Amplivox Otowave 102
Hand Held Portable Tympanometer
Service Manual

(Firmware versions up to 1.67)

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1. Introduction

1.1. Intended applications

The Amplivox 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 via an infrared link to a thermal printer.
- Transfer to Windows XP via an infrared IrDA link for storage and display using NOAH.

1.3. Standard contents

Amplivox Otowave 102 tympanometer
4 x 1.5V ‘AA’ Batteries (UK only)
Test cavity
Set of disposable ear-tips
Carrying case
Operating manual
Calibration certificate
Warranty card

1.4. Optional accessories

Portable thermal printer
Amplivox NOAH3 impedance module
Infra-red USB Adapter
Additional sets of ear tips
Additional rolls of thermal printer paper

2. Principles of Operation

2.1. 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.

2.2. 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.

2.3. 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 tone at a different frequency is presented. Where the reflex is elicited the stapedial muscles respond causing the tympanic membrane to become stiffer. More probe tone sound energy is reflected back into the ear, and the measured ear volume as determined from the microphone signal appears to get smaller. This change in volume is shown as a plot of compliance in ml 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 reflex stimulus sound pressure level (SPL) is increased in steps until the change in compliance exceeds a predetermined threshold. The change in compliance at that level when the stimulus is applied is displayed as a plot against time.

3. Notes on using the Otowave

3.1. Installing & replacing batteries

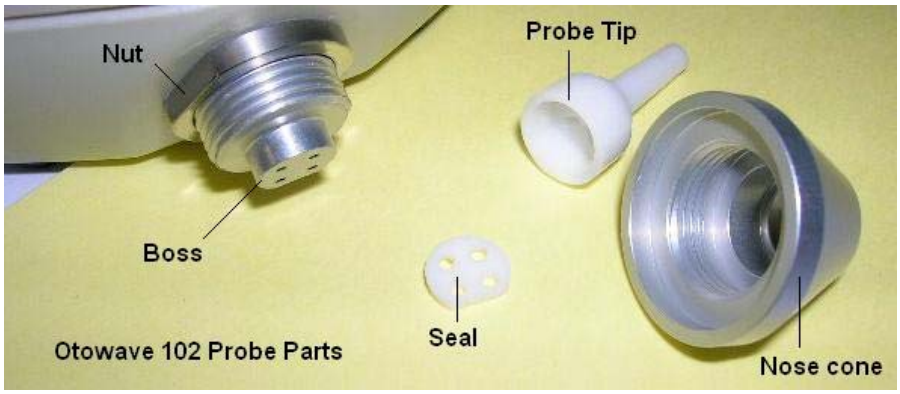
The Otowave may be powered from Alkaline 'AA' / LR6 batteries (e.g. Duracell MN1500) or rechargeable Nickel-Metal Hydride (NiMH) batteries. Four batteries are required.

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.

You must set which type of cell is fitted in the CONFIGURATION menu. By default this is set to ALKALINE. To change the setting select CONFIGURATION from the main menu and scroll to BATTERY TYPE as described later in this manual.

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

3.2. 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 should be 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.

When replacing the tip, ensure that the seal is correctly inserted with its flat aligned with the flat on 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.

3.3. Communicating with a printer

The designated thermal printer is supplied correctly configured for communication with the Otowave. If for any reason you need to change the configuration instructions are given in the printer manual. (Option 4 (RS232 Baud Rate) – Setting Number 4 (2400 baud))

The Otowave sends data to the printer through the small window to the right of the probe. The data is received through the window in the front of the printer below the on/off switch. The Otowave should be placed on the desk 10-20cm in front of the printer with the two communication windows in line and pointing directly at each other. Both units must be out of direct sunlight for good communication.

The infra-red link must not be broken once printing has started. If the printer or Otowave are moved, or something comes between them, the printed results will be corrupted. If this happens press ← to cancel printing and turn the printer off. Turn the printer on again and restart printing.

3.4. Communicating with a computer

The Otowave can send test results to a computer via an infra-red link for inclusion in a NOAH database or for use by other applications.

If your computer does not have an infra-red port you will need a suitable infra-red adapter. The Otowave has been tested with the Actysis ACT-IR2000U USB adapter and we recommend that you use this device. This may be purchased from Amplivox.

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

The Otowave sends test results to a computer through the small window to the right of the probe. The Otowave should be placed on the desk 10-20cm from the computers infra-red receiver and pointing directly at it. The receiver and the Otowave must be out of direct sunlight, to ensure good communication.

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

where nnn is the identifier entered when you stored the test in the tympanometer (see section 6), or "xxx" if no identifier is available. DDMMYYYY is the date the measurement was saved and HHMM is the time the measurement was saved.

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

- The Otowave is pointing directly at the computers infra-red receiver from no more than 20cm away.
- 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 your computer.
- The IrDA adapter on your 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 you will get a “Link was unreliable” message. Press ← to cancel sending the data and start the operation again.

If you see any other messages while sending data, turn the Otowave off and then on again. Try sending the data again. If the problem persists contact your Amplivox service centre.

4. Servicing the Otowave

The Otowave 102 has no user serviceable parts inside and should be returned to Amplivox for repair.

5. Calibration

5.1. Equipment required

To carry out calibration of the Otowave 102 you will require the following:

1. A calibrated pressure meter capable of showing air pressure in the range – 400daPa to + 200 daPa.

2. A means of applying a known pressure to the Otowave probe. We recommend a 2ml syringe connected to the pressure meter with a T-piece as shown below. Standard medical connectors allow the syringe and the Otowave to be connected.

3. A calibrated sound pressure level meter with a 2 ml acoustic coupler to IEC126. The meter must be capable of displaying dB SPL for the standard third-octave bands. A standard Amplivox 9.5mm ear tip (pale

blue) may be used to provide a means of connection the Otowave to the coupler as illustrated below.

4. Test cavities with capacities of 0.2ml, 1ml and 5ml. These are obtainable from Amplivox Ltd. The 1ml test cavity supplied with the Otowave may be used for calibration.

5.2. Calibrating the probe tone level

1. You will need the serial number of the instrument. This is shown on a label inside the battery compartment. It can also be found by selecting SYSTEM INFORMATION from the main menu.

2. Hold down the UP and LEFT keys and turn on the Otowave. Keep the keys held down while the instrument powers up.

3. Scroll to the end of the main menu and select the TYMP CALIBRATION option.

4. Enter the calibration code for the instrument. This may be obtained from Amplivox Ltd.

To enter the code select the number you wish to enter and then press and hold the > key.

When all four digits have been entered press and hold the > key again and the calibration menu will be shown.

(To delete a digit press and hold the < key. When all digits have been deleted pressing and holding the < key will return you to the main menu.)

5. Set the sound level meter to display SPL in dB with a third octave filter centred at a frequency of 250Hz.

Insert the Otowave probe into the 2 ml coupler.

6. Select “PROBE TONE” from the calibration menu.
   Select “226 Hz”
   Select “SET TONE LEVEL”
   Press > to show the ADJUST LEVEL screen.

Use the Up and Down keys on the Otowave to adjust the level shown on the meter to 85 dB ±1 dB. When the level is correct press and hold “Save” to store the calibration setting.

5.3. Calibrating the reflex tone levels

1. Set the sound meter to display SPL in dB with a third octave filter centred at the frequency of interest, in this case 500 Hz (for Otowave102-4).

2. Select “REFLEX TONE” from the calibration menu.
   Select 500Hz.
   Press “Next” to display the set level screen.

Use the UP and DOWN keys to adjust the SPL shown on the meter to between 85.0dB and 86.0dB. When the level is correct press “Save” to store the calibration setting.

3. Carry out steps 1 and 2 for the 1 KHz tone (Otowave 102-1 and 102-4). Adjust the SPL to between 79.5dB and 80.5dB.

4. Carry out steps 1 and 2 for the 2 KHz tone (Otowave 102-4 only). Adjust the SPL to between 82.5dB and 83.5dB.

5. Carry out steps 1 and 2 for the 4 KHz tone (Otowave 102-4 only). Adjust the SPL to between 85.0dB and 86.0dB.

5.4. Calibrating the pressure sensors

1. Connect the instrument to the pressure meter / syringe arrangement.

2. Select PRESSURE LEVELS from the calibration menu. The “Set pressure to –400 daPa” message is displayed.

3. Slowly pull back the syringe plunger until the pressure meter reads -400 daPa ± 0.05 daPa. The pressure reading should be stable between these limits. If the pressure falls there is a problem with the instrument that must be investigated.

Press > to save the pressure calibration setting.

The “Set pressure to 200 daPa” message is displayed.

4. Push the syringe plunger slowly in until the pressure meter reads +200 daPa ±0.05daPa. The pressure reading should be stable between these limits. If the pressure falls there is a problem with the instrument that must be investigated.

Press > to save the pressure calibration setting.
The “Expose to atmosphere” message is displayed.

5. Disconnect the instrument from the pressure meter.
Press > to save the calibration setting.

5.5. Volume calibration

1. Select “PROBE TONE” from the calibration menu.
Select “226 Hz”
Select “VOLUME CALIBRATION”
Press > start the calibration sequence.

The “Insert probe into 0.2 ml cavity” message is displayed.

2. Insert the probe firmly into the 0.2ml calibration cavity. Make sure the probe is square to the cavity.

Press > to start the calibration measurement.

After a short time the “Insert probe into 1ml cavity” message is displayed.

3. Insert the probe firmly into the 1 ml calibration cavity. Make sure the probe is square to the cavity.

Press > to start the calibration measurement.

After a short while the “Insert probe into 5ml cavity” message is displayed.

4. Insert the probe firmly into the 5 ml calibration cavity. Make sure the probe is square to the cavity.

Press > to start the calibration measurement.

After a short while the display returns to the calibration menu.

5. The volume calibration can be confirmed by selecting “DAILY CHECK” from the main menu and verifying that the calibration cavities are measured correctly. Errors are usually a result of the probe not being inserted into the test cavity correctly and can usually be cleared by repeating the volume calibration.

5.6. Set the calibration dates

1. Select “SET CAL DATE” from the calibration menu. This sets the last calibration date to the current date and the next calibration date one year a head.

2. If you want a calibration interval other than one year select “NEXT CAL DATE” from the calibration menu. You can then set the next calibration date manually.

6. Menu summary

Default values are shown in **bold**.

6.1. Main menu

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

6.2. 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 & LEDs indicate

		progress. Graphical displays are shown automatically at the end.
VIEW THE LAST TEST	SELECT EAR	Recall 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 PC 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 PC 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 PC. “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 PC. 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 85, 90, **95** or 100 dB SPL. You can then set the interval between levels during the test to **5 dB** or 10 dB.
	REFLEX FREQUENCIES	Choose to perform the reflex test at a 1KHz only or at **500, 1000, 2000 and 4000 Hz**.
	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 smoothes the plot more.
	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 – 14. **Default 8.**
	EAR SEAL CHECK	Select "**QUICK**" or "THOROUGH". See section 5.3.
	REPORT CAL. DATES	Select **PRINT CAL. DATES** or HIDE CAL. DATES.
	HOSPITAL NAME	Allows the Hospital name to be entered and appear at the top of the print out.
	DEPARTMENT	Allows the Department name to be entered and appear at the top of the print out
	RELOAD DEFAULTS	The options above are reset to their default values
SYSTEM INFORMATION		Shows: Battery voltage Software version Date calibrated Next calibration date Number of stored records Current date and time

7. Error messages

Message	Meaning / Action
PROBE NOT CLEAR Please ensure the probe is not blocked or obstructed	Examine the probe tip for blockages. If necessary take it off and clean or replace it, see section 5.3. If the problem persists, contact your Amplivox 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 new tests	Replace the batteries immediately, see section 5.1
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 Amplivox service centre.
PUMP ERROR. If problem persists, contact Amplivox	
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 performed	This message should never normally be seen. If it persists contact your Amplivox service 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 any measurements. If the error persists, contact your Amplivox service centre.
ERROR Transfer failed No device found	The Otowave was unable to send data to the computer. See section 8 for details.
ERROR Transfer failed Link was unreliable	

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.
PLEASE REINSERT PROBE	The seal was lost. Reinsert the probe to repeat the test.

8. Technical Specification

8.1. 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 / accuracy	226 Hz: +/- 0.1%, 85 dB +/-2 dB over range 0.2 ml – 5 ml.
Pressure levels / accuracy	+200 daPa to - 400 daPa, +/- 10 daPa over entire range. Atmospheric compensation applied at power-up.
Ear volume measurement range and accuracy	0.2 ml – 5 ml +/- 0.1 ml or +/-10% over entire range, whichever is greater
Sweep speed	Approx. 3 s for tympanogram, equating to approx. 200 daPa/s
Software pump pressure limits	+400 to –600 daPa
Hardware pressure limits	+600 to –800 daPa
Number of samples stored	100 per tympanogram
Reflex measurements	

Measurement modes	Ipsilateral
Reflex tone levels and accuracy	500, 1000, 2000 and 4000 Hz +/- 0.1%, configurable up to 100 dB HL +/- 2 dB, referenced to 2 ml calibration volume
Reflex measurement range and accuracy	0.01 ml – 0.5 ml +/- 0.01 ml relative accuracy
Number of reflex levels	4, in 5 dB or 10 dB steps
Reflex analysis	Reflex pass/fail at each level tested; maximum amplitude of each reflex (seen on printed report & PC 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	1.1 s
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 PC, 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

Printing	
Supported printer	MCP8830
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 PC	
Interface	OBEX (Object Exchange) service running on top of IrDA stack. Auto-selects rate between 9600 - 115200 baud.
Serial Interface to PC	
Information sent	Patient header, full left and right ear data.
Power Supply	
Battery Types	4 Alkaline AA Cells or; 4 NiMH rechargeable NiMH batteries which must be of greater than 2.3 Ah capacity.
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 S
Idle current	90 mA
Current while testing	270 mA
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	+10 C to +40 C
Operating humidity range	10% – 90% RH, non-condensing

Operating atmospheric pressure range	980 – 1040 mb
Storage temperature range	- 40 C to +70 C
Storage humidity range	10% – 90% RH, non-condensing
Storage atmospheric pressure range	900 – 1100 mb
Standards conformance	
Safety	EN60601-1: 1990
EMC	EN60601-1-2: 1993
Performance	EN60645-5: 2005, Type 2 Tympanometer
CE mark	To the Medical Device Directive

8.2. 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 Medical Devices Directive. It is intended for transient use as a screening tympanometer instrument.

8.3. Symbols

Definition: Type BF equipment – equipment providing a particular degree of protection against shock, particularly regarding allowable LEAKAGE current and reliability of the protective earth connection (if present).

Definition: Attention, consult accompanying documents.

9. 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
T517	Probe tip
T518	Sealing Washer
T018	Test Chamber Volume, 0.5 and 1 ml
T10	Ear Tip Set
T101	Ear Tip Otowave 6mm
T102	Ear Tip Otowave 7mm
T103	Ear Tip Otowave 8mm
T104	Ear Tip Otowave 9.5mm
T105	Ear Tip Otowave 11mm
T106	Ear Tip Otowave 12.5mm
T107	Ear Tip Otowave 14mm
T108	Ear Tip Otowave 16mm
T109	Ear Tip Otowave 18mm
B132	Carrying case
MANOW	Amplivox Otowave Operating Manual
A091	Thermal Printer
C01	Thermal Printer rolls (20metres)
T91	ACTiSYS Infrared USB adapter
T003	Amplivox NOAH Impedance module
T004	Amplivox NOAH Impedance module + IrDA PC port

10. 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><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√P 80MHz to 800MHz d = 2.3√P 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site 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.