peak admittance was found in daPa
- The Gradient (the width of the trace measured between values of 50% of the peak admittance), in daPa (Gr)
- The Ear Canal Volume (ECV) in ml measured at the selected baseline offset (see Section 5.5.3 - in this case +200 daPa)
- A plot of admittance against pressure
- The normalised rectangle showing the ideal location for the tympanogram peak

Review the tympanogram to ensure that the peak admittance point selected by the Otowave is suitable. If required it is possible to select an alternative peak using the ▲ and ▼ keys. The figures displayed will change to reflect the peak selected, and will be saved with the tympanogram. Separate peaks for all Baseline Modes can be set, saved and recalled but this function is not available when Component display mode is used with 1000Hz probe tone ^{H} (see Section 5.5.3).

To repeat the test, press ◄.

When satisfied with the tympanogram press ►.

If reflex test(s) were carried out these results will now be displayed. The tympanogram is shown on the left hand side of the screen with up to four reflex traces shown on the right. The ear under test, “L” or “R”, is also shown at the centre.

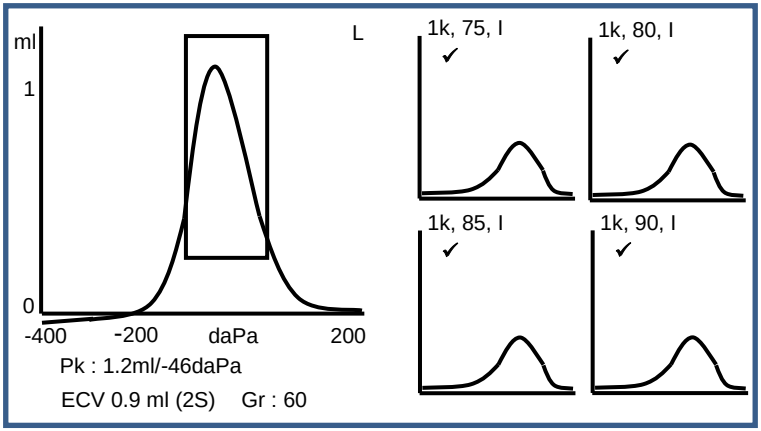


The reflex traces indicate:

- The frequency of the reflex stimulus
- “✓” if a reflex was found, otherwise “**X**”
- The lowest level of tone (dBHL) at which a reflex was found
- The type of reflex stimulus used (ipsilateral or contralateral)
- A trace of the admittance change against time

If no response is detected the trace recorded for the highest reflex stimulus used is displayed (as shown for 4kHz above).

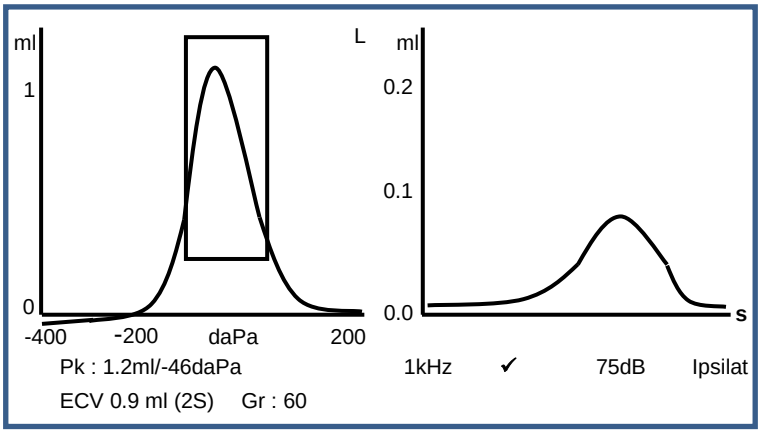
If a single frequency is used for reflex testing the reflex traces for each of the four levels of stimulus are displayed as shown below (in this case 75dBHL, 80dBHL, 85dBHL & 90dBHL at 1kHz).



The tympanogram shown is the same as the full-screen version shown on the previous display (but the peak cannot be changed). Press ◄ once to display the full sized tympanogram again or twice to repeat the test.

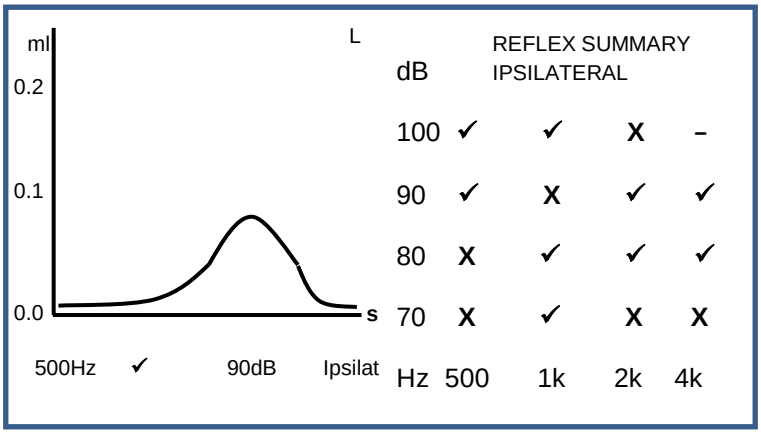
To view the reflex traces in more detail press ►. One of two displays will then be shown depending on whether or not Reflex autostop has been selected (see Section 5.6).

If Reflex autostop has been selected the tympanogram remains on the left hand side of the screen with a larger scale trace of the reflex at the lowest selected frequency with the lowest level that gave a response



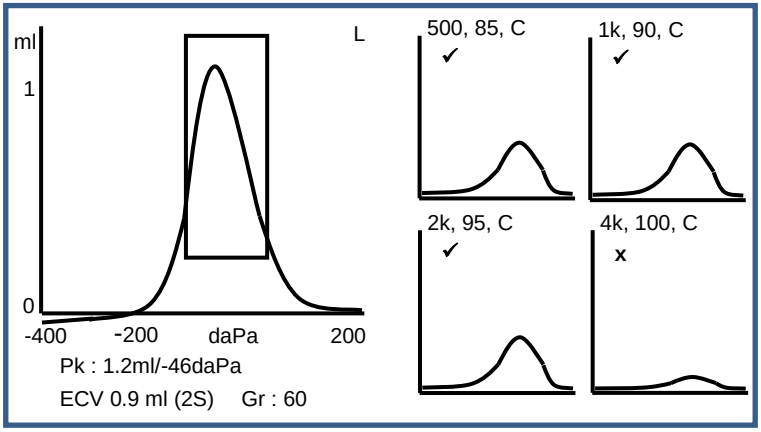
If Reflex autostop has not been selected the larger scale trace of the reflex at the lowest frequency with the lowest level that gave a response is shown on the left hand side of the screen (see the diagram below).

A summary of the levels and frequencies at which a reflex tone was presented is shown on the right hand side of the screen along with the result of the test ("✓" if a reflex was found, otherwise "**X**"). The dash symbol "**-**" is shown if a reflex tone was not presented at the level indicated.



In both cases, if the reflex test was performed at more than one frequency use the ▲ and ▼ keys to view the results for the other frequencies.

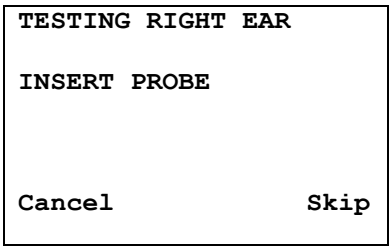
If contralateral reflex measurements were taken pressing the ► key will display similar results for these reflexes.



Press ◄ to return and view the tympanogram, reflex results or to repeat the test. When satisfied with the results press ►.

The message “Saving as last test” will be displayed and the results will be saved in the “last test” memory.

If both ears were chosen for test the entire sequence will now be repeated for the right ear:



Press ► to skip testing of the right ear and display the PROCESS RESULTS menu. Press ◄ to cancel and return to the ear selection menu. In both cases the left ear results are retained and may be viewed as the LAST TEST.

Otherwise insert the probe and contralateral transducer (if used); the right ear test will then proceed as described above.

When the selected ears have been tested and the results saved the PROCESS RESULTS menu will be displayed. This accesses the following functions:

- Print the results (SEND TO PRINTER)
- Save the results in the internal database (SAVE RESULTS)
- Review the results as described above (VIEW TEST)
- Return to the main menu (MAIN MENU)

See Sections 6 to 9 for more information on these options.

The results of the last test performed remain available even if the Otowave has been turned off. To view these results select VIEW THE LAST TEST from the main menu. After selecting the required ear the tympanogram will be displayed. It will then be possible to view the results and select the PROCESS RESULTS menu as if the test had just been completed.

Results of the last test will be erased as soon as a new test is started. Test results should be saved to the Otowave's database, printed or sent to a computer to ensure that data is not lost.

5.5. Sweep settings

A number of settings are available to control the way in which a tympanogram is taken and the results displayed. To modify these settings the CONFIGURATION > SWEEP SETTINGS menu options shown in Section 12.2 are used, and these are described below.

5.5.1 Sweep speed

The rate of change of air pressure may be selected to be 100daPa/s 200daPa/s or 300daPa/s. This determines the time taken for a pressure sweep from +200 to -400 daPa (6, 3 and 2 seconds, respectively).

5.5.2 Probe frequency [H]

If the instrument is configured for high frequency operation the probe tone frequency may be set to 226Hz or 1000Hz.

5.5.3 Baseline mode

The Otowave 302 can display tympanograms in a variety of graphical formats allowing the operator to choose the most appropriate for the patient under examination.

This is achieved by altering the "display mode" and the meatus compensation (or "baseline offset"). The display mode determines how the tympanogram trace is derived from the raw data, and the baseline offset selects the pressure to which the meatus compensation is referenced (either -400daPa or +200daPa). Display mode and baseline offset are collectively referred to as "BASELINE MODE" in the instrument menus and the accompanying documentation.

The tympanogram is initially presented using default settings for display mode and baseline offset. These settings may be changed using the BASELINE MODE option in the CONFIGURATION > SWEEP SETTINGS menu (see Section 12.2). Additionally, whenever a tympanogram is shown

it may be re-displayed using any of the alternative display modes & baseline offsets available described in this section.

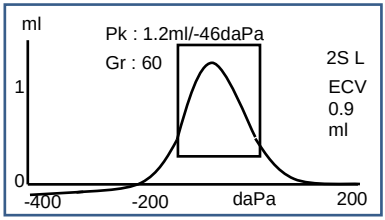
When a new test is “saved as last test” the baseline mode most recently viewed will be saved, although any of the other modes can be re-created when the test is loaded back into the instrument using “View the last test”. The same applies to results stored in the instrument’s database. This allows a different display mode and baseline offset to be used for display or printing, but it does not affect the baseline mode originally stored in the database.

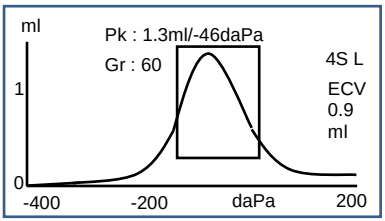
The various baseline modes are described in the following sub-sections.

5.5.3.1 **226Hz probe tone**

Scalar Mode

Tympanograms generated using the 226Hz probe tone are displayed in a traditional manner described as “Scalar” mode (and also known as “Y-only compensation”) as shown below.





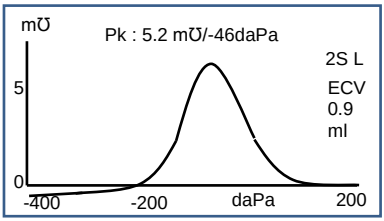
The default baseline offset is +200daPa offset (as shown in the diagram on the left and indicated by 2S on the display) but an offset of -400daPa may be selected if required (as shown in the diagram on the right and indicated by 4S on the display). See Section 5.5.3.3 for details of how to switch between the available display modes.

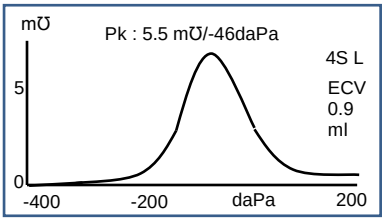
5.5.3.2 **1000Hz probe tone** [H]

Scalar Mode

For 1000Hz operation a similar scalar display mode is available as used for 226Hz (Y-only compensation). The tympanogram format is shown below and it is generally preferred when testing very young children. However

vector display mode (see below) may provide better results for some patients (e.g. adults) when using the 1000Hz probe tone.



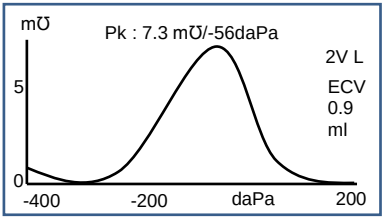


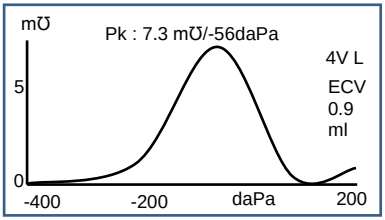
The default 1000Hz baseline mode is Scalar with -400daPa baseline offset (as shown in the diagram on the right and indicated by 4S on the display) but alternative 1000Hz modes may be selected if required (see below). The units displayed on the vertical axis are mmho (mʊ) which is normal practice for 1000Hz operation. The ear canal volume (ECV) is shown in ml.

Note that 1000Hz tympanograms do not include either a rectangle inside which the tympanogram peak should ideally fall, or a calculation of the gradient, because no standardised interpretations for such tympanograms currently exist.

Vector Mode

For 1000Hz operation an alternative display mode is available known as “Vector” mode. This is based on the definition given in Clause 3.17.2 of IEC 60645-5:2004 and takes account of phase information in the measurements. It is also known as B-G compensation and is suitable for all patients other than neonates. The tympanogram format is shown below.



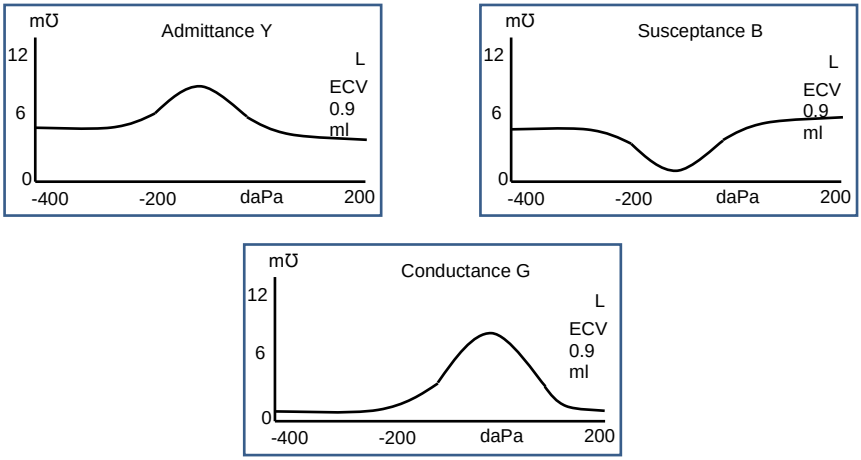


The format is similar to that used for scalar mode with the 1000Hz probe tone. Baseline offsets of +200daPa offset (2V) and -400daPa (4V) are available as required.

Note that a consequence of the vector mode calculation is that the resulting tympanogram cannot take negative values. It is thus theoretically possible for the trace to appear to rise (i.e. take higher positive values) at the end opposite to the selected offset. The user is advised to view traces with each of the +200daPa and -400daPa baseline offsets selected before deciding which result to save.

Component Mode

This 1000Hz mode displays the separate admittance, susceptance & conductance (YBG) information contained within the tympanogram. This is suitable for all patients, and the display format is shown below.



Component mode is used as required by the audiologist. In this case the ECV value is measured at the +200daPa baseline offset in Scalar mode.

Further Information

For the display modes and baseline offsets described above the user is referred to the various publications & papers available for more detail and discussion regarding the possible methods of displaying 1000Hz tympanograms and the interpretation of the associated tympanometric data.

Section 19 provides details of the way 1000Hz measurements are performed in comparison with those at 226Hz and the differences in the mathematical analysis used to treat the two cases.

5.5.3.3 **Selecting alternative baseline modes**

Switching between display modes and baseline offsets is carried out using the DISPLAY MODE key on the front panel (see Section 4.2) or the function button on the probe (see Section 4.3).

Press and briefly hold the key or button to cycle round Scalar, Vector ^{H} and Component ^{H} display modes (note that only the Scalar display mode is available for 226Hz probe frequency).

Within each display mode a short press of the button will:

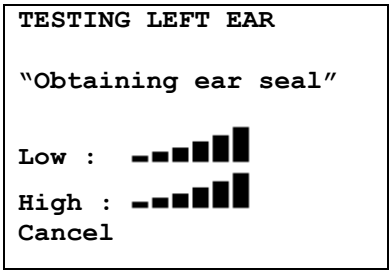
- switch between the two baseline offset values available (+200daPa and -400daPa) for Scalar and Vector ^{H} display modes
- cycle round admittance, susceptance & conductance for Component ^{H} display mode

Note that the default baseline mode for future tests may be changed if required using the BASELINE MODE option in the CONFIGURATION > SWEEP SETTINGS menu (see Section 12.2).

5.5.4 Ear seal check

The type of ear seal check employed at the start of a test can be set in the CONFIGURATION menu (Section 12.2). The default STANDARD option is adequate for most tests, although it may not always be possible to generate the extremes of pressure during a tymopanogram measurement with this setting.

However if difficulty is experienced in using the eartips to create a seal the alternative EXTENDED option may be helpful. This checks that a range of pressures will be available before starting a test by means of a visual indication of the quality of the seal:



The number of bars shown indicates the robustness of the seal. The probe should be adjusted in the ear until two or more bars are shown for Low & High. The method used for the extended ear seal check places a maximum limit on the ear canal volume of ~4.5ml.

5.6. Reflex Settings

A number of settings are available to control the way in which reflex tests are taken and the results displayed. To modify these settings the CONFIGURATION > REFLEX SETTINGS menu options shown in Section 12.2 are used, and these are described below. Refer also to Section 3.3.

Reflex sequence

Use the ▲ and ▼ keys to choose the type of reflex stimulus to apply (ipsilateral only, ipsilateral followed by contralateral or contralateral only). Press the ► key to confirm the selection or the ◄ key to cancel.

Reflex levels

Choose ipsilateral or contralateral and press the ► key to confirm the selection.

Then use the ▲ and ▼ keys to choose the maximum level of reflex stimulus to apply and the step size between the levels of the preceding stimuli. The maximum level of ipsilateral stimulus may be set between 85dBHL & 100dBHL; the maximum level of contralateral stimulus may be set between 85dBHL & 110dBHL. Press the ► key to confirm the selection.

Reflex frequencies

Use the ▼ key to scroll through the frequencies available for each of the ipsilateral and contralateral stimuli (500Hz, 1000Hz, 2000Hz & 4000Hz), and then the ▲ key to select (✓) or deselect (-) the frequencies at which the reflex stimulus is to be applied. Then press ► to save the entire selection.

Reflex selection

Use the keys to choose the circumstances when a reflex measurement is to be made (always, never, only if an admittance peak is found, or only after confirmation is made at the start of the test sequence). In cases where an admittance peak has not been established a pressure of 0daPa is used.

Reflex threshold

Use the keys to choose the change in admittance required to signify that a reflex response has been detected (0.01ml to 0.5ml). The default is 0.03ml.

Reflex auto-stop

By default the reflex test at each frequency will stop at the lowest level of stimulus that produces a response. By setting REFLEX AUTO-STOP to NO the Otowave will test for a reflex at all selected levels. (Refer to Section 14.1 for limits on the ipsilateral & contralateral reflex stimulus levels.)

Reflex filter

Use the keys to choose either 2Hz or 1.5Hz. The default of 2Hz is suitable for most circumstances. However if a smoother reflex plot is required for better interpretation 1.5Hz may be chosen.

5.7. Error messages

Refer to Section 13 for error messages that may be displayed while taking measurements.

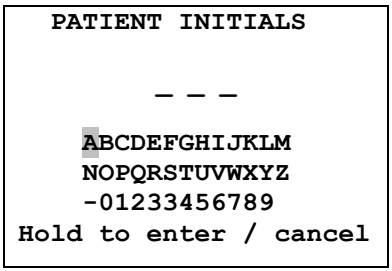
6. Saving Results in the Internal Database

Up to 36 tests can be stored in the Otowave's internal database.

To save the results of a test select SAVE RESULTS from the PROCESS RESULTS menu that is displayed on completion of a test. This option can also be accessed by selecting VIEW THE LAST TEST from the main menu and scrolling through the results using the ► key as long as the test results have not already been saved or deleted (e.g. by starting and then aborting a new test).

A three character identifier is used for the record. This is also used as the reference for the patient's name on the printed record and for data transferred to a computer. The identifier would typically be the patient's initials, and as the tympanometer uses a combination of this identifier and the date/time of a test to refer to stored records this same identifier may be used for different tests for the same patient.

6.1. Data entry



To enter the data:

Use the ▲ ▼ ◄ and ► keys to select a character
Press and hold the ► key to enter the selected character
Press and hold the ◄ key to delete the last character

To save the test results:

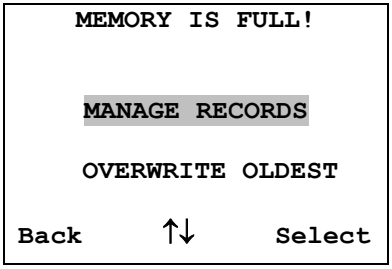
Enter all three characters for the identifier
Press and hold the ► key to save the record

To cancel saving the last test:

Delete any characters that have been entered
Press and hold the ◄ key

6.2. Database full

A warning will be displayed if the database is full when attempting to save a test:



Selecting MANAGE RECORDS will display the DATA MANAGEMENT menu (Section 9) which provides options for printing or transferring data to a computer prior to deleting records to make space for the new test.

OVERWRITE OLDEST will overwrite the oldest record in memory with the results being stored.

Back will return to the previous menu.

7. Sending the Results to a Printer

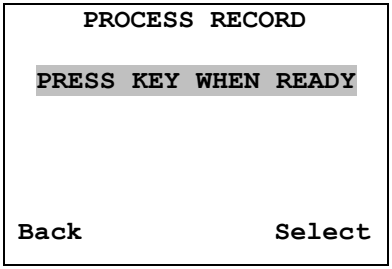
The Sanibel MPT-II thermal printer is available as an option for use with the Otowave 302 and is connected using the cable supplied. The printer may be specified when ordering and only this printer should be used. It will be correctly configured for use.

The three character identifier for the record (see Section 6) is printed in the "Name" field followed by the Otowave graphical displays, the analysis and the results. The name of the hospital, the department, and the calibration dates for the instrument may also be printed if required (see Section 12.2). There is space for additional details to be handwritten by the clinician (patient name/age, operator & comments).

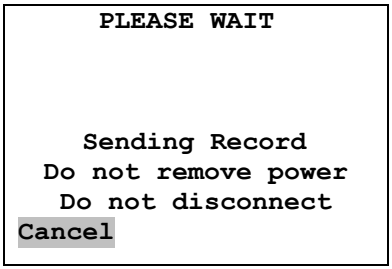
Thermal paper printouts can fade with exposure to light or heat. Consider transferring the data to a computer for permanent storage.

To print the results of the last test select SEND TO PRINTER from the PROCESS RESULTS menu on completion of the test. (Similar facilities for printing are available from the VIEW THE LAST TEST and DATA MANAGEMENT options in the MAIN MENU.)

The following display is then presented:

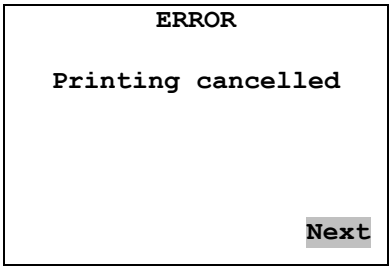


Press ► when the printer is ready. The Otowave will then attempt to connect to the printer and the following screen is displayed:



After printing the PROCESS RESULTS menu is displayed.

To stop the print operation (for example if a printer is not connected) press ◄ to select Cancel. The following confirmation screen is displayed:



Press ►to return to the PROCESS RESULTS menu.

Note that, if required, it is possible to change to an alternative baseline mode prior to printing (see Section 5.5.3.3). However the mode that was stored in the instrument when the test was saved will always be retained.

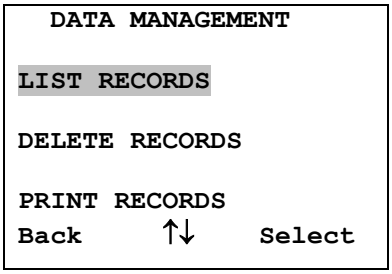
8. Data Transfer to NOAH or TympView

To transfer test results stored within the tympanometer to a NOAH database the Amplivox NOAH Impedance module must be installed on to a computer. Alternatively, Amplivox TympView allows data to be transferred to a computer and subsequently viewed, annotated & printed. This software is supplied on a CD which includes this operating manual.

The computer will automatically detect the instrument when it is connected with the USB cable. Data transfer is initiated from the computer (not from the Otowave). Refer to the installation & operating instructions provided with the NOAH Impedance Module or TympView for further details. To disconnect simply remove the cable when data transfer is completed.

9. Data Management

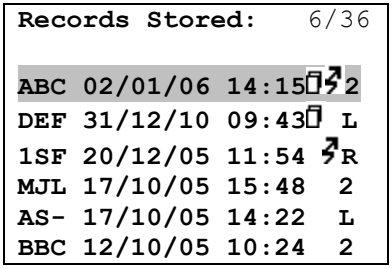
Records stored in the database of the Otowave can be listed, viewed, printed or deleted using the DATA MANAGEMENT option of the main menu:



If it is required to work with the record of an individual test, select LIST RECORDS. All other options operate on groups of records.

9.1. List records

LIST RECORDS shows the stored tests, 6 at a time, most recent first:



Each entry shows:

- The three-letter patient identifier entered when the test was stored
- Date and time of the test
- Whether the test has been printed ( )
- Whether the test has been sent to a computer ( )
- Whether the test is for the Left (L), Right (R) or both (2) ears

Press ▲ or ▼ to scroll through the records
Press ► to select the highlighted record
Press ◄ to return to the previous menu

When a record is selected the PROCESS RECORD menu will be displayed. This accesses the following functions:

- View the selected record (which may then be displayed using the various baseline modes as described in Section 5.5.3)
- Print the selected record (using the currently displayed baseline mode)
- Delete the selected record

See Sections 7 and 8 for further information on printing the record or sending it to a computer.

9.2. Delete records

DELETE RECORDS allows a group of records to be deleted. It is possible to delete all records, all records that have been printed or all records that have been sent to a computer.

Confirmation of the deletion is required.

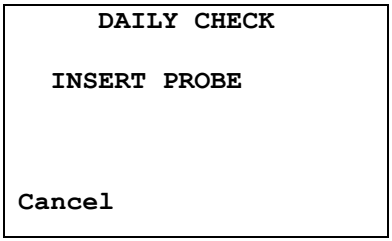
9.3. Print records

PRINT RECORDS allows a group of records to be sent to the printer. It is possible to print all stored records or just those records that have not already been printed. Note that when printing a group of records the baseline mode originally saved for each record will be used. To print a record using an alternative baseline mode use the Print option described in Section 9.1. Refer to Section 7 for more general information about using a printer. If printing the entire database it is recommended that a full roll of paper is loaded into the printer.

10. Performing Daily Checks

The operation of the Otowave should be checked daily using the 4 in 1 test cavity assembly supplied with the instrument.

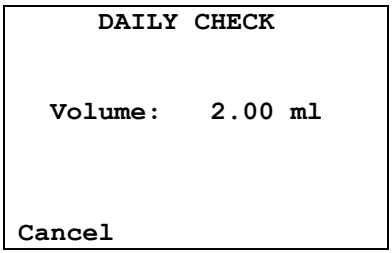
Select the DAILY CHECK option in the main menu:



Wait until “INSERT PROBE” is displayed.

Insert the probe, without an ear tip, into the hole at the 2ml end of the test cavity. Make sure that the probe is pushed fully home and is held tight against the stop. The probe must be square to the end of the test cavity.

The display should show the volume of the test cavity to within ± 0.1ml.



Remove the probe, wait until “INSERT PROBE” is displayed and repeat the test with the three remaining test cavities. The display should show the volume of the 0.2ml, & 0.5ml test cavities to within ± 0.1ml. The volume of the 5.0ml test cavity should be shown within ± 0.25ml.

When the checks have been completed press ◄ to return to the main menu.

11. Routine Maintenance

11.1. Cleaning the Otowave

Before cleaning always:

- switch off the instrument
- disconnect from the power supply

Recommended cleaning and disinfection solutions:

- Warm water with mild, nonabrasive cleaning solution (soap)
- Clinical wipes (for example Clinell Universal)

Procedure:

- Follow local best practice and safety guidelines if available
- Use a soft lint-free cloth lightly dampened with cleaning solution to clean:
  - all exposed surfaces
  - other parts that contact the patient
- Single use components such as ear-tips do not require cleaning

Precautions:

- **Handle the instrument carefully**
- **Do not allow any liquid to enter any part of the instrument or accessories**
- **Do not autoclave or sterilize the instrument or any accessory**
- **Do not use hard, sharp or pointed objects to clean any part of the instrument or an accessory**
- **If parts have been in contact with fluids do not allow them to dry before cleaning**

11.2. Eartips and Probe

Ear tips should be replaced after a single use. This applies to ear tips used with the main probe assembly and the contralateral transducer.

The probe tip and its associated sealing washer are disposable devices. The probe tip should be checked before each ear insertion to ensure it is undamaged and that none of the tubes through it are blocked. It should be replaced if necessary.

The sealing washer should be replaced when the probe tip is replaced, if it shows signs of wear, or if a pressure leak is suspected.

Refer to Section 4.5 for illustrations of these components

Handle the probe and accessories with care. Do not allow moisture, condensation, fluids or debris to enter the probe.

11.3. Calibration and Return of the Instrument

Amplivox recommends that the Otowave is calibrated annually. A warning message will be displayed at power up if the instrument was calibrated more than twelve months ago. The date of the last calibration is displayed on the SYSTEM INFORMATION screen (see Section 12.2).

Please contact Amplivox or the designated distributor for details of calibration services.

If the instrument is to be used at elevations above that specified in Section 2.1 re-calibration must be undertaken at the intended operating elevation.

The instrument should be returned to the manufacturer for service & repair. There are no user-serviceable parts within it.

When packing the instrument for shipping, please use the original shipping carton and packing materials. Place the instrument parts in plastic bags before packing to prevent dirt and dust getting into the probe.

12. Menu Summary

Default values are shown in **bold** where appropriate.

12.1. Main menu

Menu	Sub-menu
MAIN MENU	NEW TEST
	CONFIGURATION
	VIEW THE LAST TEST
	DAILY CHECK
	DATA MANAGEMENT
	SYSTEM INFORMATION

12.2. Sub-Menu selections

Sub-menu	Option	Choices / Description
NEW TEST	SELECT EAR	Choose which ear(s) to test and start the test. A tympanogram is taken followed by reflex measurements, if selected. On-screen messages & indicators on the base unit and probe show progress. Graphical displays are shown automatically at the end.
CONFIGURATION (> SWEEP SETTINGS)	SWEEP SPEED	Select 100daPa/s **200daPa/s** or 300daPa/s See Section 5.5.
	PROBE FREQUENCY [H]	Select **226Hz** or 1000Hz for the frequency of the probe signal.
	BASELINE MODE	For 226Hz probe tone select either **+200daPa** or -400daPa baseline offset (in Scalar mode only). [H] For 1000Hz probe tone select from +200daPa or **-400daPa** baseline offset (in **Scalar** mode); +200daPa or -400daPa baseline offset (in Vector mode); or Component mode (Y/B/G). See Section 5.5.3 for details.

Sub-menu	Option	Choices / Description
	EAR SEAL CHECK	Select **STANDARD** or EXTENDED. See Section 5.5.
CONFIGURATION (> REFLEX SETTINGS)	REFLEX SEQUENCE	Select **ipsilateral**, both or contralateral for the reflex stimulus.
	REFLEX LEVELS	Select IPSILATERAL or CONRALATERAL then select the maximum tone level to be used for the reflex test. For ipsilateral set the level to 100dB (with 5dB or 10dB steps) or **95dB**, 90dB or 85dB with **5dB** steps. For contralateral set the level to 110dB, 105dB or 100dB (with 5dB or 10dB steps) or 95dB, **95dB** or 85dB with **5dB** steps.
	REFLEX FREQUENCIES	See Section 5.6 to choose the frequencies at which to perform the reflex test. Default: **ipsilateral** at **1kHz**.
	REFLEX SELECTION	See Section 5.6. Select when reflexes will be measured: ALWAYS MEASURE NEVER MEASURE **ONLY IF PEAK FOUND** PROMPT TO MEASURE
	REFLEX THRESHOLD	See Section 5.6. Default: **0.03 ml**.
	REFLEX AUTO-STOP	See Section 5.6. Default: **YES**.
	REFLEX FILTER	See Section 5.6. Default: **2 Hz.**
CONFIGURATION (> SYSTEM SETTINGS)	SET TIME/DATE	Set the internal clock date and time; use the ◄ & ► keys to select a field and the ▲ & ▼ keys to adjust the value.
	LCD CONTRAST	Adjust the display contrast using the ▲ & ▼ keys.
	LCD BRIGHTNESS	Adjust the display brightness using the ▲ & ▼ keys.

Sub-menu	Option	Choices / Description
	REPORT CAL. DATES	Select **PRINT CAL. DATES** or HIDE CAL.DATES for the printout.
	SET DATE FORMAT	Select **DD/MM/YY** or MM/DD/YY
	HOSPITAL NAME	Allows the Hospital name to be entered (this will appear at the top of the print out). See Section 6.1 for data entry method; then position the cursor on the # symbol and hold ► to confirm or ◄ to cancel. Not all of the characters have to be used.
	DEPARTMENT	Allows the Department name to be entered (similar to Hospital Name).
	RELOAD DEFAULTS	Select YES to reset the options above to their default values.
	SELECT LANGUAGE	Select **ENGLISH**, DEUTSCH, FRANÇAIS, ESPAÑOL, PORTUGUÊSE or ITALIANO for the operating language.
VIEW THE LAST TEST	SELECT EAR	Recalls the last test(s) carried out. The symbols ✓ or **X** are used to signify whether results are available for each ear. This option also allows the data to be saved or printed as described in Sections 6 & 7.
DAILY CHECK		Shows the volume in ml measured by the probe using 226 or 1000 Hz probe tones
DATA MANAGEMENT	LIST RECORDS	Lists the test results stored in the internal database. Allows individual records to be viewed, printed or deleted.

Sub-menu	Option	Choices / Description
	DELETE RECORDS	Select: ALL PRINTED RECORDS to delete all records that have previously been printed ALL SENT RECORDS to delete all records that have previously been sent to a computer ALL RECORDS to delete all records
	PRINT RECORDS	Select: UNPRINTED RECORDS to print all records that have not previously been printed ALL RECORDS to print all records
SYSTEM INFORMATION		Shows: Instrument variant Date calibrated Next calibration date Instrument serial number Software version Current date and time

13. Error Messages & Fault Conditions

If a fault condition cannot be cleared, the operator is cautioned against repeatedly starting the instrument. In some fault conditions the internal pump may progressively advance towards the end of its travel in an attempt to clear the fault. If the end of travel is reached in such conditions the instrument may lock up and become un-usable.

If difficulties resolving fault conditions occur the equipment distributor (or Amplivox if purchased directly) should be consulted.

13.1 General error messages

Message Displayed	Indicator Status	Likely Cause(s)
PROBE NOT CLEAR Please ensure the probe is not blocked or obstructed	Yellow Steady	Check that the probe is not inserted into a test cavity at start-up. Examine the probe tip for blockages. If necessary take it off and clean or replace it, see Section 4.5. If the problem persists, contact your Amplivox service centre.
AIRFLOW ERROR Unknown pump fault. Restart the unit. If problem persists, contact Amplivox	Yellow Steady	
AIRFLOW ERROR Cannot determine pump direction. If problem persists, contact Amplivox	Yellow Steady	Fault with air system and/or pump. If the fault persists contact your Amplivox service centre.
AIRFLOW ERROR RESTART THE UNIT. If problem persists, contact Amplivox	Yellow Steady	Fault with air system and/or pump. If the fault persists contact your Amplivox service centre.
WARNING! CALIBRATION EXPIRED Recalibration needed before further tests are performed	Yellow Steady	The current date is later than the next calibration date. Check that the clock is set to the correct date. If so, arrange for the instrument to be recalibrated. Tests can still be performed.
WARNING! DEVICE UNCALIBRATED. One or more default values require recalibration before further tests are performed	Yellow Steady	This message should never normally be seen and it will not be possible to run a test or perform a Daily Check while the error exists. Please contact your Amplivox service centre to arrange calibration.
WARNING! DEFAULTS RELOADED. Default configuration settings reloaded. Check before making new tests	Yellow Steady	This message should never be seen. Check all the CONFIGURATION settings before taking any measurements. If the error persists, contact your Amplivox service centre

13.2 Messages related to testing

Message Displayed	Indicator Status	Likely Cause(s)
WITHDRAW PROBE	Green & Yellow (Fast alternate)	The probe has been moved during measurement. A test has been started with the probe already inserted into the ear.
Volume outside range WITHDRAW PROBE	Green & Yellow (Fast alternate)	The ear canal volume is above 5ml. This message may also occur when the probe is not properly inserted into the ear.
Blocked ear WITHDRAW PROBE or Blocked probe WITHDRAW PROBE	Green & Yellow (Fast alternate)	These messages occur when the probe tip or ear is blocked. Check that the ear is not blocked. Check that the probe is clear and correctly inserted into the ear.
Blocked probe WITHDRAW PROBE	Yellow Fast	Test started while probe is not connected to base unit.
Pressure lost WITHDRAW PROBE	Green & Yellow (Fast alternate)	The ear seal has been broken while testing for seal.
INSERT PROBE	Green & Yellow (Fast alternate)	An error condition has been recovered and the test may continue The seal was lost and a test needs to restart. This message may also occur when the ear canal volume is out of range.
Measurement timed out	Green & Yellow (Fast alternate)	This occurs when the ear seal check is set to EXTENDED if: (i) The pump failed to achieve the starting pressure within 4 seconds. This may be because the probe was moved in the ear.

Message Displayed	Indicator Status	Likely Cause(s)
		(ii) The pressure failed to reach -400 daPa within 12 seconds. Retry the test. If the problem persists, contact your Amplivox service centre.

13.3 Messages related to sending data to a computer

Refer to the installation & operating instructions provided with the NOAH Impedance Module or TympView software for details of the data transfer operation and errors that may occur.

14. Technical Specification

14.1. Performance

Tympanometry	
Instrument type	Meatus compensated tympanometer
Analysis performed	Admittance peak level (in ml or mʊ ^{H}) pressure at peak; Gradient in daPa (for 226Hz); Ear Canal Volume (ECV) @ 200 daPa or -400 daPa
Probe tone frequency, level and accuracy	226Hz +/- 2%; 85dB SPL +/-2dB ^{H} 1000Hz +/- 2%; 79dB SPL +/-2dB over ECV range
Pressure levels and accuracy	+200daPa to -400daPa +/-10daPa or +/-10% (whichever is larger) over range 0.1ml to 5ml
Ear canal volume measurement range and accuracy	226Hz: 0.2ml to 5ml +/- 0.1ml or +/-5% (whichever is larger) ^{H} 1000Hz: 0.1ml to 5ml +/- 0.1ml or +/-5% (whichever is larger)
Sweep speed	Selectable: 100, 200 or 300daPa/sec
Pressure limits (safety cutout)	+600 and -800 daPa
Number of samples stored	100 per tympanogram
Reflex measurements	
Measurement modes	Ipsilateral, contralateral or both
Reflex tone levels and accuracy	**Ipsilateral** - configurable over range: 500Hz, 1kHz, 2kHz & 4kHz (+/-2%) 70dBHL to100dBHL (+/-3dB)

(referenced to 2ml calibration volume - compensates for measured ear volume)	(2kHz level is restricted to maximum 95dBHL for ear canal volumes greater than ~3.5ml) (4kHz level is restricted to maximum 85dBHL for ear canal volumes greater than ~3.5ml & maximum 95dBHL for all ear canal volumes) **Contralateral** - configurable over range: 500Hz, 1kHz, 2kHz & 4kHz (+/-2%) 70dBHL to110dBHL (+/-3dB) (1kHz level is restricted to minimum 75dBHL for ear canal volumes less than ~0.2ml) (4kHz level is restricted to maximum 100dBHL for ear canal volumes greater than ~3.5ml
Reflex tone distortion (ipsi & contra)	<5%
Number of reflex levels presented below the selected maximum and step size(s) available	Ipsilateral - three lower levels: 100dBHL max, with 5dB or 10dB steps 95/90/85dBHL max, with 5dB steps Contralateral - three lower levels: 110/105/100dBHL max, with 5dB or 10dB steps 95/90/85dBHL max, with 5dB steps
Reflex analysis	Reflex pass/fail at each level tested; maximum amplitude of each reflex; nominal pressure used for the reflex test (computer display only)
Pressure used for reflex measurement	Pressure at tympanogram peak (if found) or at 0daPa
Reflex stimulus control	Stimulus presented at all levels, or Stimulus ceases when a reflex is found

Reflex detection threshold and accuracy	0.01ml to 0.5ml +/-0.01ml (configurable in 0.01ml steps)
Reflex tone duration	0.6 seconds
Database	
Number of records stored in Patient Database	36
Data storage	Any recording can be stored once the tympanogram is viewed. Patient Initials (A-Z, 0-9, "-") must be entered before storage.
Data held	Patient Initials, Tympanogram and Reflex graphs and analysis for Left Ear and/or Right Ear, Time and Date of recording, which ears were tested, whether or not the record has been printed and/or sent to a computer, parameters used for analysis, 128 bit Globally Unique Identifier (GUID)
Data presentation	Records listed in reverse chronological order (latest first), with indication of data stored as described above
Real Time Clock	
Time stamps	Time and date stamp applied to all recordings, and to the last calibration date
Languages	
Operating languages (user-selectable)	English, German, French, Spanish, Portuguese or Italian
Printing	
Supported printer	Sanibel MPT-II
Interface	Cable supplied
Information printed	Tympanogram, Tympanogram analysis parameters, Reflex graphs, Reflex analysis parameters, Serial Number of device, Last and Next Due Calibration dates; space for patient & clinician's details to be entered.
Serial Interface to Computer	
Interface	USB Version 1.1
Information sent	Patient header, full left & right ear data.

Power Supply	
Mains power	100-240Vac; 50/60Hz; 0.4A
Warm-up period	None at room temperature
Idle current	70mA
Current while testing	230mA
Physical	
Display	256 x 64 pixels / 8 lines of 21 characters
Dimensions (base unit)	270mm wide x 175mm deep x 70mm high excluding connections
Weight (base unit)	760 g
Dimensions (probe)	130mm long x 25mm (max) diameter
Weight (probe, incl connection)	115g
Interconnection (probe to base)	1.5m combined electrical cable and air tube
Environmental	
Operating temperature range	+15^{o}C to +35^{o}C
Operating humidity range	30% to 90% RH (non-condensing)
Operating atmospheric pressure range	980mb to 1040mb (see Section 2)
Transport and storage temperature range	-20^{o}C to +70^{o}C
Transport and storage humidity range	10% to 90% RH (non-condensing)
Transport and storage atmospheric pressure range	900mb to 1100mb
Standards conformance	
Safety	IEC 60601-1 (plus UL, CSA & EN deviations)
EMC	IEC 60601-1-2
Performance	IEC 60645-5, Type 2 Tympanometer
CE mark	To the EU Medical Device Directive

14.2. Equipment classification

Type of protection against electric shock	Powered via SELV ClassII mains adapter
Degree of protection against electric shock	Type B applied parts
Degree of protection against ingress of water	Not protected
Mode of operation	Continuous operation
Equipment mobility	Portable

The Otowave 302 Tympanometer is classified as a Class IIa device under Annex IX (Section 1) of the EU Medical Devices Directive.

14.3. Symbols

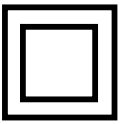
The following symbols appear on the tympanometer or mains adapter:

Definition: Refer to instruction manual (mandatory)

Definition: Type B applied part – an applied part providing protection against electric shock, particularly regarding allowable patient leakage current and patient auxiliary current.

The applied parts are the probe assembly, contralateral transducer and the associated cables.

Definition: The output from the mains AC adapter is Direct Current



Definition: Class II equipment – equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions.

15. Ordering Consumables and Accessories

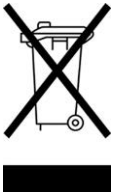
To order consumables, additional accessories and to replace detachable parts that have been damaged, please contact Amplivox for current prices and delivery charges. The items available are listed below:

Stock No.	Description
T527	Probe tip
T518	Seal
T030	4 in 1 test cavity assembly (0.2ml/0.5ml/2.0ml/5.0ml)
T20	Ear tip set
T205	Ear tip Otowave 3-5mm
T206	Ear tip Otowave 4-7mm
T207	Ear tip Otowave 7mm
T208	Ear tip Otowave 8mm
T209	Ear tip Otowave 9mm
T210	Ear tip Otowave 10mm
T211	Ear tip Otowave 11mm
T212	Ear tip Otowave 12mm
T213	Ear tip Otowave 13mm
T214	Ear tip Otowave 14mm
T215	Ear tip Otowave 15mm
T219	Ear tip Otowave 19mm
W007	Otowave probe assembly (with interconnections) *
T040	Contralateral reflex transducer, probe tip & earpiece lead *
T041	Contralateral reflex transducer probe tip
C14	Earpiece lead
A091-7	Approved mains adapter (FW7660M/05)
B135	Carrying case
PT02	Sanibel MPT-II Thermal Printer
A102	Printer cable – Otowave to Sanibel MPT-II
C104	Thermal Printer paper for Sanibel MPT-II
F07	USB Cable, 1.8m

Accessories marked * require calibration with the specific tympanometer to be used. Do not attempt to use these accessories until the tympanometer has been calibrated to match their characteristics.

Shipping documentation will reference the stock number quoted above, and images of the parts alongside the relevant stock number are available on the Amplivox website (www.amplivox.ltd.uk). The required fitting instructions are supplied with each part.

16. Disposal Information



Amplivox Limited is fully compliant with the WEEE (Waste Electrical and Electronic Equipment) Regulations. Our PRN (Producer Registration Number) is WEE/GA0116XU and we are registered with the approved WEEE Compliance Scheme, B2B Compliance, approval number WEE/MP3338PT/SCH.

The main purpose of the WEEE Regulations is to encourage the segregation of waste electrical items from the general waste stream and into reuse, recovery and recycling routes.

Therefore for any waste electrical units purchased from Amplivox that either:

- bear the crossed out wheeled bin symbol with black bar underneath, or
- have been replaced with new Amplivox products on a like-for-like basis

please contact our WEEE Compliance Scheme, B2B Compliance, using the details below. B2B Compliance will be able to provide further information on how to recycle your waste electrical units and answer any queries you may have.

B2B Compliance
Tel: +44 (0) 1691 676 124 (Option 2)
Email: operations@b2bcompliance.org.uk

17. EMC Guidance & Manufacturer's Declaration

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The Otowave 302 Tympanometer is intended for use in the electromagnetic environment specified below. The customer or user of the Otowave 302 Tympanometer should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions

CISPR 11</td><td>Group 1</td><td rowspan="1">The Otowave 302 Tympanometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions

CISPR 11</td><td>Class A</td><td rowspan="3">The Otowave 302 Tympanometer is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions

IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/flicker emissions

IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity (1)			
The Otowave 302 Tympanometer is intended for use in the electromagnetic environment specified below. The customer or user of the Otowave 302 Tympanometer should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T **(>95% dip in U_T) for 5 sec**	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Otowave 302 Tympanometer requires continued operation during power mains interruptions, it is recommended that the Otowave 302 Tympanometer be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to the application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity (2)			
The Otowave 302 Tympanometer is intended for use in the electromagnetic environment specified below. The customer or user of the Otowave 302 Tympanometer should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Otowave 302 Tympanometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m	$d = 1.2\sqrt{P}$ (80MHz to 800MHz0 $d = 2.3\sqrt{P}$ (800MHz to 2.5GHz) where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).

Guidance and manufacturer's declaration – electromagnetic immunity (2)			
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Otowave 302 Tympanometer is used exceeds the applicable RF compliance level above, the Otowave 302 Tympanometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Otowave 302 Tympanometer.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Otowave 302 Tympanometer

The Otowave 302 Tympanometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Otowave 302 Tympanometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Otowave 302 Tympanometer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter**		
	m		
W	**150 kHz to 80 MHz**	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.

NOTE 1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

18. Use with Non-medical Electrical Equipment

Any person who connects external equipment to signal input, signal output or other connectors has created a medical electrical system and is therefore responsible for the system complying with the requirements of clause 16 of IEC 60601-1:2005 *(General requirements for basic safety and essential performance).*

If connections are made to standard equipment such as printers and computers, special precautions must be taken in order to maintain medical safety. The following notes are provided for guidance in making such connections to ensure that the general requirements of clause 16 of IEC 60601-1:2005 are met.

The following signal inputs and outputs on the Amplivox Otowave 302 tympanometer are electrically isolated to the requirements of IEC 60601-1 in order to reduce any potential hazard associated with the use of mains-powered equipment connected to these interfaces:

Socket Label	Socket Type	Typical Connection
PRINTER	RJ12 socket (6-way)	Designated printer
	USB Connector Type B	Computer

External equipment intended for connection to signal input, signal output or other connectors, shall comply with the relevant IEC or international standards (e.g. IEC 60950, CISPR 22 & CISPR 24 for IT equipment, and the IEC 60601 series for medical electrical equipment).

Equipment not complying with IEC 60601 shall be kept outside the patient environment, as defined in IEC 60601-1:2005 (at least 1.5m from the patient).

The operator must not touch the connected equipment and the patient at the same time as this would result in an unacceptable hazard.

Refer to Diagrams 1 to 3 below for typical configurations of connected peripheral equipment.

Refer to Amplivox Limited at the address given on the front of this user manual if advice is required regarding the use of peripheral equipment.

Diagram 1: Otowave 302 used with the medically-approved mains adapter

Mains Outlet

Medical Mains Adapter

Otowave 302
Tympanometer

Diagram 2: Otowave 302 used with the supplied printer

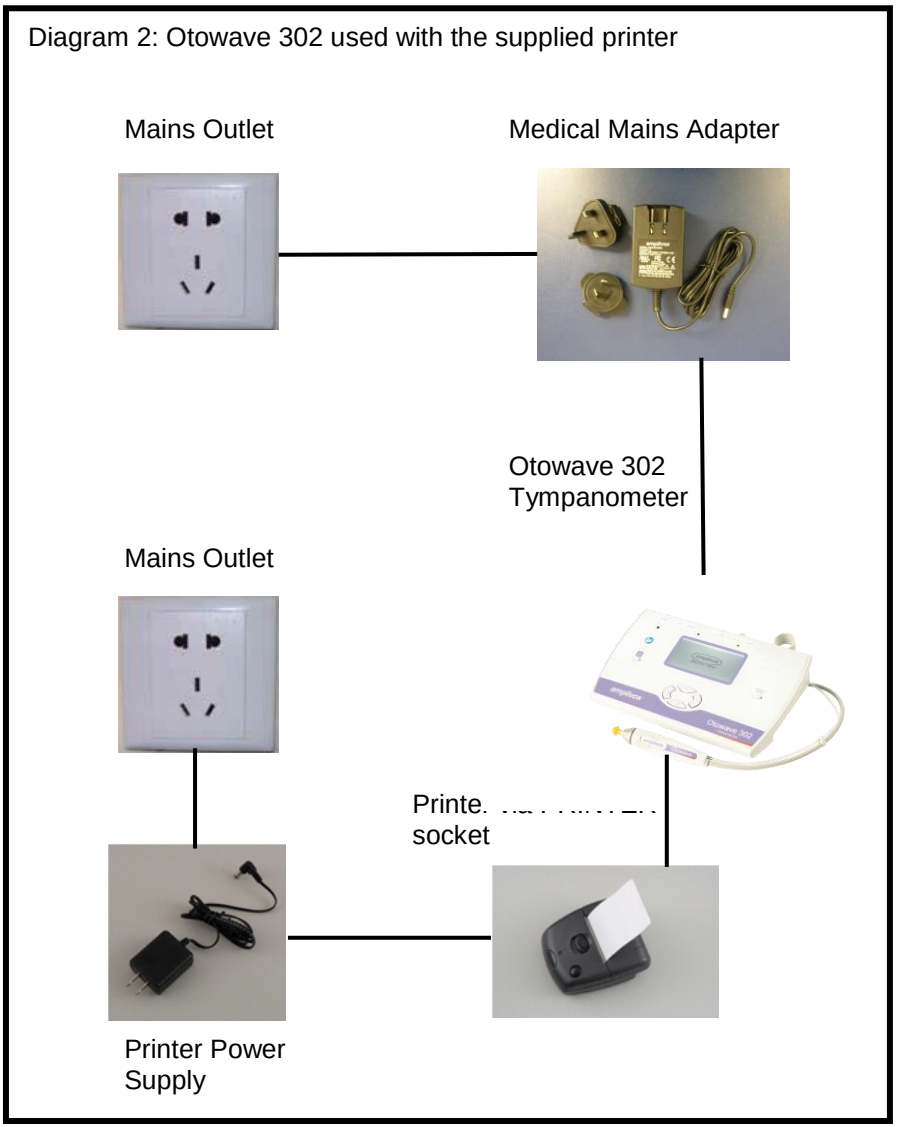
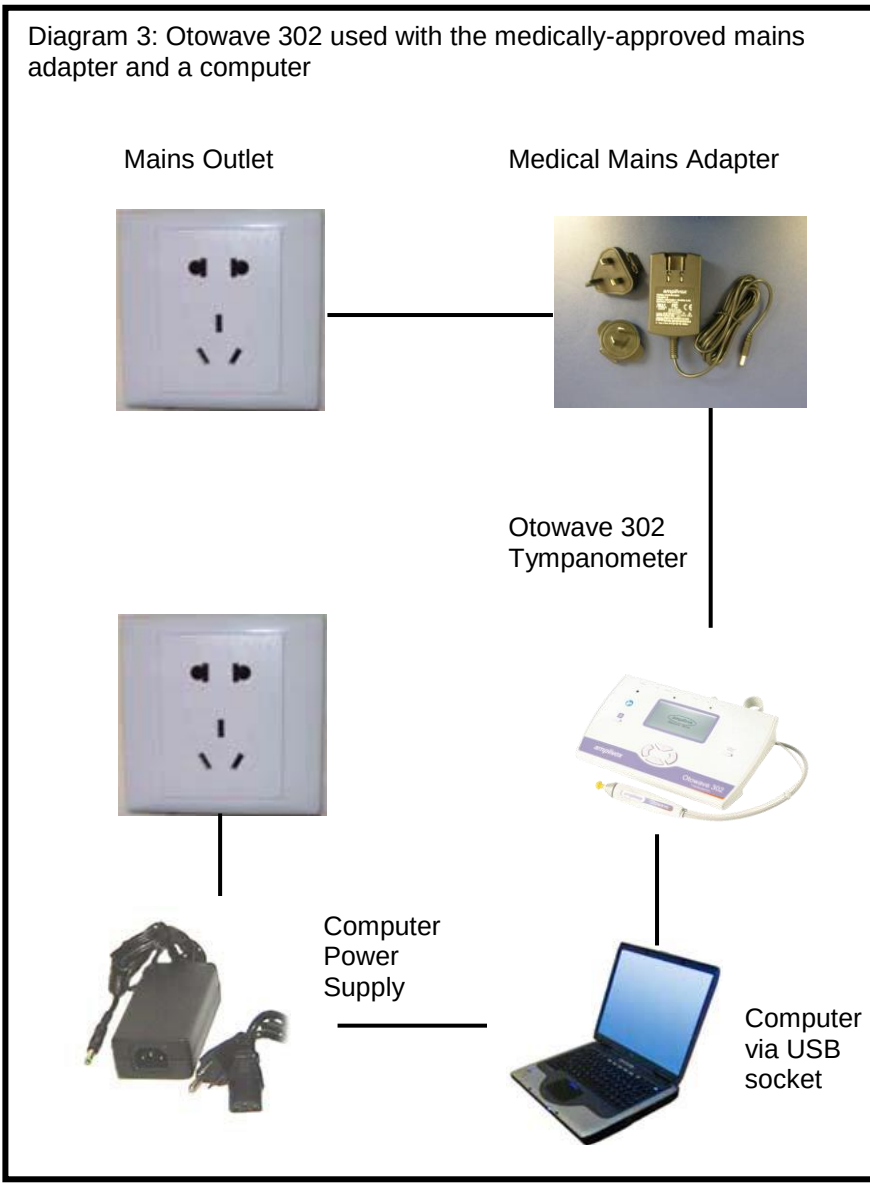


Diagram 3: Otowave 302 used with the medically-approved mains adapter and a computer



19. 1000Hz Tympanometry and Meatus Compensation

19.1. Tympanometric Properties

Tympanometric measurements of the ear are affected by a large number of physiological characteristics, but from a tympanometer's perspective these can be reduced to the three physical properties:

- Stiffness
- Mass
- Friction

These may be represented by equivalent electrical impedances, divided into positive reactance (mass), negative reactance (stiffness) and resistance (friction) - note that friction can only be positive in passive systems. For tympanometry however, it is easier to consider their inverse admittance (Y) components: susceptance (B, inverse of reactance) and conductance (G, inverse of resistance). The units of all these admittance components are mhos (the inverse of ohms used for impedance). The reason for using these inverse measures is because the admittances of the ear canal and middle ear components can then be treated as being in series with each other, making their values easy to separate. For example the ear canal admittance/impedance is often not of immediate interest, and is removed from the measurement as described later. If considered as impedances these components are in parallel, which makes their separation much more difficult to calculate and to visualise.

When considering a simple stiffness like that of the ear canal air volume, its susceptance is positive and is related to the commonly used term “compliance”. At low frequencies, such as 226Hz used in most tympanometers, the middle ear and the ear canal air volume both behave quite like a simple stiffness and use of the term compliance is appropriate (to an approximation). However, at higher frequencies such as 1000Hz, this simplification breaks down, as described below.

19.2. Tympanometric Measurements

The main intrinsic aim of tympanometry is to separate out the admittance contribution of the ear canal air volume (Y_{ec}) from the total measured admittance (Y_{meas}), to yield the admittance in the plane of the tympanic membrane (Y_{tm}). This separation is variously called baseline removal or meatus compensation (the value removed is displayed separately as the Ear Canal Volume). Note that when using a 226Hz probe tone, one can

substitute the word *compliance* for *admittance* in this description, with minor loss of accuracy, and the calculation is a simple *scalar* subtraction of the magnitudes of the admittance values:

$$Y_{tm} = |Y_{meas}| - |Y_{ec}|$$

When considering the general case, including probe tone frequencies at higher frequencies than 226Hz, the above subtraction of the effect of the ear canal air volume is more complicated. In mathematical terms, a *complex* subtraction is required, which involves taking into account the G and B components separately. In graphical terms, this can be described as a *vector* subtraction, and the equation now takes on the form:

$$Y_{tm} = |\overline{Y_{meas}} - \overline{Y_{ec}}|$$

The baseline value (Y_{ec}) is the measured admittance of the ear when at maximum pressure (normally +200daPa for the Otowave 302). This approximates Y_{ec} because the applied pressure reduces Y_{tm} towards zero (but not all the way to zero, otherwise it would not be possible to hear the probe tone at all; nonetheless the approximation is sufficient for clinical purposes). This value is subtracted from each of the tympanogram measurements in turn to generate the meatus-compensated tympanogram normally presented to the clinician.

The above subtractions are represented in terms of vectors in Figs. 1 and 2 shown at the end of this section for probe tone frequencies of 226Hz and 1000Hz respectively. In Fig. 1, it can be seen that there is minimal loss of accuracy by performing a scalar subtraction instead of a vector subtraction. In other words, the phase angles of the vectors (directions of arrows) are similar. Contrast this with Fig. 2 where the phase angles are very different and a scalar subtraction would erroneously give a value close to zero, instead of the length of the vector shown in red.

Even for 226Hz probe tones, the subtraction strictly should be a complex subtraction, but the loss of accuracy arising from using the scalar subtraction method described above is not large enough to be of clinical importance (as shown in Fig. 1), and this approach is taken by most if not all commercial tympanometers. But for 1000Hz measurements, the Otowave 302 optionally can take the more advanced approach, employing vector based subtraction. It is a mathematically more thorough and accurate way of performing compensation and is made possible by the advanced electronics and software within the device.

Although vector subtraction is the only correct solution at 1000Hz, it may be unfamiliar to users and therefore the Otowave 302 offers the option of selecting either scalar or vector baseline compensation for 1000Hz tympanograms. Use of scalar baseline compensation will give results similar to those from some other instruments and be comparable with publications that have used scalar baseline compensation.

There are differences between the tympanograms obtained with scalar and vector baseline compensation: 1000Hz tympanograms may appear quite flat when viewed with scalar baseline compensation; they are typically clearer with vector compensation. Moreover, vector baseline compensation leads to results that follow a more easily interpretable pattern, which means that the middle-ear pressure can be defined with greater certainty.

An additional feature of the Otowave 302 not found on other screening tympanometers is that the user can decide whether to use +200daPa or −400daPa as the reference point for the baseline value.

The Otowave 302 also provides a component display when using a 1000Hz probe tone where separate uncompensated Y, B and G traces can be shown. These may help to interpret the tympanograms and help to define the middle-ear pressure in cases where the Y display alone gives misleading or ambiguous conclusions.

All these display modes are available via Amplivox “TympView”, an application which allows tympanometric test results to be downloaded and displayed on a computer.

19.3. Additional Points to Consider

1. Vector based baseline compensation always generates positive values; it calculates the length of a line joining two points in 2-D space and can therefore never be negative. This can cause a tympanogram to rise up at the end opposite to that used for the baseline reference. If that is the case, changing the baseline from +200daPa to −400daPa or vice versa can improve the display. This effect can be most clearly demonstrated by performing a tympanometric sweep on a 2ml or 5ml hard walled cavity. When viewed in Scalar mode the baseline should always rise from +200 to −400daPa and switching between +200 & −400 should simply raise or lower the trace so that the selected end is at 0; but when the Vector mode is selected the baseline always rises from the selected end, so the slope changes direction.

2. The presentation of 1000Hz tympanograms does not include either a rectangle inside which the tympanogram peak should ideally fall, or a calculation of the Gradient, because no standardised interpretations for 1000Hz tympanograms currently exist.
3. It is the responsibility of the clinician to decide which probe tone frequency and baseline compensation method to adopt for a particular patient, and how to interpret the results.
4. The Otowave 302 allows the baseline compensation mode to be changed after a test has been performed, for comparative purposes. The test can then be stored with the new mode applied. It can also be reloaded and the baseline compensation mode changed again for further review and printing.

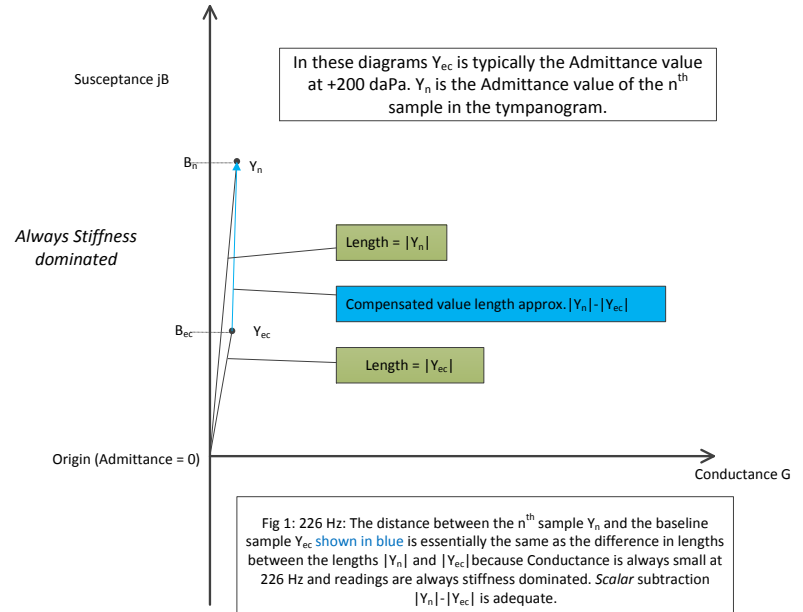


Fig 1: 226 Hz: The distance between the n^{th} sample Y_n and the baseline sample Y_{ec} shown in blue is essentially the same as the difference in lengths between the lengths $|Y_n|$ and $|Y_{ec}|$ because Conductance is always small at 226 Hz and readings are always stiffness dominated. *Scalar* subtraction $|Y_n|-|Y_{ec}|$ is adequate.

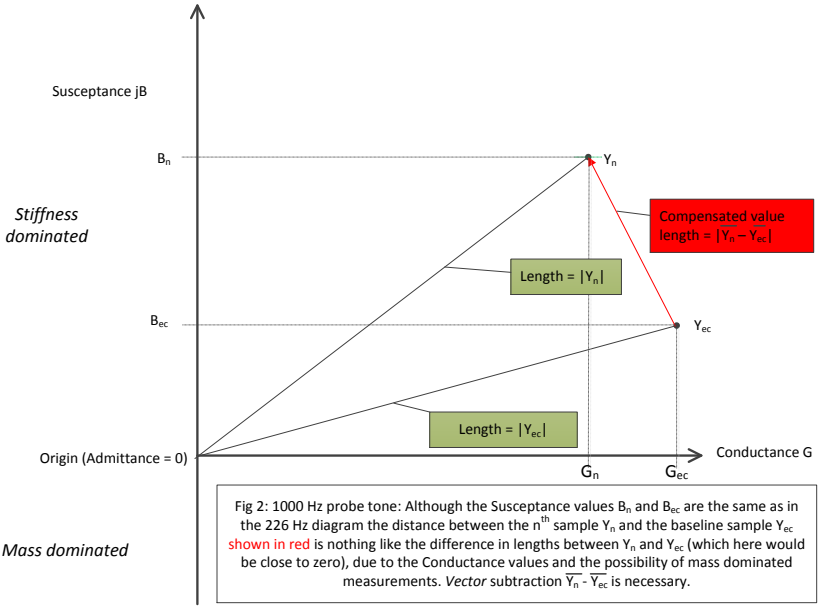


Fig 2: 1000 Hz probe tone: Although the Susceptance values B_n and B_{ec} are the same as in the 226 Hz diagram the distance between the n^{th} sample Y_n and the baseline sample Y_{ec} shown in red is nothing like the difference in lengths between Y_n and Y_{ec} (which here would be close to zero), due to the Conductance values and the possibility of mass dominated measurements. *Vector* subtraction $\overline{Y_n}$ - $\overline{Y_{ec}}$ is necessary.

Figures 1 & 2: Vector Subtractions