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Technical Specifications

# OtoRead™





# Configurations and test protocols

## 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

(Diagnostic version also includes DP 4s screening protocol)

Grey fields are customizable fields:

- L1/L2 : 40 to 70 dB SPL
- 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



## Included and optional parts

### Standard Components for all versions (Screener, Screener+, Standard & Clinical)

OtoRead™ device including plug for hook cavity

Hook

Micro-Probe 1

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)

<sup>1</sup> Applied part according to IEC 60601-1



## General technical specifications

### OtoRead™ hardware – Technical specifications

Medical CE-mark		The CE-mark in combination with MD symbol indicates that Interacoustics A/S meets the requirements of the Medical Device Regulation (EU) 2017/745 Annex I. Approval of the quality system is made by TÜV – identification no. 0123. The OtoRead™ is an active, diagnostic medical product according to the class IIa of the Medical Device Regulation (EU) 2017/745 Annex I.
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:	HM-E200 thermal wireless printer
	Battery:	Lithium-Ion rechargeable
	Paper width:	57.5 ± 0.5 mm on thermal printer

<b>DPOAE</b>		
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
<b>Other</b>		
Test Pressure		Ambient pressure

<b>TEOAE</b>		
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 (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
<b>Other</b>		
Test Pressure		Ambient pressure



## Reference equivalent threshold values for transducer

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

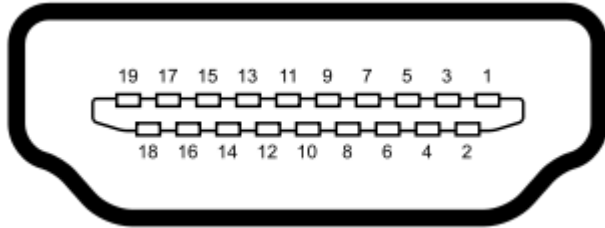
Output Frequency (Hz)	Minimum Frequency (Hz)	Maximum Frequency (Hz)	Minimum Magnitude (dB SPL)	Maximum Magnitude (dB SPL)
732.4	727	737	83	93
1037.6	1033	1043	85	95
1464.8	1460	1470	88	98
2075.2	2070	2080	92	102
2929.7	2925	2935	92	102
4150.4	4145	4155	85	95
5859.4	5855	5865	76	86

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)

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 follows 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.

This instrument operates RF receivers in the frequency band: 2402-2480 MHz

This instrument operates RF transmitters in the frequency band: 2402-2480 MHz , modulation type: GFSK,  $\pi/4$ -DQPSK, 8-DPSK with power: up to +12 dBm



Portable and mobile RF communications equipment can affect the **OtoRead™**. Install and operate the **OtoRead™** according to the EMC information presented in this chapter. The **OtoRead™** has been tested for EMC emissions and immunity as a standalone **OtoRead™**. Do not use the **OtoRead™** 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 <b>OtoRead</b> is intended for use in the electromagnetic environment specified below. The customer or the user of the <b>OtoRead</b> should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The <b>OtoRead</b> 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 <b>OtoRead</b> is suitable for use in all commercial, industrial, business, and residential environments.
RF emissions CISPR 11	Class B	
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 <b>OtoRead</b> .			
The <b>OtoRead</b> is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the <b>OtoRead</b> can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the <b>OtoRead</b> 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 2.7 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. <b>Note 1</b> At 80 MHz and 800 MHz, the higher frequency range applies. <b>Note 2</b> 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 <b>OtoRead</b> is intended for use in the electromagnetic environment specified below. The customer or the user of the <b>OtoRead</b> should assure that it is used in such an environment.			
<b>Immunity Test</b>	<b>IEC 60601 Test level</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic Discharge (ESD) IEC 61000-4-2	+8 kV contact  +15 kV air	+8 kV contact  +15 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%.
Immunity to proximity fields from RF wireless communications equipment IEC 61000-4-3	Spot freq. 385-5.785 MHz Levels and modulation defined in table 9	As defined in table 9	RF wireless communications equipment should not be used close to any parts of the <b>OtoRead</b> .
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 Line to line  +2 kV Line to earth	+1 kV Line to line  +2 kV Line to earth	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	0% <i>UT</i> (100% dip in <i>UT</i> ) for 0.5 cycle, @ 0, 45, 90, 135, 180, 225, 270 and 315°  0% <i>UT</i> (100% dip in <i>UT</i> ) for 1 cycle  40% <i>UT</i> (60% dip in <i>UT</i> ) for 5 cycles  70% <i>UT</i> (30% dip in <i>UT</i> ) for 25 cycles  0% <i>UT</i> (100% dip in <i>UT</i> ) for 250 cycles	0% <i>UT</i> (100% dip in <i>UT</i> ) for 0.5 cycle, @ 0, 45, 90, 135, 180, 225, 270 and 315°  0% <i>UT</i> (100% dip in <i>UT</i> ) for 1 cycle  40% <i>UT</i> (60% dip in <i>UT</i> ) for 5 cycles  70% <i>UT</i> (30% dip in <i>UT</i> ) for 25 cycles  0% <i>UT</i> (100% dip in <i>UT</i> ) for 250 cycles	Mains power quality should be that of a typical commercial or residential environment. If the user of the <b>OtoRead</b> requires continued operation during power mains interruptions, it is recommended that the <b>OtoRead</b> be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Radiated fields in close proximity — Immunity test IEC 61000-4-39	9 kHz to 13.56 MHz. Frequency, level and modulation defined in AMD 1: 2020, table 11	As defined in table 11 of AMD 1: 2020	If the <b>OtoRead</b> contains magnetically sensitive components or circuits, the proximity magnetic fields should be no higher than the test levels specified in Table 11
<b>Note:</b> <i>UT</i> 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 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	3 Vrms 150kHz to 80 MHz  6 Vrms In ISM bands (and amateur radio bands for Home Healthcare environment.)	3 Vrms  6 Vrms	Portable and mobile RF communications equipment should be used no closer to any parts of the <b>OtoRead</b> , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance:</b>  $d = \frac{3,5}{V_{rms}} \sqrt{P}$
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,7 GHz  10 V/m 80 MHz to 2,7 GHz Only for Home Healthcare environment	3 V/m  10 V/m (If Home Healthcare)	

$$d = \frac{3,5}{V_{rms}} \sqrt{P}$$

$$d = \frac{3,5}{v/m} \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$$

$$d = \frac{7}{v/m} \sqrt{P} \quad 800 \text{ MHz to } 2,7 \text{ GHz}$$

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,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup>

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.

<sup>a</sup>) 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 reorienting or relocating the **OtoRead**.  
<sup>b</sup>) 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