MedRx Otowave 102
Hand Held Portable Tympanometer
Operating Manual
(Applies from serial number 37400 onwards)

Distributor: MAICO Diagnostics GmbH
MedRx International Sales
Sickingenstr. 70-71, 10553 Berlin, Germany
Tel.: +49 30/70 71 46-50, Fax: -99
E-mail: medrx-sales@maico.biz
Web: www.medrx-int.com

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1. Introduction

Thank you for purchasing a MedRx 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 MedRx Otowave 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 of data via an infrared link to one of two thermal printers that may be selected by the user
- Transfer of data to a computer via an infrared IrDA link for storage and display using the NOAH application
- English, French or German operating language

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 tympanometer or MedRx if you purchased direct.

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 102 Tympanometer
4 x 1.5V ‘AA’ Batteries (UK only)
4 in 1 test cavity assembly
Set of disposable ear-tips
Carrying case
Operating manual
Calibration certificate
Warranty card

1.5. Optional accessories

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

Note: If the thermal printer has been purchased it should be charged for a period of 8 hours before being used. Refer to the printer instructions for further details.

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 one year from the date of dispatch if returned, carriage paid, to the MedRx service department. Return carriage is free of charge for customers in the UK and chargeable for overseas customers.

The following exceptions apply:

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

2. Important Safety Instructions

The Otowave 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.

Use the recommended batteries (see Section 4.1); do not mix battery types or old and new batteries.

Remove batteries from the instrument if the instrument is not going to be used for more than a month.

Always set the BATTERY TYPE in the CONFIGURATION MENU to show which type of batteries are fitted. See Section 12.

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.

Thermal paper printouts fade with exposure to light or heat. Photocopying the patient record test results will ensure a more permanent record is kept.

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 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 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 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 sound pressure level (SPL) of this stimulus is increased in steps until the stapedial muscles respond causing the tympanic membrane to become stiffer, or a preset maximum SPL 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).

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 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 we recommend alkaline cells are fitted. NiMH batteries have a high self-discharge rate and are likely to need recharging if left unused for several weeks.

To fit the cells remove the battery compartment cover on the base of the Otowave. Fit the cells as indicated inside the battery compartment.

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

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).

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 has **!** in front of it, or when advised to do so at switch-on.

Removing 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, 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 (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.

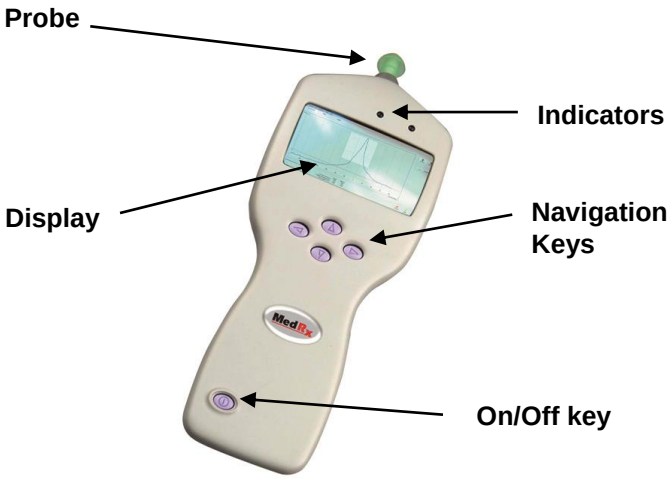
Press the up ▲ and down ▼ navigation keys to scroll through the menus or set values

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.

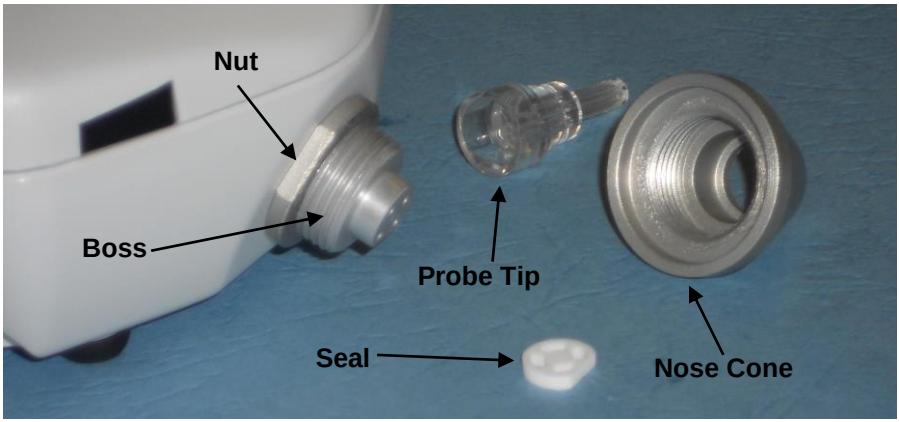
When not performing a test the Otowave will switch off automatically if no key is pressed for 90 seconds. This time can be extended to 180 seconds in the CONFIGURATION menu (see Section 12.2).



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 & ready to use
Off	Slow flash	Waiting for probe to be inserted
Slow flash	Off	Taking a measurement
On	Off	Pump error at switch-on. Measurement error, see Section 13.
On	Flickering	Sending data to a computer

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 tip must be removed and cleaned or replaced.

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

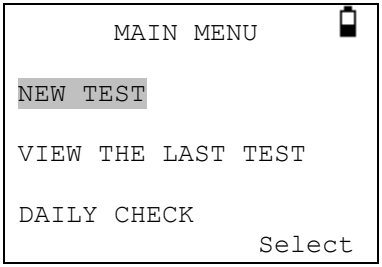
When replacing the probe tip, ensure that the seal is correctly located with the flat side aligned with the flat side within the base of the probe tip. Push the probe tip over the boss and replace the nose cone. Make sure that the nose cone is screwed home firmly but do not over-tighten. Do not use any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

After replacing the tip a Daily Check should be carried out, as described in Section 10.

4.5. Start-up and menu displays

When the Otowave 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 as shown below:

Menu items and instructions are shown in upper case text. Information and error messages are generally in lower case. The menus are summarised in Section 12.



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 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

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.

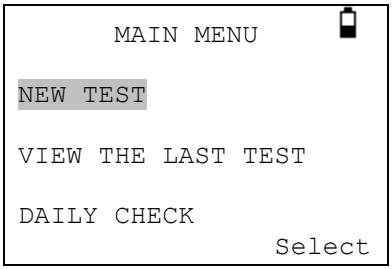
Refer to Sections 2.1 and 11.2 regarding these single-use parts.

5.3. Performing a test

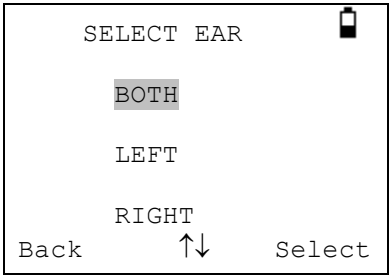
Other than remaining still, no specific action is required by the patient during the automatic test.

A typical tympanogram measurement and reflex test is carried out as follows.

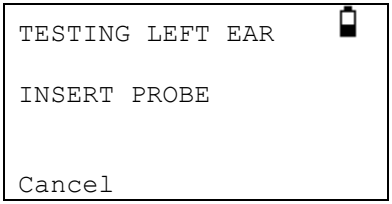
From the MAIN MENU select NEW TEST:



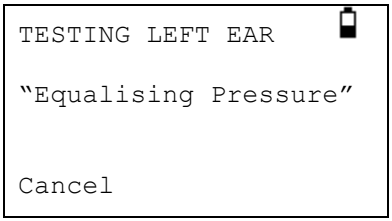
Select the ear(s) you wish to test:

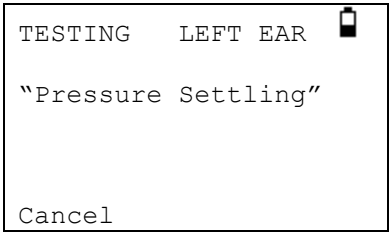


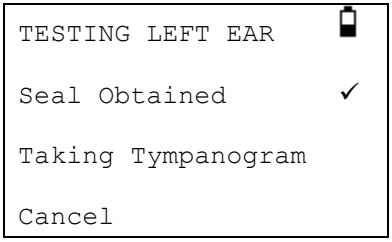
The message “Deleting last test” will be displayed momentarily. You will then be asked to insert the probe into the ear to be tested:



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



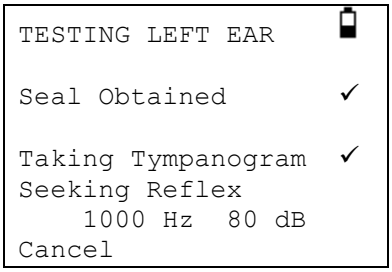




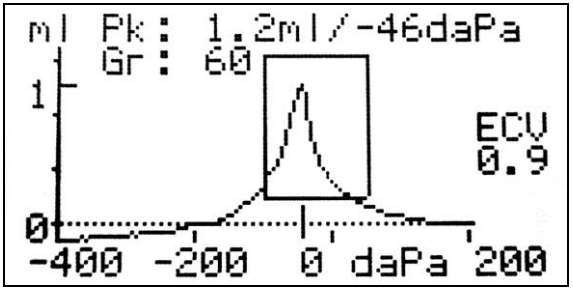
Once an adequate seal is detected the tympanogram measurement is made. This takes about 3 seconds. It is important not to move the probe and to ask the patient to remain very still during the test.

When the test is complete the instrument will go on to the reflex test, if selected. By default this test is only performed if a peak is found in the tympanogram. You may change this and other reflex test options in the CONFIGURATION menu, see Section 12.

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:



When the measurement is complete the tympanogram will be displayed:



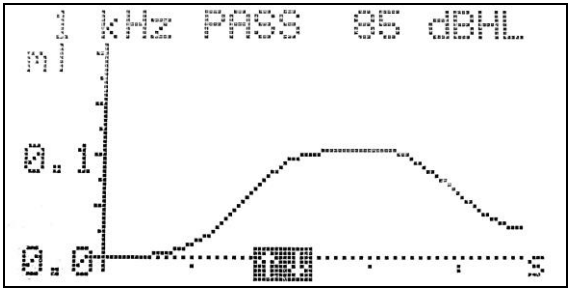
The display shows:

- 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 make sure that the peak compliance point selected by the Otowave is correct. If you are not satisfied you may select another peak using the ▲ and ▼ keys. The figures displayed will change to reflect the peak you select.

To repeat the test, press ◄.
When you are satisfied with the tympanogram press ►.

If the reflex test was carried out the results will now be displayed:



The display shows:

- The frequency of the measurement.
- "PASS" if a reflex was found, else "NR" (No Response).
- The level of the tone for which a reflex was first found.
- 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.

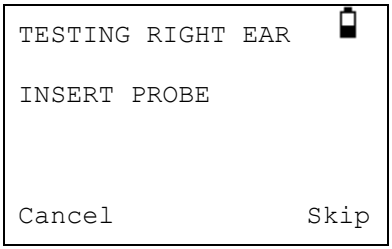
If the Otowave 102 was set to test for a reflex at all levels of the stimulus (see Reflex autostop in Section 5.5) press ► to view an additional display following the reflex graphs. This shows a summary of the levels and frequencies at which a reflex was detected. The dash symbol "-" is shown if a reflex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

REFLEX SUMMARY				
dB				
100	✓	✓	x	-
90	✓	x	✓	✓
80	x	✓	✓	✓
70	x	✓	x	x
Hz	500	1k	2k	4k

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

The message "Saving as last test" will be displayed briefly 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 you chose to test both ears the test sequence will now be repeated for the right ear:



Press ► to skip testing of the right ear and view results for the left ear.
Press ◄ to return to the main menu.

When all the selected ears have been tested the PROCESS RESULTS menu will be displayed. This allows you to:

- Print the test results
- Send the test results to a computer
- Save the test results in the instrument's database
- View the test results
- Return to the main menu

See Sections 7 to 9 for more information on these options.

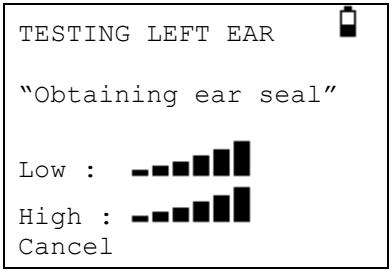
The results of the last test performed remain available even if the Otowave has been turned off. To view these results select VIEW THE LAST TEST from the main menu. After selecting the required ear the tympanogram will be displayed. It will then be possible to view the results and select the PROCESS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

5.4. 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 the majority of circumstances, and this checks that an adequate pressure can be created in the ear canal before starting the test.

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.

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.

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 that determines that a reflex has been detected (0.01ml to 0.5ml). Press the ► key to confirm the selection.

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. Press the ► key to confirm the selection. (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. Press the ► key to confirm the selection.

5.6. Error messages

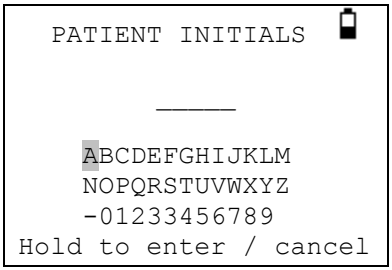
The following error messages may be seen during the test sequence.

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 correctly inserted into the ear. Also check that the probe is not blocked.
INSERT PROBE	Yellow Flashing	The seal was lost. Reinsert the probe to repeat the test.

6. Saving Results in the Database

Up to 30 tests can be saved 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 menu can also be found by selecting VIEW THE LAST TEST from the main menu.
You will be asked to enter a three character identifier for the record. We suggest using the patient's initials. As the tympanometer uses a combination of this identifier, the date and time to identify saved tests you may reuse the same identifier for different tests if you wish.



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.

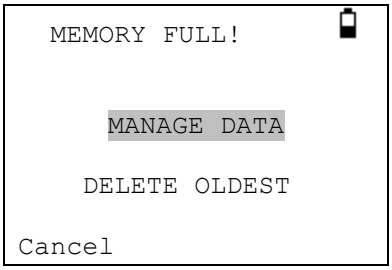
To save the test results:

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.

You will be warned if the database is full when you attempt to save a test:



MANAGE DATA will take you to the DATA MANAGEMENT menu (Section 9). You may then choose which records to delete to make space for the new test. Records may be printed or sent to a computer before being deleted.

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

Cancel will return you to the previous menu.

7. IrDA Communications

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 MedRx (see Section 15) and only this device should be used for this purpose.

The Otowave sends data through a communication the window to the right of the probe. For a printer the data is received through a similar communication window at the front of the printer; for a computer the data is received through a communication window either located 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

Two designated thermal printers (the Able AP1300 or the Martel MCP8830) 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).

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

It should also be noted that if the Martel MCP8830 printer is to be used with other devices (e.g. an 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 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. The same option is available through the VIEW THE LAST TEST and DATA MANAGEMENT options in the MAIN MENU.

Press ◄ to cancel printing.

The printed report provides the analysis results and the graphical displays plus space for a patient summary that can be filled in by the clinician.

8.2. Sending the results to a computer

Data may be sent to a computer for inclusion in a NOAH database or for use by other applications.

Please refer to the operating manual for the NOAH Impedance module to ensure that all of the necessary software is correctly installed on the computer.

To send the results of the last test select SEND TO COMPUTER from the PROCESS RESULTS menu on completion of the test. The same option is available through the VIEW THE LAST TEST and DATA MANAGEMENT options in the main menu.

After confirming that you wish to send data the message “Trying to connect…” will be displayed.

This will change to “Connection OK” when a connection to the computer has been made, and then to “Sending record…”. A message will appear on the computer screen asking if you wish to accept the data. Click the “Yes to all” button and the data will be transferred.

When the data has been sent you will be returned to the previous menu.

Press ← at any time to stop sending data.

The transmitted results are placed in a folder called “Amplivox”. By default this is placed on the current users desktop. If the folder already exists subsequent data will be saved in folders called “Copy 1 of Amplivox”, “Copy 2 of Amplivox” and so on.

Each test is stored in a separate file within the folder. Files are named thus:

nnn_DDMMYYYY_HHMM.APX (default)

or

nnn_MMDDYYYY_HHMM.APX

where nnn is the identifier entered when the test was stored in the tympanometer, or "xxx" if no identifier is available. DDMMYYYY (or MMDDYYYY) is the date the measurement was saved and HHMM is the time the measurement was saved.

If a “Device not found” message is displayed while trying to send data check the following:

- 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

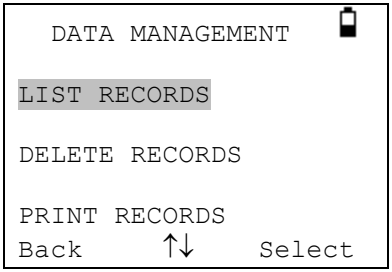
- The IrDA adapter on the computer is compatible with the Otowave
- Turn the Otowave off and on again before trying to send the data again

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.

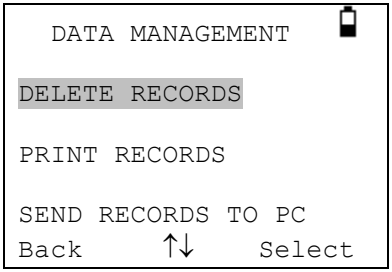
If any other messages are displayed while sending data, turn the Otowave off and then on again and try re-sending the data. If the problem persists contact your MedRx service centre.

9. Data Management

Up to 30 patient records can be stored in the database of the MedRx Otowave 102. Records can be listed, viewed, deleted, printed or sent to a computer using the DATA MANAGEMENT option of the main menu:



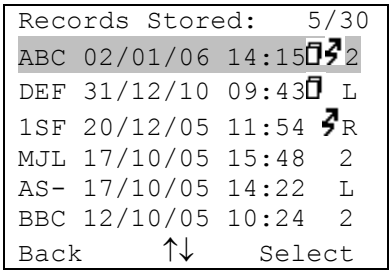
Scroll down to see the remaining choice:



If you wish 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 saved 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

When you select a record the PROCESS RECORD menu will be displayed. This allows you to:

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

See Sections 7 and 8 for further information on printing records or sending them to a computer.

9.2. Print records

PRINT RECORDS allows you to send a group of records to the printer. You may choose to send all stored records or all records that have not already been printed. Refer to Section 8.1 for more general information.

9.3. Send records to a computer

SEND RECORDS TO A PC allows you to send a group of records to a computer. You may choose to send all stored records or all records that

have not already been sent. Refer to Section 8.2 for more general information.

9.4. Delete records

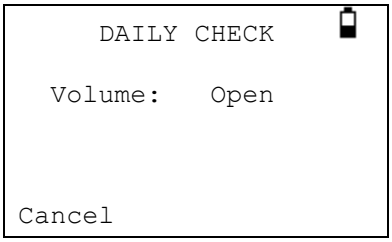
DELETE RECORDS allows you to delete a group of records. You can choose to delete all records, all records that have been printed or all records that have been sent to a computer.

You will be asked to confirm the deletion before any records are erased.

10. Performing Daily Checks

We recommend that the calibration of the Otowave is checked daily using the 4 in 1 test cavity assembly supplied with the instrument.

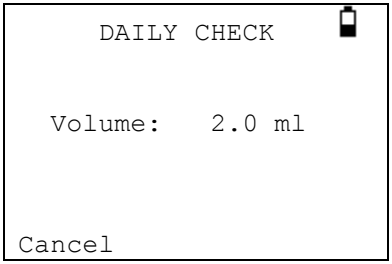
Select the DAILY CHECK option in the main menu:



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 when required. Ensure no moisture enters the instrument.

11.2. Eartip and Probe

Ear tips should be replaced after a single use.

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. Refer to Section 4.4.

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.

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

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 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 saved 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.

	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 LEVELS	Select the maximum tone level to be used for the reflex test. Set to 100dB (with 5dB or 10dB steps) or **95dB**, 90dB or 85dB with **5dB** steps. (See Section 3.3)
	REFLEX FREQUENCIES	Choose to perform the reflex test at a 1KHz only or at **500, 1000, 2000 and 4000 Hz** (for 102-4)
	REFLEX THRESHOLD	Select the change in compliance that determines that a reflex has been detected. Adjustable in 0.01 ml steps from 0.01 to 0.5 ml. **Default 0.03 ml**
	REFLEX AUTO-STOP	If selected, reflex measurement at each frequency stops as soon as a reflex is found. **Default YES**
	REFLEX FILTER	Select either **2 Hz** or 1.5 Hz. The lower value will smooth the plot more.
	PRINTER	Select **Able AP1300** or Martel MCP8830
	BATTERY TYPE	Select **Alkaline** or NiMH (This effects the battery state display and low battery warning).

	POWER-OFF DELAY	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 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"
	HOSPITAL NAME	Allows the Hospital name to be entered (this will appear at the top of the print out).
	DEPARTMENT	Allows the Department name to be entered (this will appear at the top of the print out).
	RELOAD DEFAULTS	The options above are reset to their default values
	SELECT LANGUAGE	Select "**ENGLISH**", "GERMAN" or "FRENCH" for operating language
SYSTEM INFORMATION		Shows: Battery 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 then MedRx 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 MedRx service centre.
PUMP ERROR. Unknown pump fault. 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 spent. Replace the batteries.
PUMP ERROR. Cannot determine pump direction. If problem persists, contact Amplivox	Pump fault. If the fault persists contact your MedRx service centre.
PUMP ERROR. If problem persists, contact Amplivox	Contact your MedRx 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 MedRx service centre.
“WARNING! DEVICE UNCALIBRATED. One or more default values require recalibration before further tests are performed	This message should never normally be seen. If it persists contact your MedRx service centre.
WARNING! DEFAULTS RELOADED. Default configuration settings reloaded.	This message should never be seen. Check all the

Check before making new tests	CONFIGURATION settings before taking any measurements. If the error persists, contact your MedRx 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 of same; 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 modes	Ipsilateral
Reflex tone levels and accuracy	102-1: 1kHz 102-4: 500Hz, 1kHz, 2kHz, 4kHz Frequency +/-2%, configurable over range 70dB to100dB HL (4kHz restricted to 95dBHL) +/-2dB, referenced to 2ml calibration volume; Compensates for measured ear volume
Reflex measurement range and accuracy	0.01ml to 0.5ml +/-0.01ml configurable in 0.01ml steps
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 (seen on printed report & computer report); pressure at which reflex was performed
Pressure used for reflex measurement	Pressure at Tympanogram peak, or 0 daPa (Always and Prompt Before Each Test modes)
Reflex level cut-off	Optionally, Auto-stop when reflex found
Reflex threshold detection	Configurable 0.01 – 0.50 ml in 0.01 ml increments
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 or Able AP1300
Interface	Infra-red, IrDA hardware, 9600 baud
Information printed	Space for patient & clinician's details, Tympanogram analysis parameters, Tympanogram, Reflex analysis parameters, Reflex graph, Serial Number of device, Last and Next Due Calibration dates
Serial Interface to computer	
Interface	OBEX (Object Exchange) service running on top of IrDA stack. Auto-selects rate 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: 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.

Definition: Refer to instruction manual (mandatory).

15. Ordering Consumables and Accessories

To order consumables, additional accessories and to replace detachable parts that have been damaged, please contact MedRx for current prices and delivery charges under medrx-sales@maico.biz.

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 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="2">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><td rowspan="3">The Otowave 102 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>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

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] Interference may occur in the

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

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 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 MedRx 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

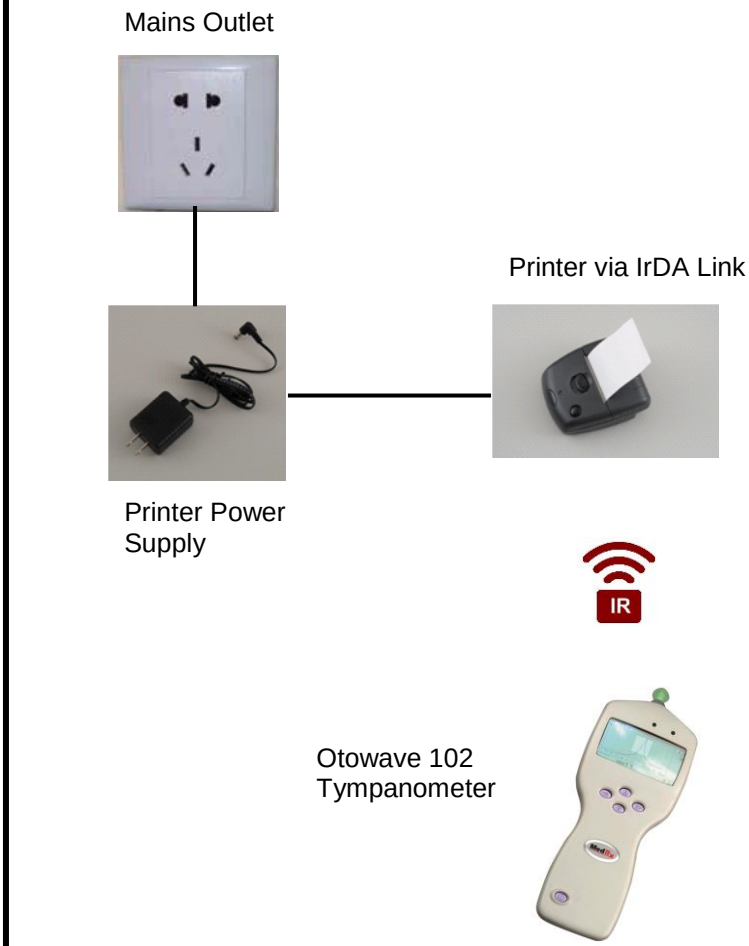


Diagram 2: Otowave 102 used with a computer & IrDA Link