

Technical specifications

Otoport

Note:

The Otoport has no user serviceable parts. Any required servicing must be conducted by Otodynamics Ltd or authorised service facilities only

Physical

Hand-held device: 197mm x 70mm(max) x 30mm
Weight 0.55lbs (250g)
Charger: 90mm x 38mm x 28mm – Weight 120g

Interfaces

Probe connector compatible with Otodynamics UGx probes (8 pin)
Charging/Data connector - connects to Otodynamics PSU (charging) or to PC USB port (USB 1.1 or 2.0) via Data Cable
Bluetooth wireless print (option)
RFID reader (option)

Indicators

Data Display: Resolution: QVGA (320 x 240 pixels), 166 dpi
Technology: Colour LCD, 16 bit (displaying 65K colours)
Viewable Area: 46.5mm x 36.5mm
Backlight: White - intelligent control
Probe fit: Noise OK: Blue LED ('N')
Stimulus OK: Blue LED ('S')
Power/Charge: Power OK: Green LED
Fast charge: Amber LED
Audible: Wide range speaker provides audio feedback of status

Keypad

19 key alphanumeric with cursor control and soft keys

Clock/Calendar

Internal Real Time Clock/Calendar operates to 2099

Power

Li-Polymer Battery

Intelligent multi-level power control for charging/testing/idle/sleep/shutdown:

After 1.5 minutes unit will enter sleep mode

After 20 minutes in sleep mode unit will shut down

Sleep time: 20 hours minimum (with fully charged battery)

Running time: 6 hours minimum (continuous data collection)

Battery voltage

operating range: 3-4.2V

Max consumption

when testing: 720mW

Max consumption

when charging: 2.5W

Source: 1000mAh lithium polymer internal rechargeable cells

Charge time: 3 hours to 90% capacity
Approximately 4 hours to 100%

Hardware Options

Bluetooth wireless printing

Barcode scanner

RFID reader

Hardware processing and storage

Embedded microcontroller plus dedicated hardware DSP engine

4GB of non-volatile memory for storing programs, configuration, patient details and test results

Analogue performance

Output channels: 2 x 16bit resolution

Input channels: 1 x 16bit resolution

Sample rate: Variable

Frequency response: Electrical – 160Hz to 12KHz

Environmental



Protect from heat and radioactive sources



Keep dry

Transport and storage:



Temperature range: 0 to 40 Celsius



Pressure: 23KPa to 101KPa



Humidity: 10% to 90% non-condensing

Warm-up time: <10s when unit is stored within stated temperature range

Operating:

Indoor use



Temperature range: 5 to 40 Celsius



Humidity: Max 80% up to 31C decreasing linearly to 5% RH at 40C

Otodynamics instruments and probes are calibrated at an ambient pressure of 101 kPa (standard atmospheric pressure at sea level). Lowering the ambient pressure significantly (e.g. when operating at altitude) alters the acoustic response of the probe. For instance, at an ambient pressure of 80 kPa (standard atmospheric pressure at 2000m) changes of up to 2 dB can be observed in the response of the probe around 2KHz. This could cause the probe to fail standard calibration tests.

Classifications and standards

Device Class 2a	(Directive 93/42/EEC)
BS EN ISO 13485:2003	(REF: EN46001 superseded 01/03/2004)
ISO 14971:	Application of risk management
BS EN 60601-1:	Medical Electrical Equipment Part 1: General Requirements for Safety
BS EN 60601-1-1:	Medical Electrical Equipment - Part 1: General Requirements for Safety - Collateral Standard - Safety Requirements for Medical Electrical Systems
BS EN 60601-1-2:	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility
BS EN 60601-1-4:	Medical electrical equipment - Part 1 General requirements for safety. Section 4 Collateral standard, programmable electrical medical systems
UL 60601-1:	Medical Electrical Equipment, Part 1: General Requirements for Safety
CSA-C22.601:	Medical Electrical Equipment

Electromagnetic Compatibility: Otoport

The Otoport should be put into service according to the EMC (Electromagnetic Compatibility) information provided here.

Portable and mobile RF (Radio Frequency) communications equipment can affect the operation of the Otoport. In particular, mobile telephones ('cellphones') should not be operated within 3.3m of the Otoport.

The use of probes, chargers and connection cables other than those supplied by Otodynamics Ltd, and specifically for use with the Otoport may result in increased emissions or decreased immunity of the Otoport.

Guidance and manufacturer's declaration – electromagnetic emissions

The Otoport is intended for use in the electromagnetic environment specified below. The user of the Otoport should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Otoport 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 equipment.
RF emissions CISPR 11	Class B	The Otoport is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

The Otoport should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary the Otoport should be observed to verify normal operation in the configuration in which it is used.

Guidance and manufacturer's declaration – electromagnetic immunity

The Otoport is intended for use in the electromagnetic environment specified below. The user of the Otoport should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ±1 kV for input/output lines	± 2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<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 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Otoport requires continued operation during power mains interruptions, it is recommended that the Otoport be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.


NOTE U_T is the a.c. mains voltage prior to application of the test level.

The following functions of the Otoport are deemed 'essential performance' and were tested for immunity in compliance with IEC60601-1-2:

- (a) The collection of Otoacoustic Emissions (OAEs)
- (b) The retention of user settings and test results

Guidance and manufacturer's declaration – electromagnetic immunity

The Otoport is intended for use in the electromagnetic environment specified below. The customer or the user of the Otoport should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz	3 V _{rms}	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Otoport including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	<p>$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

Notes:

- 1 At 80 MHz and 800 MHz, the higher frequency range applies.
- 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 Otoport is used exceeds the applicable RF compliance level above, the Otoport should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Otoport.

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

Recommended separation distances between portable and mobile RF communications equipment and the Otoport

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes:

- 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The Otoport can be optionally configured with either/both Bluetooth and RFID functions. The frequency bands for reception and transmission of RF energy for these functions are as follows:

- (a) Bluetooth – 2.4GHz to 2.4835GHz
- (b) RFID – 13.56MHz

The Bluetooth and RFID functions of the Otoport may be interfered with by other equipment, even if that equipment complies with CISPR emission requirements.

Electromagnetic Compatibility: Otoport OAE+ABR

The Otoport OAE+ABR should be put into service according to the EMC (Electromagnetic Compatibility) information provided here.

Portable and mobile RF (Radio Frequency) communications equipment can affect the operation of the Otoport OAE+ABR. In particular, mobile telephones ('cellphones') should not be operated within 10m of the Otoport OAE+ABR.

The use of probes, electrodes, chargers and connection cables other than those supplied by Otodynamics Ltd, and specifically for use with the Otoport OAE+ABR may result in increased emissions or decreased immunity of the Otoport OAE+ABR.

Guidance and manufacturer's declaration – electromagnetic emissions

The Otoport OAE+ABR is intended for use in the electromagnetic environment specified below. The user of the Otoport OAE+ABR should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Otoport OAE+ABR 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 equipment.
RF emissions CISPR 11	Class B	The Otoport OAE+ABR is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

The Otoport OAE+ABR should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary the Otoport OAE+ABR should be observed to verify normal operation in the configuration in which it is used.

Guidance and manufacturer's declaration – electromagnetic immunity

The Otoport OAE+ABR is intended for use in the electromagnetic environment specified below. The user of the Otoport OAE+ABR should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ±1 kV for input/output lines	± 2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<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 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Otoport OAE+ABR requires continued operation during power mains interruptions, it is recommended that the Otoport OAE+ABR be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.


NOTE U_T is the a.c. mains voltage prior to application of the test level.

The following functions of the Otoport OAE+ABR are deemed 'essential performance' and were tested for immunity in compliance with IEC60601-1-2:

- (a) The collection of Otoacoustic Emissions (OAEs)
- (b) The retention of user settings and test results

Guidance and manufacturer's declaration – electromagnetic immunity

The Otoport OAE+ABR is intended for use in the electromagnetic environment specified below. The customer or the user of the Otoport OAE+ABR should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	1 Vrms 150 kHz to 80 MHz	1 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Otoport OAE+ABR including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 3.5\sqrt{P}$
Radiated RF IEC 61000-4-3	1 V/m 80 MHz to 2.5 GHz	1 V/m	$d = 3.5\sqrt{P}$ 80 MHz to 800 MHz $d = 7\sqrt{P}$ 800 MHz to 2.5 GHz <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

The conducted and radiated RF immunity levels are less than the IEC 60601 test levels. This is because the Otoport OAE+ABR depends for its operation on the measurement of very low level physiological signals. Two physiological signals are measured: an electro-physiological (ABR) signal of about 0.01 FemtoWatts (giving about 100nV RMS across 1K); and, an acoustic signal of about 0.1 FemtoWatt acoustic power (giving about 700nV RMS across 5K input impedance). It is impractical to measure these signals in the presence of RF energy at the IEC 60601 test levels.

At high levels of RF energy both the ABR and OAE tests will be caused by the artifact rejection functions of the instrument - it will go into 'reject mode'. If this occurs then either the source of RF energy should be reduced or the measurement should be taken further from the source. In practice this means either switching off other equipment (for example, mobile phones and noisy wall plug power supplies) or moving to another location.

Notes:

- 1 At 80 MHz and 800 MHz, the higher frequency range applies.
 - 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 Otoport OAE+ABR is used exceeds the applicable RF compliance level above, the Otoport OAE+ABR should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Otoport OAE+ABR.

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

Recommended separation distances between portable and mobile RF communications equipment and the Otoport OAE+ABR

The Otoport OAE+ABR is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Otoport OAE+ABR can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Otoport OAE+ABR 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 $d = 3.5\sqrt{P}$	80 MHz to 800 MHz $d = 3.5\sqrt{P}$	800 MHz to 2.5 GHz $d = 7\sqrt{P}$
0.01	0.35	0.35	0.7
0.1	1.1	1.1	2.2
1	3.5	3.5	7
10	11	11	22
100	35	35	70

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes:

- 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The Otoport OAE+ABR can be optionally configured with either/both Bluetooth and RFID functions. The frequency bands for reception and transmission of RF energy for these functions are as follows:

- (a) Bluetooth – 2.4GHz to 2.4835GHz
- (b) RFID – 13.56MHz

The Bluetooth and RFID functions of the Otoport OAE+ABR may be interfered with by other equipment, even if that equipment complies with CISPR emission requirements.

EN60645-3 conformance notes

These notes are provided in compliance with EN60645-3 "Electroacoustics audiometric equipment - Part 3: test signals of short duration."

(a) Types of short duration stimuli:

The Otoport TEOAE test uses short duration stimuli. During test setup a 'rectangular stimulus' is used. During data collection a 'bipolar stimulus' is used. The rectangular is a unipolar pulse of 78uS length. The bipolar stimulus is 1 cycle of a triangle waveform of 240uS period. Both stimuli are low pass filtered by a 10kHz anti-alias filter, which 'rounds' any 'sharp edges'.

(b) Transducers and headband force:

The stimulus is delivered to the patient's ear using a UGS or UGD Otodynamics probe. The probe tip holds the probe ear piece in the ear canal, with no headband or other retaining device required.

(c) Sound field system:

The sound field is generated by the probe sealed in the ear canal by its tip.

(d & e) Calibration cavity and measurement type:

For the purposes of EN60645-3 calibration was performed in an occluded ear canal simulator conforming to IEC 60711 (Bruel and Kjaer type 4157). The probe was mounted in a DB2012 adaptor using an Otodynamics probe tip. The sound ports of the probe were aligned with the 4157 reference plane. A UGD probe was used for the calibration. Sound levels from the 4157 ear simulator were measured in dB SPL peak-to-peak equivalent, as defined in EN60645-3.

(f) Signal levels:

The following conversion factors convert between the stimulus level reported on the Otoport screen and the signal level in the IEC 60711 occluded ear simulator:

rectangular stimulus: -6.1dB

bipolar stimulus: -7.1dB

The following conversion factors convert between the signal level generated in the ear simulator by the Otoport stimulus and the level that would be generated by a 'reference stimulus' of the same peak to peak electrical drive. (The 'reference stimulus is a 100uS unipolar rectangular pulse, as defined in EN60645-3.):

rectangular stimulus: +3.0dB

bipolar stimulus: +2.4dB

Suppose, for example, that a stimulus level of 90dB is reported by the Otoport during stimulus setup (rectangular stimulus). If this stimulus was replaced by the reference stimulus, of the same amplitude, the level generated in a IEC 60711 ear simulator would be:

$$90\text{dB} + -6.1\text{dB} + 3.0\text{dB} = 86.9 \text{ dB SPL peak-to-peak equivalent.}$$

(g) Polarity of stimulus:

The polarity of the stimulus varies between positive and negative, according to the TEOAE test sequence.

(h) Repetition rate:

The stimulus is repeated every 12.5mS during standard Otoport TEOAE setup and testing.

(i) Covered in (a) above

(j) Covered in (f) above

ABR Module

Note:

The ABR Module has no user serviceable parts. Any required servicing must be conducted by Otodynamics Ltd or authorised service facilities only.

Physical

Hand-held module: 278mm x 84mm x 38mm
Weight: 240g (490g with Otoport fitted)

Interfaces

Probe connectors compatible with Otodynamics UGS and UGD probes (8 pin)
Electrode connectors compatible with 1.5mm 'Touchproof' DIN 42-802 connectors
Charging/Data connector - connects to Otodynamics PSU (charging) or to PC USB port (USB 1.1 or 2.0) via Data Cable

= Indicators

Data display:	Data is displayed via Otoport (refer to section 24.1)
Probe Fit:	Indicators on Otoport: Noise OK - Blue LED ('N') Stimulus OK - Blue LED ('S')
Impedance check:	Impedance OK - Green LED (one for each electrode socket)
Power/Charge:	Power OK - Green LED
Fast charge:	Amber LED
Audible:	Audio feedback via Otoport speaker

Symbol explanations



Class II



Type BF



Caution



USB 1.1



When discarded, the item must be sent to separate collection facilities for recovery and recycling



Probe socket



Battery charging indicator



Power supply connection

S

Stimulus OK indicator

N

Noise OK indicator



Refer to operating instructions



Training required