MedRx Otowave 202
Portable Tympanometer
Operating Manual
(Software Version 2.91)

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For supply in US only

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

CONTENTS

1. Introduction

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].

1.1. Intended applications

The MedRx 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.

1.2. Features

- Automatic measurement of ear canal volume, tympanic admittance peak and placement of the peak using either 226Hz or 1000Hz [H] probe tone with 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 16, 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 and display using the NOAH application
- English, German, French, Spanish, Portuguese or Italian operating language (selectable by the user)

1.3. Unpacking

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

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

1.4. Standard contents

MedRx Otowave 202 Tympanometer
Mains adapter, see 2.3
4 x 1.5V 'AA' Batteries
Set of disposable ear-tips
Operating manual
Warranty card
Detachable probe assembly
Contralateral transducer
4 in 1 cavity assembly
Carrying case
Calibration certificate

1.5. Optional accessories

NOAH impedance module
Additional sets of ear tips
Additional rolls of thermal paper
Portable thermal printer
Additional probe tip
USB cable

1.6. Warranty card

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

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 two years from the date of dispatch if returned, carriage paid, to the MedRx service department.

The following exceptions apply:

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

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

2. Important Safety Instructions

The Otowave 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 mains adapter supplied, which is specified as part of the equipment. **Do not use any other type of mains adapter with this instrument. Refer to Section 15 for the stock number of the adapter.**

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

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

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 if it is to be used at elevations greater than 800m above mean sea level.

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

2.2. Electromagnetic compatibility (EMC) considerations

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in Section 16. This provides guidance on the electromagnetic environment in which to operate the instrument.

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

2.3. Power supply options

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

Do not connect or disconnect the mains adapter 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 mains adapter 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.

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

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

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

If a replacement mains adapter 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 15.

For connected parts marked * only connect the accessories supplied with the instrument or supplied by MedRx or a MedRx distributor. These parts have been tested for use with the MedRx 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 17.

2.5. Data transfer to a printer

Please refer to Section 17 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 17 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 to a computer with the NOAH application for the transfer of the tympanometric

test results (see Section 8). This is carried out via a standard USB connection and a designated cable is supplied with this option.

3. Principles of Operation

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

3.1. 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 226Hz or 1000Hz ^{H}. The level of this tone is calibrated to give 85dB SPL (226Hz) or 79dB SPL (1000Hz ^{H}) into a 2ml cavity. The sound level this produces in the ear canal is measured using a microphone and the admittance calculated from the result. In line with normal audiometric practice admittance is displayed as an equivalent volume of air in ml (for 226Hz) or mmho/m℧ (for 1000Hz ^{H}).

3.2. Tympanogram

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

3.3. Stapedial reflex measurement

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

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

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

The Otowave 202 can measure a stapedial reflex at 500Hz, 1000Hz, 2000Hz and 4000Hz; any combination of these frequencies may be selected for ipsilateral and contralateral mode. The maximum level for the reflex stimulus may be preset, along with the step size in dB between the three preceding lower levels of stimulus (see Section 5.7).

4. Using the Otowave

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

4.1. 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 12.2).

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.

A battery state indicator is shown in the top right corner of the display (except when showing test results). This shows the battery state as a progressively emptying battery. The batteries should be replaced when the symbol "**!**" appears next to the battery state indicator, or when advised to do so, for example at switch-on.

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

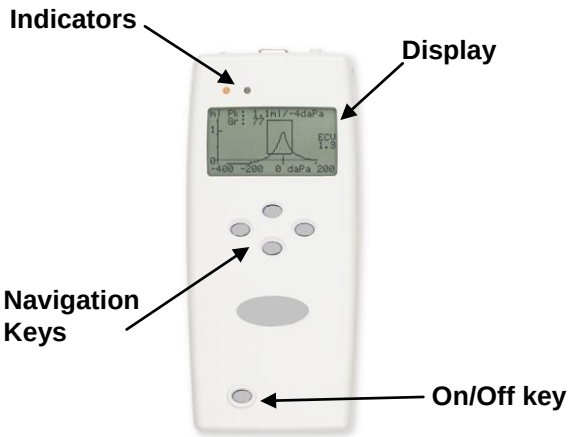
4.2. Operating language

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

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.



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

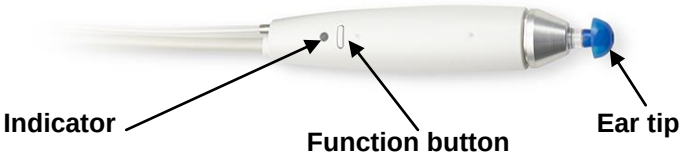
Press the right navigation key ► to accept a menu choice or go to the next step.

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.

When powered by batteries and not performing a test the Otowave 202 will switch off automatically after 90 or 180 seconds if no key is pressed (see Section 12.2 to make this selection).

4.4. Controls and indicators (probe)



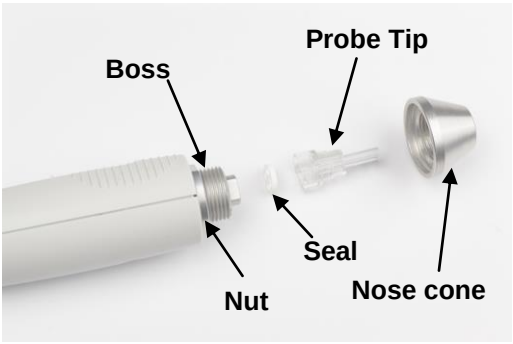
4.5. Indicators and system status

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

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

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

4.6. Probe components



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

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

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

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

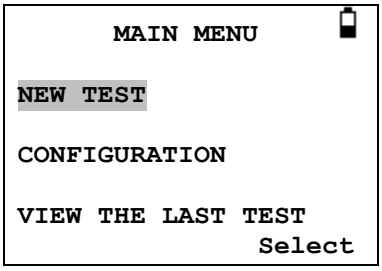
4.7. Contralateral transducer

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

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

4.8. 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. The menus are summarised in Section 12.

4.9. Initial settings

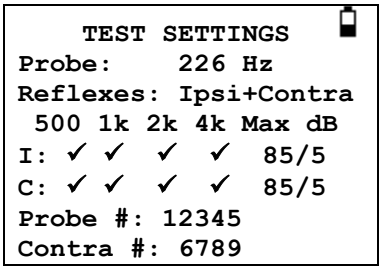
Use the CONFIGURATION options (see Section 12.2) to select the following options as required:

- 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 12.2

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



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.

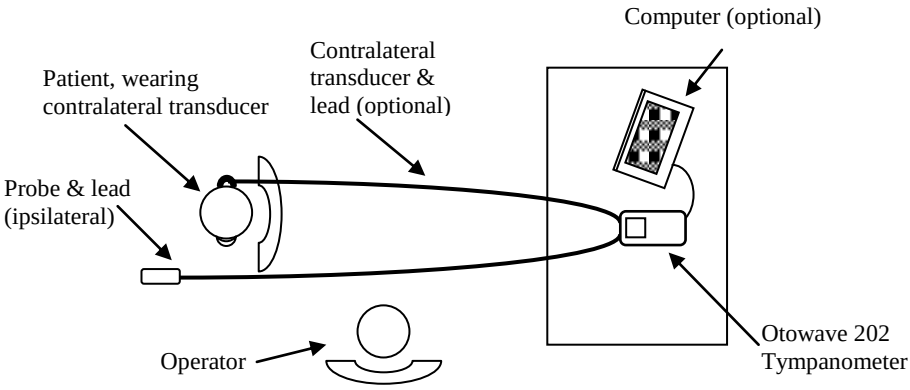
5.1. Prior to testing and ambient conditions

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

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

5.2. Test arrangement

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



The patient is seated in front of the desk as shown and is positioned relative to the operator such that the ipsilateral probe may subsequently be applied. If required, a contralateral transducer is applied to the ear of the patient that is not under test (see also Section 5.3). All necessary patient leads must be connected to the instrument prior to fitting to the patient.

Other than remaining still, no further action is required by the patient during the automatic test.

5.3. Ear tip(s)

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

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

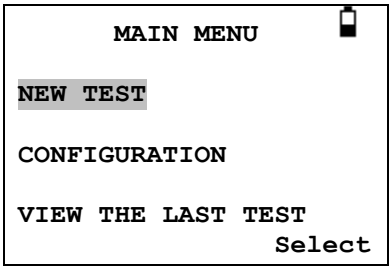
If a contralateral reflex stimulus is to be applied, fit a new ear tip to the contralateral transducer before presenting it to the patient's opposite ear canal.

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

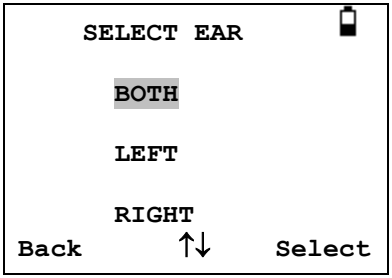
5.4. Performing a test

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

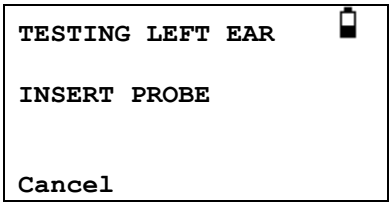
From the MAIN MENU select NEW TEST:



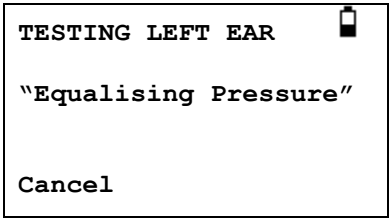
Select the ear(s) required for test:

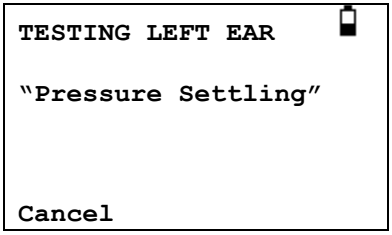


The message "Deleting last test" will be displayed momentarily and a message displayed to insert the probe into the ear to be tested:

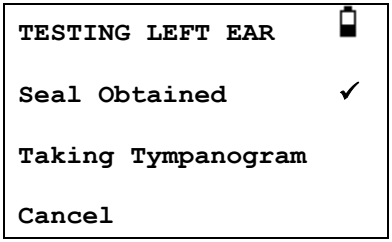


Present the ear tip to the ear and obtain a seal. If a good seal has been detected the following sequence of messages will be seen





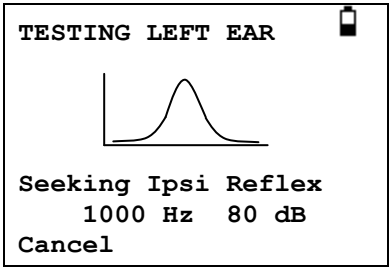
Press ◄ at any time to cancel the test and return to the ear selection menu.



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

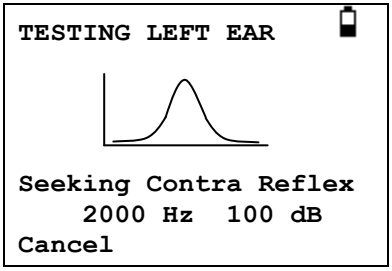
When the tympanogram is complete the instrument will perform the reflex test(s), if selected. By default this test is only performed if a peak is found in the tympanogram. This and other reflex test options may be changed in the CONFIGURATION menu, see Section 12.2.

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.

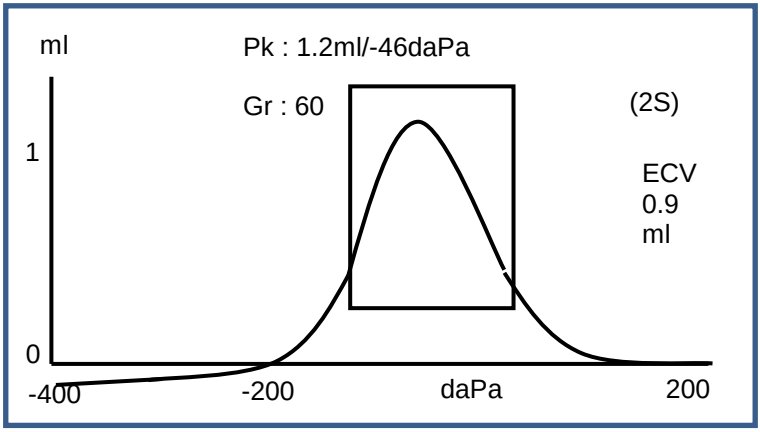
This will be followed by a contralateral reflex test if this has been selected, with the display showing the frequency and level being used:



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:

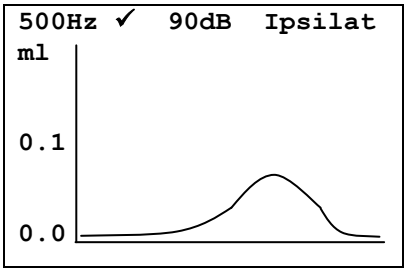
- The peak admittance, in ml (Pk)
- The pressure which gave the peak admittance in daPa
- The Gradient, in daPa (Gr)
- The Ear Canal Volume (ECV) in ml measured at 200 daPa.
- A plot of admittance against pressure

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:

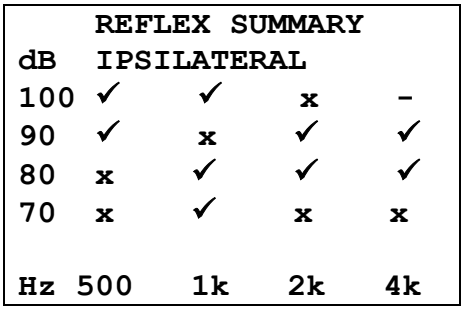


The display shows:

- 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

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.

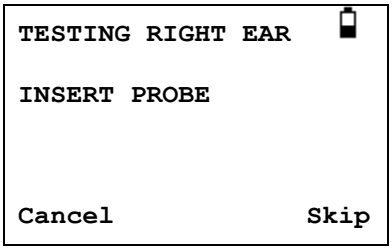


If contralateral reflex measurements were taken pressing the ► key will display similar results for these reflexes.

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.

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

5.5. Baseline modes and associated displays

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.

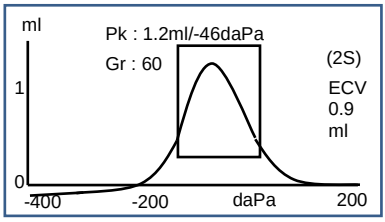
The initial baseline display mode may be changed from the default using the CONFIGURATION menu (see Section 12.2). When viewing a completed test any of the available display modes may be selected prior to saving the test (see Section 5.5.3).

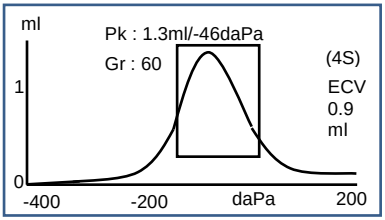
The display mode most recently viewed will be saved when the data is "saved as last test" (see Section 5.4) but any of the other display modes can be re-created when the test is loaded back into the instrument (see Section 5.4 & Section 9) and/or transferred into the NOAH database (Section 8). The various baseline modes are described in the following sub-sections.

5.5.1 **226Hz probe tone**

Scalar Mode

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



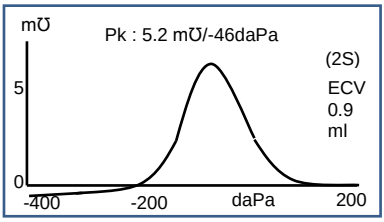


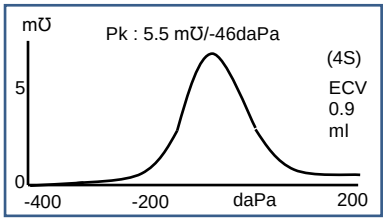
The default display mode is +200daPa offset (as shown in the diagram on the left and indicated by 2S on the display) but an offset of -400daPa may be selected if required (as shown in the diagram on the right and indicated by 4S on the display). See Section 5.5.3 for details of how to switch between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

5.5.2 **1000Hz probe tone** [H]

Scalar Mode

For 1000Hz operation a similar scalar display mode is available as used for 226Hz (Y-only compensation). The tympanogram format is shown below; however vector display mode may provide better results for some patients (e.g. adults) when using the 1000Hz probe tone.

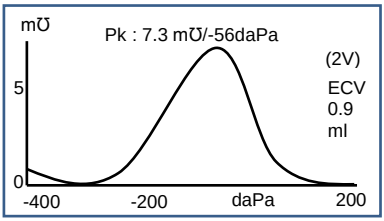


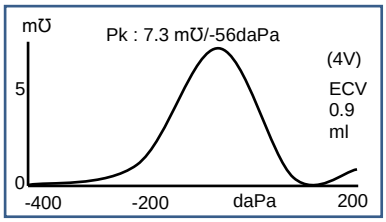


The default 1000Hz display mode is Scalar with -400daPa offset (as shown in the diagram on the right and indicated by 4S on the display) but alternative 1000Hz modes may be selected if required (see Section 5.5.3). The units displayed on the vertical axis are mmho (mʊ) which is normal practice for 1000Hz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



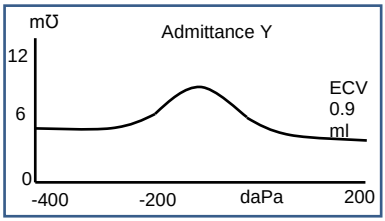


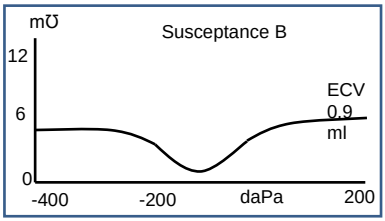
The format is generally similar to that used for scalar mode with the 1000Hz probe tone. Again, the +200daPa offset (2V) and -400daPa offset (4V) are available as required.

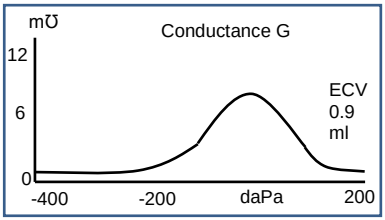
Note that a consequence of the vector mode calculation is that the resulting tympanogram cannot take negative values. It is thus theoretically possible for the trace to appear to rise (i.e. take higher positive values) at the end opposite to the selected offset. The user is advised to view traces with 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 18 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.

5.5.3 **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).

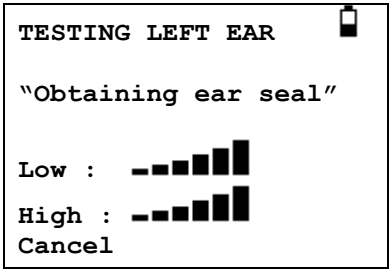
Press and briefly hold the button to cycle through Scalar, Vector ^{H} and Component ^{H} modes (note that only scalar mode is available for 226Hz probe frequency).

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.

5.6. Ear seal check

The type of ear seal check employed at the start of a test can be set in the CONFIGURATION menu (Section 12.2). The default 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.

5.7. Reflex options

The CONFIGURATION options (Section 12.2) may be used to make the following settings for the reflex test conditions. Refer also to Section 3.3.

Reflex source

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

Reflex levels

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

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

Reflex frequencies

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

Reflex selection

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

Reflex threshold

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

Reflex autostop

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 in the configuration menu the Otowave 202 will test for a reflex at all

selected levels. (Refer to table 14.1 in the specification for limits on the ipsilateral & contralateral reflex stimulus levels.)

Reflex filter

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

5.8. Error messages

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

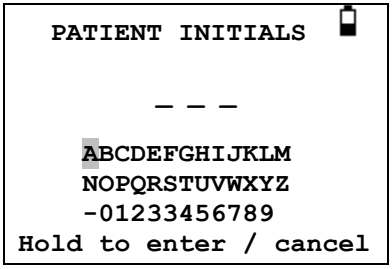
6. Saving Results in the Internal Database

Up to 16 tests can be stored in the Otowave's internal database.

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

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

6.1. Data entry



To enter the 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:

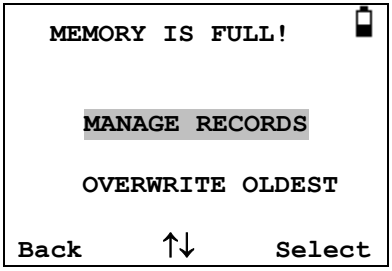
Enter all three characters for the identifier
Press and hold the ► key to save the record

To cancel saving the last test:

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

6.2. Database full

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



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

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

Back will return to the previous menu.

7. Sending the Results to a Printer

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 12.2 to select the required printer.

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

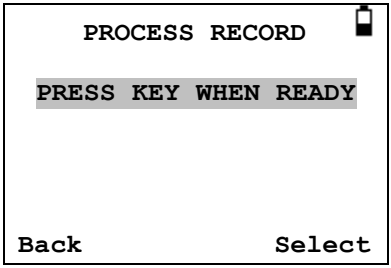
Thermal paper printouts can fade with exposure to light or heat. Consider transferring the data to a computer for permanent storage.

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.

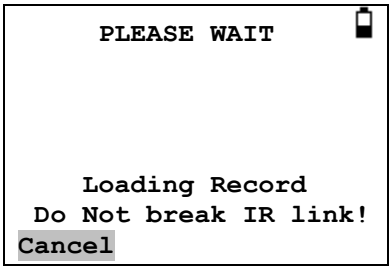
- The Otowave 202 should be placed on the desk 10-20cm in front of the printer
- The two communication windows should be in line and pointing directly at each other
- Both units must be out of direct sunlight for optimum communication
- Ensure that no printer other than the one to be used is within range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

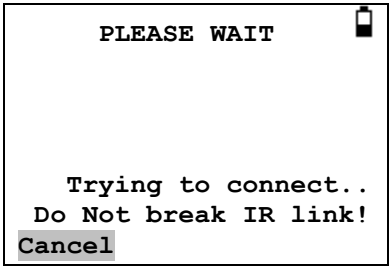
To print the results of the last test select SEND TO PRINTER from the PROCESS RESULTS menu on completion of the test. (Similar facilities for printing are available from the VIEW THE LAST TEST and DATA MANAGEMENT options in the MAIN MENU.)

The following display is then presented:

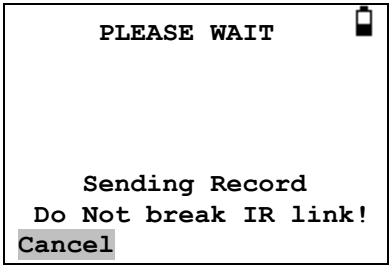


Press ► when the printer is ready and the following two displays will be presented:

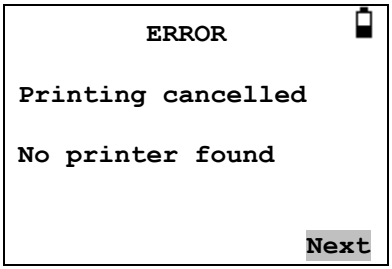




The Otowave 202 will then attempt to connect to the printer. When this has been done the data will be transferred. During this time the following message is displayed and the yellow indicator will flicker rapidly.



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.

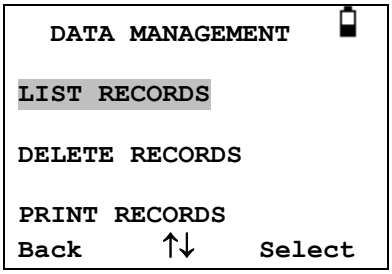
8. Data transfer to a NOAH database

For transfer of test results stored within the tympanometer to a NOAH database the NOAH Impedance module (USB Version) is required for installation on to a computer (see Section 15).

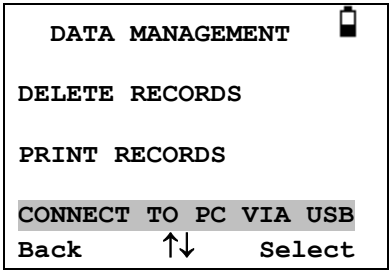
To begin data transfer ensure that the main menu is displayed on the screen of the Otowave 202 and then connect it to the computer using the USB lead provided. Refer to the installation & operating instructions provided with the NOAH Impedance Module.

9. 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:



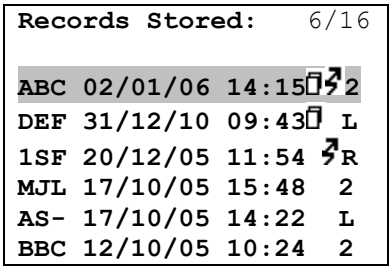
Scroll down to see the remaining choice:



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

9.1. List records

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



Each entry shows:

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

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

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

- View the selected record (which may then be displayed using the various baseline modes as described in Section 5.5)
- Send the selected record to a computer
- Print the selected record (using the currently displayed baseline mode)
- Delete the selected record

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

9.2. Delete records

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

Confirmation of the deletion is required.

9.3. Print records

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

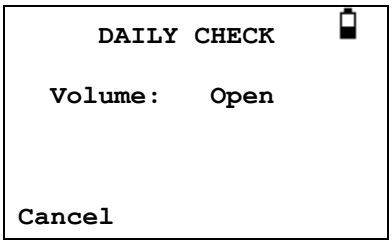
9.4. Connect via USB

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

10. 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.

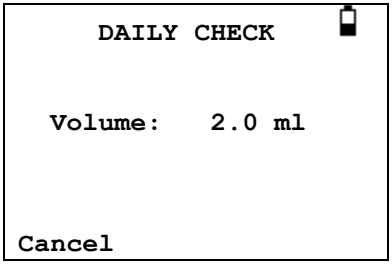
Select the DAILY CHECK option in the main menu:



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.

11. Routine Maintenance

11.1. Cleaning the Otowave

The Otowave is a precision instrument. Handle it carefully in order to ensure its continued accuracy and service. Before cleaning the instrument remove the batteries. Use a soft damp cloth and mild detergent to clean the instrument panel and case. Ensure no moisture enters the instrument.

11.2. Eartips and Probe

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

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

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

Refer to Section 4.6 for illustrations of these components

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

11.3. Calibration and Return of the Instrument

MedRx recommends that the Otowave is calibrated annually. 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.

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.

12. Menu Summary

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

12.1. Main menu

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

12.2. Sub-Menu selections

Sub-menu	Option	Choices / Description
NEW TEST	SELECT EAR	Choose which ear(s) to test and start the test. A tympanogram is taken followed by reflex measurements, if selected. On-screen messages & indicators on the base unit and probe show progress. Graphical displays are shown automatically at the end.
CONFIGURATION	PROBE FREQUENCY [H]	Select **226Hz** or 1000Hz for the frequency of the probe signal.
	REFLEX SEQUENCE	Select **ipsilateral**, contralateral or both for the reflex stimulus.

Sub-menu	Option	Choices / Description
	REFLEX LEVELS	Select CONRALATERAL or IPSILATERAL; then select the maximum tone level to be used for the reflex test. For ipsilateral set the level to 100dB (with 5dB or 10dB steps) or **95dB**, 90dB or 85dB with **5dB** steps. For contralateral set the level to 110dB, 105dB or 100dB (with 5dB or 10dB steps) or 95dB, **95dB** or 85dB with **5dB** steps.
	REFLEX FREQUENCIES	Choose the frequencies at which to perform the reflex test; use the ▼ key to scroll through the options available and the ▲ key to choose (✓) or delete (-) the frequency from the reflex measurement; then press ► to save the entire selection. The default is **ipsilateral** at **1kHz**.
	BASELINE MODE	For 226Hz probe tone select either **+200daPa** or -400daPa offset (in Scalar mode only). [H] For 1000Hz probe tone select from +200daPa or **-400daPa** offset (in **Scalar** mode); +200daPa or -400daPa offset (in Vector mode); or Component mode (Y/B/G). See Section 5.5 for details of these display modes.
	EAR SEAL CHECK	Select "**QUICK**" or "THOROUGH". See Section 5.6.

Sub-menu	Option	Choices / Description
	REFLEX SELECTION	Select when reflexes will be measured: “ALWAYS MEASURE” – Reflexes are always measured “NEVER MEASURE” – Reflexes are never measured. “**ONLY IF PEAK FOUND**” – Reflexes will be measured only if the Otowave detects a peak on the tympanogram. “PROMPT TO MEASURE” – The user is asked whether to perform a reflex at the start of each test.
	REFLEX THRESHOLD	Adjustable in 0.01 ml steps from 0.01 to 0.5 ml. **Default 0.03 ml**.
	REFLEX AUTO-STOP	Selected YES to stop the test once a measurement is found at each frequency. **Default YES**.
	REFLEX FILTER	Select either **2 Hz** or 1.5 Hz.
	TODAY’S DATE	Set the internal clock date and time; use the ◄ & ► keys to select a field and the ▲ & ▼ keys to adjust the value.
	PRINTER	Select **Sanibel II** or Able AP1300
	BATTERY TYPE	Select **Alkaline** or NiMH (This determines the battery state display and low battery warning).
	POWER-OFF DELAY	When battery powered, the time before the unit turns off automatically if no key is pressed. Select **90** or 180 seconds.
	LCD CONTRAST	Change the display contrast. 0 – 15. **Default is 7**.
	REPORT CAL. DATES	Select “**PRINT CAL. DATES**” or “HIDE CAL.DATES” for the printout.
	SET DATE FORMAT	Select “**DD/MM/YY**” or “MM/DD/YY”

Sub-menu	Option	Choices / Description
	HOSPITAL NAME	Allows the Hospital name to be entered (this will appear at the top of the print out). See Section 6.1 for data entry method; then position the cursor on # symbol and hold ► to confirm or ◄ to cancel.
	DEPARTMENT	Allows the Department name to be entered (this will appear at the top of the print out). See Section 6.1 for data entry method; then position the cursor on # symbol and hold ► to confirm or ◄ to cancel.
	RELOAD DEFAULTS	Select YES to reset the options above to their default values.
	SELECT LANGUAGE	Select "**ENGLISH**", "GERMAN", "FRENCH", "SPANISH", "PORTUGUESE" or "ITALIAN" for operating language.
VIEW THE LAST TEST	SELECT EAR	Recalls the last stored test for the selected ear. Shows the tympanogram and reflex responses, if available. Also allows the last test to be printed, sent to a computer or stored in the internal database.
DAILY CHECK		Shows the volume in ml measured by the probe.
DATA MANAGEMENT	LIST RECORDS	Lists the test results stored in the internal database. Allows individual records to be viewed, printed, sent to a computer or deleted.
	DELETE RECORDS	Delete stored records. Select: "ALL PRINTED RECORDS" – Delete all records that have been printed "ALL SENT RECORDS" – Delete all records sent to a computer "ALL RECORDS" – Delete all records

Sub-menu	Option	Choices / Description
	PRINT RECORDS	Print stored records. Select: “UNPRINTED RECORDS” – Print all records not previously printed “ALL RECORDS” – Print all records
	CONNECT VIA USB	Initiates connection to a computer as an alternative to the automatic process used by connecting the USB cable with the main menu displayed; the device drivers must have been installed.
SYSTEM INFORMATION		Shows: Battery (or d.c.) voltage Software version Date calibrated Next calibration date Instrument serial number Current date and time

13. Error Messages & Fault Conditions

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

If difficulties resolving fault conditions occur the equipment distributor should be consulted.

13.1 General error messages

Message Displayed	Indicator Status	Likely Cause(s)
PROBE NOT CLEAR Please ensure the probe is not blocked or obstructed	Yellow Steady	Check that the probe is not inserted into a test cavity at start-up. Examine the probe tip for blockages. If necessary take it off and clean or replace it, see Section 4.6. If the problem persists, contact your MedRx service centre.
AIRFLOW ERROR Unknown pump fault. Restart the unit. If problem persists, contact supplier	Yellow Steady	
AIRFLOW ERROR Cannot determine pump direction. If problem persists, contact supplier	Yellow Steady	Fault with air system and/or pump. If the fault persists contact your MedRx service centre.
AIRFLOW ERROR Airflow error RESTART THE UNIT. If problem persists, contact supplier	Yellow Steady	Fault with air system and/or pump. If the fault persists contact your MedRx service centre.
WARNING! CALIBRATION EXPIRED Recalibration needed before further tests are performed	Yellow Steady	The current date is later than the next calibration date. Check that the clock is set to the correct date. If so, arrange for the instrument to be recalibrated. Tests can still be performed.
WARNING! BATTERIES LOW Replace batteries before performing tests	Yellow Steady	Replace the batteries immediately, see Section 4.1
Powering down	Off	The Otowave is turning off because the batteries are discharged. Replace the batteries.
WARNING! DEVICE UNCALIBRATED. One or more default values require recalibration before further tests are performed	Yellow Steady	This message should never normally be seen. If it persists contact your MedRx service centre.

Message Displayed	Indicator Status	Likely Cause(s)
WARNING! DEFAULTS RELOADED. Default configuration settings reloaded. Check before making new tests	Yellow Steady	This message should never be seen. Check all the CONFIGURATION settings before taking any measurements. If the error persists, contact your MedRx service centre

13.2 Error messages related to testing

Message Displayed	Indicator Status	Likely Cause(s)
WITHDRAW PROBE	Green & Yellow (Fast alternate)	The probe has been moved during measurement. A test has been started with the probe already inserted into the ear.
Volume outside range WITHDRAW PROBE	Green & Yellow (Fast alternate)	The ear canal volume is above 5ml. This message may also occur when the probe is not properly inserted into the ear.
Blocked ear WITHDRAW PROBE or Blocked probe WITHDRAW PROBE	Green & Yellow (Fast alternate)	These messages occur when the probe tip or ear is blocked. Check that the ear is not blocked. Check that the probe is clear and correctly inserted into the ear.
Blocked probe WITHDRAW PROBE	Yellow Fast	Test started while probe is not connected to base unit.
Pressure lost WITHDRAW PROBE	Green & Yellow (Fast alternate)	The ear seal has been broken while testing for seal.
INSERT PROBE	Green & Yellow (Fast alternate)	An error condition has been recovered and the test may continue The seal was lost and a test needs to restart. This message may also occur when

Message Displayed	Indicator Status	Likely Cause(s)
		the ear canal volume is out of range.
Measurement timed out	Green & Yellow (Fast alternate)	This occurs when the ear seal check is set to THOROUGH if: (i) The pump failed to achieve the starting pressure within 4 seconds. This may be because the probe was moved in the ear. (ii) The pressure failed to reach -400 daPa within 12 seconds. Retry the test. If the problem persists, contact your MedRx service centre.

13.3 Error messages related to printing (Able AP1300 only)

Message Displayed	Indicator Status	Likely Cause(s)
ERROR Printing cancelled No printer found	Green Steady	IR link timed out (approx 30sec) or printing cancelled
ERROR Printing cancelled Link was lost	Green Steady	The IR link was broken or the printer powered down or otherwise interrupted the communications

13.4 Error messages related to sending data to a computer

Connection to a computer is made automatically when the USB cable is connected as long as the appropriate software (NOAH Interface or TympView) 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 TympView 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.

14. Technical Specification

14.1. 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 cutout)	+600 and -800 daPa
Number of samples stored	100 per tympanogram
Reflex measurements	
Measurement modes	Ipsilateral, contralateral or both
Reflex tone levels and accuracy (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 90dBHL 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 ~0.15ml) (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%
Reflex detection threshold and accuracy	0.01ml to 0.5ml +/-0.01ml (configurable in 0.01ml steps)
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 threshold detection	Configurable 0.01ml to 0.50ml in 0.01 ml increments
Reflex tone duration	0.6 seconds
Number of records stored in Patient Database	16
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 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; 0.4A
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^{o}C to +35^{o}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^{o}C to +70^{o}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
CE mark	To the EU Medical Device Directive

14.2. Equipment classification

Type of protection against electric shock	Powered via SELV ClassII mains adapter 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 IX (Section 1) of the EU Medical Devices Directive.

14.3. Symbols

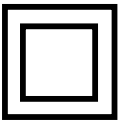
The following symbols appear on the tympanometer or mains adapter:

Definition: Refer to instruction manual (mandatory)

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

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

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



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

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

15. Ordering Consumables and Accessories

To order the following consumables, additional accessories and to replace detachable parts that have been damaged, please contact MedRx.

Stock No.	Description
T527	Probe tip
T518	Sealing Washer
T030	4 in 1 cavity assembly - volumes 0.2ml, 0.5ml, 2.0ml & 5.0ml
T20	Ear Tip Set
T205	Ear Tip Otowave 3-5mm
T206	Ear Tip Otowave 4-7mm
T207	Ear Tip Otowave 7mm
T208	Ear Tip Otowave 8mm
T209	Ear Tip Otowave 9mm
T210	Ear Tip Otowave 10mm
T211	Ear Tip Otowave 11mm
T212	Ear Tip Otowave 12mm
T213	Ear Tip Otowave 13mm
T214	Ear Tip Otowave 14mm
T215	Ear Tip Otowave 15mm
T219	Ear Tip Otowave 19mm
T007	Otowave probe assembly (with interconnections) *
T040	Contralateral reflex transducer, probe tip & earpiece lead *
T041	Contralateral reflex transducer probe tip
C14	Earpiece lead
A091-7	Approved mains adapter (FW7660M/05)
B135	Carrying case
MAN-202-MR	MedRx Otowave 202 Operating Manual (OM031)
PT01	Able AP1300 Thermal Printer
C0103	Thermal Printer paper for Able AP1300
PT02	Sanibel MPT-II Thermal Printer
C104	Thermal Printer paper for Sanibel MPT-II
T009	NOAH Impedance module (USB Version) + cable
F07	USB Cable, 1.8m

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

16. EMC Guidance & Manufacturer's Declaration

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The Otowave 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.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions

CISPR 11</td><td>Group 1</td><td rowspan="3">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.</td></tr>
<tr><td>RF emissions

CISPR 11</td><td>Class B</td><td rowspan="3">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.</td></tr>
<tr><td>Harmonic emissions

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

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

Guidance and manufacturer's declaration – electromagnetic immunity (1)			
The Otowave 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

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
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms	d = 1.2√P 80MHz to 800MHz
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m	d = 2.3√P 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site

Guidance and manufacturer's declaration – electromagnetic immunity (2)			
			survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Otowave 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.

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

Diagram 1: Otowave 202 used with the medically-approved mains adapter

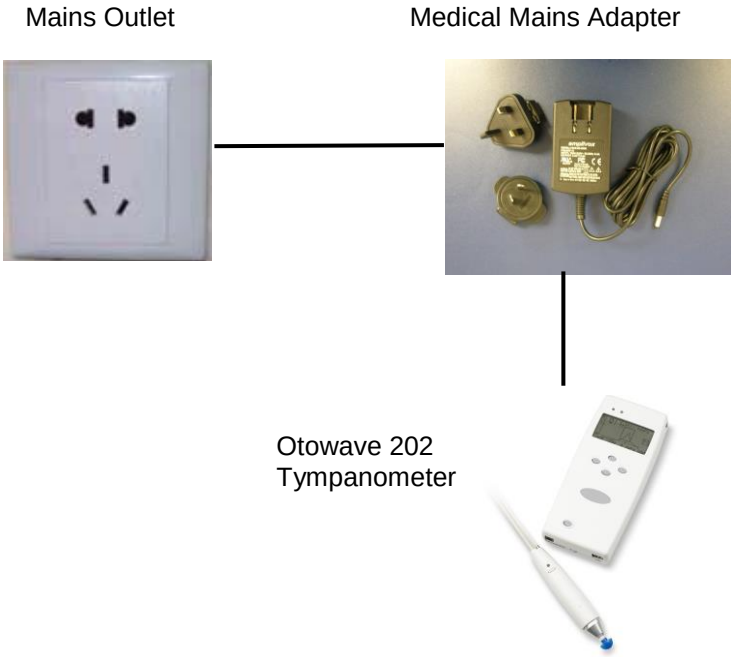


Diagram 2: Otowave 202 used with the supplied printer

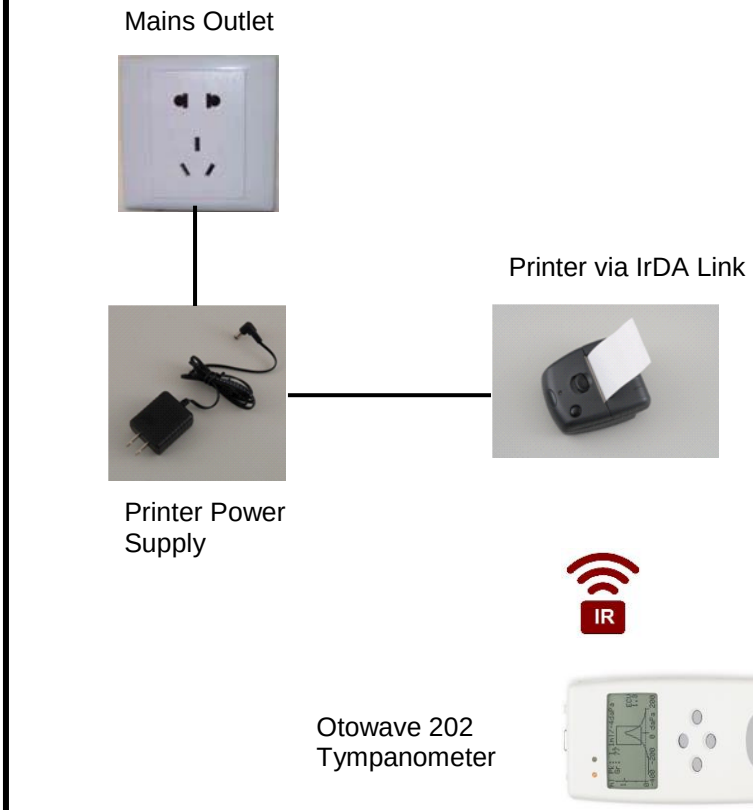
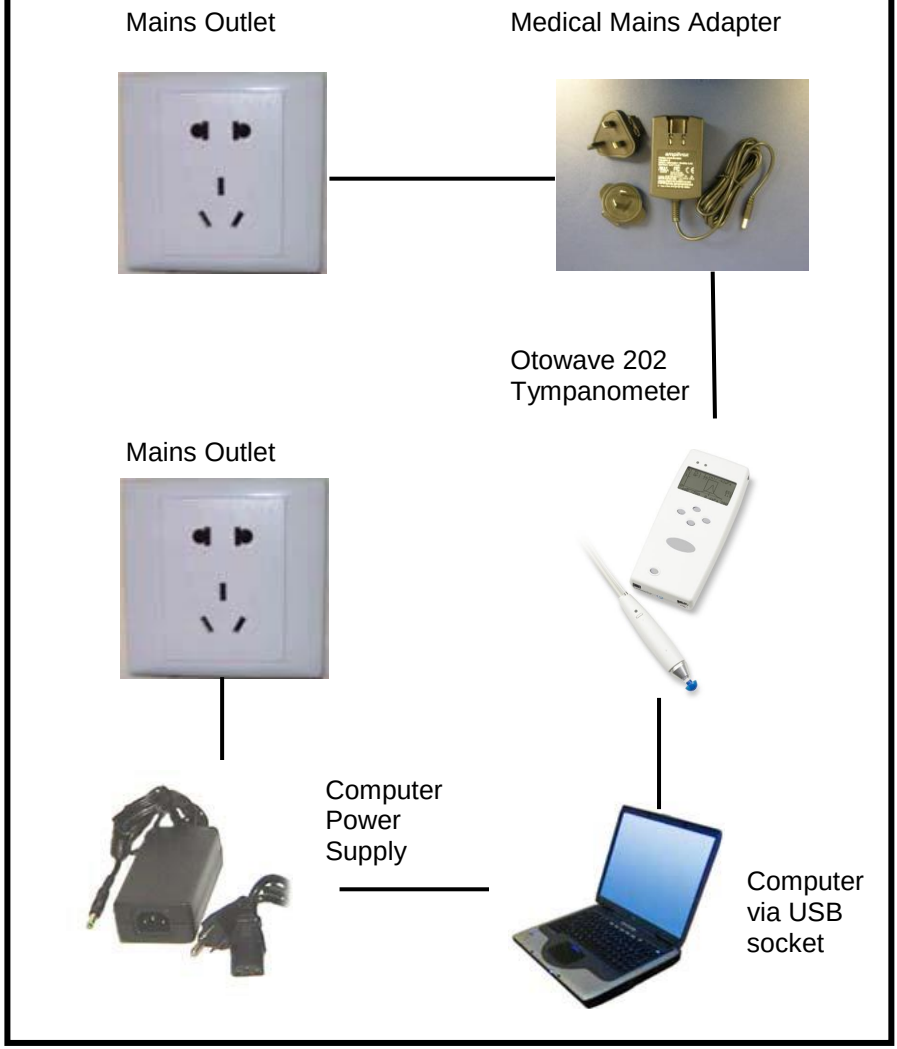


Diagram 3: Otowave 202 used with the medically-approved mains adapter and a computer



18. 1000Hz Tympanometry and Meatus Compensation

18.1. Tympanometric Properties

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

- Stiffness
- Mass
- Friction

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

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

18.2. 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.

18.3. 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.

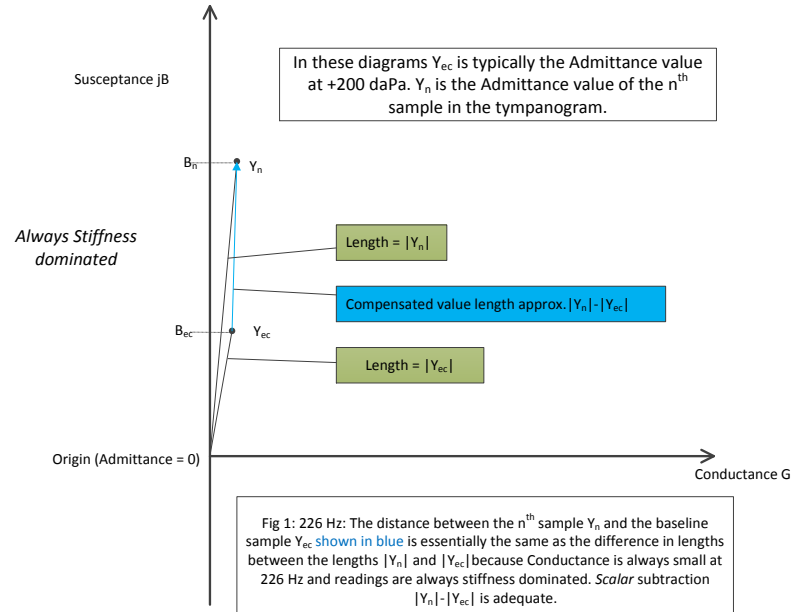


Fig 1: 226 Hz: The distance between the n^{th} sample Y_n and the baseline sample Y_{ec} shown in blue is essentially the same as the difference in lengths between the lengths $|Y_n|$ and $|Y_{ec}|$ because Conductance is always small at 226 Hz and readings are always stiffness dominated. *Scalar* subtraction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

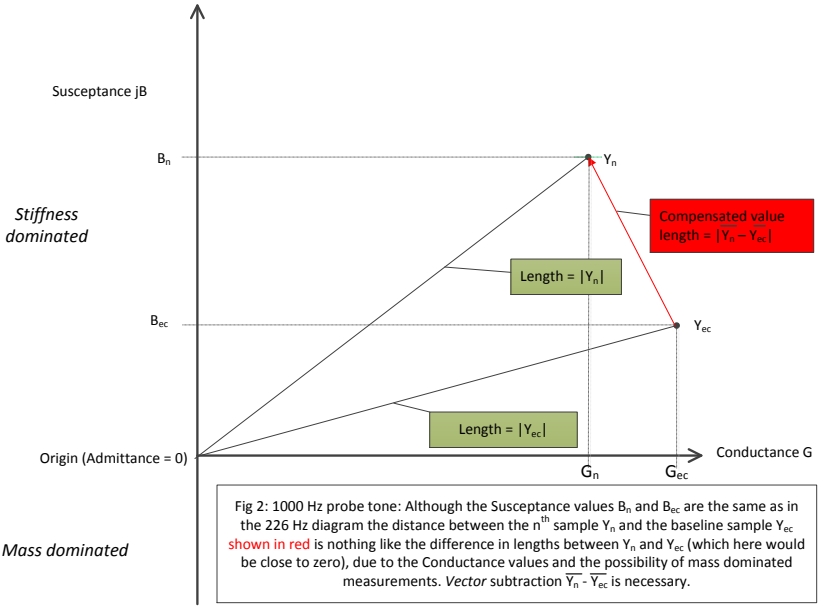


Fig 2: 1000 Hz probe tone: Although the Susceptance values B_n and B_{ec} are the same as in the 226 Hz diagram the distance between the n^{th} sample Y_n and the baseline sample Y_{ec} shown in red is nothing like the difference in lengths between Y_n and Y_{ec} (which here would be close to zero),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

Figures 1 & 2: Vector Subtractions