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Instructions for Use - US

OtoRead™



Interacoustics

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1 Introduction

1.1 About this manual

This manual is valid for the OtoRead™ (valid from UI V3.41.0 FW version 113). This product is manufactured by:

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1.2 Intended use

The OtoRead™ Otoacoustic Emission Test Instrument is designed to be a screening device for hearing loss in infants, children, and adults by measuring otoacoustic emissions (OAE).
This instrument is suitable for use in all settings, including hospitals, schools, physicians' offices, and audiologists' practices. The OtoRead™ is intended to be used by hearing healthcare professionals (i.e. ENT doctors, audiologists) and/or technicians, neonatal nurses and school nurses who have been trained by a hearing healthcare professional.

1.3 Otoacoustic Emissions

1.3.1 What are DPOAEs?

Distortion Product Otoacoustic Emissions (DPOAEs) are acoustic signals that can be detected in the ear canal of a person with normal outer hair cell function, subsequent to stimulation of the auditory system with a pair of pure tones at frequencies f1 and f2. The resulting emission of interest is the distortion product tone at the frequency 2f1 - f2.

1.3.2 What are TEOAEs?

Transient Evoked Otoacoustic Emissions (TEOAEs) are acoustic signals that can be detected in the ear canal of a person with normal outer hair cell function, subsequent to stimulation of the auditory system with a series of wideband clicks.

1.3.3 What do Otoacoustic Emissions results tell us?

Available evidence suggests that otoacoustic emissions (OAEs) are generated by the cochlea's outer hair cells, and that the presence of OAEs is an indication that the outer hair cells are normal. Although OAE test data provide no indication of inner hair cell function, or of hearing ability, current research indicates that the majority of hearing-impaired individuals will be identified by a simple OAE test. Patients who fail to generate OAEs should be rescreened and/or referred for additional audiological testing.

1.3.4 How does the OtoRead™ device measure DPOAEs?

The OtoRead™ instrument generates a series of test tones, directs them into the ear canal, and then measures the level of the DPOAE tone generated by the cochlea. By using different test frequencies, the OtoRead™ device provides an estimate of outer hair cell function over a wide range of frequencies.

1.3.5 How does the OtoRead™ device measure TEOAEs?

The OtoRead™ instrument generates a series of clicks, directs them into the ear canal, and then analyzes the spectrum of the returning signal, separating the noise from the emission. By using band pass filters, the OtoRead™ device provides an assessment of outer hair cell function over a wide range of frequencies.

1.3.6 What frequency range is assessed?

DPOAEs: Approximately 1 kHz to 12 kHz (depending on the frequency range selected). Since the health of the hair cells in the region of the f2 test frequency is assessed, and a) the 2f1-f2 emission frequency is at about six-tenths of the f2 frequency, b) emissions tend to be weak below 600 Hz or so, and c) the ambient noise tends to be highest at low frequencies, the lowest f2 test frequency that can be routinely measured is about 1 kHz.

TEOAEs: Roughly 500 Hz to 4 kHz. TEOAEs can be reliably recorded at lower frequencies than DPOAEs, but cannot be measured reliably above 4 kHz.

1.4 Contraindications

Contraindications to testing include recent stapedectomy or middle ear surgery, a discharging ear, acute external auditory canal trauma, discomfort (e.g., 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.

For US only: Federal law restricts the sale, distribution, or use of this device to, by, or on the order of a licensed medical practitioner.

1.5 Product description

The OtoRead™ is a hand-held device designed to provide an objective measure of outer hair cell function through the measurement of cochlear emissions. It consists of the handheld unit, printer (optional), single-use eartips and other accessories.

Factory-defined protocols allow for simple screening measurements (Screener and Screener+ versions) and by using customizable protocols it can also assist in diagnostic evaluations (Standard and Clinical versions).

The purpose of the OtoRead™ test system is to provide rapid measurement and documentation of Distortion Product Otoacoustic Emissions (DPOAEs) or Transient Evoked Otoacoustic Emissions (TEOAEs) at several frequencies. The digital signal processor in the instrument generates two pure tones (f1 and f2) for DPOAEs or a series of wideband clicks for TEOAEs through a digital-to-analog converter. These tones or clicks are presented to the ear via speaker tubes located in the probe. A microphone in the probe measures the sound in the ear canal and transmits the signal to the analog-to-digital converter. The digital signal processor then uses Fast-Fourier Transforms (FFTs) to filter the signal into narrow frequency bands, and detects any emissions present. The level of these emissions can be compared with the level of the noise. The SPL and frequencies of the test tones and the averaging time used to process the signals can be determined by the tester through adjustable settings maintained in static memory within the OtoRead™ instrument.

The OtoRead™ instrument may be used as a screening tool or in conjunction with conventional tests as part of a full audiological evaluation.

1.6 Included and optional parts

The system consists of the following included and optional parts:

Standard Components for all versions (Screener, Screener+, Standard & Clinical)
OtoRead™ device including plug for hook cavity
Hook
Micro-Probe1
Micro-USB Power Supply for Charging the Lithium-Ion Battery
Micro B to A USB Cable for PC Communication/Charging
Ear tip Assortment Box
Package of Probe Tubes (100)
Instructions for Use
Quick Guide DPOAE and/or TEOAE
Infant ear simulator
Neckstrap
OtoRead™ Module & Auto Print software bundle

Accessories included only in Standard and Clinical version
Carrying Case
Cradle

Optional Accessories
Carrying Case
Cradle
Printer (with power supply & thermal paper)

1.7 Warnings

Throughout this manual, the following definitions of warning, caution and notice are used:



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



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

NOTICE — **NOTICE** is used to address practices not related to personal injury.

Federal law restricts this device to sale by or on the order of a licensed medical practitioner

1.8 Data protection

The General Data Protection Regulation (GDPR) came into force on May 25, 2018 and stipulates how patient data is handled and stored. The OtoRead™ instrument together with the OtoRead™ Module and Auto Print software is used to test patients, store and view measurement data. It is the customer's responsibility to ensure that the way you use the software and device and how you share information within your organization and with third parties is complaint with the guidelines set out in the GDPR.

[1] Applied part according to IEC 60601-1

It is also the customer's responsibility to clean up any computer where the OtoRead Module™ is installed or any OtoRead™ device where patient data is present prior to disposal, in accordance with the GDPR guidelines.

2 Unpacking and installation

2.1 Unpacking and inspection

Check box and contents for damage
When the instrument is received please check the shipping box for rough handling and damage. If the box is damaged it should be kept until the contents of the shipment have been checked mechanically and electrically. If the instrument is faulty please contact your local distributor. Keep the shipping material for the carrier's inspection and any potential insurance claim.

Keep carton for future shipment
The OtoRead™ comes in its own shipping carton, which is specially designed for the OtoRead™. Please keep this carton. It will be needed if the instrument has to be returned for service.
If service is required please contact your local distributor.

Reporting imperfections
Inspect before connection
Prior to connecting the product it should once more be inspected for damage. All of the cabinet and the accessories should be checked visually for scratches and missing parts.

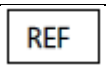
Report immediately any faults
Any missing part or malfunction should be reported immediately to the supplier of the instrument together with the invoice, serial number, and a detailed report of the problem. In the shipping box you will find a 'Return Report' where you can describe the problem.

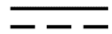
Please use 'Return Report'
Please realise that if the service engineer does not know what problem to look for he may not find it, so using the Return Report, which can be found in the shipping box, will be of great help to us and is your best guarantee that the correction of the problem will be to your satisfaction.

Storage
If you need to store the OtoRead™ for a period, please ensure it is stored under the conditions specified in the section for technical specifications.

2.2 Markings

The following markings can be found on the instrument:

Symbol	Explanation
	Type B applied parts. Patient applied parts that are not conductive and can be immediately released from the patient.
	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.
 0123	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. TÜV Product Service, Identification No. 0123, has approved the quality system.
	Date of manufacture.
	Manufacturer.
	Do not re-use. Parts like ear tips and similar are for single use only.
 E359876	Underwriters Laboratories, Inc. label MEDICAL-GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES 60601-1 (2005) + AMD (2012) CAN/CSA-C22.2 No. 60601-1 (2008) + (2014)
	Serial Number.
	Reference Number.
	Global Trade Item Number.
	Logo.
	FCC marking with ID.
	The instrument includes a RF transmitter.

	DC- Direct current.
	China RoHS label. Indicates that the product does not contain toxic and hazardous substances or elements above the maximum concentration values, and that it is an environmentally-friendly product which can be recycled and reused.
	Keep Dry.

2.3 General warnings and precautions

Read these instructions carefully and completely before using the product

2.3.1 Electrical system safety



WARNING

When connecting the instrument to the computer, the following warnings must be observed:
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 shall 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 – shall comply with the safety requirements stated the general standard IEC 60601-1, edition 3, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support or shall 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 the requirements. If in doubt, contact qualified medical technician or your local representative. If the instrument is connected to a PC (IT equipment forming a system) ensure not to touch the patient while operating the PC.
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 such 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

2.3.2 Electrical safety



WARNING

Do not modify this equipment without authorization of Interacoustics Do not disassemble or modify the product as this may impact on the safety and/or performance of the device. Refer servicing to qualified personnel.

For maximum electrical safety, turn off the power when it is left unused The power plug shall be placed so it is easy to pull out the plug

Do not use the equipment if it is showing visible signs of damage.

The instrument is not protected against ingress of water or other liquids. If any spillage occurs, check the instrument carefully before use or return for service
No part of the equipment can be serviced or maintained while in use with the patient.

2.3.3 Explosion hazards



WARNING

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 anesthetic gases.

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

Before cleaning make sure to disconnect power source

2.3.4 Electromagnetic compatibility (EMC)



CAUTION

Although the instrument fulfills 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.

Use of accessories, transducers and cables other than specified, with the exception of transducers and cables sold by Interacoustics or representatives, may result in increased emission or decreased immunity of the equipment. For a list of accessories, transducers and cables that fulfil the requirements please also refer to the appendix regarding EMC.

2.3.5 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 Interacoustics' 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 components 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 Interacoustics.

Interacoustics will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist authorized service personnel to repair those parts of this instrument that are designated by Interacoustics 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 Interacoustics to the instrument. Only accessories which have been stated by Interacoustics to be compatible are allowed to be connected to the device.

Never insert, or in any way use, the insert headset without a new clean and non-defective ear-tip. Always make sure that the foam or ear-tip is mounted correctly. Ear-tips and foam are for single use only.

The instrument is not intended for use in environments exposed to fluid spills.

Check calibration if any parts of the equipment are exposed to shock or rough handling.

Components marked for ‘single use’ are intended for a single patient during a single procedure, and there is a risk of contamination if the component is re-used. Components marked for ‘single use’ are not intended to be reprocessed.

Use only transducers calibrated with the actual instrument.

In case of a serious incident with serious health impact for the patient or user Interacoustics shall be informed. Beside that the competent authority in patient’s home country shall be informed. Interacoustics has a vigilance system to help with this.

2.3.6 Environmental factors



CAUTION

Storage outside temperature range as specified in Section 6 may cause permanent damage to the instrument and its accessories.

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 authorized service technician.

Do not place the instrument next to a heat source of any kind, and allow sufficient space around the instrument to ensure proper ventilation.

2.3.7 NOTICE

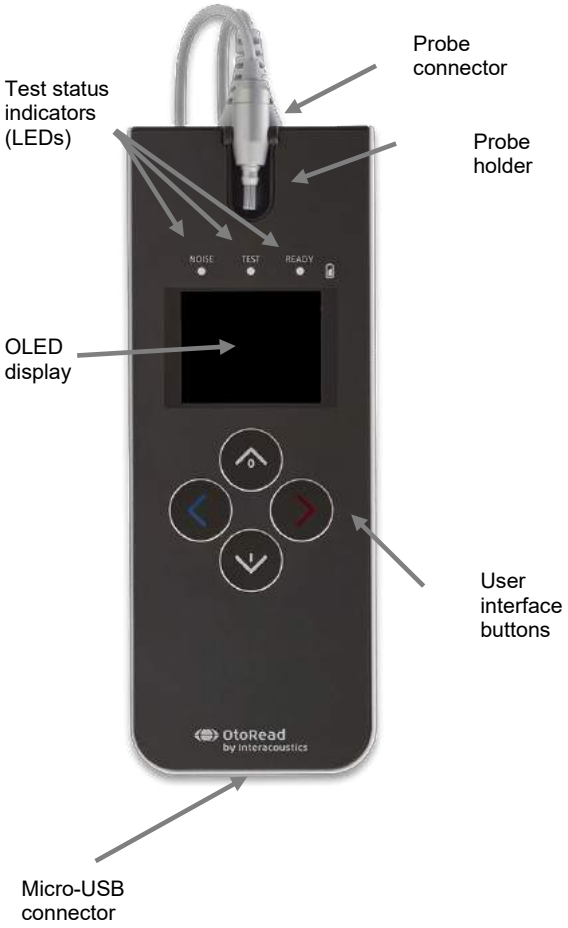
To prevent system faults take appropriate precautions to avoid PC viruses and similar.

Within the European Union, it is illegal to dispose of electric and electronic items in unsorted municipal waste. Electric and electronic waste may contain hazardous substances and therefore has to be collected separately. Such products will be marked with the crossed-out wheeled bin symbol, shown below. The cooperation of the user is important in order to ensure a high level of reuse and recycling of electric and electronic waste. Failing 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 end of life.

2.4 The harware

2.4.1 The OtoRead™ test instrument



The OtoRead™ consists of the instrument, Micro-Probe, single-use ear tips, replaceable probe tubes and other accessories.

The OtoRead™ contains the hardware and software for generating the test stimuli, measuring and displaying the OAEs, and storing the results until they are printed or saved to the database.

The plastic housing contains circuit boards that provide the signal processing and display the test results. The instrument also contains a rechargeable lithium-ion battery to power the device. On the top of the device, a probe holder can be found, to ensure safe storage of the probe.

The instrument uses an organic light-emitting diode (OLED) display screen and three light-emitting diodes (LEDs) to provide a visual display of test status to the operator. Four membrane-type push buttons located on the keypad of the device allow the user to control testing and printing, and to reset test protocols.



The probe houses the speaker and microphone which produce test stimuli and measure the sound pressure level (SPL) present in the sealed ear canal. Interface of the instrument to the ear canal is accomplished through disposable ear tips which fit onto the probe tube. The disposable ear tips are color coded to facilitate easy selection by size.

2.4.2 Connecting the Micro-Probe to the OtoRead™



Turn off the OtoRead™ and insert the Micro-Probe plug into the socket on the top of the OtoRead™. The plug will only fit in one orientation.

The Interacoustics logo on the probe plug will align with the instrument control panel.

Misalignment of the plug and socket can cause damage. The plug and socket should be visually inspected prior to each installation of the remote probe.

Note: Do not remove or connect the probe from the probe socket unless the device is off.

2.4.3 Micro-Probe calibration

The Micro-probe transducer used with OtoRead™ uses a HDMI connector that allows the calibration data to be stored within the cable/plug (also known as an ID tranducer). Micro-probe transducers can be swapped between devices without requiring recalibration to the specific OtoRead™ instrument. OtoRead™ will automatically detect the Micro-probe when connected.

2.4.4 Connecting the hook to the OtoRead™



Remove the plug on the top of the OtoRead™

Insert the hook into the plug.

Store the plug for future use.

The instrument can now be placed safely anywhere near you and gives you the benefit of handsfree operation.





2.4.5 Connecting the neckstrap to the OtoRead™



The provided neckstrap can be connected to the OtoRead™ for easy transportation and handsfree testing.

To connect the neckstrap:

1. Insert the loop of the neckstrap into the hole on the back of the OtoRead™ and push the loop through until it comes out the hole on the top of the OtoRead™.
2. Thread the necktrap through the loop.
3. Pull the neckstrap to secure it in place.

2.5 Installation and use of the cradle



Connect the Type B Micro USB plug of the power supply to the rear of the cradle.

USE ONLY UES12LCP-050160SPA POWER SUPPLY.

The separable mains connector for UES12LCP-050160SPA is used to safely disconnect mains from the device. Do not position the power supply in a position so that it is difficult to disconnect the device.

Do not attempt to use any other power supply. It could cause risk of fire or electrical shock to operator or patient.



Place the cradle upright on your desk. There are insertion guides to place the instrument properly into the cradle.

Two pins can be found on the bottom of the instrument bay to guide the OtoRead™ into place.

Place the OtoRead™ into the cradle so that it sits within the U-shaped placement guides. Proper placement in the cradle is needed to ensure charging of the battery.

To remove the OtoRead™ from the cradle, grasp the upper portion of the OtoRead™ above the cradle placement guides and lift it out.



2.6 Charging and powering the OtoRead™

2.6.1 The battery

The OtoRead™ instrument is powered by an integrated rechargeable lithium-ion battery (1800 mAh) providing 20 hours (500 tests, minimum) of operation between full charging.

The battery can be charged in three ways:

1. While placed in the powered cradle
2. When connected via USB cable to the PC
3. When connected via the USB mains power adapter

Please note that the battery life will vary depending on each product configuration and that the maximum capacity of this battery will decrease with time and usage. To prolong the battery life, do not completely deplete the battery, but re-charge when 5 %-10 % of the battery charge remains.



The Micro-USB port on the bottom of the instrument is the connection point for the USB used for charging via the USB cable to PC or mains



The blue battery indicator provides a visual indication (blue) of the battery recharging function and battery status during operation.

2.6.2 Battery charging indication lights



During battery charging the indicator will be lit whenever the Micro-USB connector is engaged and powered. The rate of illumination of the indicator provides a means of identifying the status of the charging function, and is defined as follows:

- **Steady-state illumination** indicates that the battery is fully charged. This identifies that the charging cycle has been completed or was not implemented because the battery was already fully charged.
- **Slow blinking** illumination indicates that the charging function is in process.
- **Fast blinking** illumination indicates a fault condition. Contact your local distributor for instrument service.
- During instrument operation, the user is warned of a low battery condition **by two fast blinks followed by a pause** which is repeated until the battery is charged.

2.6.3 Battery lifetime and charging time

NOTICE

Please observe the following precautions:

- **The battery can only be maintained by service personnel**
- Keep the battery fully charged
- Do not place the battery in a fire or apply heat to the battery
- Do not damage the battery or use a damaged battery
- Do not expose the battery to water
- Do not short circuit the battery or reverse the polarity
- The battery automatically starts charging when the OtoRead™ is placed properly into the AC-powered cradle or when connected via USB to the PC
- Use only the charger provided with the OtoRead™.

The OtoRead™ will shut down automatically when the battery charge is too low to support continued operation.

When fully charged, the OtoRead™ battery will last for a full day of testing under normal test conditions and when the default ‘power save’ and ‘power off’ options are enabled.

It takes approximately five hours to completely recharge the instrument. Note that this is an average; some batteries may re-charge a little faster and others a little slower.

2.7 Installing the wireless thermal printer

The OtoRead™ communicates with the thermal printer using a wireless connection protocol. Use only the recommended label printer provided with the equipment.

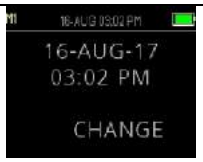
Refer to the recommended thermal printer's Instructions for Use for initial setup and installation of the battery and paper.

2.7.1 Pairing the wireless printer to OtoRead™

Pairing with the instrument is necessary before wireless printing is possible.

Pairing process:

1. Power on the printer.
2. Power on the OtoRead™ by pressing the **DOWN** key.
3. From the Main Menu, press CHANGE (**DOWN** key).
4. From the Protocol Menu, press SETUP (**DOWN** key).
5. From the Date Screen, hold down the **DOWN** key for a few seonds until the green 'READY' LED turns off.
6. You are now at the NEW WL menu and can press **LEFT** or **RIGHT** key to search for the printer.
7. Wait for the device to find the printer (ensure it is switched on) and then press PAIR (**DOWN** key).
8. The printer is now paired to your device.

					
3	4	5	6	7	8

Note: Do not have several printers powered on and within range while searching.
It is possible to pair up to 8 instruments with one printer. If more instruments are paired, the oldest will be deleted.

2.8 OtoRead™ Module & Auto Print software

The OtoRead™ can be used in conjunction with the OtoRead™ Module & Auto Print software for storing, viewing, printing and managing patient information. For further information about the software, refer to the OtoRead™ Module & Auto Print Instructions for Use.

3 Operating instructions

The OtoRead™ instrument is switched on by pressing the **DOWN** key.

3.1 General precautions

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



1. Use this device only as described in this manual.
2. Use only the disposable Sanibel 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 tube into the ear canal without affixing an ear tip as this may damage the patient's ear canal. Make sure that the ear tip covers the probe tube fully. Ear tips that are not sufficiently attached to the probe tube risk getting detached from the probe during removal from the ear canal.
5. Keep the ear tip box outside the reach of the patient.
6. Be sure to insert the probe 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.
8. It is recommended to conduct a probe test at the beginning of each day to ensure that the probe and/or cable is functioning correctly for TEOAE and DPOAE measurements.
9. Dispose of and replace any probe tube that is contaminated, to ensure wax or other debris stuck in the probe tube does not affect the measurement. Do not attempt to clean it.
10. Contraindications to testing include recent stapedectomy or middle ear surgery, a discharging ear, acute external auditory canal trauma, discomfort (e.g, 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

NOTICE

1. Careful handling of the instrument whenever in contact with a patient should be given high priority. Calm and stable positioning while testing is preferred for optimal accuracy.
2. The OtoRead™ should be operated in a quiet environment, so that measurements are not influenced by outside acoustic noise. This may be determined by an appropriately skilled person trained in acoustics. ISO 8253 Section 11, defines a quiet room for audiometric hearing testing in its guideline.
3. It is recommended that the instrument be operated within an ambient temperature range of 15°C / 59°F – 35°C / 95°F.
4. Never clean the transducer housing with water or insert non-specified instruments into the transducer.
5. Do not drop the instrument and avoid any other undue impact to the device. If the instrument is dropped or otherwise damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.
6. 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, caution must be taken to observe that no mutual disturbance appears.

3.2 The control panel



The OtoRead™ uses 4 buttons to control all functions of the instrument. These buttons are arranged in a directional cursor format. The arrows on the keypad (**LEFT**, **RIGHT**, **UP**, and **DOWN**) correspond to the arrows that are used on the screen. The screen will indicate which button to push by showing the appropriate arrow.

Note: The **UP** key will always bring the instrument back to either the previous screen, menu or the main menu. The **UP** key will also access the print command from the Main Menu.

3.3 Turning the OtoRead™ on

To turn on the OtoRead™, press the **DOWN** key located below the instrument's display screen. The yellow 'TEST' light will appear briefly just above the display screen. The green 'READY' light will remain on, indicating the instrument is ready for use. A splash screen will appear briefly. This display will indicate the firmware version, serial number (for example IA1234567) and type of instrument:

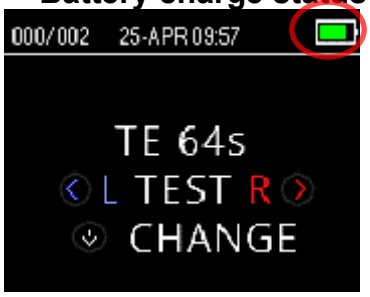
SCR	Screener with TE or DP
SC+	Screener with TE and DP
STD	Standard Diagnostic with TE or DP
CMB	Combined Diagnostic with TE and DP

If the battery is sufficiently charged, the OtoRead™ will automatically remember the last time and date setting. If there are no date/time errors detected, the Main Menu will appear on the display.
If this is the first time the OtoRead™ is being used, or if you wish to change the date or time, refer to section ***Date and time settings (menu M1)***. If a time/date error message is indicated, follow the instructions in this section to set the correct date and time.

3.4 Turning the OtoRead™ off

The **UP** key can be used to manually power off the instrument.
Furthermore, the OtoRead™ has an automatic 'shutdown' feature, designed to prolong battery life. The unit will automatically shut down after 1 minute (default) of inactivity. To turn it back on, simply press the large **DOWN** key. This feature can be re-programmed for differing periods of inactivity before 'shutdown'. Refer to section ***Changing Instrument Settings – Auto Shutdown Time.***

3.5 Battery charge status indicator



When the OtoRead™ battery's power capacity becomes low, the first indication you will see is a change of color in the battery symbol in the top right hand corner of the display.

Full battery charge is represented by a full battery symbol on the display and reduces to an empty battery in increments corresponding to the discharge of the battery.

Table 1: Explanation of charge status symbols

Symbol	Charge status
	> 95 %
	95 - 75 %
	75 - 50 %
	50 - 25 %
	25 – 12 %
	< 12%

3.6 LED Indicators (lights)

The OtoRead has 3 LED test status indicators located above the OLED display. The table below describes the meaning of the indictor lights.



Table 2: Explanation of LED indicators

	The indicator labeled ‘NOISE’ provides a visual indication (RED) that the noise level measured during the test exceeds a nominal threshold. Also used to indicate some error conditions and when the outcome of test is REFER, NOISY, or NO SEAL.
	The indicator labeled ‘TEST’ provides a visual indication (ORANGE) that the selected test is being performed. This indicator will remain on during the test function.
	The indicator labeled ‘READY’ lets the user know that the instrument is not currently performing a test function and that it is available to perform a test function.
	The battery symbol provides a visual indication (BLUE) of the battery recharging function and battery status. The rate of illumination of the indicator provides a means of identifying the status of the charging function.

When the 

and the 

lights are displayed simultaneously and continuously during TEOAE testing, the test is paused for a maximum of 30 seconds before displaying “NOISY” as the test result. Refer to the section ***Test environment and noise sources*** for more information.

3.7 Calibration reminder

The OtoRead™ comes with a calibration reminder to remind you that the yearly calibration of the device will be required soon. The calibration reminder will be prompted when the OtoRead™ is switched on.

3.8 Daily system check for OAE devices

It is recommended to perform a daily check of your OAE equipment to ensure that it is in good working order, before testing on patients. As the probe and probe tube often come into contact with wax or other debris in the ear canal, a common fault affecting testing can be a blocked or partially obstructed probe tube. Running a probe integrity test and a real-ear check allows for any probe faults or system distortions that can masquerade as biological responses to be detected. A daily check ensures that you can be certain that the results obtained throughout the day are valid.

3.8.1 Probe integrity test

The probe integrity test ensures artifact responses (system distortions) are not being generated by the probe or hardware.



- The probe tube should be inspected for wax or debris prior to conducting the test.
- Replace the probe tube if necessary before testing.
- Testing should always be conducted in a quiet environment.

Test procedure:

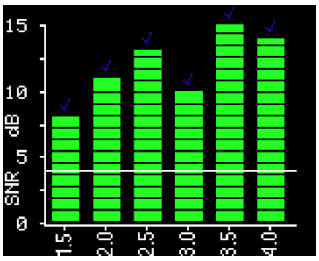
1. Place a red flanged ear tip onto the probe tube and insert the probe into the provided infant ear simulator.
2. Select an OAE test protocol. As system distortion is dependent on stimulus output level, select a protocol that reflects what is used most often in clinical practice.
3. Turn the OtoRead™ on and press and hold down either the **LEFT** or **RIGHT** key until the green READY light goes off.
4. Allow the test to run until it stops automatically. Do not stop the test manually.

Test results:

If the probe is functioning correctly, none of the frequency bands (TEOAE) or points (DPOAE) should have a checkmark, i.e, no artifacts/OAEs should be detected above the noise floor. The test result should be *Refer*.



Example of a *refer* result. There were no responses that matched the *pass* criteria.





Example of a *pass* result.

If an error message appears during testing or if one or more of the OAE bands or points has a checkmark (meaning detected), the probe integrity test has failed. This could indicate that:

- There is wax or debris in the probe tube and replacing it is required.
- The probe was not placed in the infant ear simulator correctly, or,
- The probe's calibration needs to be checked.

Check and replace the probe tube if necessary and retry the test. If the probe test fails a second time, the probe should not be used to test on patients. Contact your local service technician for assistance.

NOTE: It is possible for system distortion to appear at levels below -10dB SPL. Ensure that the MIN OAE LEVEL is set to -10 dBSPL on the device for the protocols in use before conducting the probe integrity test.

3.8.2 Real-Ear Check

This test can be done by placing the probe in one's own ear and running a commonly used test protocol.

If OAE results do not match the tester's expected OAE result, this could be an indication that:

- The probe is not connected correctly to the device.
- The ear tip is not attached correctly to the probe tube.
- There is wax or debris in the probe tube and it needs to be replaced.
- The environment is too noisy for testing.
- The probe was not placed correctly in the ear canal.
- The probe's calibration needs to be checked.



If results from the real-ear test do not match the expected result after checking items 1 to 5 above, the probe should not be used to test on patients. Contact your local service technician for assistance.

3.9 Preparing the patient for testing

Otoscopic examination of the patient's ear canals should be performed prior to testing. Excessive cerumen or vernix in the ear canals may interfere with the test and give invalid or incomplete results. Patients with excessive cerumen, debris, or foreign bodies in the ear canals should be referred to an audiologist or physician for removal of the blockage prior to testing.

3.9.1 Testing adults or older children

Place the patient in a position that will allow easy access to the ear canal. Use the shirt clip on the Micro-Probe cable to secure the probe to clothing or bedding. The patient should remain still and quiet while the test is being performed.

Pull gently up and back on the outer ear during probe insertion to straighten the ear canal and esure a good probe fit.

3.9.2 Testing infants

When testing infants. They should be relatively quiet and calm. It is usually preferred for the infant to be asleep. A pacifier may be used during testing to calm the infant, however, sucking will add noise to the test and increase the likelihood of a refer.

Pull gently down and back on the outer ear to straighten the ear canal while gently placing the probe into the ear canal.

3.9.3 Test environment and noise sources

Otoacoustic emissions are very low-level sounds. Any noise in the ear canal at the time of testing can mask this emission. This noise can come from a variety of sources.

The largest source of noise usually comes from the patient. This is biological noise, such as movement, coughing, sucking, crying, talking, etc. The patient must be calm and not move or talk. Ambient noise in the testing environment can also be a large source of noise during the test. A properly sealed eartip can block out a large amount of this noise, but performing the testing in a relatively quiet environment is recommended.

When the noise level exceeds the noise rejection limit of the instrument, the red NOISE light will appear. It is common for the NOISE light to appear while testing. The light will appear infrequently if the noise level in the ear canal is low, and it will appear more often if the noise level in the ear canal is high.

For TEOAE protocols, the test will pause when noise levels exceed the noise rejection limit. Pause is indicated when the Noise, Test and Ready lights turn on simultaneously. Testing will automatically resume when noise levels decrease. Total pause time will not exceed 30 seconds.

3.10 Handling and selection of ear tips

3.10.1 General

When using the OtoRead™ Micro-Probe, Sanibel ear tips must be used

The Sanibel ear tips are single use only and should not be reused. The ear tips are disposable and should be replaced after each patient. Reuse of ear tips can lead to the spread of infection from patient to patient.

The probe tube must have an ear tip attached before inserting it into an ear canal. Your choice of ear tip will depend on the size and shape of the ear canal and ear. Your choice may also depend on personal preference and the way you perform your test.

The OtoRead™ instrument comes with a variety of disposable ear tips that fit different ear canal sizes.

The ear tip must seal the ear canal. The best test results are obtained when the ear tip is inserted deeply into the ear canal instead of flush with the ear canal opening. Caution must be taken, however, to ensure that the ear tip does not extend too deeply into the ear canal.

3.10.2 Attaching ear tips



After selecting an ear tip, push it onto the probe tube until it is flush against the base of the probe body. Twisting the ear tip slightly while pushing it onto the probe is recommended.



Be sure the ear tip is fully seated on the probe. There should be no gaps between the ear tip and the probe body.

3.10.3 Removing ear tips



Grasp the ear tip at the base with your fingers and twist it while pulling it off the probe tube. Grasping the base of the ear tip will prevent the probe tube from being inadvertently pulled out of the probe head along with the ear tip

3.10.4 The probe tube

Probe tubes are disposable and should be replaced when they become clogged. A package of replacement probe tubes and a probe removal tool are included with this instrument.

NOTICE

Do not attempt to clean the probe tube. This may cause damage to the probe!

Do not remove the probe tube, turn it around and insert it again – this can cause wax/debris to get into the probe body which will cause damage to the probe.

3.10.5 Probe tube removal



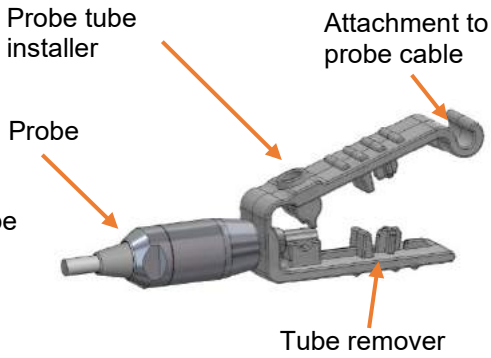
To replace the probe tube, use the ear tip to grasp the probe tube and pull the probe tube straight out of the probe body. Dispose of the used probe tube immediately to avoid confusing used tubes with new tubes.

If the probe tube is removed from the probe body and then re-used, it will not fit as well as on its initial placement.

If the probe tube is difficult to remove by hand, use the probe tube removal tool.

3.10.6 Using the probe tube removal tool for removal

1. Place the front hole of the Probe Tube Tool over the end of the probe, as shown. The probe should be seated against the face of the tool and snap in place.
2. Squeeze the tool closed and hold it.
3. Twist the tool a couple of times while holding the tool closed and pulling away from the probe
4. The probe tube will pull out from the probe. Discard the probe tube.



NOTE: if the tube gets caught in the tool, open the tool wide and discard the tube, or punch out the tube from the tool and discard.

3.10.7 Probe tube insertion



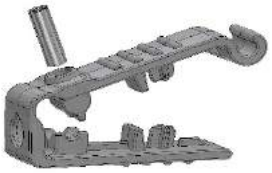
Take a new probe tube from the package and insert the tube into the probe head until it is fully seated. A properly inserted probe tube will snap securely into place when it is inserted correctly. The probe tube can also be inserted using the probe tube removal tool.

3.10.8 Using the probe tube removal tool for insertion

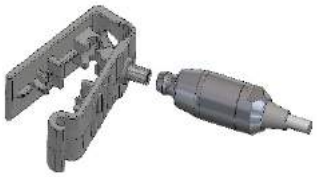
1. Place a new tube into the hole on the top of the tool.

2. Align the probe with the tube.

3. Push the probe onto the probe tube until the probe contacts the face of the probe tube tool and a snapping sound is heard.
4. Slide the tool off leaving the tube in place in the probe.



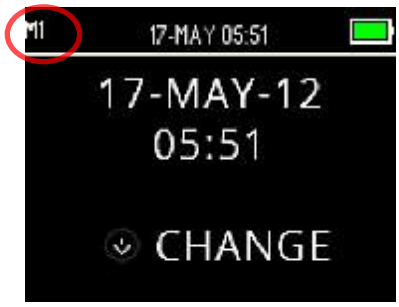




3.11 Menu structure

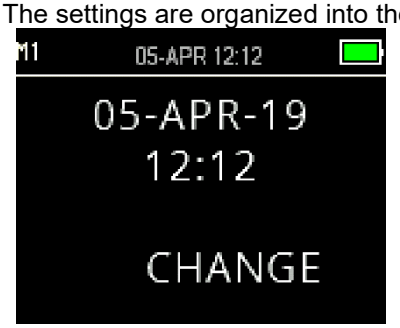
3.11.1 Menus

The OtoRead™ allows the user to change many of the instrument's settings or functions. Settings and functions are separated into 4 different menus.



For a better understanding as to which menu you are currently in, the menu number can be found in the upper left corner of the screen.

The settings are organized into the following structure:



Menu 1 (M1)

- Date and time



Menu 2 (M2)

- Wireless device pairing
- Clearing test results
- Auto shutdown time
- Saving mode
- Minimum OAE level
- Clock Mode
- Graph view type
- Normative data display
- Reverse frequency
- Auto stop
- Language
- Reset to default settings



DPOAE Menu (DP)

- DP Level
- Averaging time (test time per DP frequency)
- Pass SNR
- # frequencies for a pass
- Reset protocol
- Save protocol

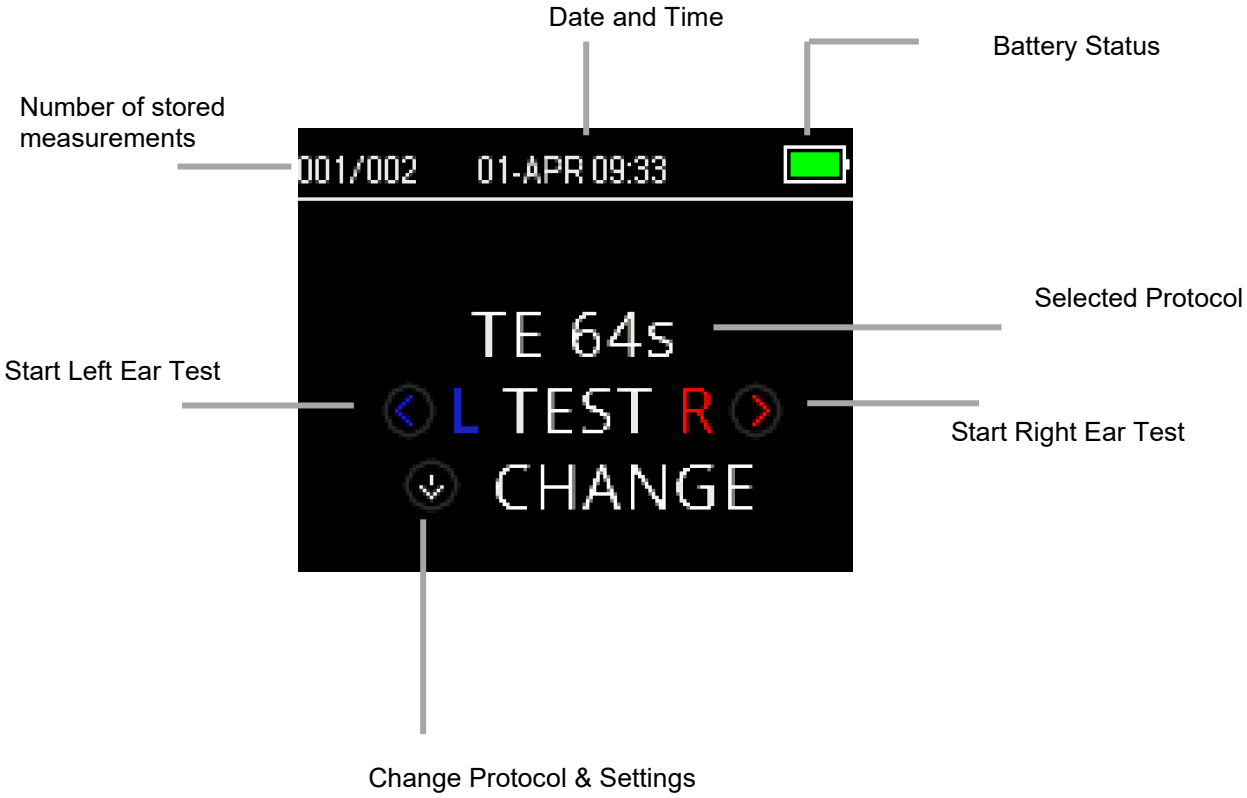


TEOAE Menu (TE)

- Averaging time (total test time)
- Pass SNR
- # frequencies for a pass
- Reset protocol
- Save protocol

3.11.2 Main menu

The OtoRead™ starts on the Main Menu. The following can be viewed or initiated from this screen:



3.12 Performing a test

3.12.1 Selecting the Test Protocol



The currently selected protocol is shown on the *Main Menu*.
To change the selected protocol press the **DOWN** arrow at the Main Menu. The *Change Protocol* menu will appear.



Use the **CHANGE** arrow buttons to change the selected protocol.

Press the **UP** key to return to the *Main Menu* to begin testing.
Press the **SETUP** key to enter the setup menus.

For either DPOAE or TEOAE screener devices, there are two default test protocols that vary based on averaging time (test time). Screener default protocols cannot be customized. For diagnostic devices, there is one default test protocol and a number of customizable protocols. See Appendix C for an overview of the available protocls.

3.12.2 Starting a test



To begin a test, insert the probe into the ear and select either the **LEFT** or **RIGHT** key depending on the ear to be tested.

NOTE: To measure emissions, gently insert the ear tip into the patient's ear canal. It should fit snugly and comfortably. The best test results are obtained when an ear tip is inserted deeply into the ear canal instead of flush with the ear canal.

3.12.3 Probe check

After the test ear is selected, the probe check will be begin automatically. This probe check screen displays the selected ear side in the corresponding color (red for right ear, blue for left ear) and a gauge representing the probe check status .



Leaking: The needle points to the orange, right side of the gauge.

The detected ear canal is too large for the test to begin as the probe is not in the ear or there is a large leak.

The indicator will remain orange until a seal is obtained. Appropriate adjustment of the probe/ear tip position and ear tip size selection should be made until the indicator falls within the green area and remains stable.



Sealing: The needle points to the top, yellow part of the gauge.

The ear canal volume is in the target range for testing. A seal has been detected and now the instrument is looking for a consistent seal. Once this is confirmed, it changes to 'in ear' and can begin a test.



In Ear: The needle points to the green, left side of the gauge.

The test will begin automatically if the probe fit is stable. When the 'in ear' status is confirmed, the unit will automatically begin testing (AutoStart) and the yellow 'TEST' LED will be illuminated throughout the test.

If the test does not progress past the probe check phase, change the probe tube and check that the Micro-probe connector is fully seated in the OtoRead™ device socket and try again.

3.12.4 Testing children with PE tubes

To test children with PE (pressure equalizing/ventilation) tubes, the probe check needs to be disabled. This is accomplished by first inserting the probe with an appropriate ear tip into the ear canal and obtaining a proper seal. To disable the Probe Check at the main menu select the ear to be tested by holding down the 〈 **LEFT** or **RIGHT**〉 keys for 3 seconds until the green 'TEST' light turns off. Once the key is released, the OtoRead™ will perform the in-ear calibration and test as usual.

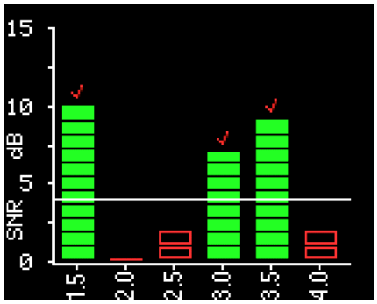
3.12.5 In-ear stimulus calibration after probe check

Immediately after the probe check, the OtoRead™ will automatically perform an in-ear stimulus calibration prior to the start of each test. During calibration a series of tones will be presented to the ear canal to calibrate the stimulus levels of the frequencies to be tested.

Following calibration of the test tones, the test phase will begin automatically.

3.12.6 Test phase

During the testing phase, the screen will display the ongoing measurement in graphical format. The result can also be reviewed after the test is complete.
There are two options for viewing the results – **SNR** or **Value** graph view. The user can set desired view from the **M2 menu**.

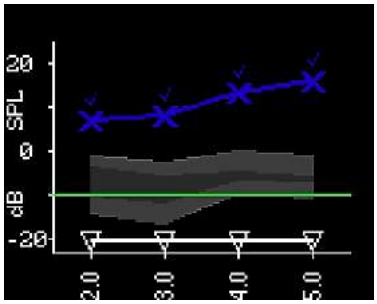


The SNR graph view displays the signal-to-noise-ratio (SNR) for each DP test frequency or TE test band.

Each column represents one test frequency (DP) or frequency band (TE). The height of each column represents the SNR measured.

When a protocol with Pass/Refer criteria has been selected, the user will see a horizontal white line at the decibel level corresponding to the SNR required for the test frequency (DP) or frequency band (TE) to be classified as detected. Green bars indicate the test frequency or band has met the detection criteria. A checkmark in the color of the measured ear will be displayed on top of these bars.

Red or blue empty bars indicate no detection at that frequency or band. The blue or red indicates the test ear side.



The value graph view displays the absolute OAE level and noise levels for each DP test frequency or TE frequency band.

Blue “x” symbols (left ear) or red “o” symbols (right ear) represent the absolute emission levels at each DP test frequency or TE frequency band. White upside-down triangles represent the noise floor at each DP test frequency or TE frequency band.

The green line indicates the min OAE level set (the default setting is -10 dBSPL for both TEOAE and DPOAE).

The shaded area is the Expanded Boys Town Normative data. Refer to the section ***Viewing DPOAE results with normative data*** for more information.

Refer to the section ***Graph style*** for instructions on how to change the view setting.

Testing is complete when the green ‘READY’ light is illuminated. Both the tester and patient should remain as still and quiet as possible until the green light turns on. The ^ **UP** key can be used to abort a test in progress. Aborted tests are not saved on the device..

3.12.7 Saving results

The results of the test are automatically saved in memory as soon as the test is completed. The results will be saved even if the unit turns off or the battery is temporarily depleted.
By default (Save L/R Mode), the OtoRead™ will save only the last test for each ear. Starting a new test for the same ear will overwrite the existing test result.

Refer to section ***Managing results*** for more information on how the OtoRead™ saves results.
Refer to section ***Instrument Settings – Save Mode*** for more information on the OtoRead™ save mode options.

3.12.8 Viewing results



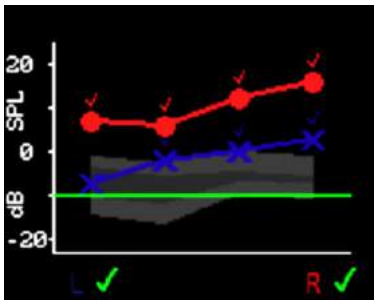
When testing is complete, the green 'READY' light is illuminated and the display shows the test ear and test result (for screening tests). The following results may be displayed:

- 'PASS' on the screen indicates that the patient passed the screening
- 'REFER' indicates that the patient did not pass the screening
- 'NOISY' indicates that excessive noise was present during the test
- 'NO SEAL indicates that a seal was not maintained throughout the test
- 'FIT ERR' indicates inadequate probe placement in the ear canal to produce target stimulus intensities



When the test result is 'NOISY', 'NO SEAL', or 'FIT ERR' the tester should reposition the probe, selecting a different size ear tip if necessary, and retest.

If the test result is 'REFER' the tester can determine from the printout whether the test should be repeated.



To review the graphical results, push the **DOWN** key.

When Save L/R mode and value graph view is active, results from both ears will be displayed together. The noise floor values are not shown on this combined graph.

For screening tests, the overall test result is displayed next to the Right and Left ear indicator beneath the graph.

 A checkmark indicates a 'PASS'

 A cross indicates a 'REFER'

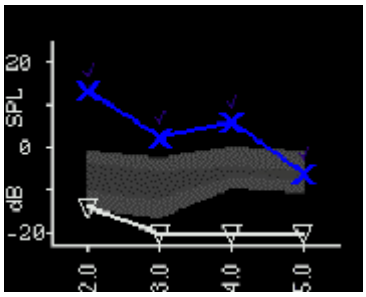
 A question mark indicates 'NOISY', 'NO SEAL', 'FIT ERR'.

Press the **LEFT** or **RIGHT** key to view the results for each ear individually.

After reviewing the results, again push the **DOWN** key to return to the Results display or the **UP** key to return to the **Main Menu**.

Once the review screen is exited, results are no longer viewable on the device. Print or transfer the results to the PC for further review.

3.12.9 Viewing DPOAE results with normative data



The OtoRead™ will display the Expanded Boys Town Norms template for eligible DPOAE test results. The norms template has no effect on the overall test results and is for display purposes only. The values used to create the template are shown in Table A1 in Gorga, M.P., Neely, S.T., Ohlrich, B., Hoover, B., Redner, J. and Peters, J. (1997). “From laboratory to clinic: a large scale study of distortion product otoacoustic emissions in ears with normal hearing and ears with hearing loss.” Ear & Hearing, 18, 440-455. The template may be used as a guide when evaluating DPOAE test results. The light shaded area at the top of the template represents the 90th to 95th percentile of DP amplitudes from the hearing impaired population. DP amplitudes within or above this range indicate a high probability of normal hearing. The light shaded area at the bottom of the template represents the 5th to 10th percentile of DP amplitudes from the normal hearing population. DP amplitudes within or below this range indicate a high probability of hearing loss. The dark shaded area in between represents a range of uncertainty where the normal hearing and hearing impaired populations overlap.

3.13 Managing results

Users have the option of printing results to the thermal printer (optional), transferring results to the OtoRead™ Module or printing to a PC printer or PDF using the Auto Print software.

3.13.1 Saving results on the device

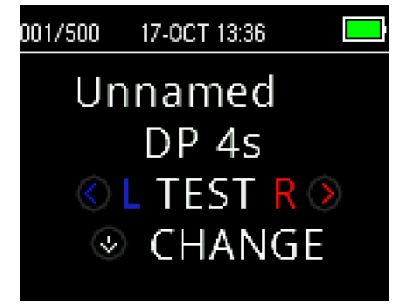
The OtoRead™ automatically saves the results of completed tests in the non-volatile memory. Tests are saved even if the battery is temporarily discharged. However, the OtoRead™ is not intended for long-term storage of test results.
Note: Users are strongly encouraged to print/transfer all test results on completion of testing to avoid potential loss of data.



Save L/R mode

When operating in the default ’Save L/R’ mode, the OtoRead™ will save the most recent test results for each ear and print/transfer only these results. This allows the user to retest a patient after a REFER result and to print/transfer only the most recent test result for each ear. It is recommended that the results be printed after each patient in the default mode.





Save 500 mode

When operating in the 'Save 500' mode, the OtoRead™ will save up to 500 tests. There are two options in the 'Save 500' mode:

The OtoRead™ will automatically number each test from 1 to 500. This allows the user to save all tests for each patient (tests of the same ear are NOT overwritten) and to test multiple patients before printing or transferring results. In this mode, it is important to keep a record of the test number(s) for each patient.

The OtoRead™ Module software is used to transfer patient names to the OtoRead™ and the OtoRead™ will display the names. The maximum number of patient names that can be transferred to the device is 50 (including the 'unnamed' patient). When patient names are used, the patient names are displayed on the OtoRead™ device in the same order as displayed in the module software. To move to a different name than the one displayed on the OtoRead™ screen, use the <LEFT or RIGHT> arrows to cycle through the names until the desired name is displayed. 'Unnamed' is always included at the beginning of the OtoRead™ list for instances when a patient is being tested, but the patient name was not transferred to the OtoRead™ .

When transferring names to the device, only 15 characters are retained for first name, last name, patient ID and other supported identifiers. This limit is also reflected on thermal printouts.

Refer to ***Instrument Settings – Save Mode*** for information on changing the save mode settings.

3.13.2 Deleting results from the OtoRead™

The OtoRead™ holds data in non-volatile memory. The data stays in the memory even after data is printed or downloaded to the OtoRead™ Module. Data can be deleted using several methods depending on the Save mode setting.

3.13.2.1 Deletion from the device

Save L/R mode

A single test for the left ear and a single test for the right ear are held in the memory. Data is deleted when a new test for the left or right ear is acquired.

Note: Following printing or data transfer to the PC software, all tests saved in memory are marked for deletion and will be permanently deleted when a new test is started. It is not necessary to manually clear the results.

Save 500 mode

Data can be deleted using the Clear Test Results function in M2 (menu 2). Refer to section ***Clearing test results*** for more information.

3.13.2.2 Deletion using the OtoRead™ Module or Auto Print software

Data is deleted when new Names are transferred from the OtoRead™ Module to the OtoRead™ (a warning is provided that data will be deleted. From the Store Names to Instrument window, it is also possible to delete patients by clicking on the Clear List and then the Clear Instrument button..

Data printed using OtoRead™ Auto Print will be deleted when a new test is started.

Refer to the OtoRead™ Module & Auto Print Instructions for Use for further information.

3.14 Printing to a thermal printer

Printing to the thermal printer (optional) is by way of wireless connection. First establish wireless pairing between the OtoRead™ and the printer by following the instructions in the section ***Pairing the wireless printer to OtoRead™.***

Refer to the printer Operations Manual for more detailed instructions.



Following instructions provided with your printer, be sure the printer is on and ready for communication/printing. From the OtoRead™ instrument Main Menu, press the **UP** key to enter the device connection screen. Press the LEFT or RIGHT key to connect.



The OtoRead™ will search for the paired printer. When the printer is found, all the test results that are stored in memory will print out automatically.

The OtoRead™ will power off when printing is complete.

Note: All printed test results are marked for deletion, but will continue to be stored in memory until a new test is started at which time all tests in the memory will be erased. This allows the user to reprint the tests if printing is unsuccessful (for example, the paper runs out before printing is complete).

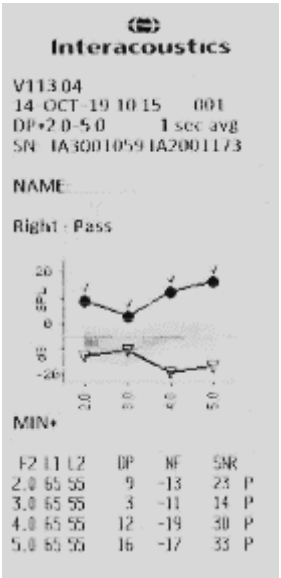
3.15 Understanding Printed Results from the Thermal Printer

The following section describes the information included on the printout.

3.15.1 Understanding the DPOAE printout

The following information is provided for each test:

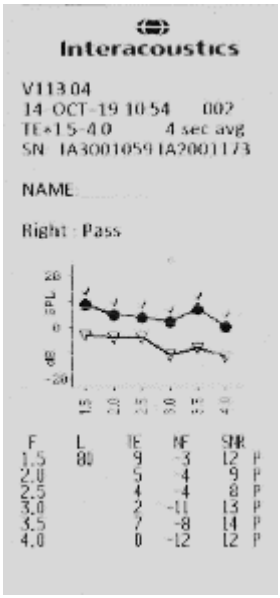
- The time and date of the test, based on the setting of the internal clock
- The test number (if operating in “Save500” mode)
- The test protocol (e.g., DP 4s)
- The averaging time used for the test (e.g., 2 sec avg.)
- Instrument and Probe serial number (SN)
- The software version number (e.g., v106.00)
- The ear tested (Right or Left)
- A PASS/REFER indication if there is a criterion set for the selected protocol
- The f2 frequency in kHz (e.g., 2.0, 3,0, 4.0, 5.0)
- The measured intensity level of f1 and f2 (L1, L2)
- The noise floor (NF) in dB SPL
- The emission level (DP) in dB SPL)
- The signal-to-noise ratio (SNR) – DP level minus the noise floor in dB
- A “P” to the right of the SNR if pass criteria were met for that frequency
- The Value or SNR graph as selected on the device
- “MIN*” if the Minimum Amplitude setting was enabled



3.15.2 Understanding the TEOAE printout

The following information is provided for each test:

- The time and date of the test, based on the setting of the internal clock
- The test number (if operating in “Save 250” mode)
- The protocol selected (e.g., TE 64s)
- The averaging time for the test (e.g., 64 sec avg.)
- Instrument and Probe serial number (SN)
- The software version number (e.g., v106.00)
- The ear tested (Right or Left)
- A PASS/REFER indication if there is a criterion set for the selected protocol
- The center frequency band (F)
- The noise floor (NF) in dB SPL
- The emission level (TE) in dB SPL
- The signal-to-noise ratio (SNR) – TE level minus the noise floor in dB
- A “P” to the right of the SNR if pass criteria were met for that frequency
- The Value or SNR graph as selected on the device
- “MIN*” if the Minimum Amplitude setting was enabled



3.15.3 Rounding results

The user needs to be aware that the SNR and single PASS criteria are calculated from the full internal precision of the instrument, and not from the values shown on the printout for the emission (TE) and noise floor (NF) estimates.

This approach is used to preserve the full precision of the test results, but can result in some apparent errors in the printout due to the effects of rounding.

Example: We assume the actual values at 1.5 kHz were TE = 4.5 dB, NF = -0.4 dB, which results in SNR = 4.9 dB. The printout values are rounded up to the nearest integer and are shown as TE = 5, NF = 0, and SNR = 5. This can result in what appears to be an error with regard to the pass criterion.

Note: If the pass criterion is 5 dB while the actual SNR = 4.9, the printed value will be 5, but a P will NOT be printed.
Again, the pass/refer criterion is based on the full precision of the results, and not the rounded values that are printed. The full precision value for the SNR must be equal to or greater than the pass criterion (5 dB in this example) for the P to be printed. A similar apparent problem can occur where the printed SNR value appears to be incorrect. If the actual values were TE = 4.5 dB, NF = 0.4 dB, resulting in SNR = 4.1 dB, the printed values would be TE = 5 dB, NF = 0, SNR = 4. The printed SN value of 4 dB appears to be an error, but is in fact correct.

3.15.4 Special characters

The device and optional printer support the printing of special language characters for all included languages.

3.16 Connecting to the OtoRead™ Module

Connection to the OtoRead™ Module or Auto Print software is achieved by using the provided Micro-USB to USB-A cable or wirelessly.

3.16.1 USB connection from device

Plug the USB-A connector into an available USB port on the computer and the Micro-USB connector into the port found on the base of the OtoRead™.

3.16.2 USB connection from cradle

Plug the USB-A connector into an available USB port on the computer and the Micro-USB connector into the port found on the back of the cradle. Ensure that the OtoRead™ is correctly seated in the cradle.

3.16.3 Wireless connection

For a wireless connection to the computer, ensure that the OtoRead has been correctly paired. From the Main Menu screen press the **UP** key to enter the device connection screen. Press the **LEFT** or **RIGHT** key to connect. Upon successful connection the device screen will display “CONNECTED”.

Refer to the OtoRead™ Module & Auto Print Instructions for Use for further instructions.

3.17 Storing results in HearSIM™ and OtoAccess®

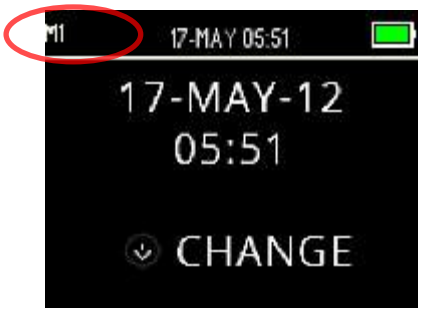
Results from screening protocols (DP 2s, DP 4s, TE 32s, TE 64s) can be stored and viewed in HearSIM™ and OtoAccess®™. For further information, consult the HearSIM™ and OtoAccess®™ manuals.

NOTE: test data from clinical protocols will be deleted during the transfer process and will not be stored in either database. To store these data, refer to the OtoRead Module manual.

3.18 Changing instrument settings

3.18.1 Menu Structure

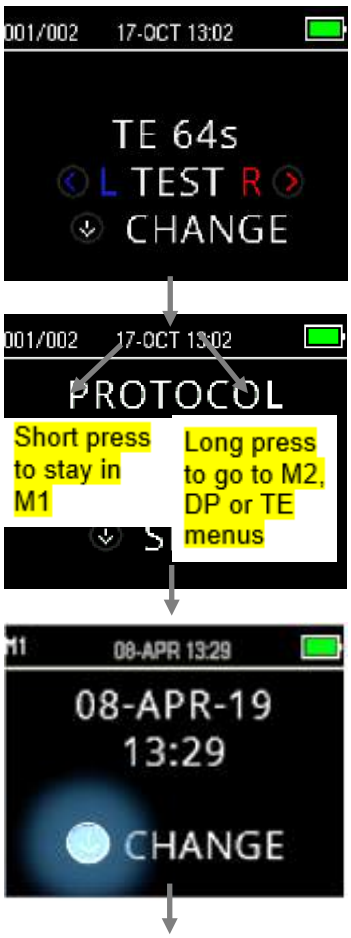
The OtoRead™ allows the user to change many of the instrument's settings or functions.



For a better understanding as to which menu you are currently in, the menu number or name can be found in the upper left corner of the screen.

Refer to section ***Menu structure*** for an overview of the settings in each menu.

3.18.2 Accessing the menus



To access the different menus, press the **DOWN** key from the Main Menu screen.

The Protocol Menu screen allows the user to change the test protocol using the **LEFT** or **RIGHT** key. Once the desired protocol is displayed on the screen, press the **UP** key to return to the Main Menu and begin testing.
To access the Setup menus M1, M2, DP and/or TE press the **DOWN** key from the Protocol menu.

The first accessible menu is M1, indicated by M1 in the top left hand corner of the screen. You will notice that the **DOWN** key is pulsing in blue. To adjust the date and time settings, press the **DOWN** key once. To move to M2, press and hold down the **DOWN** key for 3 seconds until the 'READY' light (green LED) turns off, and then release the key.

The pulsing **DOWN** key on the display indicates a long press is required to move to the next menu.

To access the TE or DP menus, you must have selected the relevant protocol. E.g., to access the DP menu, a DP protocol must have been selected and appear on the Main Menu screen.

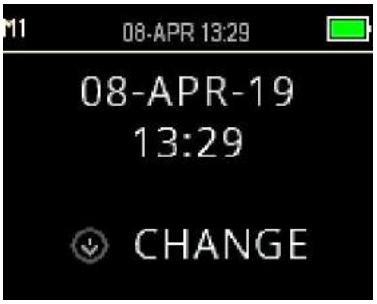
DP and TE menus are not accessible in the OtoRead™ Screening and Screener Plus Version.

3.18.3 Date and time settings (menu M1)

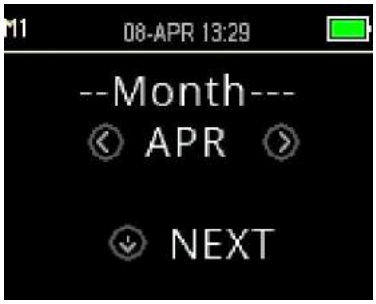
When the OtoRead™ is first used, the correct date and time will need to be set on its internal clock. The date and time are listed on the test printout as day-month-year (e.g., 07-MAR-17). The clock should be set prior to testing, as changing it after tests are saved will not change the date on the printout (i.e., the date that was previously in memory will be the date on the printout).

Seasonal time changes such as Daylight Saving Time will also require resetting the clock. If the instrument is being powered on for the first time or if the instrument's battery is completely discharged and the battery is not charged within approximately one hour a TIME/DATE ERROR message will occur. If this message appears, reset the time and date.

3.18.3.1 Changing the date and time



To change the time and date, press the **CHANGE** key at the Main Menu and then press the **SETUP** key again at the Protocol menu. The current date and time presently set in the device will be shown. If the time and date are correct, press the **UP** key to return to the Main Menu



If either the date or time is incorrect, press the **CHANGE** key to access the menu to change the month. Press the **LEFT** or **RIGHT** keys to scroll forward or backward through the months.

You will see the abbreviated name for each month. When the desired month appears on the display, press the **NEXT** key to enter the day selection screen. Pressing the **LEFT** or **RIGHT** key will scroll through the days of the month. Repeat this process for the year, hour, and minute using the **LEFT** or **RIGHT** key to make the selection and the **NEXT** key to advance to the next display.



When the correct minute is set, pressing the **DONE** key will return to the Main Menu. The time and date changes are automatically saved.

3.18.4 Device settings (menu M2)

3.18.4.1 Wireless device pairing



The OtoRead™ pairing menu allows the user to pair the OtoRead™ unit with a wireless device, such as a thermal printer or personal computer, for printing test results and data transfer.

The OtoRead™ can be paired with only one device at any one time, meaning that the pairing process will have to be repeated on previously used devices, in cases where the OtoRead has been wirelessly connected to other devices. To establish wireless pairing, turn on the device that will be paired with the OtoRead™ (e.g., thermal printer). Select **DISCOVER** to initiate discovery of available wireless devices. The OtoRead™ will search for available wireless devices for approximately 15 seconds. During this time the user will see the message 'PLEASE WAIT' on the display and the orange 'TEST' LED will flash. Discovery can be canceled by pressing the **CANCEL** key.

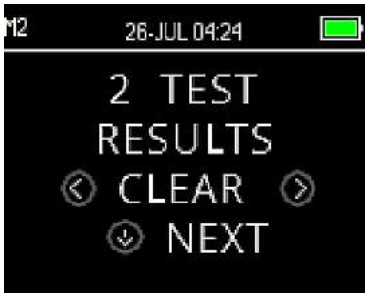
When discovery is complete, all discovered devices will be shown in the order in which they were found. A compatible thermal printer will appear as 'PRT-##-##' (e.g., PRT-ab-8f) and other devices will be shown by their name which can vary depending on the device. Use the **CHANGE** keys to select the desired device and then use the **PAIR** key to pair the OtoRead™ to the selected device.

The printer will print out a connection confirmation page.

Pairing will be confirmed. The pairing process is complete. Select **Main Menu** to exit the wireless pairing menu.

Refer to the OtoRead™ Module & Auto Print Instructions for Use for detailed information about pairing the device to a PC.

3.18.4.2 Clearing test results



The Test Results Clear menu allows the user to clear the test results stored in the unit without printing them. Select the **LEFT** or **RIGHT** key to clear the results and select **Yes** or **No** to verify clearing or to cancel. To advance to the next menu without clearing the results, press **NEXT** key.

Following printing or data transfer to the PC software, all tests saved in memory are marked for deletion and will be permanently deleted when a new test is started. It is not necessary to manually clear the results using this menu.

3.18.4.3 Power OFF mode



Set the Power OFF mode to define after what length of time the device will automatically shut down.

It can be set for 30 seconds, 1 minute, 2 minutes or 4 minutes

3.18.4.4 Save mode / storing test results





The OtoRead™ automatically stores only the most recent test result for each ear L/R, but has the capacity to store 500 individual tests. Press the 〈**CHANGE**〉 keys to change the setting to SAVE 500 TESTS. Once you have made your selection, press ﹀**NEXT**.

There are two options in the Save 500 mode:

1. The OtoRead™ automatically numbers each test from 1 to 500.

2. The OtoRead™ Module is used to transfer patient names to the OtoRead™ and the OtoRead™ displays the names. Up to 50 names can be stored in the device and 50l tests.

When numbers are used (no patient names are uploaded from the OtoRead™ Module to the OtoRead™), each test is automatically incremented, starting with test number 1.

When patient names are transferred to the device, they are displayed on the OtoRead™ in the same order as displayed in the OtoRead™ Module. To move to a different name than the one displayed on the OtoRead™ screen, use the 〈**LEFT** or **RIGHT**〉 key to cycle through the names until the desired name is on the display. The patient 'Unnamed' is always included at the beginning of the patient list for instances when a patient is being tested, but the patient name has not been transferred to the OtoRead™.

It is recommended that you go to the Test Results Clear screen to clear any previous memory locations after you changed the save mode setting.

When using the '500 test' mode, it is important to keep a record of the test number for each patient. When 495 tests have been saved, the user will be warned that the memory is almost full. When the OtoRead™ unit reaches 500 saved tests, it will not allow any further testing. At this point either the results must be printed, transferred to the OtoRead™ Module, or cleared from device memory.

3.18.4.5 Minimum value





The Minimum (Amplitude) Value setting allows the user to set the unit to include minimum amplitude values in the pass/refer criterion. The OtoRead™ is set with this feature enabled when it is shipped from the factory.

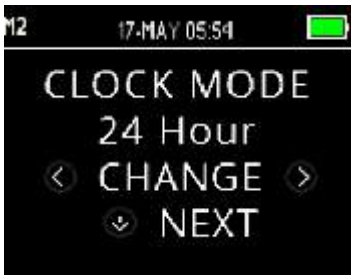
The default setting for both DP and TE is -10 dB SPL. The minimum value can be set between +5 and -10 dB SPL or OFF.

When a MIN VALUE has been set, a test band (TE) or test frequency (DP) is not considered a detected unless the absolute amplitude at each band or frequency is equal to or greater than the minimum value enabled on the device. This is in addition to meeting the other detection criteria such as the SNR.

To change the mode to MIN VALUE setting, press the 〈**LEFT** or **RIGHT**〉 key to make a selection. Once you have made your selection, press ﹀**NEXT**.

Note: It is recommended to leave the MIN VALUE setting enabled to ensure that non-biological responses are not detected as OAE responses.

3.18.5 Clock mode



The Clock Mode menu allows the user to change the clock from a 24 hour mode to a 12 hour mode. To change the clock mode, press the 〈**CHANGE**〉 keys. Press ﹀**NEXT** to exit this menu.

3.18.6 Graph style



The Graph Style menu allows the user to select from two options for viewing the results. The SNR graph view shows the signal-to-ratio for each DP test frequency or TE test band. The Value graph view shows the absolute OAE and noise levels for each DP test frequency or TE test band.

3.18.7 Languages



The Language setting allows the user to select among several languages. To change the language, press the 〈**CHANGE**〉 key until the desired language is shown. Press ﹀**NEXT** to exit this menu.

Available languages are:

- English (US)
- English (UK)
- Chinese
- Russian
- Spanish
- Polish
- Portuguese
- Turkish
- French
- German
- Italian
- Korean
- Japanese
- Arabic

3.18.8 Reset to default



The Reset to Default menu will return all instrument settings and protocol settings to their original factory defaults.

Use the 〈**RESET**〉 keys to reset and select 〈 **NO** or **YES**〉 to verify reset. PARAMETERS RESET will appear on the display as confirmation. Press the ﹀**NEXT** key to return to the Main Menu.

To exit M2 without resetting to default, press the ﹀**NEXT** key to return to the Main Menu.



Resetting to default will un-pair the wireless device, clear the test results, and reset all system and protocol settings.



3.18.9 Protocol settings for DPOAE (DP menu)

3.18.9.1 General

The DP protocol settings menu is reserved for those devices purchased as either a Standard or Clinical version. Screener and Screener Plus versions of the OtoRead™ device do not have access to this menu as the default screening protocol's parameters cannot be changed.



The DP protocol settings menu can be recognized by the abbreviation 'DP' in the top left corner.

The DP protocol settings menu permits modification of the test parameters and detection criteria for the customizable DP protocols. Changes to protocols should be made only by qualified personnel. If you are not familiar with the parameters and how changing them can affect test outcomes, do not attempt to change the protocols.
The OtoRead™ comes with pre-programmed protocol settings. See Appendix C for the manufacturer settings of these protocols. Test protocol changes are saved in the non-volatile memory so the settings will be retained even when the battery is temporarily discharged .

3.18.9.2 Customizing a test protocol

To enter the DPOAE Menu:

1. Press the **CHANGE** key at the Main menu.
2. Using the **CHANGE** keys, select the DPOAE protocol you want to customize (the 'DP 4s' protocol is not customizable).
3. Press the **SETUP** key at the Protocol menu.
4. At M1 (Date and time settings menu) the pulsing arrow appears. Hold down the **CHANGE** key for 3 seconds until the 'READY' light (green LED) turns off.
5. At M2 (Device settings menu) the pulsing arrow appears again. Hold down the **CHANGE** key for 3 seconds until the 'READY' light (green LED) turns off.
6. The device is now in the DP menu (indicated by DP in the top left corner of the screen).

From the DP menu, you can now scroll through the available protocol parameters using the **NEXT** key and make changes by using the **LEFT** or **RIGHT** keys.

3.18.9.3 Changing the levels (L1 and L2)



The Level L1 refers to the stimulus level of the primary tone f1 (frequency 1). The Level L2 refers to the stimulus level of the primary tone f2 (frequency 2). The intensity of the primary tones (L1, L2) may be changed to any level between 40 dB SPL and 70 dB SPL. The L1 and L2 stimulus levels can be changed in 1 dB increments by pressing the **CHANGE** keys.

Typical L1 and L2 levels in DPOAE testing are L1 = 65 and L2 = 55 dB SPL.



After setting the L1 stimulus level, press the **NEXT** key to go to Level L2.

3.18.9.4 Setting the averaging time



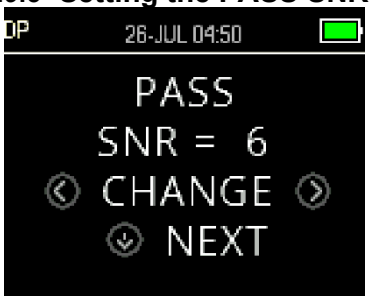
The Averaging Time refers to the test time per DP frequency. The Averaging Time will have a large impact on the time required to perform the test and on the signal-to-noise ratio (SNR). A 2 second average for 6 frequencies would produce a test in about 18 seconds.

The possible settings for the Averaging Time are:
0.5 sec., 1.0 sec., 2.0 sec., or 4.0 sec.

Use the **CHANGE** keys to select an option and the **NEXT** key to go to the next test parameter.

Longer averaging times help to reduce the noise floor which can improve the likelihood of obtaining a pass result, particularly with a noisy patient (e.g., a baby sucking a pacifier) or in a noisy environment. However, shorter averaging times may be preferred for young children and/or uncooperative patients. A minimum avering time of 2 seconds is recommended.

3.18.9.5 Setting the PASS SNR level



In order to provide a PASS/REFER determination for each test, the PASS SNR for all DP test frequency must be set. This number refers to the number of decibels that the DPOAE signal must be above the noise to be considered as present (detected) at each frequency. The PASS SNR can set between 3 - 10 dB.

A checkmark will appear above the test frequency in cases where the SNR and minimum value criteria are met.

Use the **CHANGE** keys to increase or decrease the value. This criterion is used in combination with the number of frequencies required for a pass (discussed below) to determine an overall PASS/REFER for each test.

After setting the desired PASS SNR, press the **NEXT** key to go to the next test parameter.

3.18.9.6 Setting the number of frequencies for PASS



The number of frequencies required for determining a PASS can be set from 0 to 12. If the setting is on 0, then no assessment of PASS/REFER will be made. This setting is used in conjunction with the PASS SNR and MIN LEVEL criteria to determine the overall test outcome (PASS or REFER).

For example, if the MIN LEVEL is set to -10 dB, the PASS SNR is set to 5 dB and the number of frequencies for PASS is set to 3, then the test must contain at least 3 frequencies where the emission is at least 5 dB above the noise at a minimum level of -10 dB to indicate a PASS.

The number of frequencies for PASS should also be based on the number of frequencies being tested. Setting the number of frequencies for PASS to 5 when only 4 frequencies are being tested would result in every test being labeled as a REFER.

To disable the PASS/REFER assessment set the number of frequencies for pass to 0.

Once the 'Number of Frequencies for PASS' is set above zero, green bars are displayed to identify this setting, the green colour indicating that the frequency band in question has passed the selected pass criteria.

Use the 〈**CHANGE**〉 keys to select an option and the ﹀**NEXT** key to go to the next test parameter.

3.18.9.7 Reset protocol



Use the 〈**RESET**〉 keys to return the selected protocol parameters to their original factory settings. To skip this option, press the ﹀**NEXT** key.

This does not affect the instrument settings or the settings of any other protocol.



After pressing one of the 〈**RESET**〉 keys, a confirmation that the protocol was reset will be displayed. Press the ﹀**DONE** key to return to the Main menu.

3.18.9.8 Save protocol



Once all of the parameters have been set for the protocol, these settings can be saved by pressing one of the 〈**SAVE**〉 keys.

To exit without saving protocol setting changes press the ﹀**DONE** key to return to the Main menu.

When one of the 〈**SAVE**〉 keys have been pressed, CUSTOM PROTOCOL SAVED will be displayed as confirmation. Press the ﹀ **DONE** key to return to the Main menu.

3.18.10 Advanced options for TEOAE testing (TE menu)

3.18.10.1 General

The TE protocol settings menu is reserved for those devices purchased as either a Standard or Clinical version. Screener and Screener Plus versions of the OtoRead™ device do not have access to this menu as the default screening protocol's parameters cannot be changed.



The TE protocol settings menu can be recognized by the abbreviation 'TE' in the top left corner.

The TE protocol settings menu permits modification of the test parameters and detection criteria for the customizable TE protocols. Changes to protocols should be made only by qualified personnel. If you are not familiar with the parameters and how changing them can affect test outcomes, do not attempt to change the protocols.

The OtoRead™ comes with pre-programmed protocol settings. See Appendix C for the manufacturer settings of these protocols. Test protocol changes are saved in the non-volatile memory so the settings will be retained even when changing the batteries.

3.18.10.2 Customizing a test protocol

To enter the TEOAE Menu:

1. Press ﹀**CHANGE** at the Main menu.
2. Using the 〈**CHANGE**〉 keys, select the TEOAE protocol you want to customize (the 'TE 64s' protocol is not customizable).
3. Press ﹀**SETUP** key at the Protocol menu.
4. At M1 (Date and time settings menu), the pulsing arrow appears. Hold down the ﹀**CHANGE** key for 3 seconds until the 'READY' light (green LED) turns off.
5. At M2 (Device settings menu) the pulsing arrow appears again. Hold down the ﹀**CHANGE** key for 3 seconds until the 'READY' light (green LED) turns off.
6. The device is now in the TE menu (indicated by TE in the top left corner of the screen).

From the TE menu, you can now scroll through the available protocol parameters using the ﹀**NEXT** key and make changes by using the 〈**LEFT** or **RIGHT**〉 keys.

3.18.10.3 TE stimulus level

The OtoRead™ TEOAE protocols all use a fixed stimulus level of 80 dBSPL. This cannot be changed by the user.

3.18.10.4 Setting the averaging time



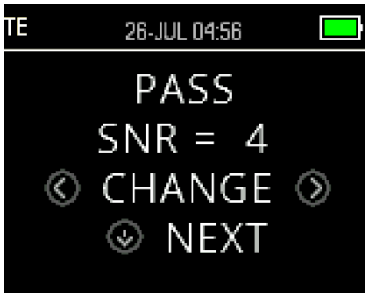
The Averaging Time for TE protocols refers to the maximum test time. The Averaging Time can have a significant impact on the signal-to-noise ratio (SNR) achieved and the final test outcome (e.g., PASS/REFER). The averaging time is independent of the probe check process.

The possible settings for the Averaging Time are:
4, 8, 16, 32 or 64 seconds.

The test will automatically stop before the maximum test time is reached in cases when the PASS criteria are met.

Use the 〈**CHANGE**〉 keys to select an option and the ﹀**NEXT** key to go to the next test parameter.

3.18.10.5 Setting the PASS SNR level



In order to provide a PASS/REFER determination for each test, the PASS SNR for all TE test bands must be set. This number refers to the number of decibels that the TEOAE signal must be above the noise to be considered as present (detected) at each frequency band. The PASS SNR can be set between 3 – 10 dB.

A checkmark will appear above the frequency bands in cases where the SNR and minimum value criteria are met.

Use the 〈**CHANGE**〉 keys to increase or decrease the value. This criterion is used in combination with the number of frequencies (discussed below) to determine an overall PASS/REFER for each test.

After setting the desired PASS SNR, press the ﹀**NEXT** key to go to the next test parameter.

3.18.10.6 Setting the number of frequencies for PASS



The number of frequencies (TE bands) for determining a PASS can be set from 0 to 6. If the setting is on 0, then no assessment of PASS/REFER will be made. This setting is used in conjunction with the PASS SNR and the MIN LEVEL criteria to determine the overall test outcome (PASS or REFER).

For example, if the MIN LEVEL is set to -10 dB, the PASS SNR is set to 4 dB and the number of frequencies for PASS is set to 3 then the test must contain at least 3 frequencies where the emission is at least 4 dB above the noise at a minimum level of -10 dB to indicate a PASS.

Use the ‹**CHANGE**› keys to select an option and the ⌄**NEXT** key to proceed to the next test paramater.

Once the 'Number of Frequencies for PASS' is set above zero, green bars are displayed to identify this setting, the green colour indicating that the frequency band in question has passed the selected pass criteria.

3.18.10.7 Reset protocol



Press the ‹**RESET**› keys to return to the selected protocol paramaters to their original factory settings. Press the ⌄**NEXT** key to return to the Main menu..

This does not affect the instrument settings or the settings of any other protocol.



3.18.10.8 Save protocol



Once all of the parameters have been set for the protocol, these settings can be saved by pressing on one of the ‹**SAVE**› keys.

To exit without saving protocol setting changes press the ⌄**DONE** key to return to the Main menu.

When one of the ‹**SAVE**› keys have been pressed, CUSTOM PROTOCOL SAVED will be displayed as confirmation. Press the ⌄ **DONE** key to return to the Main menu.



4 Care and maintenance

4.1 General maintenance procedures

It is recommended that routine check procedures are carried out weekly in full on all equipment in use. Checks 1-8 outlined below should be carried out on the equipment on each day of use.

The purpose of routine checking is to ensure that the equipment is working properly, that its calibration has not noticeably changed, and that its transducers and connections are free from any defect that might adversely affect the test result. The checking procedures should be carried out with the instrument set up in its usual working situation without being connected to a patient.

1. Clean and examine the instrument and all accessories.
2. Check probe tube, plugs, main leads and accessory leads for signs of wear or damage. Damaged or badly worn parts should be replaced.
3. On battery-powered equipment, check battery state using the manufacturer's specified method. Switch on equipment and leave for the recommended warm-up time. If no warm-up period is stated, allow 5 minutes for the circuits to stabilize. Carry out any setting-up adjustments as specified.
4. Check that the probe serial number is correct for use with the instrument.
5. Check that the instruments's output is approximately correct by conducting a simplified test on a known test subject with known hearing; check for any change.
6. Listen at low levels for any sign of noise, hum, or unwanted sounds from the device.
7. The instrument has been designed to provide many years of reliable service, but annual calibration is recommended to ensure ongoing accuracy of the transducers.
8. If the instrument or transducers have been exposed to damage (dropped or similar), please ensure that calibration has been maintained. Recalibration may be required.
9. The calibration procedure is available in the service manual.

Please note: Great care should be exercised in the handling of probes and other transducers, as mechanical shock may cause a change in calibration.

4.2 How to clean Interacoustics products

If the surface of the instrument or parts of it are contaminated, they can be cleaned using a soft cloth moistened with a mild solution of water and dish-washing cleaner or similar (e.g. normal hospital bactericides). The use of aggressive solvents and aromatic oils must be avoided. Always disconnect the USB cable during the cleaning process, and be careful that no fluid enters the inside of the instrument or the accessories.



Before cleaning always switch off and disconnect from power
Use a soft cloth lightly dampened with cleaning solution to clean all exposed surfaces
Do not allow liquid to come in contact with the metal parts inside the probe
Do not autoclave, sterilize or immerse the instrument or accessory in any fluid
Do not use hard or pointed objects to clean any part of the instrument or accessory
Do not let parts that have been in contact with fluids dry before cleaning
Rubber eartips are single use components
Ensure isopropyl alcohol does not come into contact with any screens on the instruments
Ensure that isopropyl alcohol does not come into contact with any silicone tubes or rubber parts

Recommended cleaning and disinfection solutions:
Warm water with mild, nonabrasive cleaning solution (soap)
70% isopropyl alcohol

Procedure:
Clean the instrument by wiping the outer case with a lint-free cloth lightly dampened in cleaning solution
Clean probe and cable with a lint-free cloth lightly dampened in cleaning solution
Make sure not to get moisture in the speaker portion of the probe and similar parts.

Ear tips:
Use new ear tips for each patient. Ear tips are for single patient use only.

Probe tube:
The probe tube, which does not make direct contact with the patient, should be replaced if there is any sign of contamination or if the test will not progress past the Probe Check phase. Disinfection of the probe tube between patients is not required. The probe tube requires replacement only when it becomes clogged.

The cleaning instruction outlined in this Instruction for Use may not conform to the infection control guidelines of the user's facility. The disinfection materials and procedures applied in the user's facility may be more appropriate for their circumstances than the methods outlined above (see cautions below). The frequency of cleaning and disinfecting is dependent on the facility's risk assessment, usage, and test environment.



Do not immerse the instrument or probe in fluids or attempt to sterilize the instrument or any of its accessories.
Do not allow any fluid to enter the device
Do not use autoclave sterilization
Take care not to put excessive pressure on the clear display window or allow any utensil to puncture the display window or control panel

4.3 Concerning repair

Interacoustics 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 Interacoustics.

It is important that the customer (distributor) fills out the RETURN REPORT every time a problem arises. This should also be done every time an instrument is returned to Interacoustics. (This of course also applies in the unthinkable worst case of death or serious deterioration to patient or user).

4.4 Warranty

Interacoustics warrants that:
The OtoRead™ is free from defects in material and workmanship under normal use and service for a period of 12 months from the date of delivery by Interacoustics to the first purchaser
Accessories are free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Interacoustics to the first purchaser

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the local Interacoustics service centre to determine the appropriate repair facility. Repair or replacement will be carried out at Interacoustics' 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 Interacoustics shall be at purchaser's risk.

In no event shall Interacoustics be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any Interacoustics 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 Interacoustics shall not be responsible for, any loss arising in connection with the purchase or use of any Interacoustics product that has been:
repaired by anyone other than an authorized Interacoustics service representative;
altered in any way so as, in Interacoustics judgement, to affect its stability or reliability;
subject to misuse or negligence or accident, or which has had the serial or lot number altered, effaced or removed; or
improperly maintained or used in any manner other than in accordance with the instructions furnished by Interacoustics.

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

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

5 Troubleshooting

Problem	Solutions
Instrument does not turn on	The ⌄DOWN arrow must be pressed for a full second (the Yellow 'TEST' LED will illuminate) Connect the charger as shown in chapter 2.6.2. Confirm that the blue 'Charging' LED is illuminating in a slow blink pattern. Wait at least 10 minutes and then attempt to turn on the instrument
The test will not start	Select a different sized ear tip Reposition the probe Change the probe tube Verify that the ear tip is sealed in the ear canal via feedback from the PROBE CHECK screen Check that the instrument will start in your own ear with the proper ear tip for testing yourself. If the test will not start or if the AutoStart tones sound unusual, replace the probe tube
The results will not print	Check the printer status. Turn the printer on (wake from sleep mode) by pressing the large button If the printer does not turn on, plug in the power supply to charge the battery Be sure the printer has paper If paper comes out of the printer but there is no text on the paper then the paper is in backwards Press the large printer button twice, rapidly, to run demo print
Display is frozen and instrument will not respond to button presses	Press and hold the ⌄DOWN arrow button for 10 seconds to force the instrument to power off. Powering the instrument back on again should reset/restore normal function
Error Messages	**Description & Solutions**
Attach Probe	No probe is detected at the start of a test. Check that the probe connector is fully seated in the socket Disconnect and reconnect the probe Cycle instrument power
BT Device Not Found	The paired wireless device cannot be detected. The device may be turned off or too far away. Paired to Printer: Check that the printer is turned on Move closer to the printer Try again Paired to PC Computer or dongle: Check that the serial port in the module is identical to the setting found in the Device Manager. Establish that the serial port is handled by the PC and/or the software, not by the OtoRead™ instrument
BT Error #xxx	There is an error condition with the wireless device. Check the status. Check BT device (printer or PC) status Attempt to connect to BT device again
BT Not Configured	The OtoRead™ device is not paired with any wireless device. Pair the OtoRead™ with the wireless device (printer or PC)
Device Not Responding	The printer is not responding to queries from the instrument. Check the printer status Awaken printer from sleep mode Charge printer battery if necessary
Fit Error Cannot Obtain P	For a DP test, the desired stimulus level (L1 or L2) cannot be obtained within allowable limits. User should refit the probe in the paitnet's ear and retry the test Replace the probe tube

Fit Error Too High	For a DP test, the level of the calibration tone is too high. User should refit the probe in the patient's ear and retry the test Replace the probe tube
Fit Error Too Low	For a DP test, the level of the calibration tone is too low. User should refit the probe in the patient's ear and retry the test Replace the probe tube
Limit Error	Overflow error during the calculation of the DFTs for a DP test. User should repeat the test Cycle instrument power
Memory almost full	Saved tests are within 5 tests of the maximum limit. Print or transfer test results to the PC to avoid interruption in testing
Memory Full!	The maximum saved test limit is reached. The user will need to clear the memory before any additional tests can be performed
Power Low!	The battery charge level is too low for operation. The user must charge the battery before additional tests can be performed
Printer Error	Indicates a problem with the printer. Check the printer status Reset the printer or cycle the printer power
Printer Paper Out!	Indicates the paper has run out. Replace the paper roll
Time/Date Error	The clock is checked during power on to ensure it has not lost time and been reset. In the case of clock reset, this message is shown. The user should set the correct date/time
Due for Service	Indicates that calibration of instrument is due. The message will appear upon the calibration due date set in the device. A daily reminder will appear during device startup. Arrange calibration of the instrument

Contact Interacoustics or your local distributor for service if any of the above problems persist.

6 General technical specifications

6.1 OtoRead™ hardware – Technical specifications

Medical CE-mark 	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no0123 The OtoRead™ is an active, diagnostic medical product according to the class IIa of the EU medical directive 93/42/EEC.	
Standards	Safety:	IEC 60601-1:2012 Internally powered, Type B parts
	EMC:	IEC 60601-1-2:2014
	Calibration:	ISO 389-2:1994 ISO 389-6:2006
	Test Signal:	IEC 60645-1:2012 IEC 60645-3:2007
	OAE:	IEC 60645-6 2009, Type 2
Cradle	Safety: Power: Mains voltages and frequencies: Output:	IEC 60601-1:2012 Class II UES12LCP-050160SPA 100 – 240 VAC, 50/60 Hz, 400 mA 5.0V DC, 1.6A MAX
Operation environment	Temperature: Relative Humidity: Ambient Pressure: Max. altitude: Boot-up time: Warm-up Time:	15 to 35°C, + 59°F to + 95°F 30 to 90 % (non-condensating) 98 kPa to 104 kPa 2000 m / 6561 ft above sea level < 5 sec < 1 minute
Transport & Storage environment	Storage Temperature: Transport Temperature: Storage and Transport rel. Humidity :	0°C to 50°C, 32°F to + 122°F -20 to 50°C, - 4°F to + 122°F 10 to 95% (non-condensating)

General		
Dimensions OtoRead™		6.6 x 3.1 x 14.5 cm / 2.25 x 1.23 x 5.78 inches
OtoRead™ Weight		180 g / 6.4 oz.
User Interface		OLED Display to provide user information and progress of measurement. 4-button keypad to control instrument functions
Display Size		3.5 x 2.8 cm / 1.38 x 1.1 inches
Data Interfaces		Wireless and USB
Language Settings		English, English (UK), Chinese, Russian, Spanish, Polish, Portuguese, Turkish, French, German, Italian, Korean, Japanese, Arabic
Battery	Type:	Lithium-Ion rechargeable
	Rating:	3.7V / 1750mAh
	Expected life time:	500 tests per charge, minimum 20 hours on-time
Memory		2 tests (one per ear) or 500 tests
Connector		Integrated USB communication capability for battery charging and communication with PC-based database programs or an optional printer.

		HDMI Connector for connection to the Micro-Probe Integrated Wireless + EDR with SPP Protocol for communication with optional printer
Micro-Probe	Microphone System Noise:	-20 dB SPL at 2 kHz (1 Hz bandwidth) -13 dB SPL at 1 kHz (1 Hz bandwidth)
	Dimensions and Weight:	Length: 1.0 meter (40 in.) Weight: 28 g (1.00 oz.)
	Connector:	HDMI
Thermal Printer (optional)	Type:	Sanibel MPT-II thermal wireless printer
	Battery:	Lithium-Ion rechargeable
	Paper width:	57.5 ± 0.5 mm on thermal printer

DPOAE		
Stimulus	Frequency range:	1500 to 12000 Hz
	Nominal frequency:	f2
	Level:	40 - 70 dB SPL
	Level Step:	1 dB
	Transducer:	Probe auto detection, auto calibrated
Recording	Analysis time:	0.5, 1, 2 or 4 seconds per frequency
	A/D Resolution:	16 bits
	Stimulus tolerance:	± 3 dB
	SNR criteria:	3 to 10 dB
	Probe check window:	1 sec.
	DP-response window:	0.5 – 4 seconds
	Residual noise:	-20 dB SPL @ 2kHz, -13 dB SPL @ 1kHz, (1 Hz bandwidth)
	THD:	Acoustic test signal <0,1 %, cubic distortion* < 0,01 %. *(Interactions between the two primary tones)
	Measurement Range:	-20 dB SPL – 89 dB SPL
	Accuracy of Measurement:	< ± 3 dB
Display		SNR and Value Graph, Norm data
Probe specifications	OtoRead™ probe:	DPOAE and TEOAE capable
		Replaceable probe tube
Other		
Test Pressure		Ambient pressure

TEOAE		
Stimulus	Frequency range:	700 to 4000 Hz
	Stimulus type:	Click Train
	Level:	80 dB peSPL, peak to peak calibrated
	Click rate:	64 Hz
	Stimulus tolerance:	± 3 dB
	Transducer:	Probe auto detection, auto calibrated
Recording	Analysis time (max):	4, 16, 32 or 64 seconds.
	A/D Resolution:	16 bits
	SNR criteria:	3 – 10 dB
	Measurement Range:	-30 dB SPL – 100 dB SPL (max power output)
	Accuracy of Measurement:	< ± 3 dB
	Sampling frequency	31250 Hz
Display		SNR and Value Graph
Probe specifications	OtoRead™ probe:	DPOAE and TEOAE capable
		Replaceable probe tube
Other		
Test Pressure		Ambient pressure

6.2 Reference equivalent threshold values for transducer

Table 1: Frequency and Intensity with G.R.A.S. RA0045 OES

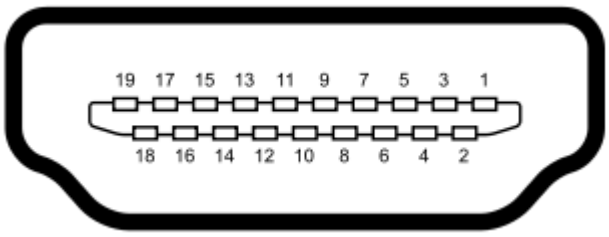
Output Frequency (Hz)	Minimum Frequency (Hz)	Maximum Frequency (Hz)	Minimum Magnitude (dB SPL)	Maximum Magnitude (dB SPL)
732.4	727	737	83	93
1037.6	1033	1043	85	95
1464.8	1460	1470	88	98
2075.2	2070	2080	92	102
2929.7	2925	2935	92	102
4150.4	4145	4155	85	95
5859.4	5855	5865	76	86

Table 3: Probe Nominal Sound Channel Magnitudes in dB SPL

Frequency [Hz]	IEC 60711, RA-0045
732.4	88.0
1037.6	90.0
1464.8	93.5
2075.2	97.8
2929.7	97.8
4150.4	90.6
5859.4	81.9

6.3 Pin assignments

The probe connector pin out:



Type A receptacle HDMI (female)

Pin 1	Rcvr +	Pin 11	Unused
Pin 2	Rcvr Shield	Pin 12	Unused
Pin 3	Rcvr -	Pin 13	Unused
Pin 4	Reserved	Pin 14	Reserved
Pin 5	Shield	Pin 15	Comm Power
Pin 6	Reserved	Pin 16	Comm Data
Pin 7	Mic Power +	Pin 17	Ground
Pin 8	Mic Shield	Pin 18	+3.3V
Pin 9	Mic Out	Pin 19	Ground
Pin 10	Mic Power -		

6.4 Electromagnetic compatibility (EMC)

- 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.

Portable and mobile RF communications equipment can affect the ***OtoReadTM***. Install and operate the ***OtoReadTM*** according to the EMC information presented in this chapter.
The ***OtoReadTM*** has been tested for EMC emissions and immunity as a standalone ***OtoReadTM***. Do not use the ***OtoReadTM*** adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.
The use of accessories, transducers and cables other than those specified, with the exception of servicing parts sold by Interacoustics as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device.
Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

Guidance and manufacturer's declaration - electromagnetic emissions		
The *OTOREADTM* is intended for use in the electromagnetic environment specified below. The customer or the user of the *OTOREADTM* should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ***OTOREADTM*** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ***OtoReadTM*** is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Complies Class A Category	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the *OtoReadTM*.			
The ***OtoReadTM*** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ***OtoReadTM*** can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ***OtoReadTM*** 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 $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (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 80 MHz and 800 MHZ, the higher frequency range applies. **Note 2** These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The ***OtoReadTM*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***OtoReadTM*** should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test level**	**Compliance**	**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 greater than 30%.
Electrical fast transient/burst IEC61000-4-4	+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 residential 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 residential environment.
Voltage dips, short interruptions and voltage variations on power supply 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	Mains power quality should be that of a typical commercial or residential environment. If the user of the ***OtoReadTM*** requires continued operation during power mains interruptions, it is recommended that the ***OtoReadTM*** be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) 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 residential environment.
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The ***OtoReadTM*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***OtoReadTM*** should assure that it is used in such an environment,			
Immunity test	IEC / EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC / EN 61000-4-6 Radiated RF IEC / EN 61000-4-3	3 Vrms 150kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any parts of the ***OtoReadTM***, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz 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 meters (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: 
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be			

predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ***OtoReadTM*** is used exceeds the applicable RF compliance level above, the ***OtoReadTM*** should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ***OtoReadTM***.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

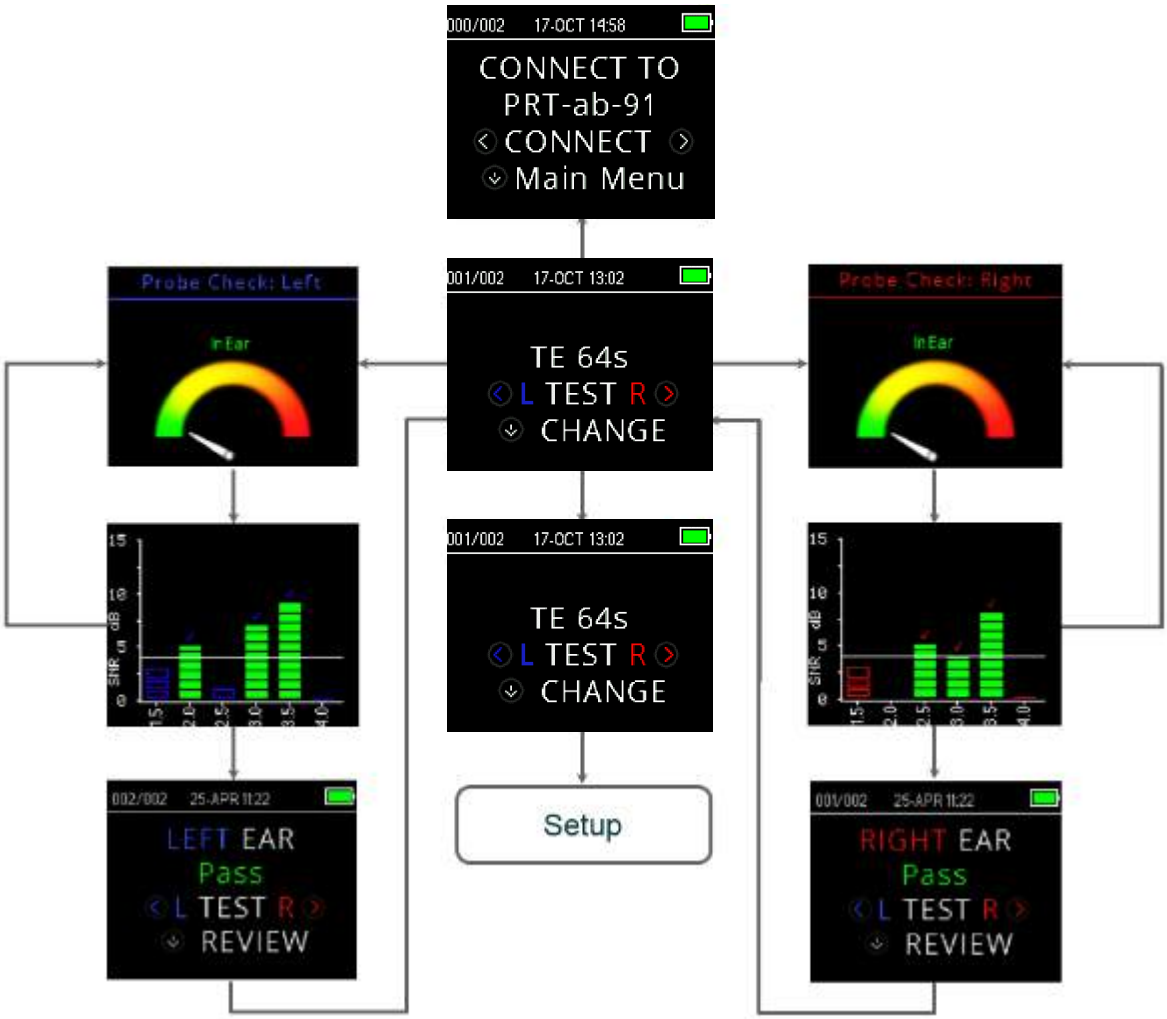
Conformance to the EMC requirements as specified in IEC 60601-1-2 is ensured if the cable types and cable lengths are as specified below:

Description	Length	Screened
OAE cable	2.0 m	Screened
USB Cable	2.0 m	Screened

7 Appendices

Workflows

The basic workflow is displayed in the flowchart below. From the Main Menu the connection to the printer can be accessed by pressing the ^**UP** key. Selecting the <**LEFT** or **RIGHT**> key will start the selected test protocol, which is displayed on the Main Menu screen. Selecting the v**SETUP** key takes you to the change protocol and settings menus.



7.1 Appendix A: test sequence

A complete test sequence consists of a probe check, calibration, and test phase. The probe check phase determines when the calibration phase should proceed, while the calibration phase calibrates the level of the tones that will be applied during the actual test phase. Artifact rejection is employed during the test phase to reduce the effect of transient noise bursts.
Immediately after the test button is pressed, the probe check phase of the test begins. The probe check phase checks both the quality and stability of the seal by measuring the response obtained from a sequence of test tones. The stability of the seal is determined by comparing the responses obtained over time. When the level of the response is within an acceptable range and is stable over time, the unit proceeds to the calibration phase.

FOR DPOAE
The calibration phase automatically measures the response obtained from a sequence of calibration tones and calculates the voltage needed to obtain the desired pressures. If the desired peak pressure cannot be obtained, the unit will use the maximum voltage. A successful calibration then leads on to the actual test phase.
The test phase consists of measuring the response obtained from the pairs of test frequencies (f1, f2) applied to the receivers. Two receivers are used, with each receiver generating one frequency in order to reduce intermodulation distortion. Frequency domain estimates of the actual L1, L2, distortion (DP) and noise floor (NF) are obtained via the discrete Fourier Transform, with a bin resolution of approximately 31 Hz. The NF estimate is obtained by averaging the power in the 4 closest (+/-2) bins to the DP bin.
FOR TEOAE
The calibration phase automatically measures the peak pressure obtained from a sequence of clicks and calculates the voltage required to obtain the target peak pressure. If the desired peak pressure cannot be obtained, the unit will use the maximum voltage.
The test phase consists of measuring the response obtained from repeated sequences of clicks applied to the receivers. The click sequence is 3-1-1-1 repeated twice. Signal and noise floor estimates are obtained by adding/subtracting the two response sequences, respectively. The energy of the signal and noise floor estimates in various frequency bands is obtained in real time and displayed once per second. The average peak pressure of the stimulus is calculated after completion of the test.
Artifact rejection is employed during the test phase to reduce the effect of transient noise bursts by the use of an adaptive rejection threshold. The unit attempts to accept the quieter sections of the test, while rejecting the noisier portions of the test. When the noise level is approximately constant during the test, the instrument will tend to accept most of the data in the test. However, as the level of the noise becomes more variable over time, the instrument will attempt to accept the quieter portions of the recording. Noise estimates are obtained approximately 32 times per second and a suitable threshold is estimated from the data. Data segments with a noise floor above this threshold are rejected, which tends to lower the noise floor of the test. In order to reduce the possibility of obtaining an artificially low noise floor, the minimum threshold level is limited.

Comment about variations in the SNR estimate:
The user needs to be aware that the SNR estimate has an inherent statistical variation due to the effects of random noise, especially when no emission is actually present. If a test is performed with the instrument's probe placed in a test cavity, it can be shown theoretically that the SNR will be greater than 6 dB approximately 7 times out of 100. This is not a limitation of the instrument, but a fundamental property of the method used to estimate the SNR in all emission testing. In order to reduce the occurrence of this "false" emission, the instrument limits the minimum value of NF, which has the effect of reducing the SNR for tests that have a low noise floor. As the noise level of the test increases, the user will notice that more "false" emissions will appear, which is to be expected.

7.2 Appendix B: test sequence

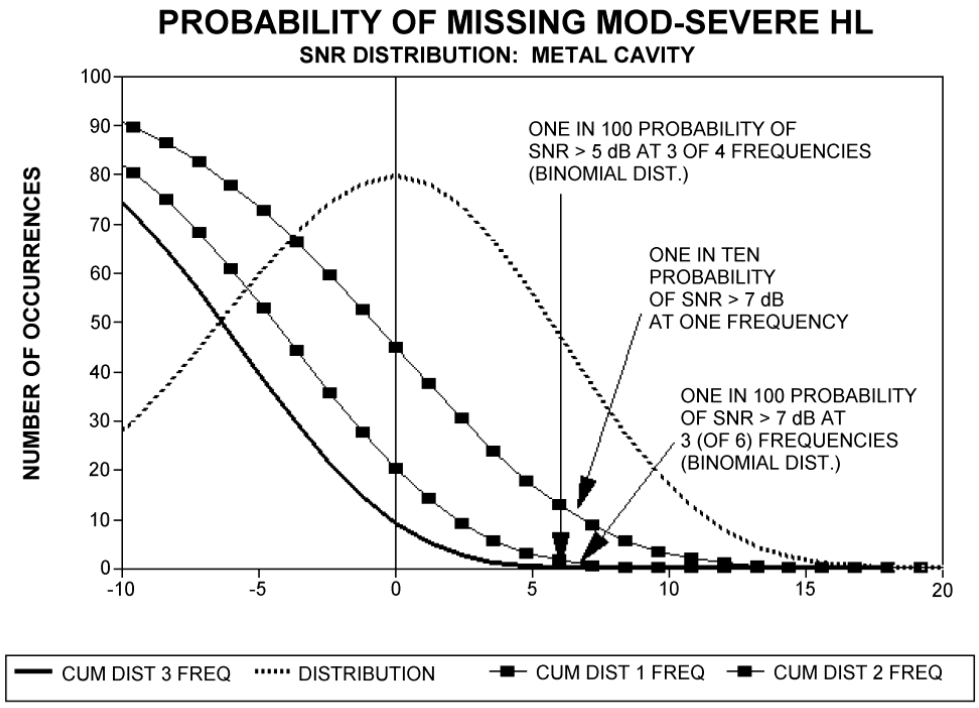
Pass/Refer criteria for DPOAE

The decision that a DPOAE exists is based on detecting a signal whose level is significantly above the background noise level. This requires a statistical decision, since the random noise level in the DPOAE filter channel can be expected to exceed the average of the random noise levels in the four adjacent filter channels — used as the reference for comparison — roughly half the time.

Extended measurements of the noise distributions in both the DPOAE filter channel 'DP level' and the rms average of the 4 adjacent channels 'N level' indicate that the signal-to-noise ratio (the difference between DP and N) has a standard deviation of 5.5 dB. As shown in the Diagram below, this implies a 10 % probability of seeing a 7 dB SNR simply from the variability of the noise levels in the 2 filter sets. Requiring an SNR of 6 dB in three out of four frequencies drops the probability of passing an ear with significant hearing loss to 1 % or less.

By the binomial distribution, two of three frequencies at >8.4 dB or three of six frequencies at >7 dB should also ensure less than 1 % probability of passing a moderately-severe hearing-impaired infant. Preliminary OtoRead™ trials with infants indicate that the tester's technique is the single most important variable in the pass rate on normal-hearing infants. Some testers begin measuring with only a couple of day's practice, producing pass rates comparable to those for other DPOAE equipment they have used for months; other testers take longer.

Occasional claims of extraordinarily low probabilities of missing an ear with hearing loss appear to be based on poor statistics. As discussed by Gorga (Mayo Clinic Teleconference, 1998), since the incidence of significant hearing loss is roughly 2 per 1,000, verifying a 99.7 % accuracy would require testing hundreds of thousands of babies with a given system. Thus to demonstrate that only 3 babies out of 1,000 with hearing loss were missed would require follow-up testing on 500,000 babies. To our knowledge, no one has performed such tests to date.

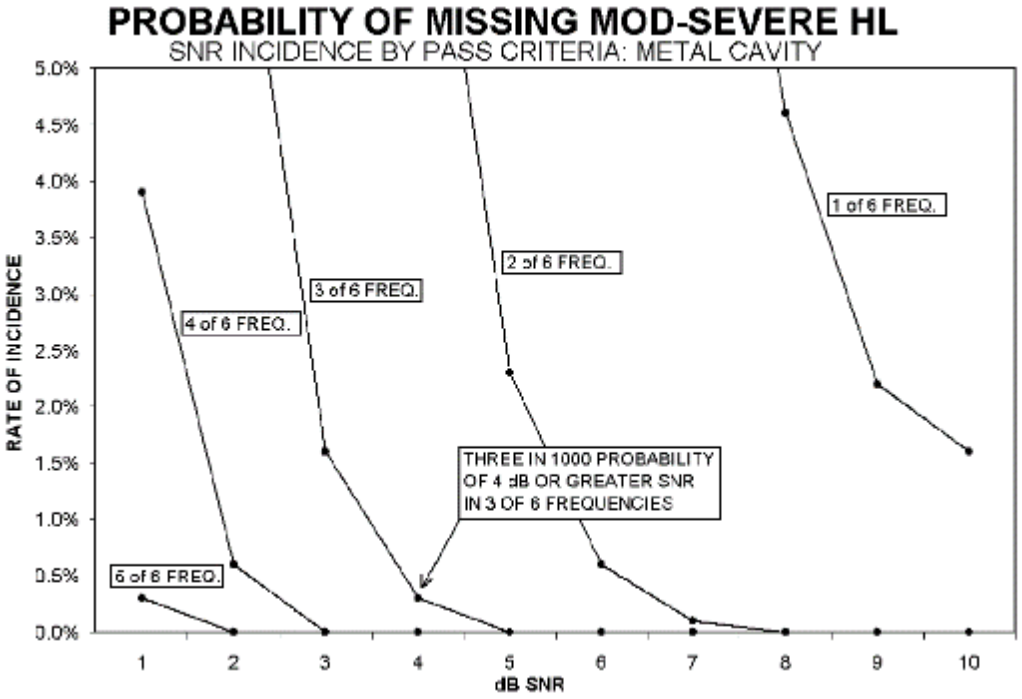


Pass/Refer criteria for TEOAE

The same basic principles that underlie DPOAE Pass/Fail criteria can be applied to TEOAE Pass/Fail criteria. In the case of transients, requiring SNR of 4 dB at any three out of the six test frequencies drops the probability of passing an ear with a significant hearing loss to less than 1 %.

Please note: The SNR limits for transients are lower than the corresponding limits for distortion products primarily because the traditional noise calculation used in TEOAE measurements (and in the OtoRead™ instrument) gives a 3 dB lower SNR than the calculation used for DPOAEs. Without that difference, the numerical SNR value for a PASS with the two methods would be quite similar.

The OtoRead™ uses a novel noise-rejection algorithm (patent pending) that permits accurate DPOAE and TEOAE measurements in background noise and babble as high as 55 dB SPL to 65 dB SPL (A-weighted). Briefly explained, use of available memory in the OtoRead™ processor permits a post-hoc statistical analysis that identifies those samples whose retention would improve the overall accuracy. Those samples are included in the final analysis; the noisier samples are rejected.
The artifact rejection can only reject the noisiest samples in a measurement period. If the ambient noise level rises too high (and/or the ear tip seal is poor), then all samples will be noisy and accurate measurements will be impossible. In such cases, the test result will indicate 'noisy'.



7.3 Appendix C: Configurations and test protocols

DPOAE protocols

	Protocolname	# of Freq.	F2 Freq. [kHz]	L1/L2	Averaging Time [s]	Pass SNR [dB]	# Passing Freq. for Test Pass
Screening	DP 2s	4	2, 3, 4, 5	65/55	2	6	3
	DP 4s	4	2, 3, 4, 5	65/55	4	6	3
Clinical	DP 2.0-5.0	4	2, 3, 4, 5	65/55	4	6	3
	DP 1.5-6.0	6	1.5, 2, 3, 4, 5, 6	65/55	4	6	0
	DP 1.6-8.0	12	1.6, 2, 2.5, 3.2, 3.6, 4, 4.5, 5, 5.6, 6.3, 7.1, 8	65/55	4	6	0
	DP 1.5-12	12	1.5, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12	65/55	4	6	0

(Diagnostic version also includes DP 4s screening protocol)

Grey fields are customizable fields:

L1/L2	: 40 to 70 dBSPL
Average time	: 0.5, 1, 2 or 4 sec.
Pass SNR	: 3 to 10 dB
Passing Freq. for Test Pass	: 1 to 12

TEOAE protocols

	Protocolname	# of Freq.	Freq. [kHz]	Averaging Time [s]	Pass SNR [dB]	# Passing Freq. for Test Pass
Screening	TE 32s	6	1.5, 2, 2.5, 3, 3.5, 4	32	4	3
	TE 64s	6	1.5, 2, 2.5, 3, 3.5, 4	64	4	3
Clinical	TE 1.5 – 4.0	6	1.5, 2, 2.5, 3, 3.5, 4	64	4	3
	TE 0.7 – 4.0	6	0.7, 1, 1.4, 2, 2.8, 4	64	4	0

(Diagnostic version also includes TE 64s screening protocol)
Grey fields are customizable fields:

Average time	: 4, 16, 32 or 64 sec.
Pass SNR	: 3 to 10 dB
Passing Freq. for Test Pass	: 1 to 6

Return Report – Form 001

Interacoustics

Opr. dato:	af:	Rev. dato:	af:	Rev. nr.:	
2014-03-07	EC		MSt	4	

Company: _____

Address: _____

_____

Phone: _____

Fax or e-mail: _____

Address

10393 West 70th Street
Prairie
MN 55344
USA

Phone
(+1) 800 947 6334

Fax
(+1) 952 903 4200

E-mail
rmd@interacoustics-us.com

Contact person: _____ Date: _____

Following item is reported to be:

☐ returned to INTERACOUSTICS for: ☐ repair, ☐ exchange, ☐ other: _____

☐ defective as described below with request of assistance

☐ repaired locally as described below

☐ showing general problems as described below

Item: Type: _____ Quantity: _____

Serial No.: _____ Supplied by: _____

Included parts: _____

Important! - Accessories used together with the item must be included if returned (e.g. external power supply, headsets, transducers and couplers).

Description of problem or the performed local repair:

_____

_____

_____

Returned according to agreement with: ☐ Interacoustics, ☐ Other : _____

Date : _____ Person : _____

Please provide e-mail address or fax No. to whom Interacoustics may confirm reception of the returned goods: _____

☐ **The above mentioned item is reported to be dangerous to patient or user** [1]

In order to ensure instant and effective treatment of returned goods, it is important that this form is filled in and placed together with the item.
Please note that the goods must be carefully packed, preferably in original packing, in order to avoid damage during transport. (Packing material may be ordered from Interacoustics)

[1] EC Medical Device Directive rules require immediate report to be sent, if the device by malfunction deterioration of performance or characteristics and/or by inadequacy in labelling or instructions for use, has caused or could have caused death or serious deterioration of health to patient or user.