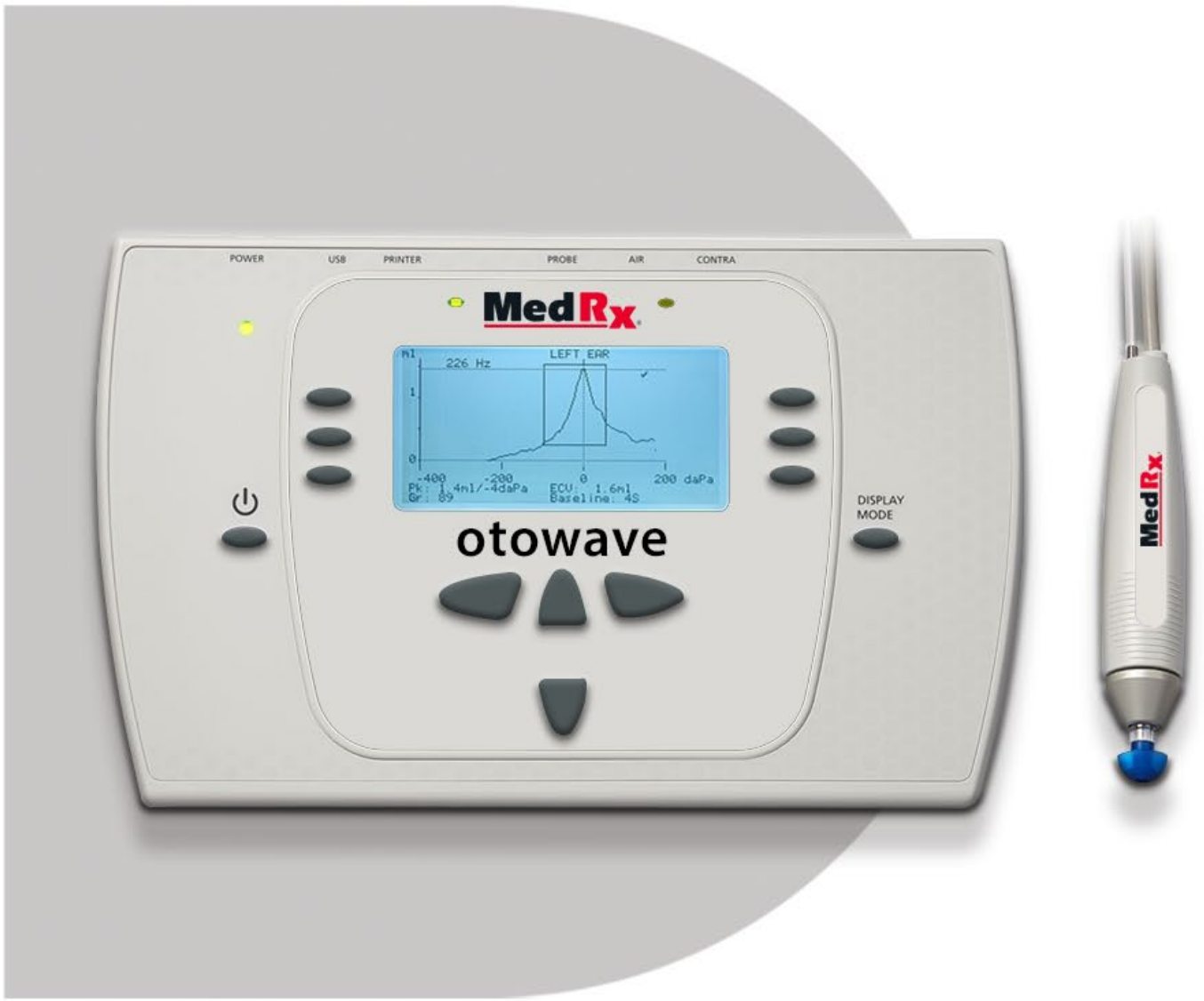


MedRx

Otowave 302+ Operating Manual

READ THIS OPERATING MANUAL BEFORE ATTEMPTING TO USE THE INSTRUMENT.

This manual is valid for the Otowave 302+ (applies from firmware version 1.0.0.085410 onwards – see System Information screen).

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

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

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

Distributors:

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

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

TABLE OF CONTENTS

1. INTRODUCTION

1.1. THANK YOU

Thank you for purchasing the MedRx Otowave 302+, a desktop-controlled impedance meter that will give many years of reliable service if treated with care.

1.2. INTENDED APPLICATIONS

This instrument is designed for use by trained personnel only, such as audiologists, ENT surgeons, doctors, general practitioners, hearing aid dispensers, child health professionals and hearing healthcare professionals with a similar level of education. It is not recommended to use the equipment without the necessary knowledge and training.

The Otowave 302+ is to be used to obtain information on medical and functional conditions of the middle and outer ear as well as to assess hearing functions throughout acoustic reflex testing. The Otowave 302+ can be used on all ages and performs two types of measurement:

- **Tympanometry:** To measure the compliance of the tympanic membrane and middle ear at 226 Hz or 1000 Hz over a range of pressures.
- **Acoustic Reflex Testing:** The Otowave 302+ measures both ipsilateral and contralateral acoustical reflexes. The tests are performed either at ambient or peak pressure, based on the outcome of the tympanometry.

1.3. CONTRADICATIONS

Always visually inspect the outer ear and the external auditory canal for abnormalities before testing. Testing should not be performed on patients if the following items are applicable.

- Acute external auditory canal trauma
- Discomfort (e.g. severe otitis externa)
- Occlusion of the external auditory canal
- Discharging ear
- Recent stapedectomy or middle ear surgery
- Presence of tinnitus, hyperacusis or other sensitivity to loud sounds may contraindicate testing when high intensity stimuli are used

1.4. STANDARD AND OPTIONAL COMPONENTS

The required fitting instructions are supplied with each part.

STANDARD COMPONENTS			
Otowave 302+ Tympanometer base unit	8519028	Contralateral reflex transducer (probe tip & earpiece lead)	8502177[1]
Power Supply - FW7660M/05	8512734	Set of disposable ear-tips	8029344[1]
USB with Software (ampliSuite and Noah impedance module) and Operating Manuals	8517685	4 in 1 cavity assembly (0.2 ml/0.5 ml/2.0 ml/5.0 ml)	8011362
Cable USB a to USB B (1.8 m)	8011241	Carrying case	8507857
Calibration certificate	8011512		

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

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

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

1.5.GUARANTEE

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

WARNING

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.

1.6. WARNINGS

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

WARNING

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

CAUTION

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

2. UNPACKING AND INSTALLATION

2.1. GENERAL

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

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

CAUTION

For supply in US only: Federal Law restricts this device to sale by or on the order of a licensed medical professional.

2.2. MARKINGS

The following markings can be found:

Symbol	Explanation
	Type B applied parts. According to IEC 60601-1. Patient applied parts that are not conductive and can be immediately released from the patient.
	Refer to instruction manual.
	WEEE (EU-directive) This symbol indicates that when the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling. Failing to do so may endanger the environment.
CE 0123	The CE-mark indicates that manufacture meets the requirements of Annex II of the Medical Device Regulation 2017/745. TÜV Product Service, Identification No. 0123, has approved the quality system.
SN	Serial number.
	Date of manufacture.
DC ⎓	The output from the mains AC adapter is Direct Current.
	Do not re-use. Ear-tips are for single use only.
	Keep dry.
	Transport and storage humidity range.
	Transport and storage temperature range.
MD	Medical device.
MedRx	Logo.
	Turns the instrument on or off. Long press to turn off. Short press to wake the device from sleep mode (display off).

2.3. SAFETY INSTRUCTIONS

2.3.1. GENERAL

The following safety precautions must be observed at all times. General safety precautions must be followed when operating electrical equipment. Failure to observe these precautions could result in damage to the equipment and injury to the operator or patient.

The employer should instruct each employee in the recognition and avoidance of unsafe conditions and the regulations applicable to his or her work environment to control or eliminate any hazards or other exposure to illness or injury.

MedRx Inc. is aware that safety rules within individual organisations vary. If a conflict exists between the instructions in this manual and the rules of the organisation using this instrument, the more stringent rules should take precedence.

The Otowave 302+ is intended to be used by hearing healthcare professionals (i.e. ENT doctors, audiologists), nurses or technicians who have been trained in the proper use of the device.

2.3.2. CAUTIONS – GENERAL

CAUTION

If the system is not functioning properly, do not operate it until all necessary repairs are made and the unit is tested and calibrated for proper functioning in accordance with MedRx, Inc. specifications.

Do not drop or in any other way cause undue impact to this device. If the instrument is damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.

This product and its accessories will perform reliably only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and/or inserts. A defective product should not be used. Make sure all connections to external accessories are secured properly. Parts which may be broken or missing or are visibly worn, distorted, or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from MedRx Inc.

Equipment is not user repairable. Repairs must be performed by an authorised service representative only. No modifications of the equipment are allowed by anyone other than a qualified MedRx Inc. representative. Modification of the equipment could be hazardous.

Amplivox Ltd. will make available on request component part lists, descriptions, calibrations instructions, or other information that will assist authorised service personnel to repair those parts of this instrument that are designated by Amplivox Ltd. as repairable by service personnel.

No parts of the equipment can be serviced or maintained while in use with the patient.

Connect only accessories purchased from MedRx Inc. to the Otowave 302+. Only accessories which have been stated by MedRx Inc. to be compatible are allowed to be connected to the device.

To comply with the standards IEC 60601-1 for safety and IEC 60601-1-2 for electromagnetic compatibility (EMC) the tympanometer is designed to be used only with the medically-approved power supply supplied, which is specified as part of the equipment. Do not use any other type of power supply adapter with this instrument.

The output from the power supply is fitted with electronic circuit protection. In case of overload the adapter will shut down. When the fault is cleared the adapter will operate as normal. However, the input to the power supply is protected with a non-replaceable fuse. If this fails the adapter will not operate

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

2.3.3. ENVIRONMENTAL FACTORS

CAUTION

Use and store the instrument indoors only. It is recommended that the instrument be operated within an ambient temperature range of 15 °C / 59 °F to 35 °C / 95 °F and in relative humidity between 30 % and 90 % (non-condensing).

Do not use the device in the presence of fluid that can come into contact with any of the electronic components or wiring. Should the user suspect fluids have contacted the system components or accessories, the unit should not be used until deemed safe by an authorised service technician.

As with all instruments of this nature the measurements taken will be influenced by significant changes in altitude & pressure. The Otowave 302+ tympanometer must be re-calibrated if it is to be used at elevations greater than 1000m above mean sea level. This applies to volume measurements up to 2.0ml maximum. Please refer to the service manual for more information.

2.3.4. ELECTRICAL AND ELECTROSTATIC SAFETY

CAUTION

Before performing any service to the contra earphone or probe, you must remove them from the patient.

WARNING

Do not touch the contacts on the back of the instrument and the patient at the same time. The consequence could be a leakage current to the patient.

Do not open the case of the instrument. Refer servicing to qualified personnel.

This equipment is intended to be connected to other equipment thus forming a Medical Electrical System. External equipment intended for connection to signal input, signal output or other connectors must comply with the relevant product standard e.g. IEC 60950-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations – Medical Electrical Systems – must comply with the safety requirements stated in the general standard IEC 60601-1, (edition 3.1), clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 must be kept outside the patient environment i.e. at least 1.5m from the patient support or must be supplied via a separation transformer to reduce the leakage currents. Any person who connects external equipment to signal input, signal output or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with these requirements. If in doubt, contact a qualified medical technician or your local representative. When the instrument is connected to a PC, or other similar items, beware of not touching the PC and patient simultaneously.

A Separation Device (isolation device) is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. In particular a Separation Device is required when a network connection is made. The requirement for the Separation Device is defined in IEC 60601-1 clause 16.

Do not use any additional multiple socket-outlet or extension cord. **Use only the MedRx, Inc. Power Supply Adaptor.**

2.3.5. ELECTROMAGNETIC COMPATIBILITY (EMC)

CAUTION

Although the instrument fulfils the relevant EMC requirements, precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g., from mobile phones, etc. If the device is used adjacent to other equipment it must be observed that no mutual disturbance appears. Please also refer to the appendix regarding EMC.

2.3.6. EXPLOSION HAZARDS

WARNING

Risk of explosion.

Do not use in the presence of flammable anaesthetics or other gases.

Do NOT use in the presence of flammable gaseous mixtures. Users should consider the possibility of explosions or fire when using this device in close proximity to flammable aesthetic gases.

Do NOT use the Otowave 302+ in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc.

2.3.7. MEASURING ACCURACY

To guarantee that the Otowave 302+ works properly, the instrument should be checked and calibrated at least once a year. The transducers supplied with the tympanometer are specifically calibrated with it; if these transducers are changed recalibration will be required.

The service and calibration must be performed by an authorised service technician. If these checks are not performed, EU Medical Device Regulation (MDR) and other regulations may be violated, and warranties may be void.

The use of non-calibrated devices can lead to incorrect test results and is not advisable.

2.3.8. MISCELLANEOUS

Please note: DO NOT connect the Otowave 302+ hardware to the computer before the software has been installed.

Storage in temperatures below 0°C /32°F and above 50°C /122°F may cause permanent damage to the instrument and its accessories.

Do not place the instrument next to a heat source of any kind.

Great care should be exercised when handling transducers, as rough handling, for example dropping onto a hard surface may break or damage the parts.

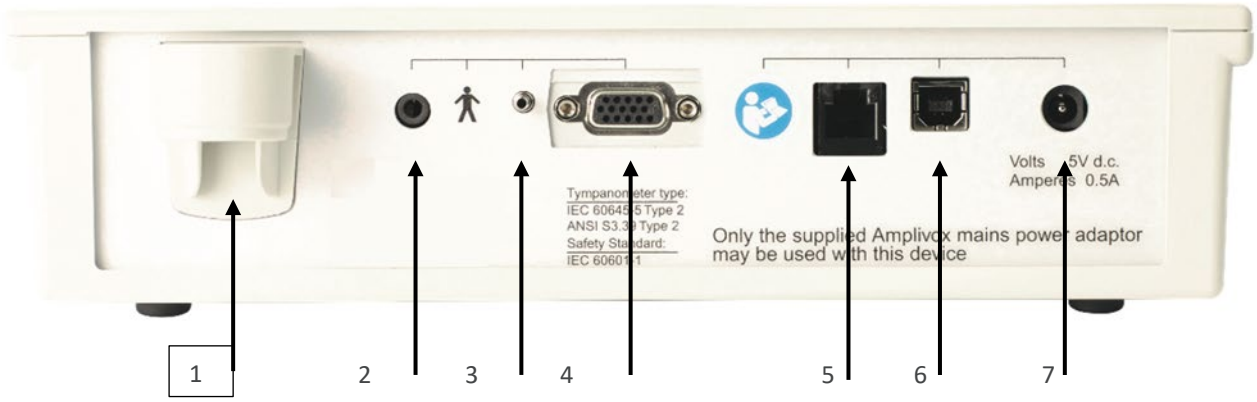
Within the European Union it is illegal to dispose of electrical and electronic waste as unsorted municipal waste. Electrical and electronic waste may contain hazardous substances and therefore must be disposed of separately. Such products will be marked with the crossed-out wheelie-bin image shown to the left. User cooperation is important in order to ensure a high level of reuse and recycling of electrical and electronic waste. Failure to recycle such waste products in an appropriate way may endanger the environment and consequently the health of human beings.
Outside the European Union, local regulations should be followed when disposing of the product after its end of life.

2.3.9. USE OF EQUIPMENT AFTER TRANSPORT AND STORAGE

Please make sure that the instrument is functioning correctly before use. If the instrument has been stored in a cold environment (even for short period of time), please allow the instrument to become acclimatised. This can take long time depending on the conditions (such as environmental humidity). You can reduce the condensation by storing the instrument in its original packaging. If the instrument is stored under warmer conditions than the actual use conditions no special precaution is required before use. Always ensure proper operation of the instrument by following routine check procedures for audiometric equipment.

2.4. CONNECTIONS

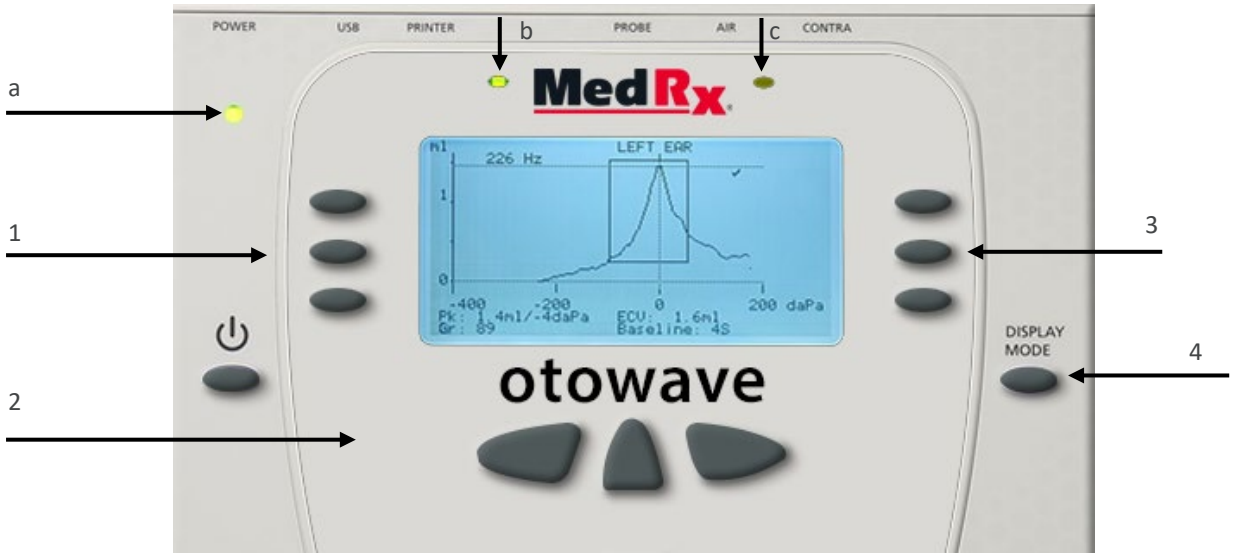
All connections are made to the rear panel of the tympanometer as shown below.



1	**Probe holder**	Holder to store probe while not in use	
2	**Contra phone**	Contralateral transducer	3.5mm jack
3	**Air channel**	Connection of probe (pressure)	Push-fit connector
4	**Probe**	Connection of probe (electrical)	15-way D connector
5	**Printer**	Connection of external printer	RJ12 socket (6-way)
6	**USB**	Connection for computer (via USB port)	USB Connector, Type B
7	**Power**	Mains AC/DC Adapter	2.5mm power jack

2.5. CONTROLS AND INDICATORS (BASE UNIT)

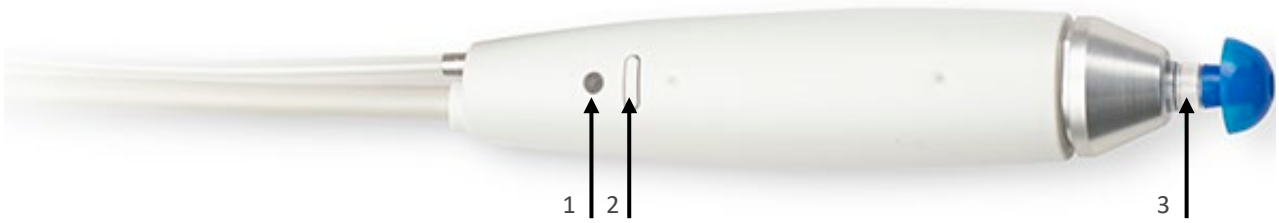
The Otowave 302+ consists of an LCD screen, buttons in groups to operate the instrument and three status LEDs.



a	**Power indicator LED**	Lights up as soon as the instrument is powered through the power supply (also when the instrument is switched off).
b	**Indicator LED**	Illuminates depending on functionality of the instrument
c	**Indicator LED**	Illuminates depending on functionality of the instrument
1	**On/Off switch**	Short press to switch on the device, long press to switch it off.
2	**Navigation keys**	• Press the up ▲ and down ▼ navigation keys to scroll through the menus or set values • Press the right navigation key ► to accept a menu choice or go to the next step. • Press the left navigation key ◄ to cancel an operation or go back to the previous step. • The function of the left and right keys is usually shown on the bottom line of the display.
3	**Soft keys**	Use the softkeys S1 to S6 to operate the instrument. Each key is associated with the corresponding line in the display.
4	**Display Mode**	Quick view of the test settings currently used or change of baseline mode.

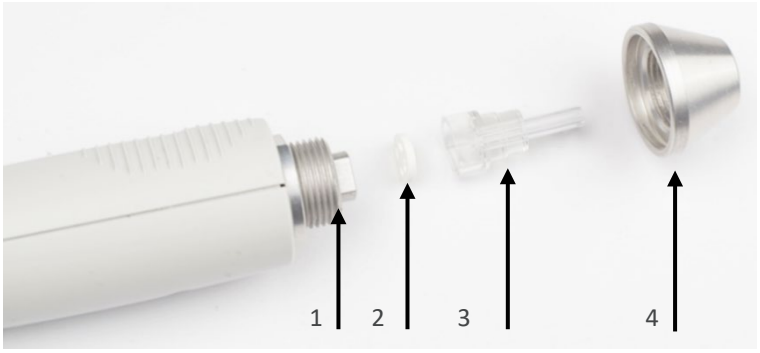
2.6. THE PROBE

2.6.1. CONTROLS AND INDICATORS (PROBE)



1	**Indicator light**	Illuminates depending on functionality of the instrument
2	**Function button**	Quick view of the test settings currently used or change of baseline mode.
3	**Probe tip with ear tip**	

2.6.2. THE PROBE HEAD



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

The small holes through the Otowave 302+ probe tip must be kept clear. If these become blocked a warning message will be displayed. The probe tip must be removed and 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.

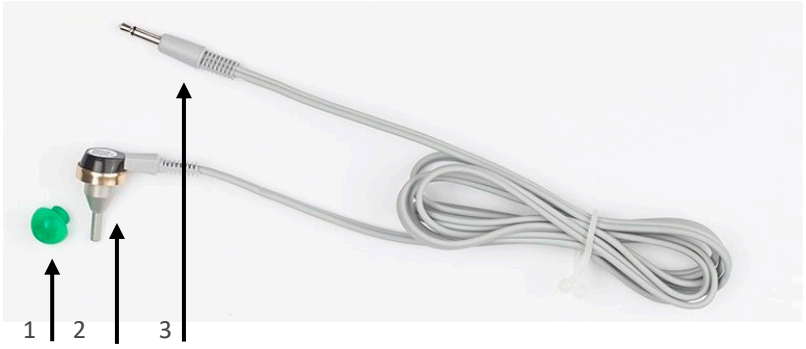
After replacing the tip, a ‘Daily Check’ should be carried out.

2.7. LIGHT INDICATORS

The indicators on the Otowave 302+ and the probe show the status of the system.

STATUS	LED B	LED C	PROBE
Otowave 302+ turned off	Off	Off	Off
Idle, test completed or test cancelled	On	Off	Green on
Insert probe or remove probe (refer to display for details)	Flashing (fast)	Flashing (fast)	Colour alternating (Green / Yellow)
Ensure probe is held steady while an ear seal is obtained	Off	Flashing (slow)	Yellow flashing (slow)
Testing - tympanogram and/or reflex measurement	Flashing (slow)	Off	Green flashing (slow)

2.8. CONTRALATERAL TRANSDUCER



1	**Ear tip**	Ear tip to be placed on probe tip of contra phone
2	**Probe tip**	Probe tip screwed onto contra phone
3	**Plug**	Connector to **CONTRA** socket on Otowave 302+

The contralateral transducer is used when it is required to provide a reflex stimulus to the opposite ear to that being tested with the main probe assembly. For use it should be connected to the **CONTRA** socket on the base unit and fitted with a new ear tip.

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

2.9. CHOOSING THE CORRECT EAR TIP SIZE

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

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

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

The small holes through the Otowave 302+ probe tip must be kept clear. If these become blocked a warning message will be displayed. The probe tip must be removed and replaced.

2.10. HARDWARE INSTALLATION

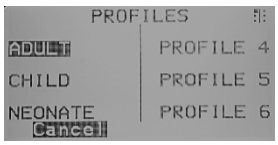
The instrument is shipped with the probe attached to the Otowave 302+. The instrument is designed for continuous operation and is powered by a power supply. Connect the output lead from the adapter into the **POWER** input socket on the back of the Otowave 302+. When powered the **Power indicator (LED a)** on the Otowave 302+ will illuminate green, showing that the instrument is ready for use.

If performing contralateral reflex testing, connect the transducer to the **CONTRA socket (2)** on the base unit of the Otowave 302+.

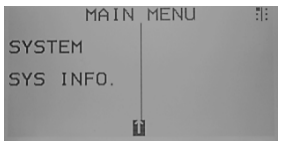
2.11. INITIAL SETTINGS

2.11.1. OPERATING LANGUAGE

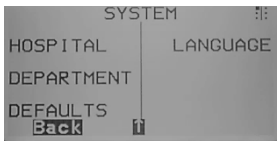
The instrument will be set in English by default. To change the operating language (English, German, French, Spanish, Portuguese or Italian) ensure you start from the **MAIN MENU.**



PROFILES
Select S1 to access Profile 1.



MAIN MENU
Select down ▼ 1x.
Select S1 to access the **SYSTEM**.
Select down ▼ 1x.
Select S4.



LANGUAGE
Select S1 to S6 to select another language.

2.11.2. DATE AND TIME

The Otowave 302+ 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.

2.12. THE MPT-II PRINTER

2.12.1. INSTALLING THE MPT-II PRINTER

The Sanibel MPT-II thermal printer is available as an option for use with the Otowave 302+ and is connected using the cable supplied. The printer may be specified when ordering and only this printer should be used. It will be correctly configured for use. Upon receipt of the printer it must be initially charged for a minimum of 15 hours prior to use.

1. Open the lid by pushing on the sides, insert paper roll as shown, and close the lid.

2. Insert the battery.

2.12.2. SWITCHING THE PRINTER ON AND OFF

Push POWER BUTTON for two seconds in order to power ON or OFF. One short beep will be heard at power ON, two short beeps at power OFF.

The green power indicator will be lit if the printer is powered by battery.

2.12.3. USING THE PRINTER

Printer self-test: While printer is powered **OFF**, press and hold **PAPER FEED** button, then press and hold **POWER BUTTON** simultaneously. When beep is heard after approx. 3 seconds, release both buttons, and a test page will print with information on current status and character samples.

Paper feed: When powered, press **PAPER FEED** button. Paper will feed as long as the button is pressed.

Connecting process:

- Connect the printer via the cable with the device
- Power on printer
- Select print option in the Otowave 302+

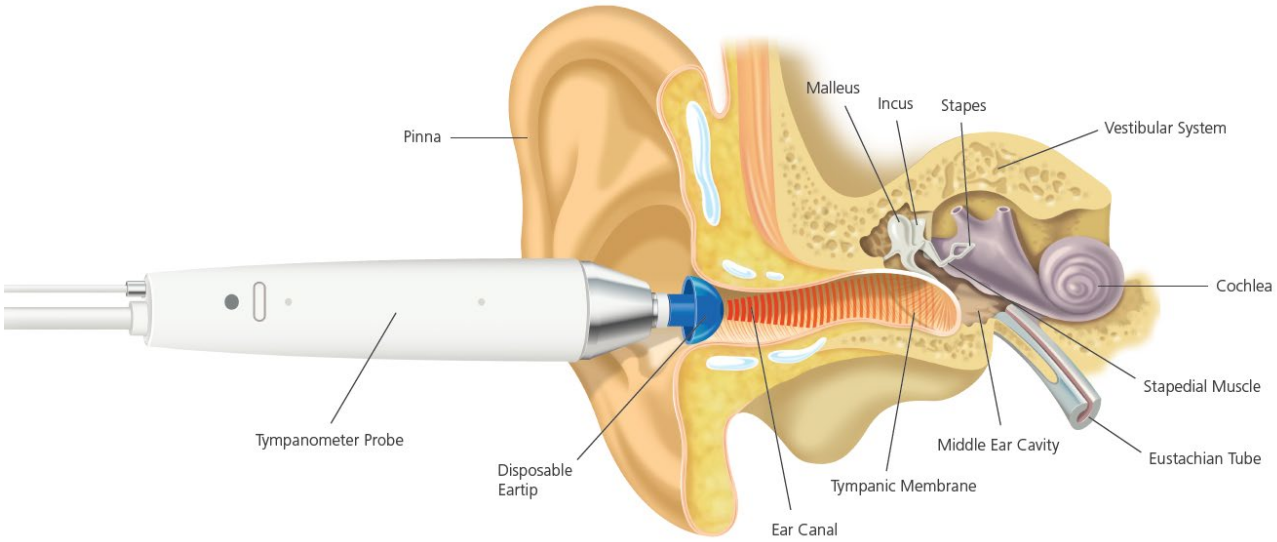
3. PRINCIPLES OF OPERATION

3.1. OTOSCOPIC EXAMINATION

A qualified health care professional should perform a thorough otoscopic examination to establish that the condition of the ear is suitable for the test options selected and that no contraindications are present. The latter would include obstruction of the external ear canal due to excessive wax and/or hairs, both of which would need to be removed. This is required to ensure that the probe tone delivered by the probe is able to reach the ear drum and is not reflected by cerumen or debris and thereby alter the test result.

3.2. PRINCIPALS OF ADMITTANCE MEASUREMENT

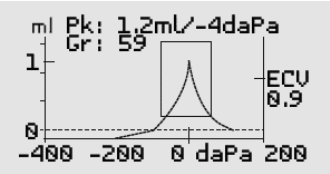
The Otowave 302+ measures the admittance of the tympanic membrane and middle ear by playing a continuous tone into the ear canal at either 226 Hz or 1000 Hz. The level of this tone is calibrated to give 85 dB SPL (226 Hz) or 79 dB SPL (1000 Hz) into a 2 ml cavity. The sound level this produces in the ear canal is measured using a microphone and the admittance calculated from the result.



In line with normal audiometric practice admittance is displayed as an equivalent volume of air in ml (for 226 Hz) or mmho/m℧ (for 1000 Hz). The residual ear canal volume between the probe and the tympanic membrane is always displayed in ml; when using a 1000 Hz probe tone the measured value in mmho is converted to ml using a conversion factor of 226/1000.

3.3. TYMPANOGRAM

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



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

3.4. ACOUSTIC REFLEX MEASUREMENT

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

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

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

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

4. USING THE OTOWAVE 302+

4.1. GENERAL PRECAUTIONS

When operating the instrument, please observe the following general precautions:

CAUTION

1. Use this device only as described in this manual.
2. Use only the disposable ear tips designed for use with this instrument.
3. Always use a new ear tip for each patient to avoid cross-contamination. The ear tips are not designed for reuse.
4. Never insert the probe tip into the ear canal without fitting an ear tip as omission may damage the patient's ear canal.
5. Keep the box of ear tips out of the reach of the patient.
6. Be sure to insert the probe tip in a way which will ensure a tight fit without causing any harm to the patient. Use of a correct and clean ear tip is mandatory.
7. Be sure to use only stimulation intensities acceptable to the patient. When presenting contralateral stimuli using the insert phones – do not insert the phones or in any way try to conduct measurements, without a correct insert ear tip in place.
8. Clean the probe and contra earphone regularly using a recognized disinfectant.
9. Check the probe tip regularly to ensure wax or other debris stuck in the probe tip does not affect the measurement. Replace if required.
10. Contraindications to testing include recent stapedectomy or middle ear surgery, a discharging ear, acute external auditory canal trauma, discomfort (eg. severe otitis externa) or occlusion of the external auditory canal. Testing should not be performed on patients with such symptoms without a medical doctor's approval.
11. The presence of tinnitus, hyperacusis or other sensitivity to loud sounds may contraindicate testing when high intensity stimuli are used.

Careful handling of the instrument whenever in contact with a patient should be given high priority.

1. Never clean the transducer housing with water or insert non-specified instruments into the transducer.
2. Do not drop and avoid other undue impact to this device. If the instrument is dropped or in any other way damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.

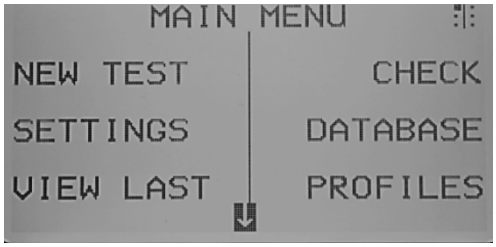
4.2. SWITCHING THE INSTRUMENT ON AND OFF

Select the on/off button for 1 second to switch the instrument on. You will see a small hourglass in the middle of the display indicating that the instrument is powering on. 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 the instrument off again, hold the button for approx. 2 seconds and the instrument and LED b will turn off.

Please note: The power indicator (LED a) will be illuminated as long as the instrument is connected to the mains.

4.3. MENU DISPLAYS



From the **MAIN MENU**, you can reach different submenus. Use the navigation keys (up ▲ and down ▼) or the Softkeys (S1 to S6) to navigate the options and select submenus.

To be brought one menu back, push the left navigation key ◄.

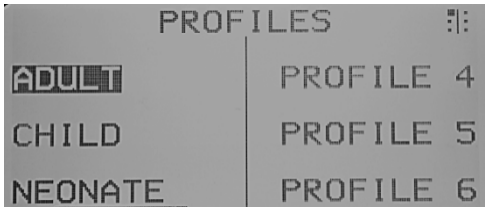
The following submenus can be reached from the **MAIN MENU**:

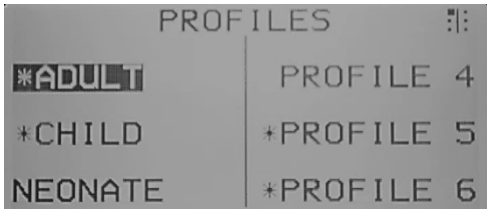
- New Test
- Settings
- View last (test)
- Check (Daily Check)
- Database
- Profiles
- System
- Sys. Info (System Information)

4.4. PROFILE STRUCTURE

4.4.1. GENERAL

The Otowave 302+ offers the possibility of creating and customising profiles. In total, 6 profiles are available.





By default, the Otowave 302+ comes with 3 pre-defined profiles offering the ideal test settings for either adults, children or nenoates. It is possible to change these 3 factory profiles and in addition 3 further profiles can be defined by the user.

When marked with a *, the profil has been modified.

PROFILE	TEST SETTINGS
Adult:	Tympanometry: 226 Hz, 200 daPa/s speed Ipsilateral Reflexes: always measure, 0.5, 1, 2 kHz (Multilevel, 100 dB in 5 dB steps, autostop enabled, 0.03 ml threshold) Contralateral Reflexes: Disabled
Child:	Tympanometry: 226 Hz, 200 daPa/s speed Ipsilateral Reflexes: only measure when peak found, 0.5, 1, 2 kHz (Multilevel, 100 dB in 5 dB steps, autostop enabled, 0.03 ml threshold) Contralateral Reflexes: Disabled
Neonate:	Tympanometry: 1000 Hz, 300 daPa/s speed Ipsilateral Reflexes: only measure when peak found, 0.5, 1, 2, 4 kHz (Multilevel, 5 dB steps to 100 dB, autostop enabled, 0.02 ml threshold) Contralateral Reflexes: Disabled

4.4.2. CHANGING PROFILES

When the start-up sequence is complete the **PROFILE** selection screen is displayed. Select a profile to be brought to the **MAIN MENU.**

Please note: Profiles can be swapped at any point, selecting S6 in the **MAIN MENU**.

The current selected profile can be identified by the profile icon in the upper right corner in the display.

Please note: An inverted profile selection icon indicates that the soft keys are currently disabled.

Profile 1 (Adult)

Profile 2 (Child)

Profile 3 (Neonate)

Profile 4

Profile 5

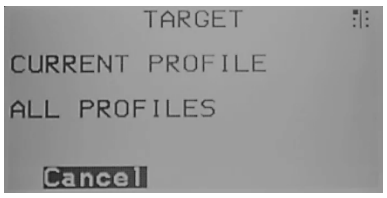
Profile 6

4.4.3. COPY PROFILE SETTINGS FROM ONE TO ANOTHER

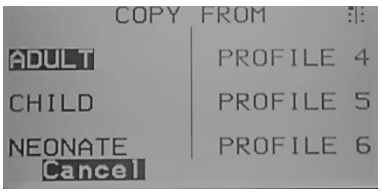
In order to transfer test settings from one profile to another, use the **COPY** function. It is important to note that individual settings can be copied (e.g. only the tympanometry or only the reflex settings) or a complete profile with all its settings.

COPY ALL SETTINGS (SWEEP + REFLEX)

1.) To overwrite all settings, access the **COPY** function from the **MAIN SETTINGS** and select '**COPY SWEEP+REFLEX**'.

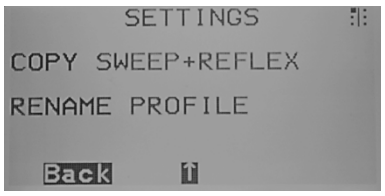


2.) Choose the profile you want to overwrite: the current selected one or all available profiles.

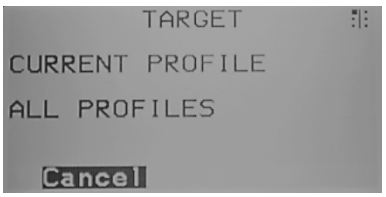


3.) Select the profile you want to copy the settings from. Confirm the overwriting afterwards.

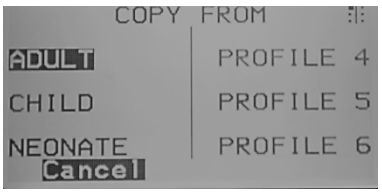
COPY ONLY 1 SETTING (SWEEP OR REFLEX)



1.) To overwrite just one setting, access the sweep or reflex settings. You will find the **COPY** function.



2.) Choose the profile you want to overwrite: either the current selected one or all profiles.

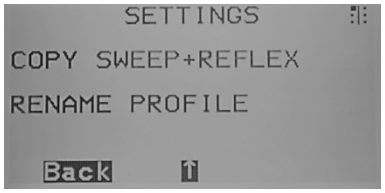


3.) Select the profile you want to copy the settings from. After selection, confirm the overwrite.

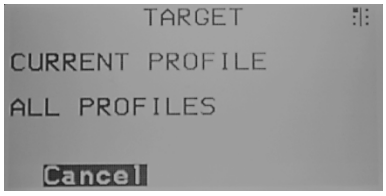
4.4.4. RESET PROFILE SETTINGS TO FACTORY DEFAULT

In order to reset test settings in one profile or all, use the **DEFAULT** function. It is important to note that individual settings can be reset (e.g. only the tympanometry or only the reflex settings) or a complete profile with all its settings.

RESET ALL PROFILE SETTINGS BACK TO FACTORY DEFAULT



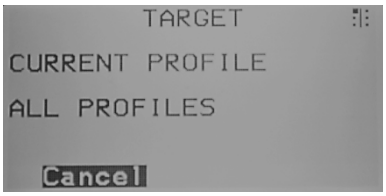
1.) To overwrite all settings, access the **DEFAULT** function from the **MAIN SETTINGS** and select '**DEFAULT SWEEP+REFLEX**'.



2.) Choose the profile you want to reset: the current selected one or all available profiles. After selection, confirm the overwrite.

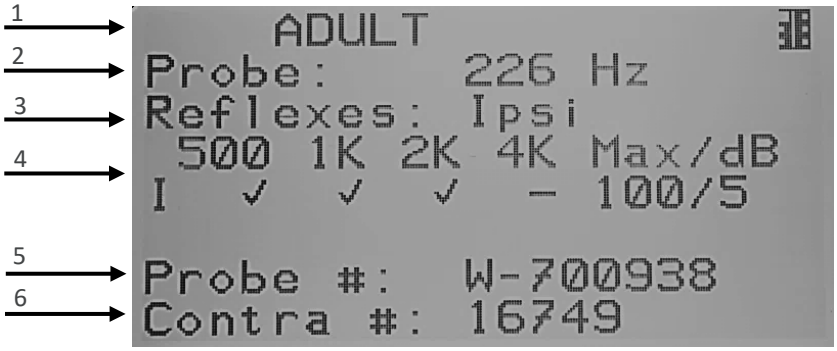
RESET ONLY 1 SETTING (SWEEP OR REFLEX)

1. **1.)** To reset just one setting, access the sweep or reflex settings. In there you will find a **DEFAULT** function.
2. **2.)** Choose the profile you want to reset: the current selected one or all available profiles. After selection, confirm the overwrite.



4.4.5. DISPLAY MODE

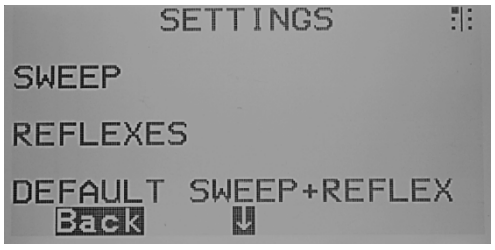
To view the current selected profile, ensure that the **MAIN MENU** is displayed and then press and hold the function button on the probe to display the **TEST SETTINGS** screen as shown below.



1	**Profile:**	Current selected Profile
2	**Probe:**	Frequency being used for tympanometry (226 or 1000 Hz).
3	**Reflexes:**	Reflexes tested (ipsilateral or contralateral or both).
4	**Frequencies and Level:**	Selected frequencies for reflex testing (marked with a ✔ when selected), max. level to test and step size.
5	**Probe #:**	Serial number of probe used.
6	**Contra #:**	Serial number of contra phone calibrated to equipment.

4.5. TEST SETTINGS

4.5.1. GENERAL



The **SETTINGS SUBMENU** contains the following settings:

- **Sweep** Settings (Tympanometry only)
- **Reflex** Settings (Acoustic reflex only)
- **Default Sweep + Reflex**
- **Copy Sweep + Reflex** Function (Profiles)
- **Rename Profile**

When selecting one of the sub settings, the target profile is required to be selected first in order to define if the **CURRENT** profile shall be changed or **ALL PROFILES**.

Please note: Selecting **ALL PROFILES** will overwrite the particular chosen setting for all profiles available in the instrument.

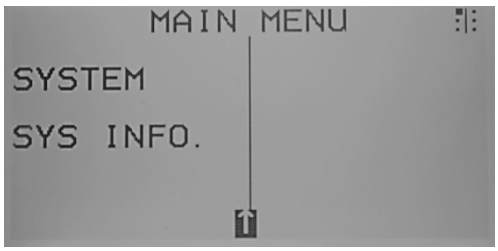
4.5.2. SWEEP SETTINGS

ITEM	DESCRIPTION	DEFAULT(ADULT)
Speed:	The rate of change of air pressure may be selected to be 100daPa/s 200daPa/s or 300daPa/s. This determines the time taken for a pressure sweep from +200 to -400 daPa (6, 3 and 2 seconds, respectively).	200 daPa/s
Probe Freq:	The probe tone frequency may be set to 226Hz or 1000Hz.	226 Hz
Baseline:	The Otowave 302+ can display tympanograms in a variety of graphical formats allowing the operator to choose the most appropriate for the patient under examination. **Please refer to the appendix for further information on how to use the Baseline mode.**	+200daPa Scalar(2S)
Sequence:	Define the order in which the ears are to be tested when **BOTH** ears are to be tested in one session.	Right - Left
Ear Seal:	The **STANDARD** option is adequate for most tests, although it may not always be possible to generate the extremes of pressure during a tympanogram measurement with this setting. If difficulty is experienced in using the ear tips to create a seal the alternative **EXTENDED** option may be helpful. This function checks that a range of pressures will be available before starting a test by means of a visual indication of the quality of the seal. The **EXTENDED** function is especially helpful if small ear canal volumes should not experience excessive pressure.	Standard
Defaults:	Reset the sweep settings of the selected profile(s) to its original settings.	
Copy:	Overwrite the sweep settings of your current profile from one of the other 5 profiles. Refer to section 4.4.3 for further information about the **Copy** function.	

4.5.3. REFLEX SETTINGS

ITEM	DESCRIPTION	DEFAULT(ADULT)
Level Mode:	**ONE LEVEL** will only test one single level at the selected frequencies. **MULTILEVEL** will run a threshold reflex test, testing at several levels.	Multilevel
Sequence:	Choose the type of reflex stimulus: ipsilateral only, ipsilateral followed by contralateral or contralateral only.	Ipsi
Levels:	Choose ipsilateral or contralateral and press the ► key to confirm the selection. **Please note:** Depending on the **LEVEL MODE** selection, the **LEVELS** screen will contain different content. **ONE LEVEL:** Use the S keys to choose the level of reflex stimulus to apply. Only one level will be tested in the measurement. The maximum level of ipsilateral stimulus may be set to maximum 100dBHL; the maximum level of contralateral stimulus may be set to 110dBHL. **MULTILEVEL:** Use the S keys to choose the maximum level of reflex stimulus to apply and the step size between the levels of the preceding stimuli. The maximum level of ipsilateral stimulus may be set between 85dBHL and 100dBHL; the maximum level of contralateral stimulus may be set between 85dBHL and 110dBHL.	100 dB 5 dB steps
Freqs:	Use the ▼ key to scroll through the frequencies available for each of the ipsilateral and contralateral stimuli (500Hz, 1000Hz, 2000Hz & 4000Hz), and then the ▲ key to select (✓) or deselect (-) the frequencies at which the reflex stimulus is to be applied. Then press ► to save the entire selection.	500, 1K, 2K, 4K Hz ipsi
Selection:	Select the circumstances when a reflex measurement is to be made (always, never, only if an admittance peak is found, or only after confirmation is made at the start of the test sequence). In cases where an admittance peak has not been established a pressure of 0daPa is used.	Always
Threshold:	Choose the change in admittance required to signify that a reflex response has been detected (0.01ml to 0.5ml).	0.03 ml
Auto-Stop:	By default, the reflex test at each frequency will stop at the lowest level of stimulus that produces a response. By setting Reflex Auto-Stop to **NO** the Otowave 302+ will test for a reflex at all selected levels.	Yes
Polarity:	Define the polarity of the reflex graphs, if the reflex is plotted upwards (**UP**) or downwards (**DOWN**).	Down
Filter:	Select either 2Hz or 1.5Hz. 2Hz is suitable for most circumstances. If a smoother reflex plot is required for better interpretation 1.5Hz may be selected.	2 Hz
Defaults:	Reset the reflex settings of the selected profile(s) to its original settings.	
Copy:	Overwrite the sweep settings of your current profile from one of the other 5 profiles. Refer to section 4.4.3 for further information about the **Copy** function.	

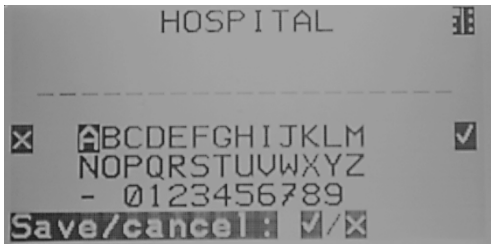
4.6. SYSTEM SETTINGS



Access the system settings from the **HOME** screen.

ITEM	DESCRIPTION	DEFAULT
Time/Date:	Set the internal clock date and time. Use the ◄ and ► keys to select a field and the ▲ and ▼ keys to adjust the value.	
Low Power:	Adjust the time when the device goes into energy saving mode (0, 30, 60 s) using the ▲ and ▼ keys.	0
Contrast:	Adjust the display contrast using the ▲ and ▼ keys.	
Brightness:	Adjust the display brightness using the ▲ and ▼ keys.	
Cal. Dates:	Select **PRINT CAL. DATES** to show the calibration dates on the print-out provided by the thermal printer.	PRINT CAL. Dates
Date Mode:	Set the format of how the date is displayed: DD/MM/YY or MM/DD/YY	DD/MM/YY
Hospital:	Allows the Hospital name to be entered. The name will appear at the top of the print-out.	
Department:	Allows the Department name to be entered. The name will appear at the top of the print-out.	
Defaults:	Reset the instrument and all profiles to the original settings.	
Language:	Change the operation language to English, German, French, Spanish, Portuguese or Italian. **Please note:** When changing the language, the profile names will default to English.	

Data entry of Hospital Name and Department:



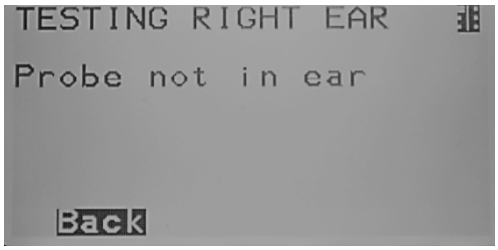
To enter the data use the ▲ ▼ ◄ and ► keys to select a character. Press and hold the ► key to enter the selected character. To delete the last character, press and hold the ◄ key.

In order to save the entry, press S4 (a). The selection will now be stored.

To cancel the entry, press S2 (**x**). You will be brought back to the **SYSTEM SETTINGS.**

4.7. DAILY) CHECK

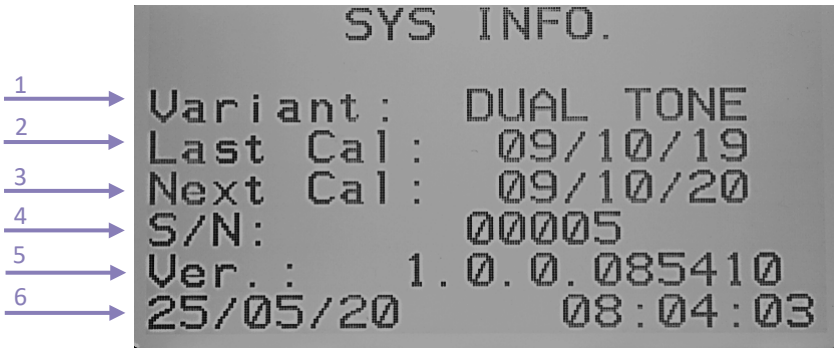
The operation of the Otowave 302+ should be checked daily using the 4-in-1-test cavity assembly supplied with the instrument.



Select the **DAILY CHECK** option in the main menu and wait until **INSERT PROBE** is displayed.
Insert the probe, without an ear tip, into any of the holes 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.
Remove the probe, wait until **INSERT PROBE** is displayed and repeat the test with the three remaining holes.
The display should show the volume for the **0.2 ml, 0.5 ml & 2.0 ml** test cavities to within ± 0.1 ml.
The volume of the **5.0 ml** test cavity should be shown within ± 0.25 ml.

When the checks have been completed press ◄ to return to the main menu.

4.8. SYSTEM INFORMATION

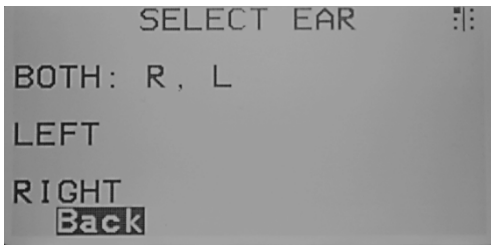


1	**Variant:**	Instrument version (Dual Tone = High Frequency option)
2	**Last Cal:**	Last calibration date
3	**Next Cal:**	Next calibration date
4	**Serial No:**	Serial number of Otowave 302+
5	**Ver.:**	Firmware version
6	**Date and Time:**	User defined date and time

4.9. PERFORMING A TEST

4.9.1. SELECTING THE EAR SIDE

Having selected the required test settings a typical tympanogram measurement and reflex tests are carried out as follows. Select **NEW TEST** by pushing S1.



Select the ear(s) required for test (**BOTH** signifies **LEFT** followed by **RIGHT**), using S1, S2 or S3.

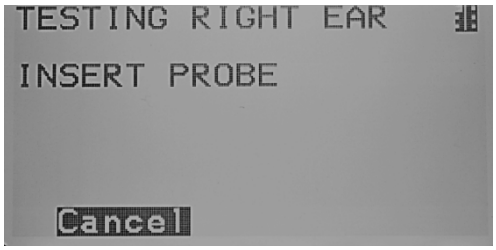
Selecting the ear will start the test procedure.

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

Please note: Continuing with the test procedure will delete the last recorded test results, stored in the short-term memory of the instrument.

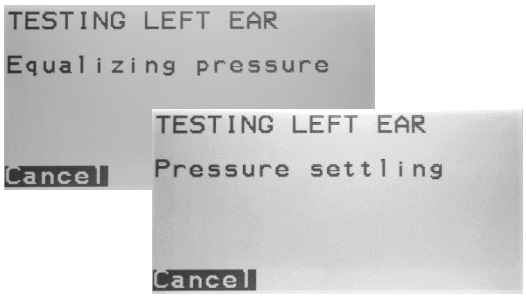
4.9.2. PERFORMING TYMPANOMETRY

Depending on the protocol selected, the test sequence will perform both tympanometry and acoustic reflex testing in one run without removing the probe.



An instruction on the screen will guide you through the test sequence. The test will start automatically by inserting the probe into the patient's ear.

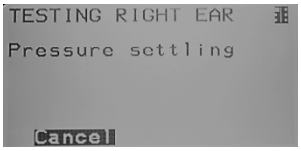
Insert the probe into the test ear, the indicator LED b and c on the device will flash alternatively, as well as the indicator light on the probe which will alternate colour from yellow to green.



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.

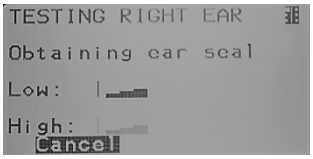
TROUBLESHOOTING:
In rare cases, no seal can be established and the test sequence will stay in the **EQUALIZE PRESSURE SCREEN**. This situation can occur for several reasons. Solution to this issue can be found in the **TROUBLESHOOTING SECTION**.

STANDARD EAR SEAL CHECK



The default **STANDARD** option only shows if a seal could be obtained.

EXTENDED EAR SEAL CHECK



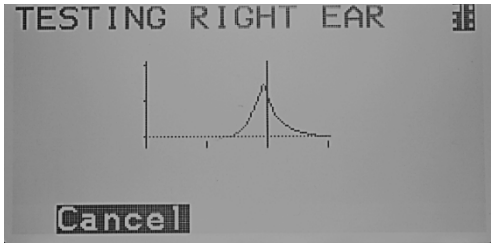
The **EXTENDED EAR SEAL CHECK** shows a number of bars indicating the level of the seal.

The probe should be adjusted in the ear until two or more bars are shown for **LOW** and **HIGH**.

LOW: The pump is moved by a fixed distance in an attempt to reduce the pressure in the ear and is held in that position. If the measured pressure reduces by a minimum amount, and remains low (within present tolerances), the seal is considered OK.

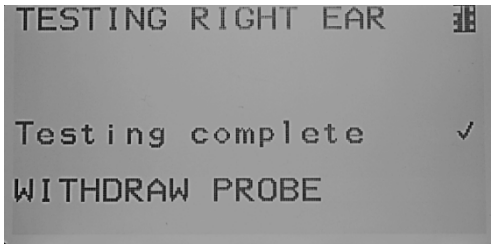
HIGH: The process is repeated, at a pressure higher than ambient. Otherwise, the process restarts. If the higher pressure is sufficiently above the ambient pressure, and is held, the seal is good, and the pump goes just above the starting pressure

The method used for the extended ear seal check places a maximum limit on the ear canal volume of ~4.5 ml.

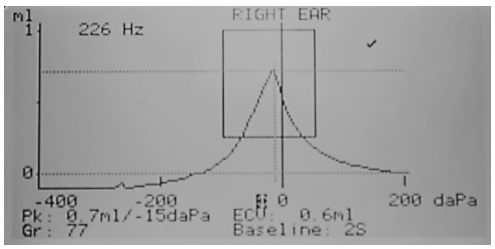


As soon as the pressure can be established, the tympanometry measurement will be performed. On screen, you can follow the real-time tympanogram.

During the actual testing phase, the indicator **LED b** on the device and the indicator light on the probe will pulse green.



When the test sequence is completed, **LED b** on the device and the indicator light on the probe will be a solid green colour. Also, the instruction on the screen will ask you to remove the probe from the patient's ear.



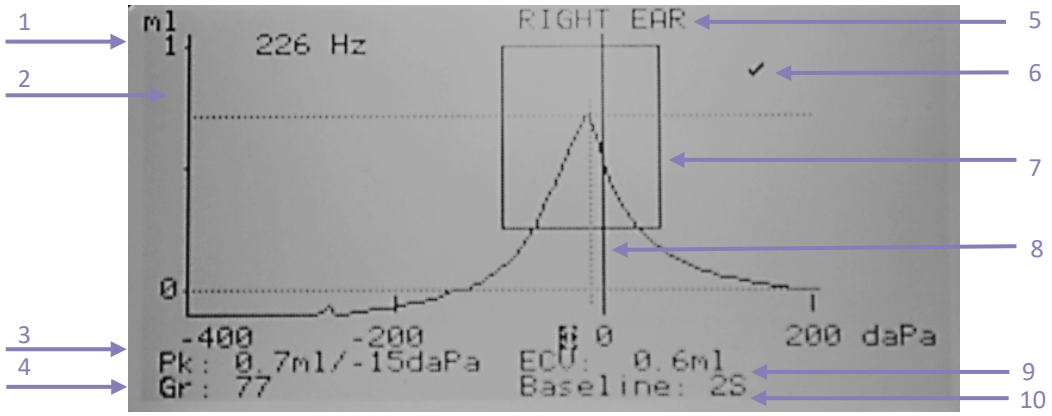
As soon as the probe is removed from the ear, the test result for the ear measured will be displayed on the screen.

Please note: If **BOTH EARS** had been selected to be tested, the test on the other ear will be performed after the test review screen. Selecting the right navigation key ► will start the test procedure on the other ear.

Selecting ◄ will cancel the procedure and return to the ear selection menu.

After the test has been successfully performed, three different options (print, store, review) can be taken. Selecting the right navigation key ► will bring you to the **PROCESS RESULTS** screen from where the data can be printed, stored or reviewed again.

4.9.3. UNDERSTANDING THE TYMPANOMETRY TEST RESULT



1 y-axis label, in ml for 226 Hz and mmho for 1000 Hz.

2 y-axis, ranging from 0 to 1 ml in this example.

3 x-axis, default baseline offset, ranging from -400 daPa to +200daPa in this example.

4 Values defining compliance curve based on cursor position and the Baseline Mode

- Pk (Peak): Volume in ml or mmho, pressure in daPa
- Gr (Gradient): Width of compliance curve at half of peak compliance in daPa

5 Ear side, L for left and R for right.

6 Pass/ Refer sign

7 Normative box (not available for 1000 Hz tympanometry).

8 Pressure cursor to be operated with up ▲ and down ▼ navigation keys.

9 The Ear Canal Volume (ECV) in ml measured at the Baseline Mode.

10 Baseline Mode to show tympanogram

- **226 Hz:** Y-only compensation, 2S or 4S mode (scalar mode).
- **1000 Hz:** Y-only compensation 2S and 4S mode, B-G compensation 2V and 4V (vector mode), admittance (Y) or susceptance (B) or conductance (G) view.

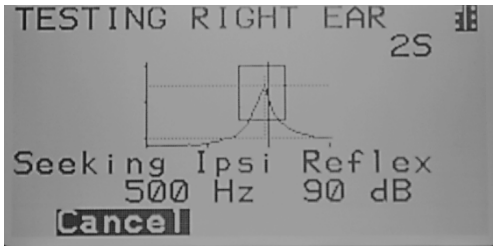
The view is changed with either the **Display Mode** (base unit) or the **Function button** (probe).

Please refer to the Appendix to read more about the Baseline Mode.

4.9.4. PERFORMING TYMPANOMETRY AND ACOUSTIC REFLEX TESTING

Before starting an acoustic reflex test, a tympanogram is performed so that the ear canal pressure will be set to the value that gave the peak admittance. The tympanometry measurement is performed the same way as described in section 4.9.2. The tympanogram will be followed immediately by an acoustic reflex test.

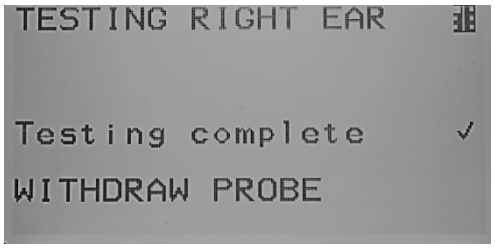
By default, the acoustic reflex testing is only performed if a peak is found in the tympanogram. This setting can be changed in the **SETTINGS** menu.



The acoustic reflex test screen consists of the preview of the measured tympanogram. Underneath the graph, the tested ear, the test frequency and intensity are listed. The reflex test starts with the lowest frequency and level selected.

The instrument will then step through the tone frequencies and levels set in the **SETTINGS** menu searching for a reflex response.

Please note: If contralateral testing is enabled, the ipsilateral reflexes are tested first.

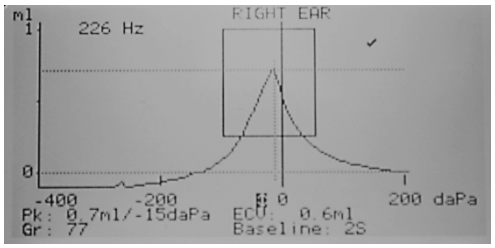


When the measurement is complete the indicator on the probe changes from flashing green to solid green. The display confirms that the test has been completed along with the instruction **WITHDRAW PROBE.**

After the test has been successfully performed, three different actions can be taken. Selecting the right navigation key ► takes you to **PROCESS RESULTS** screen so that the data can be printed, stored or reviewed again.

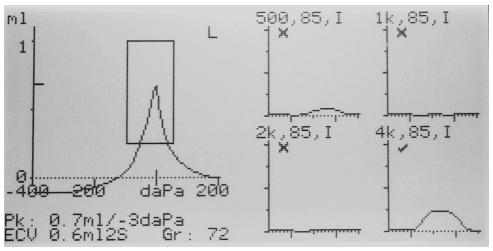
4.9.5. UNDERSTANDING THE ACOUSTIC REFLEX TEST RESULT

The navigation key ► and ◄ are required to navigate in the reflex result screens.



The acoustic reflex result screens will always start to show the tympanogram first.

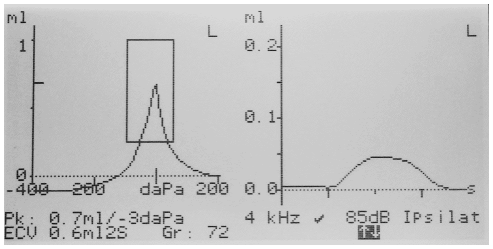
Selecting the navigation key ► will minimise the tympanogram and also show the reflex (combined view).



The combined view shows a smaller tympanogram and the measured reflexes for either the threshold measured or the loudest intensity presented, if no threshold could be found.

Selecting the navigation key ◄ will show the full tympanogram view again. Selecting the right navigation key ► will show the reflex measurements in more detail, depending on the **REFLEX AUTOSTOP** function.

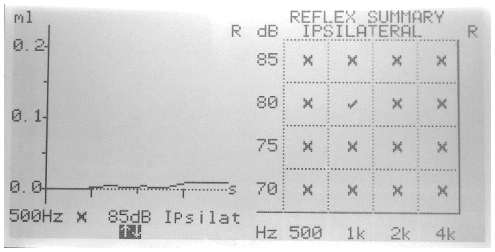
REFLEX AUTOSTOP ON



If Reflex autostop has been selected the tympanogram remains on the left hand side of the screen with a larger scale trace of the reflex at the lowest selected frequency with the lowest level that gave a response.

Select the ▲ ▼ keys to scroll through the different frequencies.

REFLEX AUTOSTOP OFF

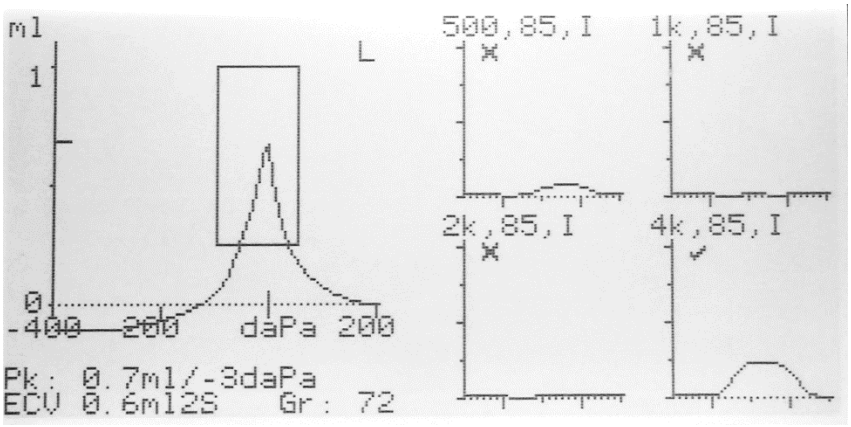


If Reflex autostop has not been selected the larger scale trace of the reflex at the lowest frequency with the lowest level that gave a response is shown on the left hand side of the screen.

A summary of the levels and frequencies at which a reflex tone was presented is shown on the right hand side of the screen along with the result of the test ("✓" if a reflex was found, otherwise "**X**"). The dash symbol "**-**" is shown if a reflex tone was not presented at the level indicated.

Selecting the navigation key ◄ will show the four frequencies again. Selecting the navigation key ► will show the **PROCESS RESULTS** screen, from where the measurement results can be processed.

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



1 Tympanogram on the left-hand side and the four reflex traces shown on the right.

2 Ear side, L for left and R for right.

3 Values defining compliance curve based on cursor position and the Baseline Mode

- Pk (Peak): Volume in ml or mmho, pressure in daPa
- The Ear Canal Volume (ECV) in ml measured at the Baseline Mode
- Gr (Gradient): Width of compliance curve at half of peak compliance in daPa

4 Four reflex traces, containing frequency of the reflex stimulus, lowest level of tone (dBHL) at which a reflex was found, and the type of reflex stimulus used (I for ipsilateral, C for contralateral).

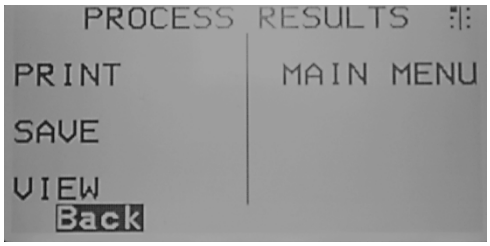
5 Graphiical display of reflex. To view the reflex traces in more detail press ▶. One of two displays will then be shown depending on whether or not Reflex autostop has been selected.

- **Single frequency used:** Diagrams contain the different levels tested for the specific frequency.
- **Several frequencies used:** each diagram represents 1 frequency, showing only the intensity where a reflex was detected.

6 "✓" if a reflex was found, otherwise "**X**".

4.9.6. GENERAL

After a test has been finished, the data can be printed and/or stored to the internal database of the instrument or transferred to NOAH or MedRx Studio software.



From the test result screen select the right navigation key ► until the **PROCESS RESULTS** screen is reached.

From here the following options are given:

- Print the current record (S1)
- Save the current record (S2)
- View the record again (S3)
- Return to the **MAIN MENU** (S4)

To return to previous screen, push the left navigation key ◄.

4.9.7. SENDING RESULTS TO A PRINTER

To print the results of the last test select **SEND TO PRINTER** from the **PROCESS RESULTS** menu on completion of the test. The printing process must be confirmed by pressing **SELECT** again. The Otowave 302+ will then attempt to connect to the printer.

To stop the print operation (for example if a printer is not connected) press ◄ to select Cancel.

The printout consists of the three characters printed in the **NAME** field followed by the Otowave 302+ graphical displays, the analysis and the results. There is space for additional details to be handwritten by the clinician (patient's full name/age, operator & comments). Also, the name of the hospital, the department, and the calibration dates for the instrument may also be printed if required (refer to section 4.6).
After successful printing the **PROCESS RESULTS** menu is displayed.

- When printing one test result, the printout will contain the last selected baseline mode.
- When printing several test results, the printout will contain the stored baseline mode.
- Thermal paper printouts can fade with exposure to light or heat. Consider transferring the data to a computer for permanent storage.

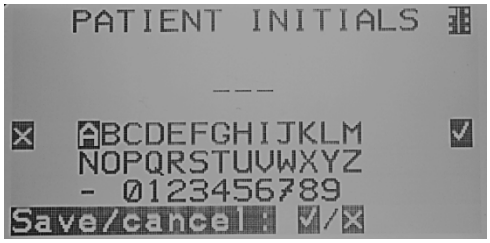
4.9.8. SAVING RESULTS TO THE INTERNAL DATABASE

Up to 36 tests can be stored in the Otowave 302+ 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.

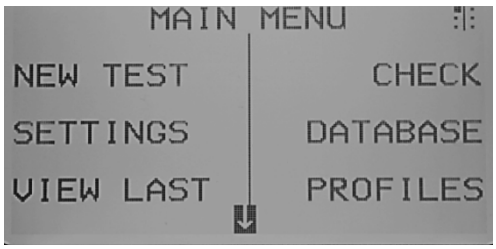


To enter the data, use the ▲ ▼ ◄ and ► keys to select a character. Press and hold the ► key to enter the selected character. To delete the last character, press and hold the ◄ key.

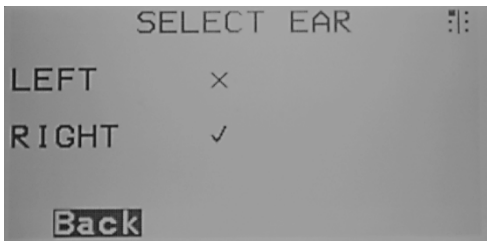
In order to save the entry, ensure all three identifier characters have been entered and then press S5 (a). The selection will now be stored. You will then be brought back to the **PROCESS RESULTS** screen**.** The save record option is now removed.

To cancel the entry, press S2 (**x**) You will be brought back to the **PROCESS RESULTS** screen**.**

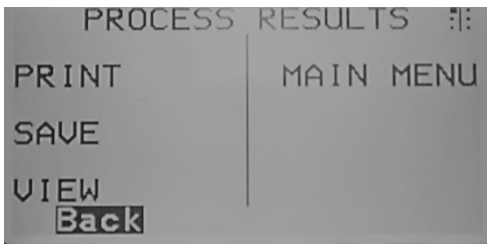
4.10. (RE)VIEW THE LAST TEST(S)



The Otowave 302+ offers a short-term memory that allows you to store the last test that has been conducted and is automatically overwritten by the next new test.



The symbols ✓ or **X** are used to signify whether results are available for each ear. Only test results with a ✓ can be selected for review.



From the test result screen select the right navigation key ► until the **PROCESS RESULTS** screen is reached.

From here the following options are available:

- Print the current record
- Save the current record
- View the record again
- Return to the **MAIN MENU**

Please refer to section 4.12.2 for further steps on how to proceed from the PROCESS RESULTS screen.

4.11. DATABASE

4.11.1. GENERAL

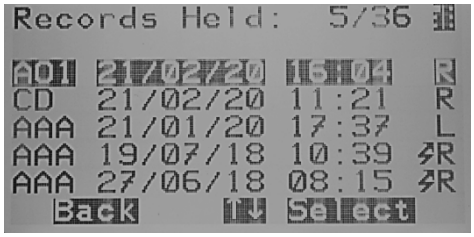
Up to 36 tests can be stored in the Otowave 302+ internal database.

Records stored in the database of the Otowave 302+ can be listed, viewed, printed or deleted using the **DATABASE**.

From here the following options are given:

- Review all stored records (view, print, delete single record) (S1)
- Delete stored record (S2)
- View the record again (S3)

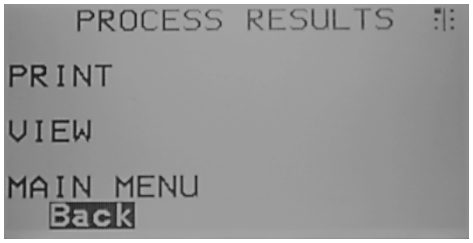
4.11.2. LIST RECORDS (VIEW, PRINT, DELETE)



LIST RECORDS displays the stored tests, 6 at a time, most recent first.

The overview contains the following information to help identify the test result status:

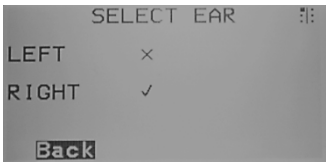
- The three-letter patient identifier entered when the test was stored
- Date and time of the test
- Whether the test has been printed ( )
- Whether the test has been sent to a computer ( )
- Whether the test is for the Left (L), Right (R) or both (2) ears

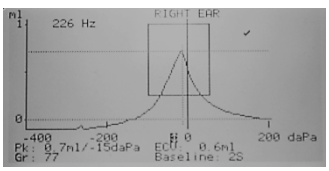


When a record is selected the **PROCESS RECORD** menu will be displayed. This accesses the following functions:

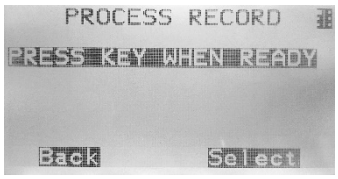
- View the selected record (S1)
- Print the selected record (S2)
- Delete a record (S3)

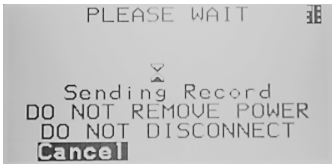
VIEW RECORD



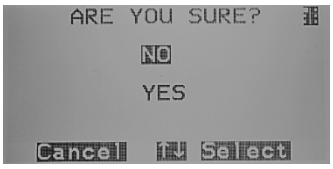


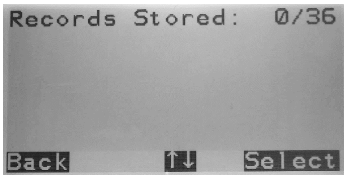
SEND TO PRINTER





DELETE RECORD





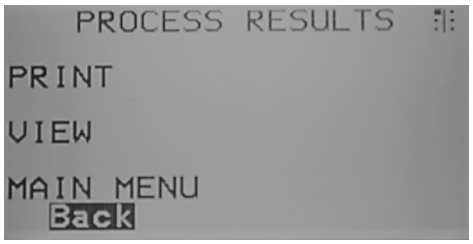
The symbols ✓ or **X** are used to signify whether results are available for each ear. Only test results with a ✓ can be selected for review.

Confirm the **SENT TO PRINTER** selection as soon as the printer is ready.

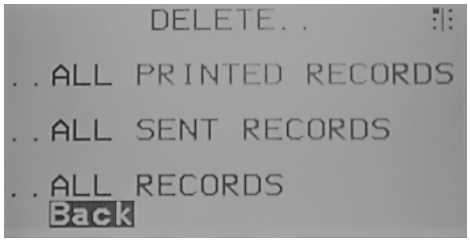
When **DELETE RECORD is selected** a confirmation of the deletion progress is required in order to proceed. If several tests are stored in the database, you will be brought back to the **LIST VIEW** after the successful deletion.

If only one record is available in the database a note will show on the screen that the database is empty.

4.11.3. DELETE RECORDS

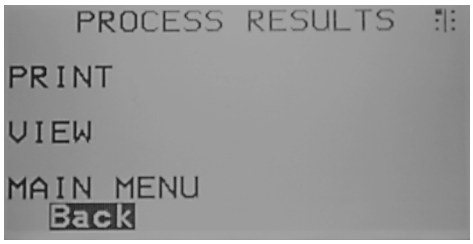


DELETE RECORDS allows a group of records to be deleted.

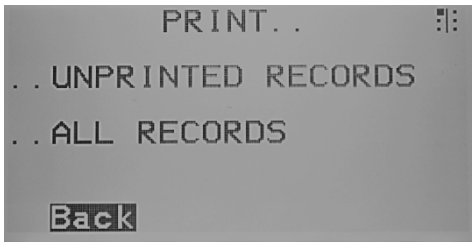


It is possible to delete all records stored in the database, only those records that have been printed or those records that have been sent to a computer.

4.11.4. 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.

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

4.11.5. DATA TRANSFER TO NOAH OR MEDRX STUDIO SOFTWARE

The Otowave 302+ is supplied with software to allow connection to a computer for the transfer of test results. You must use the designated USB cable, which is available from MedRx, Inc..

To transfer test results stored within the Otowave 302+ to a NOAH database, the NOAH Impedance module must be installed on to a computer. Alternatively, MedRx Studio Software allows data to be transferred to a computer and subsequently viewed, annotated & printed. This software is supplied on a USB stick which also includes this operating manual.

The computer will automatically detect the instrument when it is connected with the USB cable. Data transfer is initiated from the computer (not from the Otowave 302+). To disconnect simply remove the cable when data transfer is completed.

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

4.11.6. DATABASE FULL

When the internal memory is full, a warning will be displayed when attempting to save a test.

- Selecting **MANAGE RECORDS** will display the **DATABASE** menu which provides options for printing or transferring data to a computer prior to deleting records to make space for the new test.
- **OVERWRITE OLDEST** will overwrite the oldest record in memory with the results being stored.
- **BACK** will return to the previous menu.

5. TROUBLESHOOTING

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

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

	• Pump failed to achieve the starting pressure within 4 s. Pressure failed to reach -400 daPa within 12 s.	
VOLUME OUTSIDE RANGE Indicator LED b and c flash.	Probe not placed correctly in ear canal.	Reposition probe.
PROBE NOT CLEAR Indicator LED c solid light.	Probe is blocked. Probe placed incorrectly	Check that the probe is not inserted into a test cavity at start-up. Please ensure the probe is not blocked or obstructed.
AIRFLOW ERROR Indicator LED c steady light.	Fault with air system and/or pump. Cannot determine pump direction.	Unknown pump fault. Restart the unit. If problem persists, contact your MedRx service centre.
AIRFLOW ERROR **RESTART THE UNIT** Indicator LED c steady light.	Fault with air system and/or pump.	Restart the unit. If problem persists, contact your MedRx service centre.
WARNING! CALIBRATION EXPIRED Indicator LED c steady light.	The current date is later than the next calibration date. Check that the clock is set to the correct date. If so, arrange for the instrument to be recalibrated. Tests can still be performed.	Recalibration needed before further tests are performed.
WARNING! DEVICE UNCALIBRATED. Indicator LED c steady light.	One or more default values require recalibration before further tests are performed.	Contact your MedRx service centre.
WARNING! DEFAULTS RELOADED. Indicator LED c steady light.	Default configuration settings reloaded.	Default configuration settings reloaded. If the error persists, contact your v service centre.
Printing Error No connection can be established with the printer	• Printer is switched off or not charged • Connection between printer and base unit cannot be established.	• Restart the base unit • Restart the printer • Charge printer • Ensure the connection between printer and base unit is established.

If you experience difficulty in resolving faults the equipment distributor (or MedRx if purchased directly) should be consulted.

6. ROUTINE MAINTENANCE

6.1. GENERAL MAINTENANCE PROCEDURES

The performance and safety of the instrument will be maintained if the following recommendations for care and maintenance are observed:

1. It is recommended that the instrument go through at least one annual service, to ensure that the acoustical, electrical and mechanical properties are correct. This should be carried out by an authorised service centre in order to guarantee proper service and repair.
2. Observe that no damage is present to the insulation of the mains cable or the connectors and that it is not exposed to any kind of mechanical load that could involve damage.
3. To ensure that the reliability of the instrument is maintained, we recommend that the operator at short intervals, for instance once a day, performs a test on a person with known data. This person could be the operator.
4. If the surface of the instrument or parts of it is contaminated, it can be cleaned using a soft cloth moistened with a mild solution of water and detergent or similar. Always disconnect the mains power adaptor during the cleaning process and be careful that no fluid enters the inside of the instrument or accessories.
5. After each patient examination, ensure that there has been no contamination to the parts touching the patient. General precautions must be observed in order to avoid cross-contamination of disease from one patient to another. Water should be used for frequent cleaning, but in the case of severe contamination it may be necessary to use a disinfectant.

CAUTION

- Before cleaning always switch off and disconnect from the power supply
- Use a soft cloth lightly dampened with cleaning solution to clean all exposed surfaces
- Do not allow liquid to come into contact with the metal parts inside the earphones/headphones
- Do not autoclave, sterilise or immerse the instrument or accessory in any fluid
- Do not use hard or pointed objects to clean any part of the instrument or accessories
- Do not let parts that have been in contact with fluids dry before cleaning
- Rubber ear-tips or foam ear-tips are single use accessories

Recommended cleaning and disinfection solutions:

- Warm water with mild, nonabrasive cleaning solution (soap)
- 70% isopropyl alcohol only on hard cover surfaces

6.2. CLEANING THE OTOWAVE 302+

CAUTION

- Use caution while cleaning.
- Before cleaning, remove the Otowave 302+ from mains power.
- Single use components such as ear-tips do not require cleaning.
- Do not allow any liquid to enter any part of the instrument or accessories.
- Do not autoclave or sterilise the instrument or any accessories.
- Do not use hard, sharp or pointed objects to clean any part of the instrument or an accessory.
- If parts have been in contact with fluids do not allow them to dry before cleaning.
- Follow local best practice and safety guidelines if available.
- Clean the instrument by wiping the outer case with a lint free cloth lightly dampened with cleaning solution. Recommended cleaning and disinfection solutions are warm water with mild, nonabrasive cleaning solution (soap) and/or Clinical wipes (for example Clinell Universal).
- If disinfection is required, use a disinfectant wipe rather than a spray product. Make sure that excess liquid from the wipe does not seep into any sensitive areas such as connectors and seams where plastic pieces connect such as under the rubber buttons on the Otowave 302+. Follow the instructions on the disinfection product.

6.3. CLEANING THE PROBE

he probe tip should be checked before each ear insertion to ensure it is undamaged and that none of the tubes through it are blocked. It should be replaced if necessary.

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

CAUTION

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

6.4. DISPOSABLES

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

Use only the disposable supplies that are supplied with your Otowave 302+. Ear tips are intended for single use only. These should be discarded after use.

CAUTION

In the event of re-use of the single-use disposables, you enhance the risk of cross contamination!

6.5. ACCESSORIES/REPLACEMENT PARTS

Some reusable accessories are subject to wear with use over time. We recommend that you keep stock of these replacement parts.

6.6. REPAIR

The manufacturer is only considered to be responsible for the validity of the CE marking, effects on safety, reliability and performance of the equipment if:

- assembly operations, extensions, readjustments, modifications or repairs are carried out by authorised persons
- a 1-year service interval is maintained
- the electrical installation of the relevant room complies with the appropriate requirements, and
- the equipment is used by authorised personnel in accordance with the documentation supplied by manufacturer

It is important that the customer contact MedRx, Inc. or designated distributor for technical support before shipping the Otowave.

This should be done every time an instrument is returned to manufacturer.

When packing the instrument for shipping, please use the original shipping carton and packing materials. Place the instrument parts in plastic bags before packing to prevent dirt ingress.

6.7. WARRANTY

The manufacturer gives the purchaser the following Warranty;

If within three years from the date of dispatch, any defect in respect of material or workmanship within our control is discovered, we will make good the defect without charge, subject to the following conditions;

- Notice of the fault is given to manufacturer within the Warranty period.
- The instrument is forwarded, carriage paid, to the manufacturer at the above address or as otherwise directed.
- Return carriage is free of charge for customers in the UK and chargeable for overseas customers.
- The responsibility of the manufacturer under this Warranty is strictly limited to making good the defect in the instrument itself.
- No attempt has been made to effect a repair or adjust the calibration or alter the instrument from the original build standard.
- Defects caused by abnormal conditions of use, accident or neglect are expressly excluded.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the local service centre to determine the appropriate repair facility. Repair or replacement will be carried out at the manufacturer's expense, subject to the terms of this warranty. The product requiring service should be returned promptly, properly packed, and postage prepaid. Loss or damage in return shipment to the manufacturer shall be at purchaser's risk.

In no event shall manufacturer be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any the manufacturer product.

This shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and the manufacturer shall not be responsible for, any loss arising in connection with the purchase or use of any the manufacturer product that has been:

- repaired by anyone other than an authorised manufacturer service representative;
- altered in any way so as, in manufacturer opinion, to affect its stability or reliability;
- subject to misuse or negligence or accident, or that has had the serial or lot number altered; defaced or removed; or
- improperly maintained or used in any manner other than in accordance with the instructions provided by the manufacturer.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of the manufacturer. The manufacturer does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of the manufacturer any other liability in connection with the sale of the manufacturer products.

THE MANUFACTURER DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FOR FUNCTION OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

6.8. CALIBRATION AND RETURN OF THE INSTRUMENT

MedRx recommends that the Otowave 302+ is calibrated annually. A warning message will be displayed at power up if the instrument was calibrated more than twelve months ago. The date of the last calibration is displayed on the **SYS INFO.** screen.

Please contact MedRx or the designated distributor for details of calibration services.

7. TECHNICAL SPECIFICATIONS

7.1. STANDARD AND REGULATORY

Medical CE mark	The CE mark indicates that the manufacturer Meets the requirements of Annex II of the Medical Device Regulation 2017/745. TÜV Product Service, Identification No. 123, has approved the quality system.	
Class	The Otowave 302+ Tympanometer is classified as a Class IIa device under Annex VIII of the EU Medical Devices Regulation.	
Standards and Conformance	**Safety:**	IEC 60601-1 (plus ES, CSA & EN deviations), Class II, Type B applied part
	EMC:	IEC 60601-1-2
	Performance:	IEC 60645-5, Type 2 Tympanometer ANSI 3.39, Type 2 Tympanometer
Physical	**Display:**	256 x 64 pixels / 8 lines of 21 characters
	Dimensions (base unit):	270 x 70 x 175 mm / 10.63 x 2.75 x 6.89 inch (excluding connections)
	Weight (base unit):	760 g / 1.68 lbs
	Dimensions (probe):	130 x 25 mm / 5.11 x 0.98 inch
	Weight (probe):	115 g / 0.25 lbs
	Interconnection: (probe to base)	1.5 m combined electrical cable and air tube
Power Supply	**Mains power:**	100-240 Vac; 50/60 Hz; 0.4 A
	Warm-up period:	None at room temperature
	Idle current:	70 mA
	Current while testing:	230 mA
Environmental	**Operating temperature:**	+15°C to +35°C / + 59°F to +95°F
	Operating humidity:	30 % to 90 % RH (non-condensing)
	Operating atmospheric pressure:	980 mb to 1040 mb
	Transport: storage temperature:	-20°C to +70°C / -4°F to +94°F
	Transport and storage humidity:	10 % to 90 % RH (non-condensing)
	Transport and storage atmospheric pressure:	900 mb to 1100 mb

7.2. GENERAL

Time and Date	**Stamps:**	Time and date stamp applied to all recordings, and to the last calibration date
Languages:		English, German, French, Spanish, Portuguese, Italian
Database	**No. of records stored:**	36
	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)
	Data presentation:	Records listed in reverse chronological order (latest first), with indication of data stored as described above
Printing	**Supported printer:**	Sanibel MPT-II
	Interface:	Cable supplied
	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.
PC Interface	**Serial Interface:**	USB Version 1.1
	Information sent:	Patient header, full left & right ear data.

7.3. TYMPANOMETRY

Probe Tone	**Frequency:**	226 Hz ±2% and 1000 Hz ±2%
	Level:	85 dB SPL ±2dB and 79 dB SPL ±2 dB over ECV range
Pressure	**Range:**	+200 daPa to -400 daPa ±10daPa or ±10 % (whichever is larger) over range 0.1 ml to 6 ml
	Limits (safety cutout):	+600 and -800 daPa
Sweep	**Speed:**	Selectable: 100, 200 or 300 daPa/sec
Analysis		Admittance peak level (in ml or mʊ) pressure at peak; Gradient in daPa (for 226Hz); Ear Canal Volume (ECV) @ 200 daPa or -400 daPa
	Number of samples stored	100 per tympanogram

7.4. ACOUSTIC REFLEX TESTING

Ipsilateral	**Test Frequencies:**	500 Hz, 1 kHz, 2 kHz & 4 kHz (±2 %)
	Level:	70 dBHL to100 dBHL (±3 dB) (2 kHz level is restricted to maximum 95 dBHL for ear canal volumes greater than ~3.5ml) (4 kHz level is restricted to maximum 85 dBHL for ear canal volumes greater than ~3.5 ml & maximum 95 dBHL for all ear canal volumes)
	Number of reflex levels presented below the selected maximum and step size(s) available:	100dBHL max, with 5dB or 10dB steps 95/90/85dBHL max, with 5dB steps
Contralateral	**Test Frequencies:**	500Hz, 1kHz, 2kHz & 4kHz (±2%)
	Level:	70dBHL to110dBHL (±3dB) (1kHz level is restricted to minimum 75dBHL for ear canal volumes less than ~0.2ml) (4kHz level is restricted to maximum 100dBHL for ear canal volumes greater than ~3.5ml)
	Number of reflex levels presented below the selected maximum and step size(s) available:	110/105/100dBHL max, with 5dB or 10dB steps 95/90/85dBHL max, with 5dB steps
General	**THD:**	< 5 %
	Reflex analysis	Reflex pass/fail at each level tested; maximum amplitude of each reflex; nominal pressure used for the reflex test (computer display only)
	Pressure used for reflex measurement	Pressure at tympanogram peak (if found) or at 0daPa
	Reflex stimulus control	Stimulus presented at all levels, or Stimulus ceases when a reflex is found
	Reflex detection threshold and accuracy	0.01ml to 0.5ml ±0.01ml (configurable in 0.01ml steps)
	Reflex tone duration	0.6 seconds

8. EMC GUIDANCE & MANUFACTURER'S DECLARATION

CAUTION

- This instrument is suitable in hospital environments except for near active HF surgical equipment and RF shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high
- Use of this instrument adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this instrument and the other equipment should be observed to verify that they are operating normally
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. The list of accessories, transducers and cables can be found in this appendix
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this instrument, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result

NOTICE

- ESSENTIAL PERFORMANCE for this instrument is defined by the manufacturer as:
  This instrument does not have an ESSENTIAL PERFORMANCE Absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk
- Final diagnosis shall always be based on clinical knowledge There are no deviations from the collateral standard and allowances uses
- This instrument is in compliance with IEC60601-1-2:2014, emission class B group 1
  NOTICE: There are no deviations from the collateral standard and allowances uses
  NOTICE: All necessary instruction for maintaining compliance with regard to EMC can be found in the general maintenance section in this instruction. No further steps required.

Guidance and manufacturer's declaration – electromagnetic emissions		
The Otowave 302+ Tympanometer is intended for use in the electromagnetic environment specified below. The customer or user of the Otowave 302+ Tympanometer should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Otowave 302+ Tympanometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Otowave 302+ Tympanometer is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity (1)			
The Otowave 302+ Tympanometer is intended for use in the electromagnetic environment specified below. The customer or user of the Otowave 302+ Tympanometer should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T **(>95% DIP IN U_T) FOR 5 SEC**	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Otowave 302+ Tympanometer requires continued operation during power mains interruptions, it is recommended that the Otowave 302+ Tympanometer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to the application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity (2)			
The Otowave 302+ Tympanometer is intended for use in the electromagnetic environment specified below. The customer or user of the Otowave 302+ Tympanometer should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Otowave 302+ 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 d = 1.2√P (80MHz to 800MHz0 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] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m	
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.			

Guidance and manufacturer's declaration – electromagnetic immunity (2)	
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 302+ Tympanometer is used exceeds the applicable RF compliance level above, the Otowave 302+ 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 302+ 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 302+ Tympanometer

The Otowave 302+ Tympanometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Otowave 302+ Tympanometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Otowave 302+ Tympanometer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
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.

9. SAFETY PRECAUTIONS TO TAKE WHEN CONNECTING OTOWAVE 302+

Please note that if connections are made to standard equipment like printers and networks, special precautions must be taken in order to maintain medical safety. Please follow instructions given in this section.

Diagram 1: Otowave 302+ used with the medically-approved power supply

Diagram 2: Otowave 302+ used with the medically-approved power supply and printer

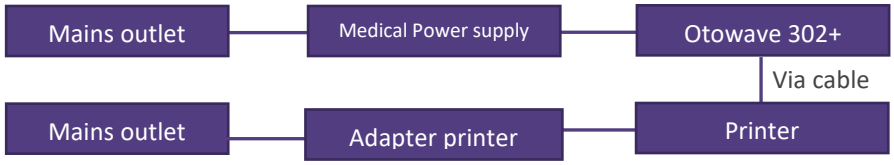
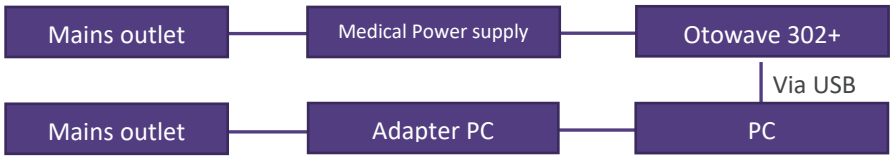


Diagram 3: Otowave 302+ used with the medically-approved power supply and PC



10. APPENDIX A – 1000 HZ TYPANOMETRY & MEATUS COMPENSATION

TYMPANOMETRIC PROPERTIES

Tympanometric measurements of the ear are affected by a large number of physiological characteristics, but from a clinical perspective the three most important, physical properties impacting the outcome of a tympanometrical measurement are:

1. Stiffness
2. Mass
3. Friction

Combined mathematical and electro-technical approaches have been developed to measure/calculate and predict the stiffness of the ear drum and the middle ear. This led to the conversion of stiffness, mass and friction into equivalent electrical impedances (**Z**):

1. Negative reactance (stiffness)
2. Positive reactance (mass)
3. Resistance (friction), whereby friction can only be positive in passive systems.

For tympanometry however, it is more usual to consider the inverse of impedance, the so-called admittance (**Y = 1/Z**), of stiffness, mass and friction:

1. Susceptance (**B**, inverse of reactance)
2. Conductance (**G**, inverse of resistance)

The units of all these admittance components are mhos (the inverse of ohms used for impedance).

The reason for using these inverse measures is because the admittances of the ear canal and middle ear components can then be treated as being in series with each other, making their values easy to separate. If considered as impedances these components are in parallel, which makes their separation much more difficult to calculate and to visualise.

For example, the ear canal admittance/impedance is often not of immediate interest and is removed from the measurement as described later. For tympanometry, it is more of interest, to find the admittance/impedance of the middle ear than the one of the ear canal.

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

10.1. TYMPANOMETRIC MEASUREMENTS

The main aim of tympanometry is to separate out the admittance contribution of the ear canal air volume (**Y_{ec}**) from the total measured admittance (**Y_{meas}**), to find the admittance in the plane of the tympanic membrane (**Y_{tm}**). This separation is variously called 'baseline removal' or 'meatus compensation'. The value removed is often displayed separately as the Ear Canal Volume. Note that when using a 226 Hz probe tone, one can substitute the word *compliance* for *admittance* in this description, with minor loss of accuracy, and the calculation is a simple scalar subtraction of the magnitudes of the admittance values:

$$Y\_tm = |Y\_meas| - |Y\_ec|$$

When considering the general case, including probe tone frequencies at higher frequencies than 226Hz, the above subtraction of the effect of the ear canal air volume is more complicated. In mathematical terms, a complex subtraction is required, which involves taking into account the **G** and **B** components separately. In graphical terms, this can be described as a vector subtraction, and the equation now takes on the form:

$$Y\_tm = |\overline{Y\_meas - Y\_ec}|$$

The baseline value (**Y_{ec}**) is the measured admittance of the ear when at maximum pressure (normally +200daPa for the Otowave 302+). This approximates **Y_{ec}** because the applied pressure reduces **Y_{tm}** towards 0 (but not all the way to 0, otherwise it would not be possible to hear the probe tone at all; nonetheless the approximation is sufficient for clinical purposes). This value is subtracted from each of the tympanogram measurements in turn to generate the meatus-compensated tympanogram normally presented to the clinician.

The above subtractions are represented in terms of vectors in Figure 1 and Figure 2 shown at the end of this section for probe tone frequencies of 226Hz and 1000Hz respectively. In Figure 1, it can be seen that there is minimal loss of accuracy by performing a scalar subtraction instead of a vector subtraction. In other words, the phase angles of the vectors (directions of arrows) are similar.

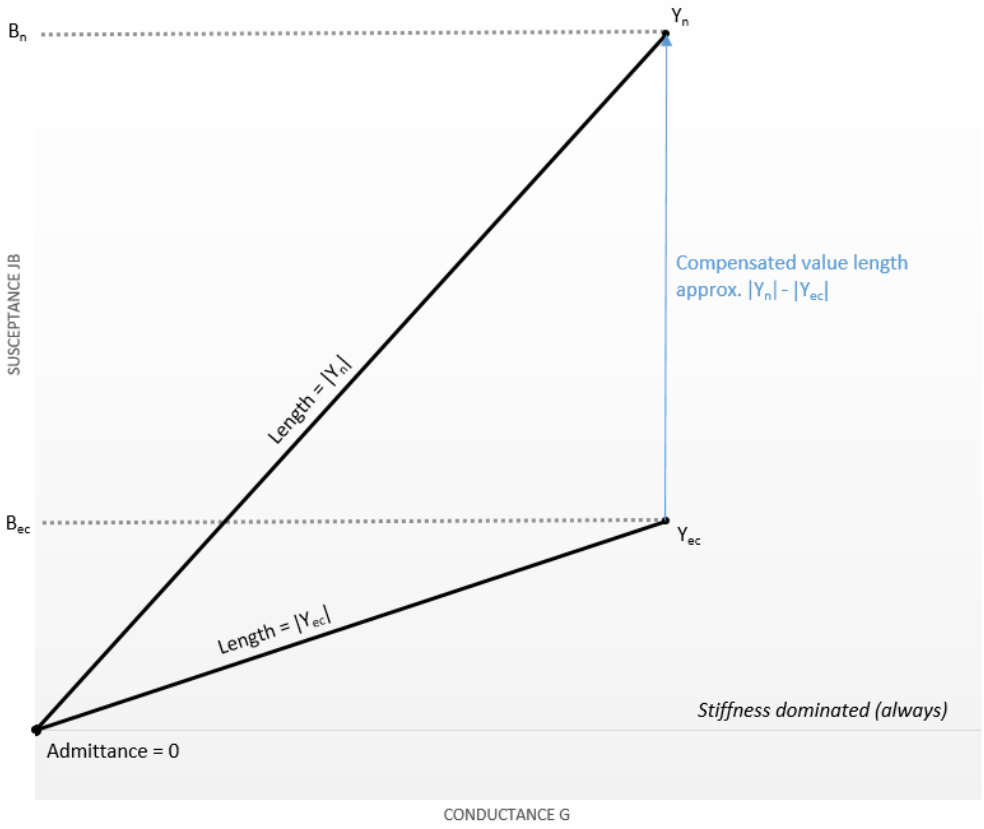


Figure 1: 226 Hz probe tone: The distance between the nth sample Y_n (admittance value of the nth sample in the tympanogram) and the baseline sample Y_{ec} is essentially the same as the difference in lengths between the length $|Y\_ec|$ because conductance is always small at 226 Hz and reading are always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

Contrast this with Figure 2 where the phase angles are very different and a scalar subtraction would erroneously give a value close to zero, instead of the length of the vector in orange (Y_{ec}).

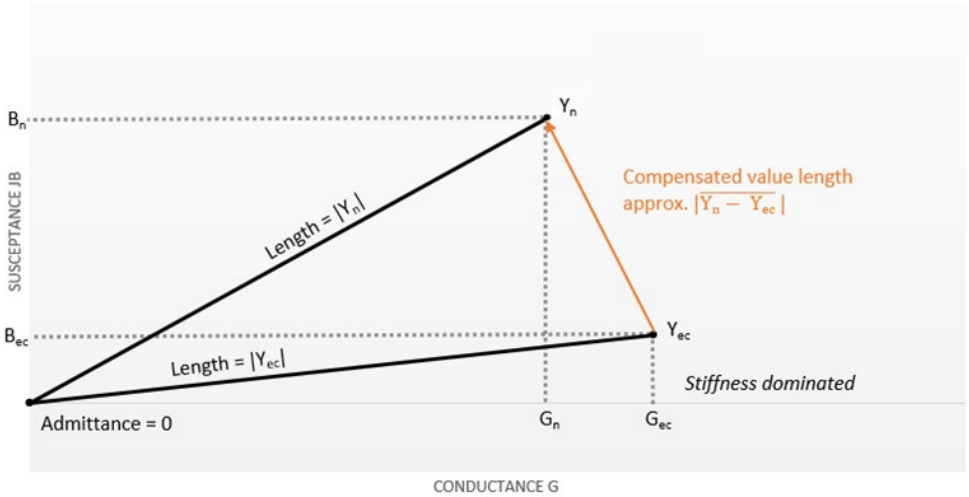


Figure 2: 1 kHz probe tone: Although the susceptance values B_n and B_{ec} are the same as in the 226 Hz diagram, the distance between the n^{th} sample Y_n and the baseline sample Y_{ec} is nothing like the difference in lengths between Y_n and Y_{ec} (which here would be close to 0), due to the conductance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

Figure 1), and this approach is taken by most if not all commercial tympanometers. But for 1 kHz measurements, the Otowave 302+ optionally can take the more advanced approach, employing vector-based subtraction. It is a mathematically more thorough and accurate way of performing compensation and is made possible by the advanced electronics and software within the device.

Vector based baseline compensation always generates positive values; it calculates the length of a line joining two points in 2-D space and can therefore never be negative. This can cause a tympanogram to rise up at the end opposite to that used for the baseline reference. If that is the case, changing the baseline from –400 or + 200 daPa or vice versa can improve the display. This effect can be most clearly demonstrated by performing a tympanometric sweep on a 2 ml or 5 ml hard walled cavity. When viewed in Scalar mode the baseline should always rise from –400 or + 200 daPa and switching between –400 or + 200 daPa should simply raise or lower the trace so that the selected end is at 0; but when the Vector mode is selected the baseline always rises from the selected end, so the slope changes direction.

10.2. SCALAR VS. VECTOR BASELINE

There are differences between the tympanograms obtained with **scalar** and **vector baseline** compensation: 1 kHz tympanograms may appear quite flat when viewed with scalar baseline compensation; they are typically clearer with vector compensation. Moreover, vector baseline compensation leads to results that follow a more easily interpretable pattern, which means that the middle-ear pressure can be defined with greater certainty.

Although vector subtraction is the only correct solution at 1 kHz, it may be unfamiliar to users and therefore the Otowave 302+ offers the option of selecting either scalar or vector baseline compensation for 1 kHz tympanograms. Use of scalar baseline compensation will give results similar to those from some other instruments and be comparable with publications that have used scalar baseline compensation.

10.3. REFERENCE POINT FOR BASELINE VALUE

An additional feature of the Otowave 302+ not found on other screening tympanometers is that the user can decide whether to use –400 or + 200 daPa as the reference point for the baseline value.

11. APPENDIX B –BASELINE MODE

11.1. GENERAL

The Otowave 302+ can display tympanograms in a variety of graphical formats allowing the operator to choose the most appropriate for the patient under examination.

This is achieved by altering the **DISPLAY MODE** and the meatus compensation (or **BASELINE OFFSET**). The **DISPLAY MODE** determines how the tympanogram trace is derived from the raw data, and the baseline offset selects the pressure to which the meatus compensation is referenced (either -400daPa or +200daPa). **DISPLAY MODE** and **BASELINE OFFSET** are collectively referred to as **BASELINE OFFSET** in the instrument menus and the accompanying documentation.

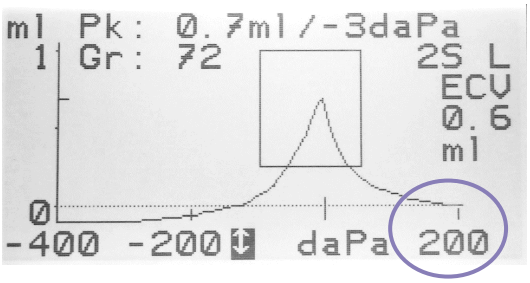
The tympanogram is initially presented using default settings for display mode and baseline offset. Additionally, whenever a tympanogram is shown it may be re-displayed using any of the alternative **DISPLAY MODES** and **BASELINE OFFSETS** available described in this section.

Switching between **DISPLAY MODES** and **BASELINE OFFSETS** is carried out using either the display mode key on the front panel or the function button on the probe.

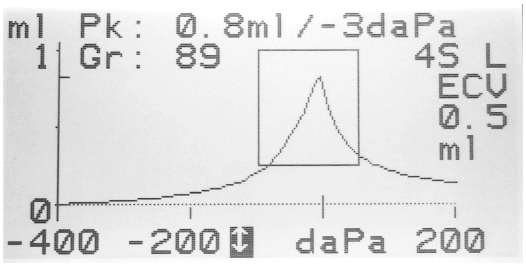
Press and briefly hold the key or button to cycle round Scalar, Vector and Component display modes. Short button presses will circle around the current selected mode, long button presses will access another display mode.

11.2. 226 HZ TYMPANOMETRY – Y COMPENSATION ONLY

2S MODE



4S MODE

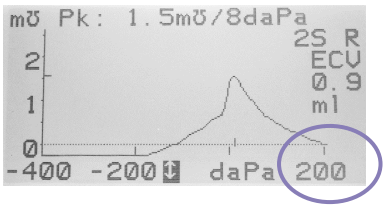


11.3. 1000 HZ TYMPANOMETRY

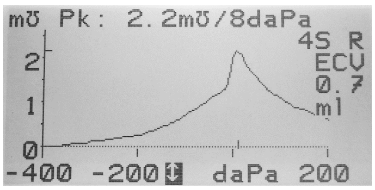
11.3.1. SCALAR MODE – Y-COMPENSATION

For 1 kHz operation a similar scalar display mode is available as used for 226Hz (Y-only compensation). This mode is generally preferred when testing very young children.

2S MODE



4S MODE

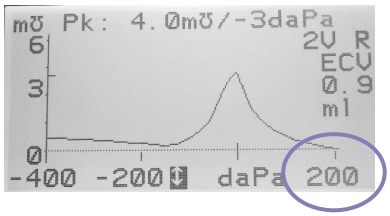


11.3.2. VECTOR MODE – B-G-COMPENSATION

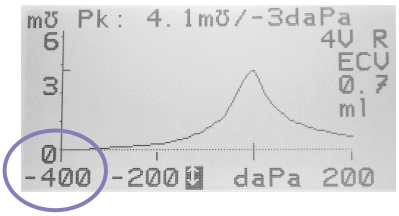
For 1 kHz operation an alternative display mode is available known as **VECTOR** mode (based on definition in Clause 3.17.2 of IEC 60645-5) and takes account of phase information in the measurements. It is also known as B-G compensation and is suitable for all patients other than neonates.

The format is similar to that used for scalar mode with the 1 kHz probe tone. Baseline offsets of +200 daPa offset (2V) and -400 daPa (4V) are available as required.

2V MODE



4V MODE

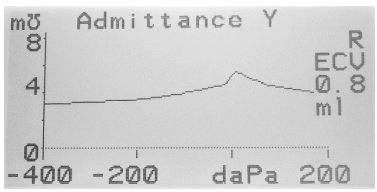


Please note that a consequence of the vector mode calculation is that the resulting tympanogram cannot take negative values. It is thus theoretically possible for the trace to appear to rise (i.e. take higher positive values) at the end opposite to the selected offset. The user is advised to view traces with each of the +200daPa and -400daPa baseline offsets selected before deciding which result to save.

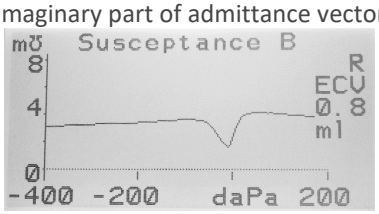
11.3.3. COMPONENT MODE – YBG

The Otowave 302+ also provides a component display when using a 1 kHz probe tone where separate uncompensated Y, B and G traces can be shown. These may help to interpret the tympanograms and help to define the middle-ear pressure in cases where the Y display alone gives misleading or ambiguous conclusions. The function is suitable for all patients. Component mode is used as required by the audiologist. In this case the ear canal volume is measured at the +200daPa baseline offset in Scalar mode.

Admittance Y



Susceptance B
(imaginary part of admittance vector)



Conductance G
(real part of admittance vector)