MedRx®

Otowave 202 Operating Manual

Software Version 2.91

CE

0123
TÜV SÜD Product Services GmbH Ridlerstraße 65 ◦
80339 Munich ◦ Germany

Amplivox Ltd
3800 Parkside, Solihull Parkway, Birmingham Business Park, Birmingham, West Midlands,
B37 7YG
www.amplivox.com

EC REP
MedRx's Authorized Representative in Europe
DGS Diagnostics A/S
Audiometer Alle 1 • 5500 Middelfart • Denmark

Distributors:

MedRx
1200 Starkey Rd., #105, Largo, FL 33771 U.S.A.
Toll Free: (888) 392-1234 • (727) 584-9600
Fax: (727) 584-9602 • Email: medrx@medrx-diagnostics.com
www.medrx-diagnostics.com

MedRx International
c/o MAICO Diagnostics GmbH
Sickingenstr. 70-71, 10553 Berlin, Germany
Tel.: +49 30/70 71 46-50
Fax: +49 30/70 71 46-99
Email: medrx-sales@maico.biz
www.medrx-diagnostics.com

TABLE OF CONTENT

1. INTRODUCTION

1.1. THANK YOU

Thank you for purchasing the MedRx Otowave 202, a portable 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 202 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].

1.2. INTENDED APPLICATIONS

The Otowave 202 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.

1.3. FEATURES

- Automatic measurement of ear canal volume, tympanic admittance peak and placement of the peak using either 226Hz or 1000Hz [H] probe tone with various display options for the tympanometric data
- 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 18, 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 via an infrared (IrDA) link to one of two thermal printers that may be selected by the user
- Data transfer to computer via a USB connection for storage, viewing & printing using either the Amplivox "MedRx STUDIO" software or the NOAH application
- English, German, French, Spanish, Portuguese or Italian operating language (selectable by the user)

1.4. 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 MedRx, Inc. if purchased directly.

Please retain the original shipping carton and packaging to transport the tympanometer for annual calibration or repair.

1.5. STANDARD CONTENTS AND OPTIONAL ACCESSORIES

STANDARD COMPONENTS			
Otowave 202 Tympanometer base unit* Otowave 202H Tympanometer base unit	8505140 8505139	Contralateral reflex transducer* (Probe tip & earpiece lead)	8502177[1]
Power Supply - FW7660M/05	8512734	Set of disposable ear-tips	8029344[1]
USB with Software (MedRx Studio and Noah impedance module) and Operating Manuals	8517685	4 in 1 cavity assembly (0.2 ml/0.5 ml/2.0 ml/5.0 ml)	8011362
Cable USB a to USB B (1.8 m)	8011241	Carrying case	8507857
Calibration certificate	8011512		

OPTIONAL COMPONENTS			
Additional sets of ear tips		Probe tip	8002592[1]
Portable thermal printer (Standard in US conf.)	8503007	Seal (in probe tip)	8002009[1]
Additional rolls of thermal printer paper (Standard in US conf.)	8029305		

Note: If the thermal printer has been purchased it should be charged for a minimum of 15 hours before being used. Refer to the printer instructions for further details.

1.6. WARNINGS

Throughout this manual, the following meanings of warnings and cautions apply:

WARNING

The WARNING label identifies conditions or practices that may present danger to the patient and/or user.

CAUTION

The CAUTION label identifies conditions or practices that could result in damage to the equipment.

1.7. GUARANTEE

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

CAUTION

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.

[1] Applied part as according to IEC 60601-1

2. IMPORTANT SAFETY INSTRUCTIONS

The Otowave 202 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 EMC the tympanometer is designed to be used only with the medically approved power supply supplied, which is specified as part of the equipment. **Do not use any other type of power supply with this instrument. Refer to Section 17 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.

When using the instrument with batteries refer to the precautions specified in Sections 2.3 and 4.1.

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 202 tympanometer must be re-calibrated (for volume measurement only) at the intended operating elevation if it is to be used at elevations greater than 800m above mean sea level. This applies to volume measurements up to 2.0ml maximum. Please refer to the service manual for more information.

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 radiofrequency (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. POWER SUPPLY OPTIONS

The tympanometer is designed for continuous operation and may be powered either by a power supply (which is supplied and specified as part of the equipment) or optional internal batteries.


CAUTION

Do not connect or disconnect the power supply lead while the instrument is operational as this may cause it to shut down. Always switch off first (see Section 4.3).

Rechargeable batteries must be charged outside of the instrument – they are <u>not</u> charged by the power supply when this used.

Battery operation

Refer to Section 4.1 regarding the types of battery that may be used and their installation, replacement, and other precautions. Note that local regulations are likely to cover disposal of used batteries.

Power supply operation

All other connections must be made before connecting the output lead from the adapter into the POWER socket on the front face of the tympanometer. Switch on the mains supply - the indicator on the adapter will illuminate green.

The output from power supply 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 power supply is protected with a non-replaceable fuse. If this fails, the adapter will not operate.

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

If a replacement power supply is required, please contact MedRx or your MedRx distributor.

2.4. TYMPANOMETER CONNECTIONS

All the relevant accessory terminals and connections are labelled to ensure correct identification and connection as follows:

Socket Label	Socket Type	Connected Part	Notes
PROBE	15-way D connector	Remote probe (electrical) *	
AIR	4mm (nominal) Luer	Remote probe (pressure) *	
CONTRA	3.5mm jack	Contralateral transducer *	
	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 16.

For connected parts marked * only connect the accessories supplied with the instrument or supplied by MedRx or an MedRx distributor. These parts have been tested for use with the Otowave 202 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 infrared (IrDA) link to one of two designated portable thermal printers 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 MedRx (see Section 15).

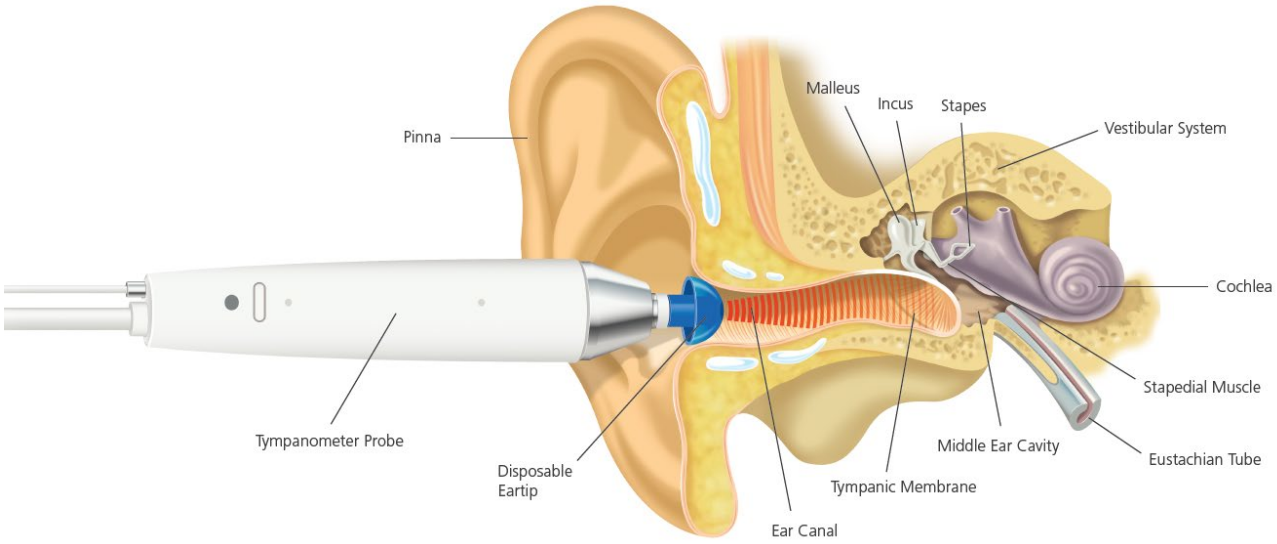
3. PRINCIPLES OF OPERATION

3.1. OTOSCOPIC EXAMINATION

A 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. This is required to ensure that the probe tone delivered by the probe can reach the ear drum and are not reflected by cerumen or debris and thereby alter the test result.

3.2. PRINCIPALS OF ADMITTANCE MEASUREMENT

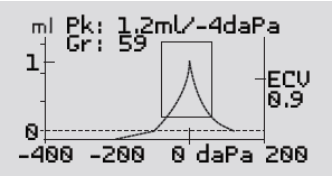
The Otowave 202 measures the admittance of the tympanic membrane and middle ear by playing a continuous tone into the ear canal at either 226 Hz or 1000 Hz. The level of this tone is calibrated to give 85 dB SPL (226 Hz) or 79 dB SPL (1000 Hz) into a 2 ml cavity. The sound level this produces in the 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 226 Hz) or mmho/m℧ (for 1000 Hz). The residual ear canal volume between the probe and the tympanic membrane is always displayed in ml; when using a 1000 Hz probe tone the measured value in mmho is converted to ml using a conversion factor of 226/1000.

3.3. TYMPANOGRAM

Tympanometry is part of the objective impedance test battery and provides information about the middle ear mobility and pressure in the middle ear system.



To record the tympanogram, the admittance is measured while the air pressure in the ear canal is varied from +200 daPa to -400 daPa 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.

3.4. ACOUSTIC REFLEX MEASUREMENT

Using the same principle as in tympanometry measures, it is also possible to establish whether an acoustical reflex is present. The acoustic reflex is caused by the contraction of the stapedial muscle as a response to high-intensity stimulation of the ear. The acoustic reflex is also a natural protection of the inner ear from too high sound pressure levels and thereby damage of the hearing organ.

In acoustic reflex testing, 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 pre-set 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.

4. USING THE OTOWAVE

This instrument is equipped with a real-time clock. Before use, please set the date & time to local values to ensure that test data and calibration status are correctly identified. Refer to Section 6.

4.1. INSTALLING & REPLACING BATTERIES

The Otowave 202 may be powered from Alkaline 'AA' batteries or rechargeable Nickel-Metal Hydride (NiMH) batteries (see Section 14). Four batteries are required. Do not mix battery types or old and new batteries.

If the Otowave is to be used infrequently the use of alkaline cells is recommended. NiMH batteries have a high self-discharge rate and are likely to need recharging if left unused for several weeks.

Remove batteries from the instrument if it is not going to be used for more than a month (refer to Section 14 for the internal memory hold-up time).

The type of cell fitted must be set in the CONFIGURATION menu. By default, this is ALKALINE. Change the setting in the CONFIGURATION menu (scroll to BATTERY TYPE as described in Section 6).

To fit the cells, remove the battery compartment cover on the base of the tympanometer. Fit the cells as indicated inside the battery compartment and replace the battery compartment cover.

Batteries should only be changed outside the patient environment. The operator should not touch the battery connectors and the patient simultaneously.

Changing the batteries does not affect the configuration, the contents of the database, the calibration settings or the results of the last test.

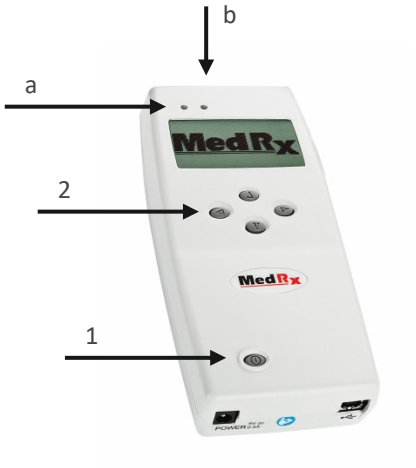
4.2. OPERATING LANGUAGE

To set the operating language (English, German, French, Spanish, Portuguese or Italian) use the options within the CONFIGURATION menu (see Section 6).

4.3. CONTROLS AND INDICATORS (BASE UNIT)

Press the On/Off key momentarily to turn the Otowave 202 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, again press the On/Off key momentarily.



a	**Indicator LED a**	Indicates if testing is in process or not.
b	**Indicator LED b**	Indicates if testing is in process or not.
1	**On/Off switch**	Short press to switch on the device, long press to switch it off.
2	**Navigation keys**	• 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.

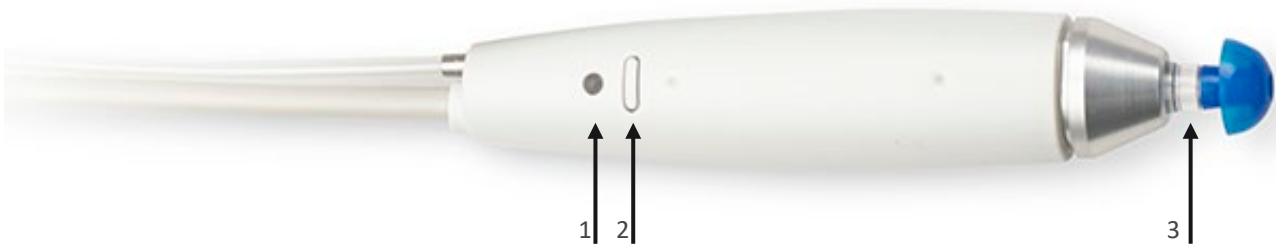
4.4. INDICATORS AND SYSTEM STATUS

The indicators on the Otowave and the probe show the status of the system.

Status	LED b	LED c	Probe
Otowave turned off	Off	Off	Off
Idle, test completed or test cancelled	On	Off	Flashing (fast)
Insert probe or remove probe (refer to display for details)	Flashing (fast)	Flashing (fast)	Color alternating (Green / Yellow)
Ensure probe is held steady while an ear seal is obtained	Off	Flashing (slow)	Yellow flashing (slow)
Testing - tympanogram and/or reflex measurement	Flashing (slow)	Off	Green flashing (slow)

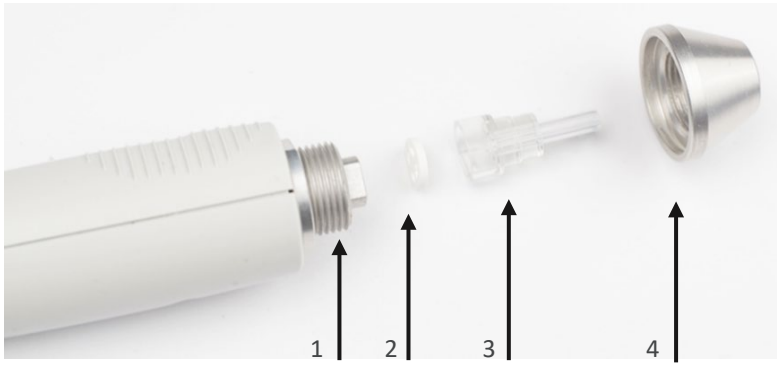
4.5. THE PROBE

4.5.1. CONTROLS AND INDICATORS (PROBE)



1	**Indicator light**	Indicates if testing is in process or not.
2	**Function button**	Quick view of the test settings currently used or change of baseline mode.
3	**Probe tip with ear tip**	

4.5.2. THE PROBE HEAD



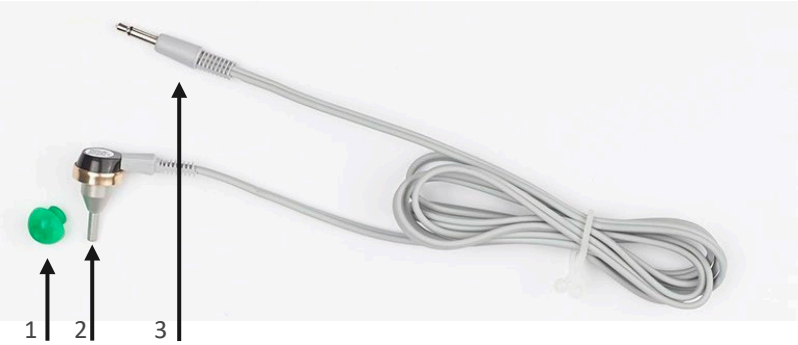
1	**Boss and Nut**	Connection on probe body for attaching nose cone
2	**Seal rubber**	Gasket used to ensure air flow
3	**Probe tip**	Transparent probe tip housing the seal rubber
4	**Nose cone**	Top part of probe to securely fasten probe tip and seal rubber

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 (refer to chapter 11).

4.6. CONTRALATERAL TRANSDUCER



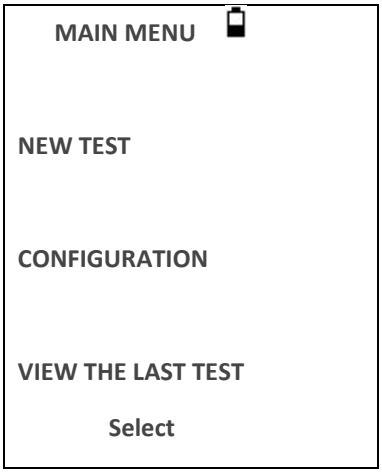
1	**Ear tip**	Ear tip to be placed on probe tip of contra phone
2	**Probe tip**	Probe tip screwed onto contra phone
3	**Plug**	Connector to **CONTRA** socket on Otowave

The contralateral transducer 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 ear tip.

The contralateral probe tip may be replaced if necessary (e.g. if damaged). 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 202 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 and select menu options.

4.8. INITIAL SETTINGS

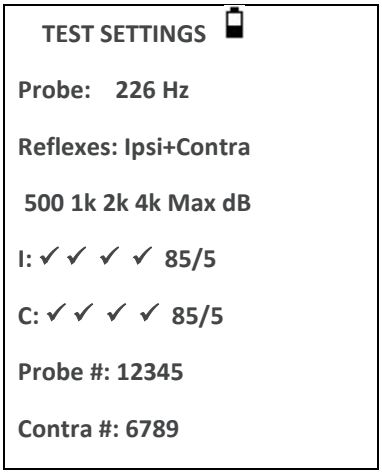
Use the CONFIGURATION options (see Section 6) to select the following options as required:

- display contrast for ease of viewing
- correct local date and time
- date format for display and printouts etc (DD/MM/YY or MM/DD/YY)
- correct battery type (if used)
- power-off delay under battery power when no key is pressed (90 or 180 seconds)
- correct printer type (if used)

5. TAKING MEASUREMENTS

Ensure that the appropriate settings have been made before carrying out a test. See below and the CONFIGURATION options in Section 6,

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.



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.

5.1. PRIOR TO TESTING AND AMBIENT CONDITIONS

A 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. EAR TIP(S)

Video available on how to choose the correct ear tip.

The probe tip must be fitted with a new ear tip before it is presented to a patient's ear canal. 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.

The ear tip size is chosen based on the diameter of the external ear canal and should suit the patient's ear but also provide a comfortable pressure seal.

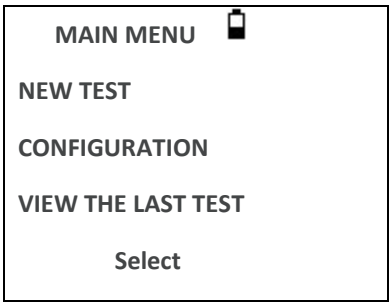
Ensure that the ear tip is pushed all the way down on the probe tip and that there is no gab between probe tip and ear tip.

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 replaced.

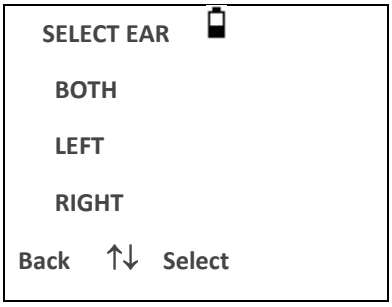
5.3. PERFORMING A TEST

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

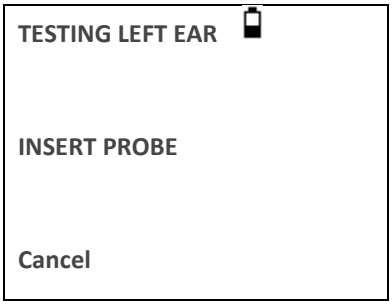
From the MAIN MENU select NEW TEST:



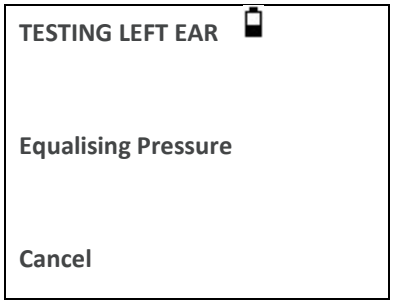
Select the ear(s) required for test:

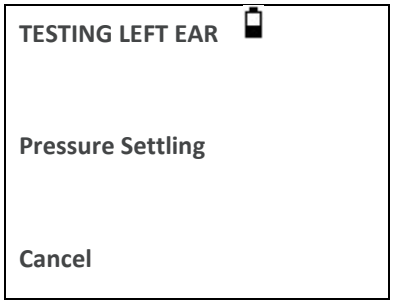


The message “Deleting last test” will be displayed momentarily followed by a message to insert the probe into the ear to be tested:

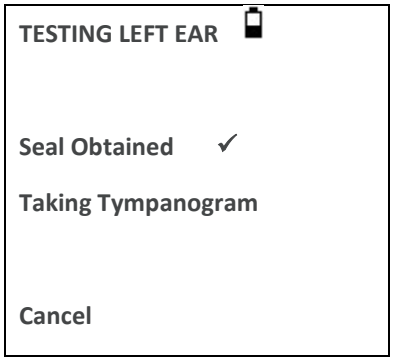


Present the ear tip to the ear and obtain a seal. If a good seal has been detected the following sequence of messages will be seen





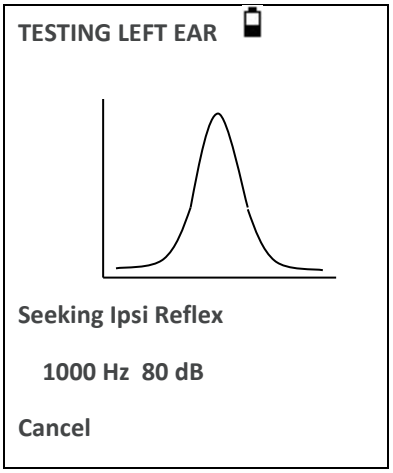
Press ◄ at any time to cancel the test and return to the ear selection menu.



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.

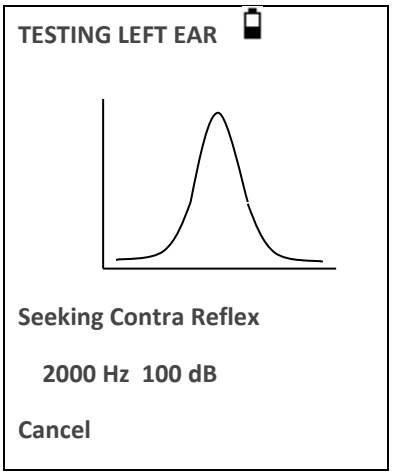
When the tympanogram is complete the instrument will perform the reflex test(s), if selected. By default, this test is only performed if a peak is found in the tympanogram. This and other reflex test options may be changed in the CONFIGURATION menu, see Sections 6 and 5.7.

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:



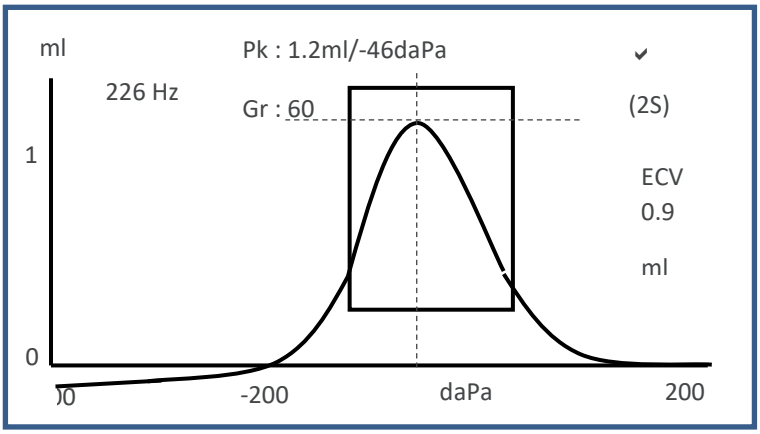
The display changes to show the frequency and level being used, starting with the lowest frequency and level selected.

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 form of the tympanogram will depend on the baseline mode selected and the following illustration is for a 226Hz probe with the default offset of +200daPa. See Section 5.5 for a description of the displays for other baseline modes.



The display shows:

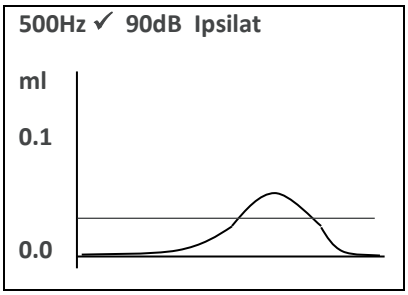
- The test frequency [Hz]
- The peak admittance, in ml (Pk)
- The pressure which gave the peak admittance in daPa
- The Gradient, in daPa (Gr)
- The Ear Canal Volume (ECV) in ml measured at 200 daPa.
- A plot of admittance against pressure
- Normative box (based on BSA recommendations)
- Pass (a) / Refer (x) sign when tymp peak falls into normative box or not (refer)
- Pressure cursor to be operated with up▲ and down ▼ navigation keys.

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).

To repeat the test, press ◄.

When satisfied with the tympanogram press ►.

If reflex test(s) were carried out these results will now be displayed:

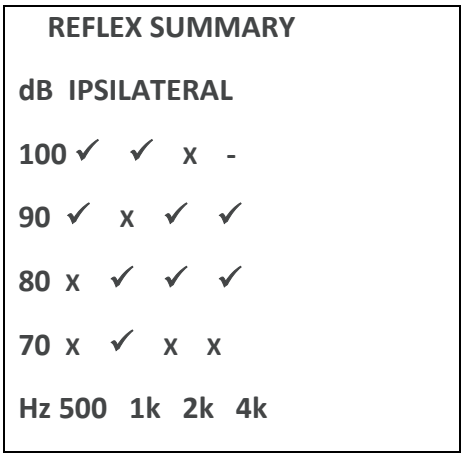


The display shows:

- The frequency of the reflex stimulus
- "✓" if a reflex was found, otherwise "**X**"
- The lowest level of tone (dBHL) for which a reflex was found
- A plot of admittance against time
- Depending on your firmware version, a threshold line will be shown in the reflex graph. This line is one of the criteria defining the pass/refer evaluation of the reflex result is based on.

If the reflex test was performed at more than one frequency use the ▲ and ▼ keys to view the results for the other frequencies.

If the Otowave 202 was set to test for a reflex at all levels of the stimulus (see Reflex autostop in Section 5.7) press ► to view an additional display following the reflex graphs. This shows a summary of the levels and frequencies at which a reflex was detected. The dash symbol "-" is shown if a reflex tone was not presented at the level indicated.

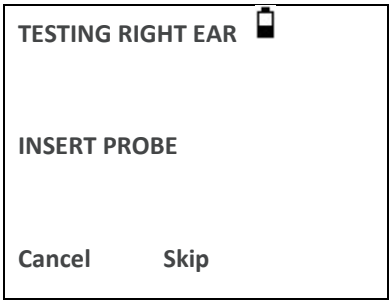


If contralateral reflex measurements were taken pressing the ► key will display similar results for these reflexes.

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. The results will remain available until a new test is started, even if the Otowave is turned off.

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.

6. CONFIGURATIONS

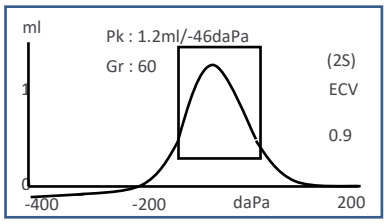
6.1. SWEEP SETTINGS

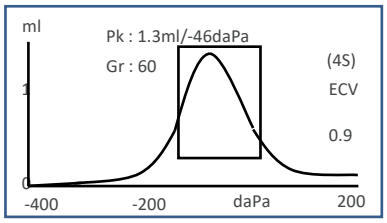
Video available on when to change tympanometry settings.

ITEM	DESCRIPTION	DEFAULT
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).	200 daPa/s
Probe Frequency:	If the instrument is configured for high frequency operation the probe tone frequency may be set to 226Hz or 1000Hz.	226 Hz
Test Sequence:	When testing both ears, define what ear side the test will start with.	R, L
Baseline Mode:	The Otowave 202 can display tympanograms in a variety of graphical formats allowing the operator to choose the most appropriate for the patient under examination. **Please refer to the appendix for further information on how to use the Baseline mode**	226 Hz
Ear Seal:	The **STANDARD** option is adequate for most tests, although it may not always be possible to generate the extremes of pressure during a tympanogram measurement with this setting. If difficulty is experienced in using the ear tips to create a seal the alternative **EXTENDED** option may be helpful. This function 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 **EXTENDED** function is especially helpful if small ear canal volumes should not experience excessive pressure.	Standard
Defaults:	Reset the sweep settings of the selected profile to its original settings.	

6.1.1. SCALAR MODE – 226 HZ

6Tympanograms 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.



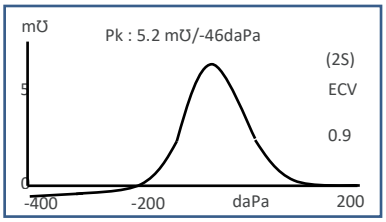


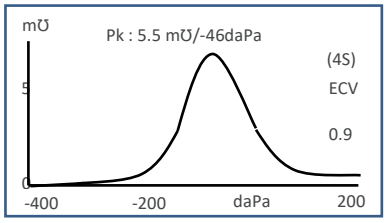
The default display mode is +200daPa offset (as shown in the diagram on the left and indicated by 2S on the display) but an offset of -400daPa may be selected if required (as shown in the diagram on the right and indicated by 4S on the display). See Section 5.5.3 for details of how to switch between the available display modes.

6.1.2. SCALAR AND VECTOR MODE – 1000 HZ (202-H OPTION)

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

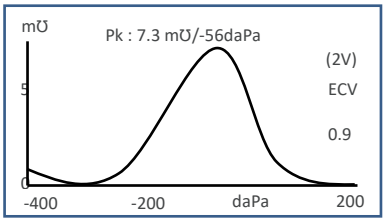


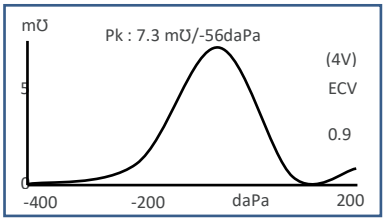


The default 1000Hz display mode is Scalar with -400daPa offset (as shown in the diagram on the right and indicated by 4S on the display) but alternative 1000Hz modes may be selected if required (see Section 5.5.3). The units displayed on the vertical axis are mmho (mʊ) which is normal practice for 1000Hz operation. The ear canal volume (ECV) is shown in ml.

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 and takes account of phase information in the measurements. It is also known as B-G compensation and is suitable for all patients. The tympanogram format is shown below.



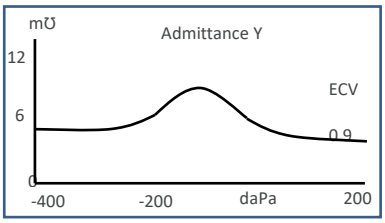


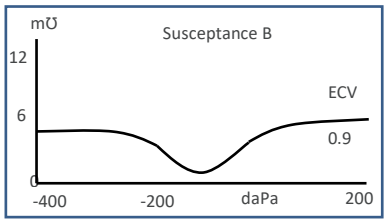
The format is generally like that used for scalar mode with the 1000Hz probe tone. Again, the +200daPa offset (2V) and -400daPa offset (4V) are available as required.

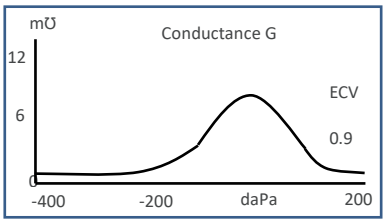
Note that a consequence of the vector mode calculation is that the resulting tympanogram cannot take negative values. It is thus theoretically possible for the trace to appear to rise (i.e. take higher positive values) at the end opposite to the selected offset. The user is advised to view traces with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

Further Information

For the display modes 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 needed to treat the two cases.

6.1.3. SELECTING ALTERNATIVE DISPLAY MODES

Switching between baseline display modes is carried out using the function button on the probe (see Section 4.4).

A short press of the button will switch between the baseline offset values of +200daPa and -400daPa (for Scalar and Vector ^{H} modes) or will cycle round the admittance, susceptance & conductance displays (for Component ^{H} mode).

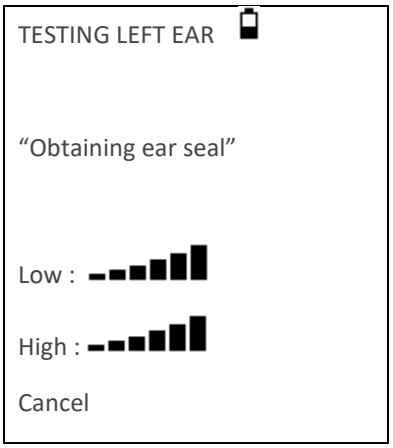
Press and briefly hold the button to cycle through Scalar, Vector ^{H} and Component ^{H} modes (note that only scalar mode is available for 226Hz probe frequency).

When a new test is "saved as last test" the display mode most recently viewed will be saved, although any of the other display 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.

6.1.4. EAR SEAL CHECK

The type of ear seal check employed at the start of a test can be set in the CONFIGURATION menu (Section 6). The default QUICK option is adequate for most tests, although it may not always be possible to generate the extremes of pressure with this setting.

However, if difficulty is experienced in using the eartips to create a seal the alternative THOROUGH 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 thorough ear seal check places a maximum limit on the ear canal volume of ~4.5ml.

6.2. REFLEX OPTIONS

Video available on how to add ipsilateral reflexes to test protocol.

ITEM	DESCRIPTION	DEFAULT
Level Mode:	**ONE LEVEL:** Use the S keys to choose the level of reflex stimulus to apply. Only one level will be tested in the measurement. The maximum level of ipsilateral stimulus may be set to maximum 100dBHL; the maximum level of contralateral stimulus may be set to 110dBHL. **MULTILEVEL:** Use the S 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 and 100dBHL; the maximum level of contralateral stimulus may be set between 85dBHL and 110dBHL.	Multilevel
Reflex Sequence:	Choose the type of reflex stimulus to apply ipsilateral only, ipsilateral followed by contralateral or contralateral only.	Ipsi
Levels:	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 stimulus may be set between 85dBHL & 100dBHL. Press the ► key to confirm the selection or the ◄ key to cancel.	95 dB 5 dB steps
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.	1kHz ipsi
Selection:	Use the ▲ and ▼ keys to choose the circumstances when a reflex measurement is to be made (always, never, only if a compliance peak is found, or only after confirmation is made at the start of the test sequence). In cases where a compliance peak has not been established a pressure of 0daPa is used. Press the ► key to confirm the selection or the ◄ key to cancel.	Only if peak found
Threshold:	Use the keys to choose the change in compliance required to signify that a reflex response has been detected (0.01ml to 0.5ml). The default is 0.03ml.	0.03 ml
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 102 will test for a reflex at all selected levels. (Note that 100dBHL at 4000Hz is not available).	No

Polarity:	Define the polarity of the reflex graphs, if the reflex is plotted upwards (**UP**) or downwards (**DOWN**).	Up
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.	2 Hz
Defaults:	Reset the reflex settings of the selected profile to its original settings.	

6.3. SYSTEM SETTINGS

Item	Description	Default
TIME/DATE:	**SET THE INTERNAL CLOCK DATE AND TIME. USE THE ◄ AND ► KEYS TO SELECT A FIELD AND THE ▲ AND ▼ KEYS TO ADJUST THE VALUE.**	
Printer:	Select thermal printer you want to use with the unit (Sanibel MPT-II or Able AP1300).	MPT-II
Battery Type:	Select what kind of batteries are used with the unit (primary or rechargeable).	Primary
Power-Off Delay:	Adjust the time when device shuts off to save power.	90 s
Contrast:	Adjust the display contrast using the ▲ and ▼ keys.	
Cal. Dates:	Select **PRINT CAL. DATES** to show the serial number for the base unit and the transducers on the print-out provided by the Sanibel Thermal printer.	PRINT CAL. Dates
Date Mode:	Set the format of how the date is displayed: DD/MM/YY or MM/DD/YY	DD/MM/YY
Hospital:	Allows the Hospital name to be entered. The name will appear at the top of the printout.	
Department:	Allows the Department name to be entered. The name will appear at the top of the printout.	
Defaults:	Reset the instrument and all profiles to the original settings.	
Language:	Change the operation language to English, German, French, Spanish, Portuguese, Italian or Chinese.	English
Defaults:	Reset the sweep settings of the selected profile(s) to its original settings.	

7. SAVING RESULTS IN THE INTERNAL DATABASE

Up to 18 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.

7.1. DATA ENTRY

To enter the identifier:

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:

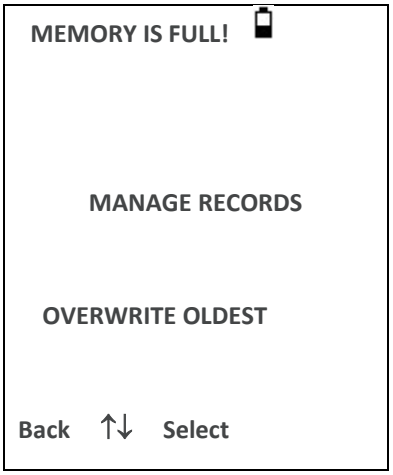
Enter all three characters for the identifier
Press and hold the ► key to save the record

To cancel saving the last test:

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

7.2. 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.

8. SENDING THE RESULTS TO A PRINTER

Video available on how to print using the Sanibel MPT-II printer.

Two thermal printers (the Able AP1300 or Sanibel MPT-II) are available as options for use with the Otowave 202 both of which communicate via an infra-red link (IrDA). Either (or both) printer model(s) may be specified when ordering and only these printers should be used. They will be correctly configured for use. Refer to Section 6 to select the required printer.

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 62). There is space for additional details to be handwritten by the clinician (patient name/age, operator & comments).

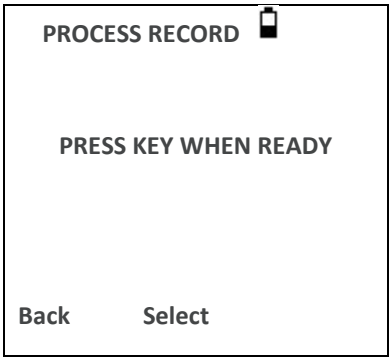
Thermal paper printouts can fade with exposure to light or heat. Consider transferring the data to a computer for permanent storage.

The Otowave sends data to the printer through a small window on the right of the base unit. The data is received through a window in the front of the printer. The environment in which the Otowave 202 and printer are used can affect the printing process. The following are recommendations but may need to be modified depending on the environment.

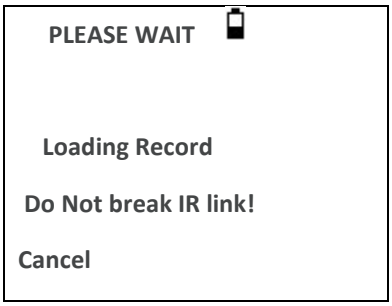
- The Otowave 202 should be placed on the desk 10-20cm in front of the printer
- The two communication windows should be in line and pointing directly at each other
- Both units must be out of direct sunlight for optimum communication
- Ensure that no printer other than the one to be used is within range
- Do not have a computer with an operating IRDA device within range

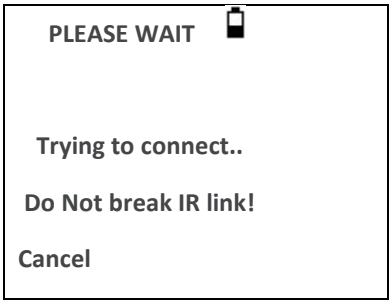
To print the results of the last test select SEND TO PRINTER from the PROCESS RESULTS menu on completion of the test. (Similar facilities for printing are available from the VIEW THE LAST TEST and DATA MANAGEMENT options in the MAIN MENU.)

The following display is then presented:

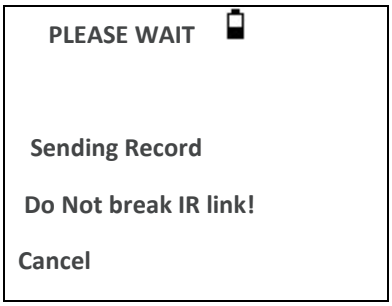


Press ► when the printer is ready and the following two displays will be presented:

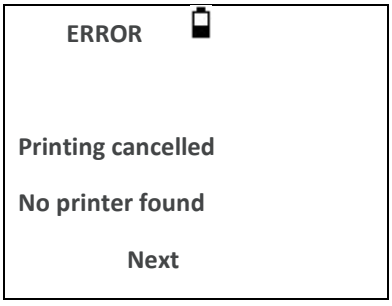




The Otowave 202 will then attempt to connect to the printer. When this has been done the data will be transferred. During this time the following message is displayed.



If a connection cannot be made the print operation will time out (Able AP1300 printer only – after approximately 30sec) and the following message will be displayed. The same message will occur if the print operation is cancelled at this stage.



Press ► to return to the PROCESS RECORD menu.

The infra-red link must not be broken once a connection has been established. If the printer or Otowave are moved, or an object between them breaks the link, the printed results may be corrupted or the Otowave may not respond to the controls until the printing process has timed out (this could take 30 to 40 seconds). This may also occur if the printer batteries are discharged while attempting to print.

Once the printing process has timed-out the resulting error message can be cleared, and the results re-sent to the printer. If the printed text is still corrupted select Cancel on the Otowave and then send the results to the printer again.

For other error messages relating to printing refer to Section 13.

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

9. DATA TRANSFER TO NOAH OR MEDRX STUDIO

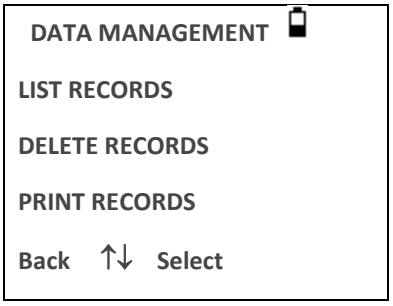
To transfer test results stored within the tympanometer to a NOAH database the NOAH Impedance module must be installed on to a computer. Alternatively, MedRx STUDIO allows data to be transferred to a computer and subsequently viewed, annotated & printed. This software is supplied on a USB which includes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

Refer to the installation & operating instructions provided with the NOAH Impedance Module or MedRx STUDIO for further details.

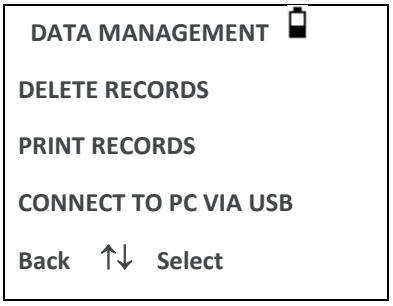
The computer will automatically detect the instrument when it relates to the USB cable. Data transfer is initiated from the computer (not from the Otowave). Refer to the installation & operating instructions provided with the NOAH Impedance Module or MedRx STUDIO for further details. To disconnect simply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

10. DATA MANAGEMENT

Records stored in the database of the Otowave 202 can be listed, viewed, printed, deleted, or sent to a computer using the DATA MANAGEMENT option of the main menu:



Scroll down to see the remaining choice:



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

10.1. 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
- Print the selected record (using the currently displayed baseline mode)
- Delete the selected record

10.2. 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.

10.3. 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. If printing the entire database, it is recommended that a full roll of paper is loaded into the printer.

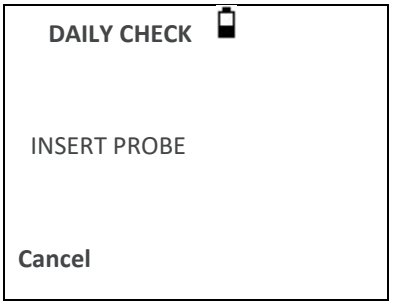
10.4. CONNECT VIA USB

May be used as an alternative to the automatic connection (see Section 8).

11. PERFORMING DAILY CHECKS

The operation of the Otowave 202 should be checked daily using the 4 in 1 test cavity assembly supplied with the instrument.

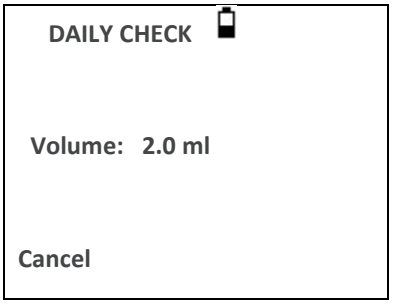
Select the DAILY CHECK option in the main menu:



Wait until “Open” 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 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 main menu.

12. SYSTEM INFORMATION

To review version related information of your instrument, access the start screen and use the down arrow key to move all the way to the bottom of the screen. Select System Information to find useful information such as variant of your instrument (102-1 or 102-4) and upcoming calibration dates.

1	**Variant:**	Instrument version (Dual Tone = High Frequency option enabled)
2	**Battery:**	Voltage information
3	**Last Cal:**	Last calibration date
4	**Next Cal:**	Next calibration date
5	**Serial No:**	Serial number of Otowave
6	**Ver.:**	Firmware version
7	**Date and Time:**	User defined date and time

13. ROUTINE MAINTENANCE

13.1. 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

13.2. 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.

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

13.3. CALIBRATION AND RETURN OF THE INSTRUMENT

MedRx 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. Please contact MedRx for details.

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.

WARNING

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. Do not return the batteries with the instrument.

14. ERROR MESSAGES & FAULT CONDITIONS

If a fault condition cannot be cleared, the operator is cautioned against repeatedly starting the instrument.

ITEM	DESCRIPTION	DEFAULT
My profiles names are gone.	The change of the operation language will automatically default the profile names to the factory description. It is important to note that the settings of each profile stay the same.	Re-name the profile names again.
No pressure can build up and the test sequence will stay in the **EQUALIZE PRESSURE SCREEN**.	• No seal can be obtained • Estimated volume is too high (perforated ear drum) • Wrong ear tip size chosen Probe is blocked	• Examine the probe tip for contamination and replace the probe tip • Reposition the probe Change the ear tip
No reflex test is conducted after the tympanometry even though the reflex test is active in the **REFLEX SEQUENCE.**	In **REFLEX SELECTION** the setting is set to **ONLY IF PEAK IS FOUND** or **NEVER MEASURE.**	Change settings in **REFLEX SELECTION** to desired option.
Last measured data cannot be found under **VIEW THE LAST TEST**.	**NEW TEST** might have been selected in between and thereby deleted the last test(s) from the short-term memory.	To be stored data should be stored immediately.
BLOCKED PROBE Indicator LED b and c flash fast.	• Probe is blocked • Probe placed against ear canal skin Probe disconnected from base unit	• Examine the probe tip for contamination and replace the probe tip • Reposition the probe • Change the ear tip Check probe connection with base unit
WITHDRAW PROBE Indicator LED b and c flash fast.	• The probe has been moved during measurement. Test has been started with the probe already inserted into the ear.	Reposition the probe
Volume outside range **WITHDRAW PROBE** Indicator LED b and c flash fast.	• Ear canal volume is > 5ml. Probe is not properly inserted into the ear.	Reposition the probe

PROBLEM	CAUSE	SOLUTION(S)
Pressure lost **WITHDRAW PROBE** Indicator LED b and c flash fast.	• Ear seal has been broken while testing for seal.	• Reposition the probe
Measurement timed out Indicator LED b and c flash fast.	• Occurs when the ear seal check is set to EXTENDED • Pump failed to achieve the starting pressure within 4 s. • Pressure failed to reach -400 daPa within 12 s.	• Reposition the probe. Retry the test. If the problem persists, contact your MedRx service centre.
VOLUME OUTSIDE RANGE Indicator LED b and c flash.	• Probe not placed correctly in ear canal.	• Reposition probe.
PROBE NOT CLEAR Indicator LED c steady light.	• Probe is blocked Probe placed incorrectly	• Check that the probe is not inserted into a test cavity at start-up. Please ensure the probe is not blocked or obstructed.
AIRFLOW ERROR Indicator LED c steady light.	Fault with air system and/or pump. Cannot determine pump direction.	Unknown pump fault. Restart the unit. If problem persists, contact your MedRx service center.
AIRFLOW ERROR **RESTART THE UNIT** Indicator LED c steady light.	Fault with air system and/or pump.	Restart the unit. If problem persists, contact your MedRx service center.
WARNING! CALIBRATION EXPIRED Indicator LED c steady light.	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.	Recalibration needed before further tests are performed.
WARNING! DEVICE UNCALIBRATED. Indicator LED c steady light.	One or more default values require recalibration before further tests are performed.	Contact your MedRx service center.
WARNING! DEFAULTS RELOADED. Indicator LED c steady light.	Default configuration settings reloaded.	Default configuration settings reloaded. If the error persists, contact your MedRx service center.
Printing Error No connection can be established with the printer	• Printer is switched off or not charged • Connection between printer and base unit cannot be established.	• Restart the base unit • Restart the printer • Charge printer • Ensure the connection between printer and base unit is established.

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

Error messages related to sending data to a computer

Connection to a computer is made automatically when the USB cable is connected if the appropriate software (NOAH Interface or MedRx STUDIO) has been installed and the Otowave 202 has the main menu displayed. The message 'Awaiting PC … OK to disconnect' is displayed if the connection is successful. Further commands are then executed from the computer.

Refer to the installation & operating instructions provided with the NOAH Impedance Module or MedRx STUDIO software for details of the data transfer operation and errors that may occur. If data transfer is not required simply unplug the USB cable and the Otowave 202 will return to normal operation.

15. TECHNICAL SPECIFICATION

15.1. PERFORMANCE

Tympanometry	
Instrument type	Meatus compensated tympanometer
Analysis performed	Admittance peak level (in ml or mʊ [H]) & pressure; Gradient in daPa (for 226Hz); Ear Canal Volume (ECV) @ 200 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	Typically, 200 to 300daPa/sec; dependent on ear/cavity volume
Pressure limits (safety cut-out)	+600 and -800 daPa
Number of samples stored	100 per tympanogram
Reflex measurements	
Measurement modes	Ipsilateral, contralateral or both
Reflex tone levels and accuracy **(Referenced to 2ml calibration volume - compensates for measured ear volume)**	**Ipsilateral** - configurable over range: 500Hz, 1kHz, 2kHz & 4kHz (+/-2%) 70dBHL to100dBHL (+/-3dB) (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) (2kHz level is restricted to maximum 105dBHL for ear canal volumes greater than ~3.5ml) (4kHz level is restricted to maximum 100dBHL for ear canal volumes greater than ~3.5ml & maximum 105dBHL for ear canal volumes greater than ~1.5ml)
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
Number of records stored in Patient Database	18
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)
Display mode	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
Backup power supply	> 30 days without main batteries fitted
Languages	
Operating Languages	English, German, French, Spanish, Portuguese or Italian
Printing	
Supported printer	Sanibel MPT-II or Able AP1300
Interface	Infra-red, IrDA hardware, 9600 baud
Information printed	Tympanogram, Tympanogram analysis parameters, Reflex graphs, Reflex analysis parameters, Serial Number of the 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	
Battery types	4 AA cells; either Alkaline (1.5V nominal) or NiMH rechargeable (1.2V nominal, which must be 2.3 Ah capacity or greater).
Mains power	100-240Vac; 50-60Hz; 205-110 mA
Input rating	5Vdc; 0.4 A
Warm-up period	None at room temperature

Number of recordings from one set of cells	Approx. 200 (Alkaline) or 100 (NiMH)
Auto power-off delay	90 or 180 seconds
Idle current	70mA
Current while testing	230mA
Physical	
Display	128 x 64 pixels / 8 lines of 21 characters
Dimensions - base unit	190mm long x 85mm wide x 40mm high excluding connections 260mm long including connections
Weight (base - no batteries)	330 g
Weight (base - with batteries)	430 g
Dimensions - probe	130mm long x 25mm (max) diameter
Weight (probe, incl connection)	110g
Interconnection (probe to base)	1.5m combined electrical cable and air tube
Environmental	
Operating temperature range	+15°C to +35°C
Operating humidity range	30% to 90% RH (non-condensing)
Operating atmospheric pressure range	980 hPa to 1040 hPa (see Section 2)
Transport and storage temperature range	-20°C to +70°C
Transport and storage humidity range	10% to 90% RH (non-condensing)
Transport and storage atmospheric pressure range	900 hPa to 1100 hPa
Standards conformance	
Safety	IEC 60601-1 (plus UL, CSA & EN deviations)
EMC	IEC 60601-1-2
Performance	IEC 60645-5, Type 2 Tympanometer ANSI 3.39, Type 2
CE mark	To the EU Medical Device Regulation 2017/745, Annex II

15.2. EQUIPMENT CLASSIFICATION

Type of protection against electric shock	Powered via SELV ClassII power supply or by internal batteries
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 202 Tympanometer is classified as a Class IIa device under Annex II (Section 1) of the EU Medical Devices Regulation 2017/745.

15.3. SYMBOLS

The following symbols appear on the tympanometer or power supply:

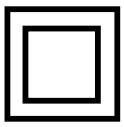
Definition: Identifies the control by means of which the instrument is switched on from (or returned to) a standby condition

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.

Definition: Industry-standard Type-B USB connection to a computer

Definition: Date of Manufacture

Definition: Manufacturer

Definition: Medical device

16. ORDERING CONSUMABLES AND ACCESSORIES

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

STANDARD COMPONENTS			
Otowave 202 Tympanometer base unit* Otowave 202H Tympanometer base unit	8505140 8505139	Contralateral reflex transducer* (Probe tip & earpiece lead)	8502177[1]
Power Supply - FW7660M/05	8512734	Set of disposable ear-tips	8029344[1]
USB with Software (MedRx Studio and Noah impedance module) and Operating Manuals	8517685	4 in 1 cavity assembly (0.2 ml/0.5 ml/2.0 ml/5.0 ml)	8011362
Cable USB a to USB B (1.8 m)	8011241	Carrying case	8507857
Calibration certificate	8011512		

optional components

Sanibel MPT-II Thermal Printer (standard in US conf.)	8503007	Thermal Printer paper for Sanibel MPT-II (standard in US conf.)	8029305
Printer cable – Otowave to Sanibel MPT-II (standard in US conf.)	8004419	Earpiece lead for contralateral reflex transducer	8004447
Probe tip for contralateral reflex transducer	8001118[1]	Probe tip	8002592[2]
Additional sets of ear tips		Seal (in probe tip)	8002009[1]
Otowave probe assembly	8502005[1]		

ADDITIONAL COMPONENTS TO ORDER

Ear tip Otowave 3-5mm, 25 pieces	8012963	Ear tip Otowave 4-7mm, 25 pieces	8012965
Ear tip Otowave 7mm, 25 pieces	8013001	Ear tip Otowave 8mm, 25 pieces	8013003
Ear tip Otowave 9mm, 25 pieces	8012969	Ear tip Otowave 10mm, 25 pieces	8012971
Ear tip Otowave 11mm, 25 pieces	8012973	Ear tip Otowave 12mm, 25 pieces	8012975
Ear tip Otowave 13mm, 25 pieces	8012977	Ear tip Otowave 14mm, 25 pieces	8012979
Ear tip Otowave 15mm, 25 pieces	8012981	Ear tip Otowave 19mm, 25 pieces	8012983

Shipping documentation will reference the stock number quoted above, and images of the parts alongside the relevant stock number are available on the manufacturer website (www.amplivox.com). The required fitting instructions are supplied with each part. Ear tip packs are available in different quantities.

[2] Applied part as according to IEC 60601-1

17. DISPOSAL INFORMATION

The manufacturer 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 manufacturer 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 manufacturer 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

18. EMC GUIDANCE & MANUFACTURER'S DECLARATION

Guidance and manufacturer's declaration – electromagnetic emissions		
The Otowave 202 Tympanometer is intended for use in the electromagnetic environment specified below. The customer or user of the Otowave 202 Tympanometer should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Otowave 202 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.
RF emissions CISPR 11	Class B	The Otowave 202 Tympanometer is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity (1)			
The Otowave 202 Tympanometer is intended for use in the electromagnetic environment specified below. The customer or user of the Otowave 202 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 202 Tympanometer requires continued operation during power mains interruptions, it is recommended that the Otowave 202 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 202 Tympanometer is intended for use in the electromagnetic environment specified below. The customer or user of the Otowave 202 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 202 Tympanometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz 3 V/m	3 Vrms	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).
Radiated RF IEC 61000-4-3	80MHz to 2.5GHz	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Guidance and manufacturer's declaration – electromagnetic immunity (2)

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 strength 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 202 Tympanometer is used exceeds the applicable RF compliance level above, the Otowave 202 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 202 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 202 Tympanometer

The Otowave 202 Tympanometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Otowave 202 Tympanometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Otowave 202 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.

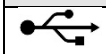
19. USE WITH NON-MEDICAL ELECTRICAL EQUIPMENT

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 Otowave 202 tympanometer uses an industry-standard infra-red means of communication (an IrDA port - as described in Section 7).

In addition, the following signal inputs, and outputs on the Otowave 202 tympanometer are electrically isolated to the requirements of IEC 60601-1:

Socket Label	Socket Type	Typical Connection
	USB Connector Type B	Computer

These measures are incorporated to reduce any potential hazard associated with the use of mains-powered equipment connecting to these interfaces.

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 the manufacturer at the address given on the front of this user manual if advice is required regarding the use of peripheral equipment.

Diagram 1: Otowave 202 used with the medically approved power supply

Diagram 2: Otowave 202used with the medically approved power supply and printer

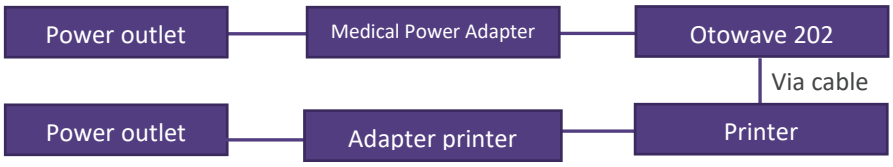
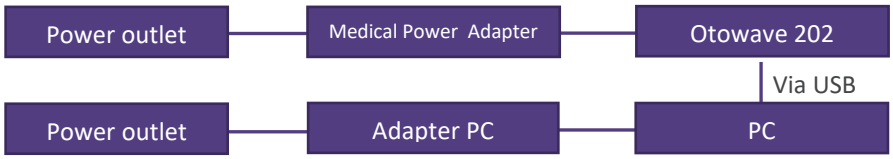


Diagram 3: Otowave 202used with the medically approved power supply and PC



20. 1000HZ TYMPANOMETRY AND MEATUS COMPENSATION

20.1. TYMPANOMETRIC PROPERTIES

Tympanometric measurements of the ear are affected by many 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.

20.2. 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 202). 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 202 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 202 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 202 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 202 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.

20.3. 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 202 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.

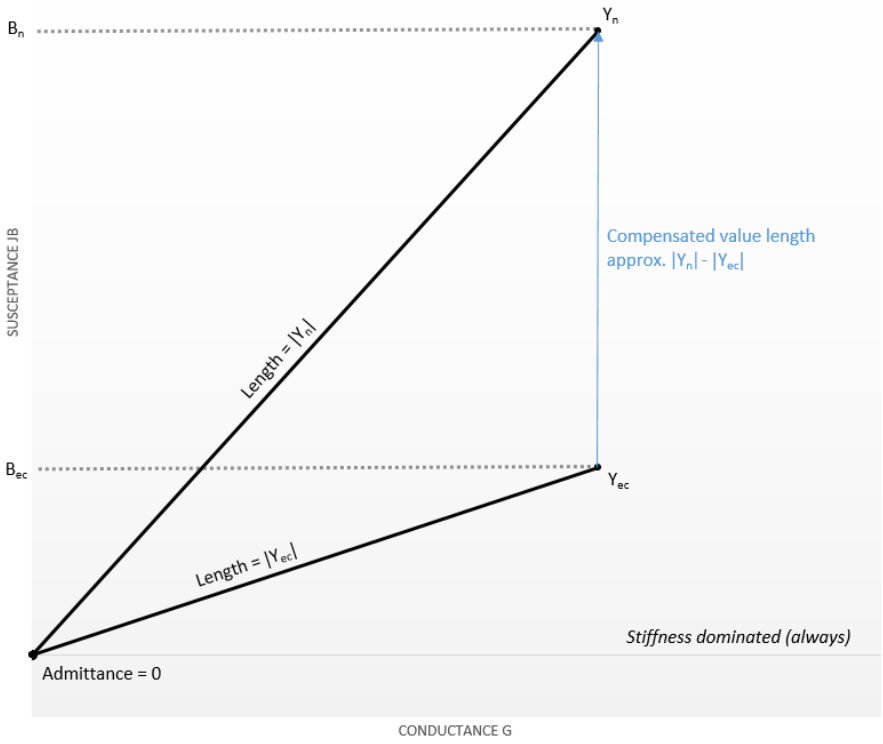


Figure 1: 226 Hz probe tone: The distance between the n^{th} sample Y_n (admittance value of the n^{th} sample in the tympanogram) and the baseline sample Y_{ec} is essentially the same as the difference in lengths between the length $|Y\_ec\ |$ because conductance is always small at 226 Hz and reading are always stiffness dominated. Scalar subtraction ($|Y_n| - |Y\_ec\ |$) is adequate.

Contrast this with Figure 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 in orange (Y_{ec}).

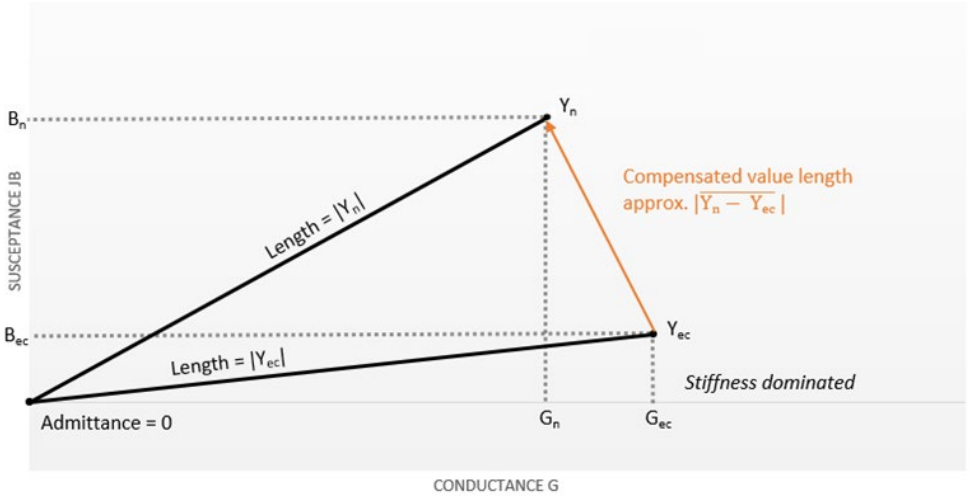


Figure 2: 1 kHz probe tone: Although the susceptance values B_n and B_{ec} are the same as in the 226 Hz diagram, the distance between the n^{th} sample Y_n and the baseline sample Y_{ec} is nothing like the difference in lengths between Y_n and Y_{ec} (which here would be close to 0), due to the conductance values and the possibility of mass dominated measurements. Vector subtraction ($\overline{Yn} - \overline{Y\_ec}$) is necessary.