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Technical Specifications

Lyra



D-0120698-E 2023/10



Interacoustics



Included parts

The system consists of the following included and optional parts:

| Standard Components, General | DPOAE | TEOAE |
|---|-------|-------|
| Lyra device with permanent OAE probe ¹ | • | • |
| BET25 Ear tips | • | • |
| Test cavity (0.2 and 0.5cc) | • | • |
| IA OAE Suite software | • | • |
| USB cable | • | • |
| Carrying pouch | • | • |

¹ Applied part according to IEC 60601-1

General technical specification

| | | |
|--------------------------------|--|--|
| 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 | |
| Standards | Safety: | IEC 60601-1:2005, A1:2012 Type B applied parts |
| | EMC: | IEC 60601-1-2:2014 |
| | Test signal: | IEC 60645-1:2012 /ANSI S3.6 , IEC 60645-3: 2007 |
| | OAE: | TEOAE IEC 60645-6:2009, Type 1 & 2 Otoacoustic emissions DPOAE IEC 60645-6:2009, Type 2 Otoacoustic emissions |
| Operation environment | Temperature: | 15°-35°C |
| | Relative humidity: | 30-90% |
| | Ambient pressure: | 98 kPa-104 kPa |
| | Boot time | Less than 2 seconds |
| | Warm-up time: | Less than 2 seconds |
| Transport & Storage | Storage temperature: | 0°C-50°C |
| | Transport temperature: | -20°-50 °C |
| | Relative humidity: | 10-95% |
| Power | Powered through USB 5V Minimum 330 mA Typical 420 mA Maximum 470 mA | |
| PC control | USB: | Input/output for computer communication. Lyra is fully operated from a PC. |
| Dimensions | 8 x 18 x 2 cm (cable length 200 cm) | |
| Lyra weight | 165 gram incl. OAE probe | |

| DPOAE | | |
|-----------------------------|-----------------------------------|---|
| Stimulus | Frequency range: | 500 to 10000 Hz |
| | Nominal frequency: | f2 |
| | Frequency step: | 1 Hz |
| | Level: | 30 to 70 dB SPL (30 to 65 dB SPL for 8 kHz to 10 kHz) |
| | Level step: | 1 dB |
| Recording | Analysis time: | 1 second to unlimited time |
| | A/D resolution: | 24 bit, 5.38 Hz resolution |
| | Artifact rejection system: | -30 to +30 dB SPL or off |
| | Stimulus tolerance: | Adjustable between 1 and 10 dB |
| | SNR criteria: | Adjustable between 3 and 25 dB |
| | DP criteria: | SNR, Min DP level, DP tolerance, Residual noise, mandatory points, DP reliability |
| | Probe check window: | 256 points frequency response of the ear canal due to a click stimulus. |
| | DP-response window: | 4096 points frequency response |
| Display | Residual noise: | An RMS average measurement in the DP-bin frequency area (26 bins at frequencies < 2500 Hz & 60 bins ≥ 2500 Hz). |
| | Other information: | In ear status (before/after test) and noise rejection level Basic or advanced view of the DP-Gram, test summary table, point summary table |
| Probe specifications | Lyra OWA probe: | Combined DPOAE and TEOAE OWA probe Replaceable probe tip |

The DPOAE module uses an improved method of stimuli level control, which more accurately delivers the specified intensity in the full range of ear canals, from infants to adults. The applicability of the IEC 60645-6 standard is currently limited to adult ears. Therefore, in order to better serve a market with a product that provides more accurate stimulus levels to a wide range of ear canal volumes (specifically infants), we have elected to utilize a more comprehensive calibration procedure for DPOAEs that is outside the scope of IEC 60645-6 for some protocols.

This improved method of stimulus control is enabled when the “Use Microphone compensation” checkbox is checked. To use the IEC60645-6 calibration method, uncheck the “Use Microphone compensation” in the Advanced tab of the protocol setup.

| TEOAE | | |
|-----------------------------|-----------------------------------|---|
| Stimulus | Frequency range: | 500 to 5500 Hz |
| | Frequency step: | 1 Hz (Custom bands) |
| | Stimulus type: | Non-Linear (according to IEC 60645-3) |
| | Level: | 30 to 90 dB peSPL, peak to peak calibrated, AGC controlled |
| | Level step: | 1 dB |
| | Click rate: | 43.5 or 80 Hz |
| | Stimulus tolerance: | Adjustable between 1 and 3 dB |
| Recording | Analysis time: | 30 seconds to 30 minutes or 300 to 30000 sweeps |
| | A/D Resolution: | 24 bit |
| | Artifact rejection system: | 0 to +60 dB SPL |
| | SNR criteria: | Adjustable between 5 and 25 dB |
| | TE criteria: | SNR, min sweeps, min Total OAE, min TE level, mandatory bands |
| | Stimulus time window: | 128 points instant recording of first click in sequence of clicks |
| | Probe check window: | 256 points frequency response of the ear canal recorded click stimulus |
| | Time recording window: | 4-23 msec (max). A and B buffer time-samples @ sampling rate 11025 Hz |
| | Frequency response window: | 256 points frequency response, bin spacing 43 Hz |
| | Residual noise: | An RMS value for each octave band, based on the Bayesian weighted average for the defined OAE time window |
| Display | Other information: | In ear status (active during test) and noise rejection level |
| | | Basic or advanced view, FFT view, test summary table, band summary table |
| Probe specifications | Lyra OWA probe: | Combined DPOAE and TEOAE OWA probe |
| | | Replaceable probe tip |

Frequencies and intensity ranges for DPOAE

| Lyra Maximums DPOAE | | |
|---------------------|---------------|---------------|
| Center Freq. [Hz] | PS1 | ch2 |
| | Reading | Reading |
| | Tone [dB SPL] | Tone [dB SPL] |
| 500 | 80 | 80 |
| 750 | 80 | 80 |
| 1000 | 80 | 80 |
| 1500 | 80 | 80 |
| 2000 | 80 | 80 |
| 3000 | 80 | 80 |
| 4000 | 80 | 80 |
| 6000 | 75 | 75 |
| 8000 | 65 | 65 |
| 10000 | 65 | 65 |

Lyra Maximum TEOAE level

Maximum TEOAE Click Intensity: 90 dB peSPL.

Specification of input/output connections

| Inputs | Connector type | Electrical properties |
|----------|----------------|----------------------------|
| Data I/O | | |
| USB | USB type "B" | USB port for communication |

Calibration properties

Calibrated Transducers

Probe system: Probe frequency transmitter and receiver are integrated in the probe system

Accuracy

General: Generally, the instrument is made and calibrated to be within and better than the tolerances required in the specified standards:

DPOAE levels: ±1.5 dB for 1000 to 4000 Hz and ±3 dB outside range
 TEOAE levels: ±2 dB for click stimulus

Coupler types used for calibration

DPOAE:

Probe stimuli L1 and L2 are calibrated individually in SPL values using the IEC 711 ear simulator coupler made in accordance with IEC 60318-4.

TEOAE:

Probe stimuli are calibrated in peSPL values using the IEC 711 ear simulator coupler made in accordance with IEC 60318-4.

General information about specifications

Interacoustics continuously strives to improve its products and their performance. Therefore, the specifications can be subject to change without notice.

The performance and specifications of the instrument can only be guaranteed if it is subject to technical maintenance at least once per year. This should be carried out by a workshop authorized by Interacoustics.

Interacoustics puts diagrams and service manuals at the disposal of authorized service companies.

Enquiries about representatives and products may be sent to:

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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 **Lyra**. Install and operate the **Lyra** according to the EMC information presented in this chapter.

The **Lyra** has been tested for EMC emissions and immunity as a standalone **Lyra**. Do not use the **Lyra** 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 Instrument (Lyra) is intended for use in the electromagnetic environment specified below. The customer or the user of the Instrument should assure that it is used in such an environment. | | |
| Emissions Test | Compliance | Electromagnetic environment - guidance |
| RF emissions CISPR 11 | Group 1 | The Instrument 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 Instrument is suitable for use in all commercial, industrial, business, and residential environments. |
| Harmonic emissions IEC 61000-3-2 | Not Applicable | |
| Voltage fluctuations / flicker emissions IEC 61000-3-3 | Not applicable | |

| Recommended separation distances between portable and mobile RF communications equipment and the Instrument (Lyra) . | | | |
|---|---|---|--|
| The Instrument (Lyra) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Instrument can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Instrument 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. | | | |
| 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 Instrument (Lyra) is intended for use in the electromagnetic environment specified below. The customer or the user of the Instrument 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 | +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 Instrument . |
| Electrical fast transient/burst IEC61000-4-4 | +2 kV for power supply lines +1 kV for input/output lines | Not applicable +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 | Not applicable | 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 | Not applicable | Mains power quality should be that of a typical commercial or residential environment. If the user of the Instrument requires continued operation during power mains interruptions, it is recommended that the Instrument 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 Instrument contains magnetically sensitive components or circuits, the proximity magnetic fields should be no higher than the test levels specified in Table 11 |
| Note: <i>UT</i> is the A.C. mains voltage prior to application of the test level. | | | |

| Guidance and manufacturer's declaration — electromagnetic immunity | | | |
|---|---|--------------------------------|---|
| The Instrument (Lyra) is intended for use in the electromagnetic environment specified below. The customer or the user of the Instrument 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 | 3 Vrms | Portable and mobile RF communications equipment should be used no closer to any parts of the Instrument , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \frac{3,5}{V_{rms}} \sqrt{P}$ |
| | 6 Vrms In ISM bands (and amateur radio bands for Home Healthcare environment.) | 6 Vrms | |
| Radiated RF IEC / EN 61000-4-3 | 3 V/m 80 MHz to 2,7 GHz | 3 V/m | $d = \frac{3,5}{V/m} \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \frac{7}{V/m} \sqrt{P} \quad 800 \text{ MHz to } 2,7 \text{ GHz}$ Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> 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:  |
| | 10 V/m 80 MHz to 2,7 GHz Only for Home Healthcare environment | 10 V/m (If Home Healthcare) | |
| 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 Instrument is used exceeds the applicable RF compliance level above, the Instrument should be observed to verify normal operation, if abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Instrument . ^{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 |