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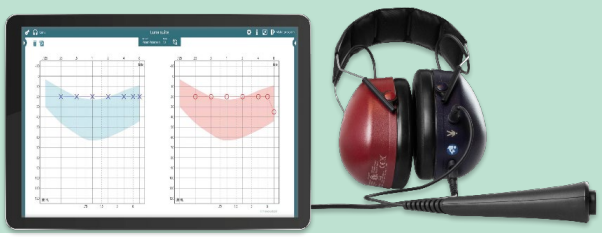
Technical Specifications

Luna



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Interacoustics

General 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. Approval of the quality system is made by TÜV – identification no. 0123.	
Standards:	**Safety:**	IEC 60601-1 2005/EN 60601-1 2006 and A1 2012 ANSI/AAMI ES60601-1:2005/(R)2012 CAN/CSA-C22.2 No. 60601-1:14 Type B applied parts
	EMC:	IEC 60601-1-2 (2014)+AMD1:2020
	Audiometer Tone:	Tone Audiometer: IEC 60645 -1 (2017), ANSI S3.6 (2018), Type 4
Construction:		Plastic cabinet.
Power:		USB-powered Average: 300mA (Max: 500mA)
Operation environment:		
Ambient noise:		The Luna audiometer should be used in a quiet place such as a separate room
Rel. Humidity: **Temperature:** **Ambient Pressure:**		15 – 90% 10-35° 98 kPa – 104 kPa
Transport temperature:		-20-50 °C
Storage temperature:		0-50 °C
Humidity transportation & storage:		10% to 95% RH. Noncondensing

Technical specifications

	Transducers
[A]	– two earphones
[A]	Hearing levels from -10 to 105 dB HL for air conductors
[A]	Frequency from 250 Hz to 8 kHz for air conductors (250 Hz, 500 Hz, 750 Hz, 1 kHz, 1.5 kHz, 2 kHz, 3 kHz, 4 kHz, 6 kHz, 8 kHz)
[A]	Output level control in 5 dB HL steps
	Test signal switching
[A]	– presentation/interruption
[A]	– continuous pure-tone
[A]	– pulsed pure-tone
[A]	– warble-tone freq. 10 Hz Sinus
[A]	– warble-tone modulation depth 10%
[A]	Subject response system
[A]	Fixed USB cable from headset to type A male connector. Optional: 4-pin to USB Micro cable. Optional: 4-pin to USB C cable. Replaceable by technician.

Reference equivalent threshold values for transducers

Hz	Max dB level HL
125	70
250	90
500	100
750	100
1000	100
1500	105
2000	105
3000	105
4000	100
6000	90
8000	85

Appendix A: 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+AMD1:2020.

NOTICE: There are no deviations from the collateral standard and allowances uses NOTICE: All necessary instruction for maintaining compliance regarding 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 LUNA. Install and operate the LUNA according to the EMC information presented in this chapter.
The LUNA has been tested for EMC emissions and immunity as a standalone instrument. Do not use the LUNA 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, except for 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* **(Luna)** 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*.			
The ***Instrument*** **(Luna)** 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*** **(Luna)** 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% *U*T (100% dip in *U*T) for 0.5 cycle, @ 0, 45, 90, 135, 180, 225, 270 and 315° 0% *U*T (100% dip in *U*T) for 1 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles 0% *U*T (100% dip in *U*T) 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 I***nstrument*** contains magnetically sensitive components or circuits, the proximity magnetic fields should be no higher than the test levels specified in Table 11
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The ***Instrument*** **(Luna)** 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**
			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:**
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	$d = \frac{3,5}{Vrms}\sqrt{P}$
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)	$d = \frac{3,5}{V/m}\sqrt{P}$ 80 MHz to 800 MHz $d = \frac{7}{V/m}\sqrt{P}$ 800 MHz to 2,7 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 ***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.			

To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the following accessories:

Item	Manufacturer	Model
Patient response switch	RadioEar	APS3
USB cable	Interacoustics	8011241

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 (m)	Screened (Yes/No)
Patient response switch	2.0	Yes
USB cable	1.9	Yes