amplivox

Otowave 102

Operating Manual

ABOUT THIS MANUAL

READ THIS OPERATING MANUAL BEFORE ATTEMPTING TO USE THE INSTRUMENT.

This manual is valid for the Otowave 102 (applies from firmware version 1.71.C onwards – please refer to SYSTEM INFORMATION screen).

This product is manufactured by:

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CE 0473

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 an Amplivox Otowave 102, a hand-held, portable tympanometer that will give many years of reliable service if treated with care. This operating manual covers product variants 102-1 & 102-4.

1.1. Intended applications

The Otowave 102 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 compliance of the tympanic membrane and middle ear at a fixed frequency over a range of pressures.

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

1.2. Features

- Automatic measurement of ear canal volume, tympanic compliance peak, placement of the peak and the gradient
- Automatic detection of stapedial reflexes
- Up to 30, dual-ear patient tests can be stored in non-volatile memory
- Configurable settings for 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 a computer via an infrared IrDA link for storage viewing & printing using either the Amplivox “TympView” software or the NOAH application
- English, French or German operating languages (user-selectable)

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 your instrument or Amplivox if you purchased direct.

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

1.4. Standard contents

Otowave 102 Tympanometer
4 x 1.5V 'AA' Batteries
Set of disposable ear-tips
Operating manual & TympView
NOAH impedance module
4 in 1 test cavity assembly
Carrying case
Calibration certificate
Warranty card

1.5. Optional accessories

Additional sets of ear tips
Portable thermal printer
Additional rolls of thermal printer paper
Additional probe tip
Infra-red USB Adapter

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

1.6. Warranty card (UK Customers only)

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

1.7. Guarantee

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

The following exceptions apply:

- The pressure pump and transducers may go out of calibration due to rough handling or impact (dropping)
- The lifetime of probe, probe seals and ear tips is dependent upon conditions of use. These parts are only guaranteed against faulty materials or manufacture.

2. Important Safety Instructions

The Otowave 102 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

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

Refer to the precautions specified in Section 4.1 regarding the use of batteries.

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 into a patient's ear canal without a suitable ear tip fitted to the probe.

Use only the recommended disposable ear tips (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 102 tympanometer must be re-calibrated at the intended operating elevation if it is to be used at elevations greater than 1000m 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 in Section 17. This provides guidance on the electromagnetic environment in which to operate the instrument.

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

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. Compliance measurement

The Otowave 102 measures the compliance of the tympanic membrane and middle ear by playing a continuous 226Hz tone into the ear canal at a level calibrated to give 85dB SPL into a 2ml cavity. The sound level this produces in the ear canal is measured using a microphone and the compliance calculated from the result. In line with normal audiometric practice compliance is displayed as an equivalent volume of air in ml.

3.2. Tympanogram

To record the tympanogram the compliance is measured while the air pressure in the ear canal is varied from +200daPa to -400daPa by means of a small pump. The compliance peaks when the air pressure is the same

on both sides of the tympanic membrane. The changing compliance with pressure is displayed as a graph.

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 compliance 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 compliance exceeds a predetermined threshold this constitutes a reflex and the change in compliance 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 compliance, so reflex measurements are taken after the tympanogram is measured when the peak compliance pressure has been established.

The Otowave model 102-1 measures stapedial reflex at 1000Hz, while the model 102-4 measures at 500Hz, 1000Hz, 2000Hz and 4000Hz. 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 5.5).

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 102 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.

Note that local regulations are likely to cover disposal of used batteries.

4.2. Operating language

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

4.3. Controls and indicators

Press the On/Off key momentarily to turn the Otowave on or off (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.

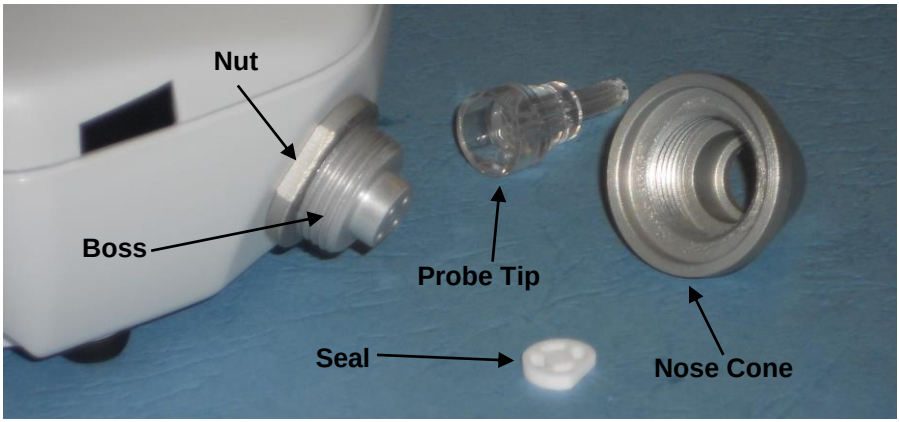
When not performing a test the Otowave 102 will switch off automatically after 90 or 180 seconds if no key is pressed (see Section 12.2 to make this selection).

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

Green Indicator	Yellow Indicator	Status
Off	Off	Otowave turned off
On	Off	Idle, test completed or test cancelled
Off	Slow flash	Ensure probe is held steady while an ear seal is obtained
Slow flash	Off	Testing - tympanogram and/or reflex measurement

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

4.4. The probe



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

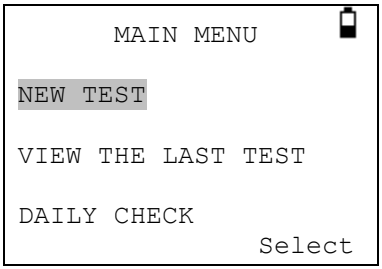
To remove the probe tip, unscrew the nose cone and remove the probe tip from the boss. A small seal will be found in the base of the probe tip. This should be examined and replaced if it is blocked or damaged. Do not remove the nut securing the boss to the body of the instrument.

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).

4.5. Start-up and menu displays

When the Otowave 102 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.

4.6. 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 (DD/MM/YY or MM/DD/YY)
- correct battery type
- power-off delay (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

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 a quiet room or in an acoustic booth.

5.2. Ear tip(s)

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

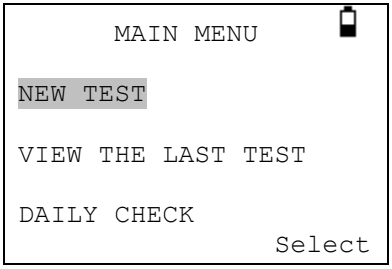
The probe tip must be fitted with a new ear tip before it is presented to a patient's ear canal. The ear tip must be fitted completely to the probe tip and must not occlude any of the four holes in the probe tip. The ear tip size is chosen to suit the patient's ear and provide a comfortable pressure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

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

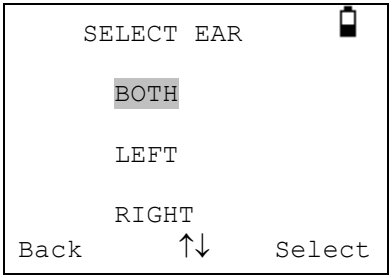
5.3. Performing a test

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

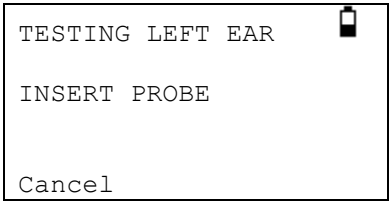
From the MAIN MENU select NEW TEST:



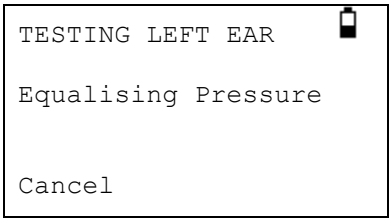
Select the ear(s) required for test:

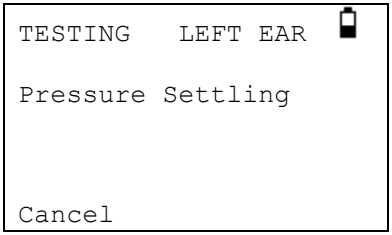


The message “Deleting last test” will be displayed momentarily followed by a message to insert the probe into the ear to be tested:

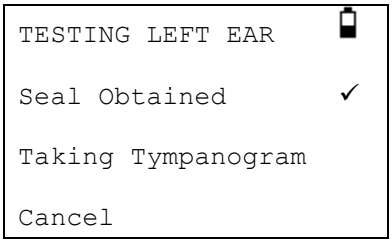


Present the ear tip to the ear and obtain a seal. If a good seal has been detected the following sequence of messages will be seen





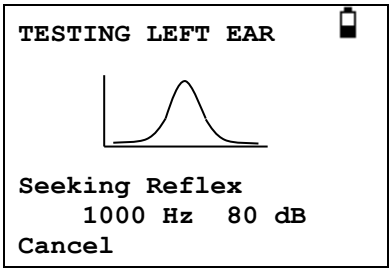
Press ◄ at any time to cancel the test and return to the ear selection menu.



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

When the tympanogram is complete the instrument will perform the reflex test(s), if selected. By default this test is only performed if a peak is found in the tympanogram. This and other reflex test options may be changed in the CONFIGURATION menu, see Sections 12.2 and 5.5.

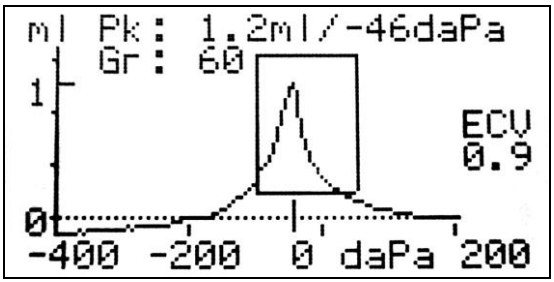
Before starting the reflex test the ear canal pressure will be set to the value that gave the peak compliance during the tympanogram test. The instrument will then step through the tone frequencies and levels set in the CONFIGURATION menu searching for a reflex response.



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

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

Remove the ear tip from the patient and after a short period the tympanogram will be displayed.



The display shows:

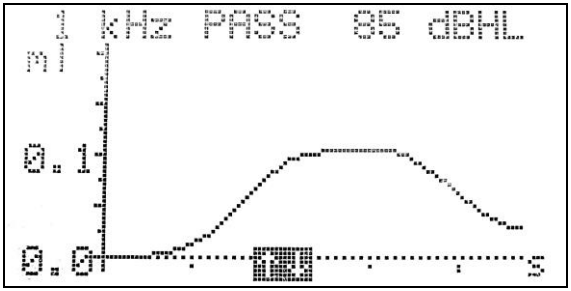
- The peak compliance, in ml (Pk)
- The pressure which gave the peak compliance in daPa
- The Gradient, in daPa (Gr)
- The Ear Canal Volume (ECV) in ml measured at 200 daPa.
- A plot of compliance against pressure.

Review the tympanogram to ensure that the peak compliance 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.

To repeat the test, press ◄.

When satisfied with the tympanogram press ►.

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

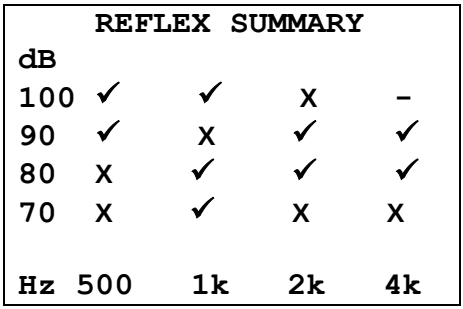


The display shows:

- The frequency and level of the reflex stimulus
- "PASS" if a reflex was found, else "NR" (No Response)
- A plot of compliance 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.

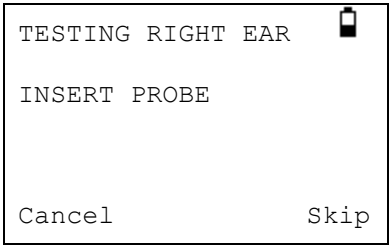
If the Otowave 102 was set to test for a reflex at all levels of the stimulus (see Reflex autostop in Section 5.5) press ► to view an additional display following the reflex graphs. This shows a summary of the levels and frequencies at which a reflex was detected. The dash symbol "-" is shown if a reflex tone was not presented at the level indicated.



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; 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 the results to a computer
- Save the results in the internal database

- Review the results as described above
- Return to the main menu

See Sections 6 to 8 for more information on these options.

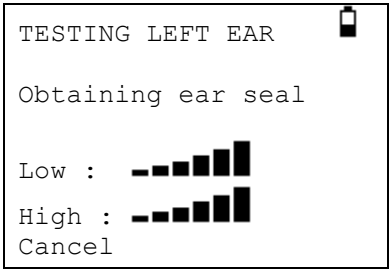
The results of the last test performed remain available even if the Otowave has been turned off. To view these results select VIEW THE LAST TEST from the main menu. After selecting the required ear the tympanogram will be displayed. It will then be possible to view the results and select the PROCESS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

5.4. Ear seal check

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

5.5. 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 selection

Use the ▲ and ▼ keys to choose the circumstances when a reflex measurement is to be made (always, never, only if a compliance peak is found, or only after confirmation is made at the start of the test sequence). In cases where a compliance peak has not been established a pressure of 0daPa is used. Press the ► key to confirm the selection or the ◄ key to cancel.

Reflex levels

Use the ▲ and ▼ keys to choose the maximum level of reflex stimulus to apply and the step size between the levels of the preceding stimuli. The maximum level of stimulus may be set between 85dBHL & 100dBHL. Press the ► key to confirm the selection or the ◄ key to cancel.

Reflex frequencies Otowave 102-4 only

Use the ▲ and ▼ keys to choose between 1000Hz only or 500Hz, 1000Hz, 2000Hz & 4000Hz for the frequencies at which the reflex stimulus is to be applied. Press the ► key to confirm the selection.

Reflex threshold

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

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 the Otowave 102 will test for a reflex at all selected levels. (Note that 100dBHL at 4000Hz is not available).

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.

5.6. Error messages

The following error messages may be seen during the test sequence.

Message Displayed	Indicator Status	Likely Cause(s)
WITHDRAW PROBE	Yellow Flashing	The probe has been moved during measurement. Re-insert the probe to repeat the test.
Volume outside range WITHDRAW PROBE	Yellow Flashing	The ear canal volume is above the 5ml. This message can also occur when the probe is not properly inserted into the ear.
Blocked ear WITHDRAW PROBE	Green Flashing	The ear canal volume is below 0.1ml. Check that the probe is not blocked and correctly inserted into the ear.
INSERT PROBE	Yellow Flashing	The seal was lost. Reinsert the probe to repeat the test.

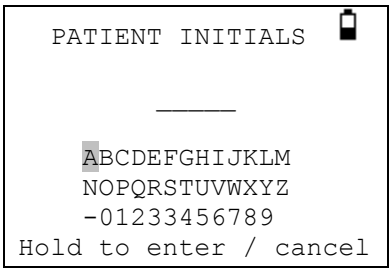
6. Saving Results in the Internal Database

Up to 30 tests can be saved in the Otowave 102 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:

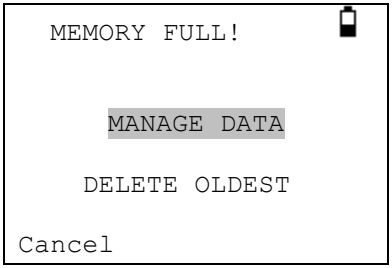
Enter all three characters for the identifier.
Press and hold the ► key to save the record.

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 DATA 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.

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

Cancel will return to the previous menu.

7. IrDA Communications

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

The Otowave 102 can send test results to a designated printer or a suitably-equipped computer via an infra-red link.

If the computer does not have an infra-red port a suitable infra-red adapter will be required. The Actysis ACT-IR2000U USB adapter is specified for and has been tested for use with the Otowave 102. This adapter may be purchased from Amplivox (see Section 15) and only this device should be used for this purpose.

The Otowave sends data through a small window on the right of the probe. For a printer the data is received through a window in the front of the printer; for a computer the data is received through a window located either on the case or on the plug-in adapter if this is used.

The environment in which the Otowave is used can affect the data transfer process. The following are recommendations but may need to be modified depending on the environment.

- The two communication windows should be in line and pointing directly at each other, 10-20cm apart
- Both units must be out of direct sunlight for optimum communication
- For transferring data to a printer ensure that no computer or printer other than the one to be used is within range
- Similarly, for transferring data to a computer ensure that no other IrDA device is within range
- The infra-red link must not be broken once a connection between the printer/computer and the Otowave has been established
- If the printer/computer or Otowave are moved, or an object between them breaks the link, the data may become corrupted or the Otowave may not respond to the controls until the data transfer 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 data transfer process has timed-out the resulting error message can be cleared and the data re-sent; if the data is still corrupted select Cancel on the Otowave and then send the data again.

8. Transferring the Results

8.1. Sending the results to a printer

Three designated thermal printers (the Able AP1300, the Martel MCP8830 or the Sanibel MPT-II) are available as options and only these printers

should be used. Printers supplied with the Otowave 102 are correctly configured for communication but it is important to ensure that the correct printer is selected (use the MENU options described in Section 12.2 to make this selection).

If the Martel MCP8830 does not communicate properly (i.e. will not print) please check that the Option2 setting (for IrDA communications) is set to 2 (9600 baud)

If the Martel MCP8830 printer is also to be used with an Amplivox audiometer it may be necessary to ensure that the Option 4 setting (for RS232 Baud Rate) is set to 4 (2400 baud). Refer to the documentation supplied with the printer.

The Able and Sanibel printer has no user-settable configuration options.

Before attempting to print ensure the printer is fully charged, switched on, loaded with paper and ready to print.

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.)

Press ◄ to cancel printing.

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

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

8.2. Data transfer to NOAH or TympView

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

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

If communication between the Otowave 102 and the computer cannot be established the message “Device not found” is displayed. The following points should be checked:

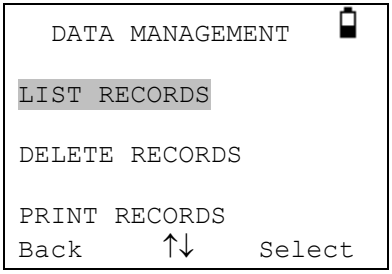
- Ensure the environment is suitable (see Section 7)
- The computer has its IrDA software properly installed and the interface enabled
- If the computer has been in “Hibernate” mode the IrDA interface is not always re-enabled; try restarting the computer
- The IrDA adapter on the computer is compatible with the Otowave
- Turn the Otowave off and on again before trying to send the data again

If communication is lost while sending the data the message “Link was unreliable” will be displayed. Press ◄ to cancel sending the data and start the operation again.

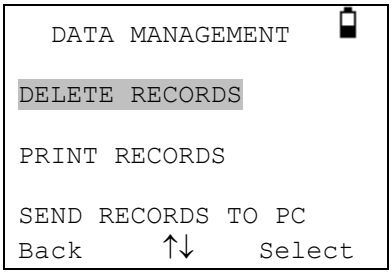
If any other messages are displayed while sending data, turn the Otowave off and then on again and try re-sending the data. If the problem persists contact an Amplivox service centre.

9. Data Management

Records stored in the database of the Otowave 102 can be listed, viewed, deleted, printed or sent to a computer using the DATA MANAGEMENT option of the main menu:



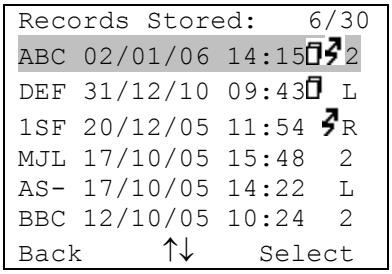
Scroll down to see the remaining choice:



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:

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

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

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

- View the selected record
- Print the selected record
- Send the selected record to a computer
- Delete the selected record

See Sections 7 and 8 for further information on printing a 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. Refer to Section 8.1 for more general information. If printing the entire database it is recommended that a full roll of paper is loaded into the printer.

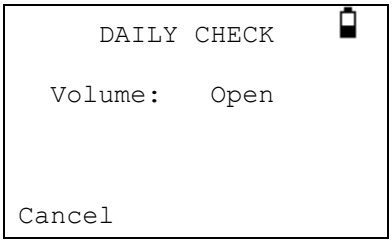
9.4. Send records to a computer

SEND RECORDS TO PC allows a group of records to be sent to a computer. It is possible to send all stored records or just those records that have not already been sent. Refer to Section 8.2 for more general information.

10. Performing Daily Checks

The operation of the Otowave 102 should be checked daily using the 4 in 1 test cavity assembly supplied with the instrument.

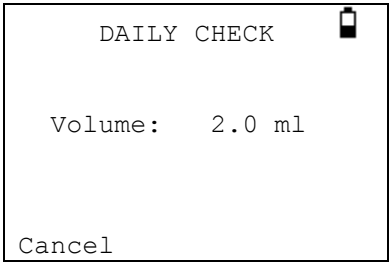
Select the DAILY CHECK option in the main menu:



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 and 0.5ml test cavities to within ± 0.1ml. The 5.0ml test cavity should be 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. Ear tip and Probe

Ear tips should be replaced after a single use.

The probe tip and its associated seal 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 seal 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 4.4 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 Repair of the Instrument

Amplivox recommends that the Otowave is calibrated annually. Please contact Amplivox 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.

Please use the original shipping carton and packaging to transport the instrument. Place the instrument in a plastic bag 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**.

12.1. Main menu

Menu	Sub-menu
MAIN MENU	NEW TEST
	VIEW THE LAST TEST
	DAILY CHECK
	DATA MANAGEMENT
	CONFIGURATION
	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 show progress. Graphical displays are shown automatically at the end.
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 that have been sent to a computer. ALL RECORDS – Delete all records
	PRINT RECORDS	Print stored records. Select: UNPRINTED RECORDS – Print all records not previously printed. ALL RECORDS – Print all records

	SEND RECORDS TO PC	Transfer records to a computer. Select: UNSENT RECORDS – Send all records not previously sent. ALL RECORDS – Send all records
CONFIGURATION	TODAY'S DATE	Set the internal clock date and time; use the ◄ & ► keys to select a field and the ▲ & ▼ keys to adjust the value.
	REFLEX SELECTION	Select when reflexes will be measured (see Section 5.5): ALWAYS MEASURE NEVER MEASURE **ONLY IF PEAK FOUND** PROMPT TO MEASURE
	REFLEX LEVELS	See Section 5.5. Set to 100dB (with 5dB or 10dB steps) or **95dB**, 90dB or 85dB with **5dB** steps.
	REFLEX FREQUENCIES	See Section 5.5. Default **500, 1000, 2000 and 4000 Hz** (for 102-4)
	REFLEX THRESHOLD	See Section 5.5. Default **0.03 ml**
	REFLEX AUTO-STOP	See Section 5.5. Default **YES**
	REFLEX FILTER	See Section 5.5. Default **2 Hz**
	PRINTER	Select **Able AP1300** or Martel MCP8830 (also use Martel for Sanibel MPT-II)
	BATTERY TYPE	Select **Alkaline** or NiMH (This effects the battery state display and low battery warning).
	POWER-OFF DELAY	The time after which the unit turns off automatically if no key is pressed. Select **90** or 180 seconds
	LCD CONTRAST	Change the display contrast. 0 – 15. Default **7.**
	EAR SEAL CHECK	Select **QUICK** or THOROUGH See Section 5.4.

	REPORT CAL. DATES	Select **PRINT CAL. DATES** or HIDE CAL.DATES
	SET DATE FORMAT	Select **DD/MM/YY** or MM/DD/YY (used for display and printouts)
	HOSPITAL NAME	Allows the Hospital name to be entered (this will appear at the top of the print out). See Section 6.1 for the 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 the 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 or FRENCH for operating language
SYSTEM INFORMATION		Shows: Battery voltage (Battery) Software version (Version) Date calibrated (Last Cal) Next calibration date (Next Cal) Instrument serial number (Serial No) Current date and time

13. Error Messages & Fault Conditions

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

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

Message	Meaning / Action
PROBE NOT CLEAR Please ensure the probe is not blocked or obstructed	Examine the probe tip for blockages. If necessary remove it and clean or replace it, see Section 4.4. If the problem persists, contact your Amplivox service centre.
PUMP ERROR Pump error. RESTART THE UNIT. If problem persists, contact Amplivox	
WARNING! CALIBRATION EXPIRED. Recalibration needed before further tests are performed	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	Replace the batteries immediately, see Section 4.1
Powering down	The Otowave is turning off because the batteries are discharged. Replace the batteries.
PUMP ERROR. Cannot determine pump direction. If problem persists, contact Amplivox	Pump fault. If the fault persists contact your Amplivox service centre.
PUMP ERROR. If problem persists, contact Amplivox	Contact your Amplivox service centre.
Measurement timed out	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 Amplivox service centre.
"WARNING! DEVICE UNCALIBRATED. One or more default values require recalibration before further tests are	This message should never normally be seen. If it persists contact your Amplivox service

performed	centre.
WARNING! DEFAULTS RELOADED. Default configuration settings reloaded. Check before making new tests	This message should never be seen. Check all the CONFIGURATION settings before taking measurements. If the error persists, contact your Amplivox service centre.
ERROR Transfer failed No device found or Link was unreliable	The Otowave was unable to send data to the computer. See Section 8 for details.
WITHDRAW PROBE	The probe has been moved during measurement. Re-insert the probe to repeat the test.
Volume outside range WITHDRAW PROBE	The ear canal volume is above the 5ml. This message also occurs when the probe is not properly inserted into the ear.
Blocked probe WITHDRAW PROBE	The ear canal volume is below 0.1ml. This message also occurs when the probe tip is blocked. Check that the probe is correctly inserted into the ear. Check that the probe is not blocked.
INSERT PROBE	The seal was lost. Reinsert the probe to repeat the test.

14. Technical Specification

14.1. Performance

Tympanometry	
Instrument type	Meatus compensated tympanometer
Analysis performed	Compliance peak level (in ml) & pressure; Gradient (in daPa); Ear Canal Volume (ECV) @ 200 daPa
Probe tone levels and accuracy	226Hz +/- 2%; 85dB SPL +/-2dB over range 0.2ml to 5ml
Pressure levels and accuracy	+200daPa to -400daPa +/-10daPa or +/-10% (whichever is larger) over range

Ear volume measurement range and accuracy	0.2ml to 5ml +/- 0.1ml or +/-5% (whichever is larger) over entire range
Sweep speed	Typically 200-300daPa/sec; dependent on ear/cavity volume
Pressure limits (safety cutout)	+600 to -800 daPa
Number of samples stored	100 per tympanogram
Reflex measurements	
Measurement mode	Ipsilateral
Reflex tone levels and accuracy (referenced to 2ml calibration volume - compensates for measured ear volume)	102-1: 1kHz (+/-2%) 102-4: 500Hz,1kHz,2kHz,4kHz (+/-2%) Configurable over range 70dB to100dBHL +/-3dB (4kHz restricted to 95dBHL)
Number of reflex levels (see Section 3.3)	Four: 100dB with 5dB or 10 dB steps; 95dB, 90dB or 85dB with 5 dB 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, or at 0daPa (if no peak found)
Reflex stimulus control	Stimulus presented at all levels, or stimulus ceases when a reflex is found
Reflex detection threshold and accuracy	0.01ml to 0.5ml +/-0.01ml (configurable in 0.01ml steps)
Reflex tone duration	0.6 seconds
Number of records stored in Patient Database	30
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 or French
Printing	
Supported printer	Martel MCP8830,Able AP1300 or Sanibel MPT-II
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	OBEX (Object Exchange) service running on top of IrDA stack. Auto-selects between 9600-115200 baud.
Information sent	Patient header, left and 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).
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	190mm long x 80mm wide x 40mm high

	excluding probe 210mm long including probe
Weight (without batteries)	285 g
Weight (with batteries)	380 g
Environmental	
Operating temperature range	+15°C to +35°C
Operating humidity range	30% to 90% RH, non-condensing
Operating atmospheric pressure range	980 to 1040 mb (see Section 2)
Transport and storage temperature range	-20°C to +70°C
Transport and storage humidity range	10% to 90% RH, non-condensing
Transport and storage atmospheric pressure range	900 to 1100 mb
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	Internally Powered
Degree of protection against electric shock	Type BF applied part
Degree of protection against ingress of water	Not protected
Mode of operation	Continuous operation
Equipment mobility	Portable

The Otowave 102 Tympanometer is classified as a Class IIa device under Annex IX (Section 1) of the EU Medical Devices Directive.

14.3. Symbols

Definition: Refer to instruction manual (mandatory)

Definition: Type BF applied part – an applied part providing a higher degree of protection against electric shock than that provided by a Type B applied part,

particularly regarding allowable patient leakage current and patient auxiliary current.

The applied part is the ear tip.

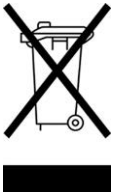
15. Ordering Consumables and Accessories

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

Stock No.	Description
T527	Probe tip
T518	Seal
T030	4 in 1 test cavity assembly (0.2ml/0.5ml/2.0ml/5.0ml)
T20	Ear tip set
T205	Ear tip Otowave 3-5mm
T206	Ear tip Otowave 4-7mm
T207	Ear tip Otowave 7mm
T208	Ear tip Otowave 8mm
T209	Ear tip Otowave 9mm
T210	Ear tip Otowave 10mm
T211	Ear tip Otowave 11mm
T212	Ear tip Otowave 12mm
T213	Ear tip Otowave 13mm
T214	Ear tip Otowave 14mm
T215	Ear tip Otowave 15mm
T219	Ear tip Otowave 19mm
B132	Carrying case
PT02	Printer Sanibel MPT-II
C0104	Thermal Printer paper for Sanibel MPT-II
PT01	Printer Able AP1300
C0103	Thermal printer paper for Able AP1300
A091	Printer Martel MCP8830
C01	Thermal printer paper for Martel MCP8830
T91	ACTiSYS infrared USB adapter

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

16. Disposal Information



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

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

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

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

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

B2B Compliance
Tel: +44 (0) 1691 676 124 (Option 2)

Email: operations@b2bcompliance.org.uk

17. EMC Guidance & Manufacturer's Declaration

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The Otowave 102 Tympanometer is intended for use in the electromagnetic environment specified below. The customer or user of the Otowave 102 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="4">The Otowave 102 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></tr>
<tr><td>Harmonic emissions

IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations/flicker emissions

IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity (1)			
The Otowave 102 Tympanometer is intended for use in the electromagnetic environment specified below. The customer or user of the Otowave 102 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	Not applicable	Not applicable
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	Not applicable

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Not applicable	Not applicable
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 102 Tympanometer is intended for use in the electromagnetic environment specified below. The customer or user of the Otowave 102 Tympanometer should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Otowave 102 Tympanometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b]

Guidance and manufacturer's declaration – electromagnetic immunity (2)			
			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 102 Tympanometer is used exceeds the applicable RF compliance level above, the Otowave 102 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 102 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 102 Tympanometer

The Otowave 102 Tympanometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Otowave 102 Tympanometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Otowave 102 Tympanometer as recommended below, according to the maximum output power of the communications equipment.

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

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

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

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

18. Use with Non-medical Electrical Equipment

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

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

The Otowave 102 tympanometer uses an industry-standard infra-red means of communication (an IrDA port - as described in Section 7) in order to reduce any potential hazard associated with the use of mains-powered equipment connecting to this interface.

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 & 2 below for typical configurations of connected peripheral equipment.

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

Diagram 1: Otowave 102 used with the supplied printer

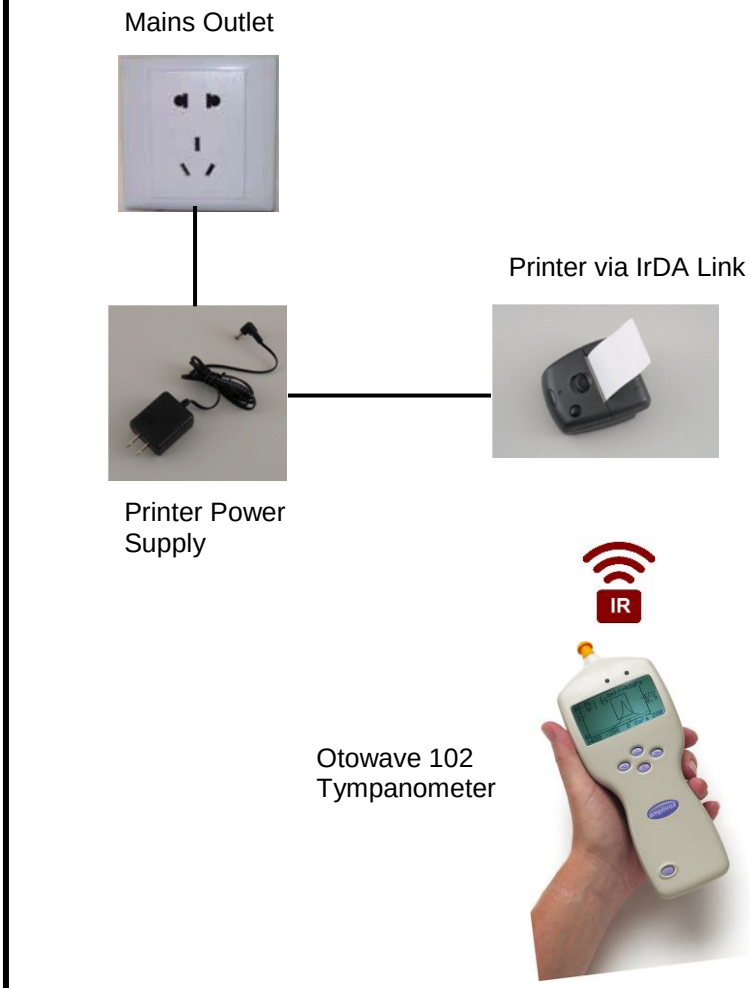


Diagram 2: Otowave 102 used with a computer & IrDA Link