

Technical Specifications
OtoRead™



OtoRead™ Configuration Overview

The OtoRead™ is available in six different configurations and the table below indicates the protocols available for the various configurations.

Protocols/ Features	Screener TE	Screener DP	Screener + (DP + TE)	Standard TE	Standard DP	Clinical (DP + TE)
TE 32s	●		●			
TE 64s	●		●	●		●
TE 1.5 – 4kHz				●		●
TE 0,7 – 4 kHz				●		●
DP 2s		●	●			
DP 4s		●	●		●	●
DP 2.0–5.0 kHz					●	●
DP 1.5–6.0 kHz					●	●
DP 1.6–8.0 kHz					●	●
DP 1.5–12. kHz					●	●
User customizable frequencies				●	●	●
User selectable stimulus levels, SNR, test time, number of frequencies for a pass				●	●	●

DPOAE Protocols

	Protocol Name	# 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

Grey fields are customizable fields:

L1/L2 : 40 to 70 dB SPL

Average time (per freq) : 0.5, 1, 2 or 4 sec.

Pass SNR : 3 to 10 dB

Passing Freq. for Test Pass : 1 to 12

TEOAE Protocols

	Protocol Name	# 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

Grey fields are customizable fields:

Average time (max test time) : 4, 16, 32 or 64 sec.

Pass SNR : 3 to 10 dB

Passing Freq. for Test Pass : 1 to 6

Included and Optional Parts



The system consists of the following included and optional parts:

Included and Optional Components	Configurations		
	Screener /Screener +	Standard	Clinical
OtoRead™ device including hook and plug	●	●	●
Micro-Probe ¹	●	●	●
Micro-USB Power Supply for Charging the Lithium-Ion Battery	●	●	●
Micro B to A USB Cable for PC Communication/Charging	●	●	●
Eartip Assortment BET55	●	●	●
Probe Tubes	●	●	●
Instructions for Use	●	●	●
Printed Quick Guides	●	●	●
Cavity (0.2/0.5 cc)	●	●	●
Neckstrap	●	●	●
OtoRead™ Module & Database	●	●	●
Carrying Case	Optional	●	●
Cradle	Optional	●	●
MPT-II printer kit (including charger & thermal paper)	Optional	Optional	Optional

¹ Applied part according to IEC 60601-1

General Technical Specifications

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, Internally powered, Type B parts
	EMC:	IEC 60601-1-2
	Calibration:	ISO 389-2 ISO 389-6
	Test Signal:	IEC 60645-1 IEC 60645-3
	OAE:	IEC 60645-6 2009, Type 2
Cradle	Safety: Power: Mains voltages and frequencies: Output:	IEC 60601-1, Class II UE08WCP-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, - 4 °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		
Data Interfaces		Wireless and USB
Language Settings		
Battery	Type:	Lithium-Ion rechargeable
	Rating:	3.7V / 1750mAh
	Expected life time:	500 tests per charge, minimum 20 hours on-time
Memory		
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 (Bluetooth® Class 2) + 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

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 to 2 sec.
	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)
	TDH:	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
Probe specifications	OtoRead™ probe:	DPOAE and TEOAE capable
		Replaceable probe tip
Other		
MPT-II	Type:	Lithium-Ion rechargeable
	Rating:	7.4V / 1500mAh
Test Pressure		Ambient pressure

TEOAE		
Stimulus	Frequency range:	700 to 4000 Hz
	Stimulus type:	Click Train
	Level:	83 dB peSPL, peak to peak calibrated
	Click rate:	64 Hz
	Stimulus tolerance:	± 3 dB
	Transducer:	Probe auto detection, auto calibrated
Recording	Analysis time:	4 – 64 sec.
	A/D Resolution:	16 bits
	SNR criteria:	3 – 10 dB
	Measurement Range:	-30 dB SPL – 100 dB SPL
	Accuracy of Measurement:	< ± 3 dB
Display	Freq. response window:	700 Hz – 4 kHz
Probe specifications	OtoRead™ probe:	DPOAE and TEOAE capable
		Replaceable probe tip
Other		
Test Pressure		Ambient pressure

Reference equivalent threshold values for transducer

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

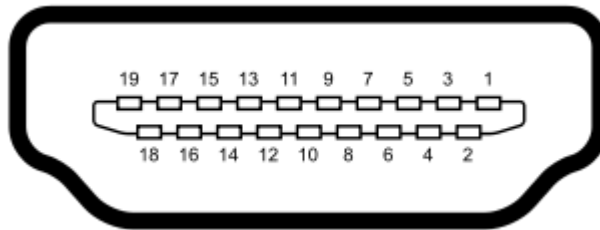
Output Frequency (Hz)	Minimum Frequency (Hz)	Maximum Frequency (Hz)	Minimum Magnitude (dB SPL)	Maximum Magnitude (dB SPL)
732.4	727	737	83	93
1037.6	1033	1043	85	95
1464.8	1460	1470	88	98
2075.2	2070	2080	92	102
2929.7	2925	2935	92	102
4150.4	4145	4155	85	95
5859.4	5855	5865	76	86

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

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 - | | |

Electromagnetic compatibility (EMC)



WARNING

- 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 checked 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 the EMC appendix of this instruction.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this instrument, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.


NOTICE

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

Guidance and Manufacturer’s Declaration - Electromagnetic Emissions		
The OtoRead™ is intended for use in the electromagnetic environment specified below. The customer or the user of the OtoRead™ should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - Guidance
RF Emissions CISPR 11	Group 1	The OtoRead™ 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. The OtoRead™ is suitable for use in all commercial, industrial, business, hospital, and residential environments.
RF Emissions CISPR 11	Class B Limits	
Harmonic Emissions IEC 61000-3-2	Class A Category	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-32	Complies	

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the OtoRead™			
The OtoRead™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the OtoRead™ can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OtoRead™ 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 transmitters, 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 OtoRead™ is intended for use in the electromagnetic environment specified below. The customer or the user of the OtoRead™ should ensure 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 IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial, hospital, 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, hospital, or residential environment.
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles 5 % UT (>95% dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles 5 % UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial, hospital, or residential environment. If the user of the OtoRead™ requires continued operation during power mains interruptions, it is recommended that the OtoRead™ be powered from an uninterrupted power supply.
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 hospital environment.
UT is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The OtoRead™ is intended for use in the electromagnetic environment specified below. The customer or the user of the OtoRead™ should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment-Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the OtoRead™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 1.17\sqrt{P}$ 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 Strengthens 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
At 80 MHz and 8000 MHz, the higher frequency range applies. These guidelines may not apply to 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 OtoRead™ is used exceeds the applicable RF compliance level above, the OtoRead™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the OtoRead™.

(b*) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.