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Technical Specifications

Sera™

D-0113907-K - 2024/11



Interacoustics

Included and optional parts


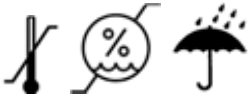
The system consists of the following included and optional parts:

Standard Components, General	Configurations		
	ABRIS	ABRIS + OAE	DPOAE and/or TEOAE
Sera™ handheld device	•	•	•
Sera™ cradle	•	•	•
Cradle power supply	•	•	•
Preamplifier ¹	•	•	-
USB Type A-B Micro cable	•	•	•
Carrying case	•	•	•
Infant ear simulator	-	•	•
Pinch clip cables for snap electrodes ¹	•	•	-
Instructions for Use	•	•	•
HearSIM™ software bundle	•	•	•
Sera™ Probe Tip Kit	Optional	•	•
Sera™ ADI Screening Ear tip Kit	•	•	•
Sera™ Probe Cleaning Kit	•	•	•
IP/Probe Accessory Kit ¹	•	•	•
EarCup Accessory Kit ¹	Optional	Optional	-
Standard Components, General	Configurations		
	ABRIS	ABRIS + OAE	DPOAE and/or TEOAE
Stylus Pen	•	•	•
Cleaning cloth for touchscreen	•	•	•
Neckstrap for preamplifier ¹	•	•	-
Transducers			
SnapPROBE™ ¹	Optional	•	•
OWA Probe 500 mm ¹	Optional	Optional	Optional
OWA Probe 1200 mm ¹	Optional	Optional	Optional
IP 30 (50 Ω) insert earphone with Ear tip adapters Kit ¹	•	•	-
IP 30 (50 Ω) insert earphone with EarCup adapters Kit ¹	Optional	Optional	-
Optional Accessories			
Sera™ ABRIS Pass Checker	Optional	Optional	-
Label Printer HM-E200 Kit (includes printer, power supply and 2 rolls of thermal label paper)	Optional	Optional	Optional

¹ Applied part according to IEC 60601-1

Disposables			
Assortment of Ear Tips	Optional	•	•
Infant earcups	Optional	-	-
Snap Electrodes	•	Optional	-
Tab electrodes	Optional	Optional	-
Gauze swaps	Optional	-	-
Conductivity gel	Optional	-	-
Alcohol pads	•	Optional	-
Printer label paper	Optional	Optional	Optional
Probe tip kit	•	•	•

Sera™ instrument – 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 no. 0123.
Standards	Safety:	IEC 60601-1:2012, Internally powered, type BF applied parts
	EMC:	IEC 60601-1-2:2014+AMD1:2020 IEC 60601-2-40:2016
	Calibration:	ISO 389-2:1994 ISO 389-6:2007
	Test Signal:	IEC 60645-3:2007
	OAE:	IEC 60645-6:2022, Type 2
	ABR:	IEC 60645-7:2009, Type 2
Cradle	Safety: Power Mains voltages and frequencies: Output:	IEC 60601-1:2012, Class II UES12LCP-050160SPA Item number 8515473 100 – 240 V~, 50/60 Hz, 400 mA 5.0V DC, 1.6A MAX
Operation environment 	Temperature: Relative Humidity: Ambient Pressure: Boot-up time: Warm-up Time:	5 – 40°C, + 41°F... + 104°F 15 – 93% (non-condensing) 98 kPa – 104 kPa < 5 sec Nil
Transport & Storage environment	Long-term storage temperature (shipment, storage, etc.):	0°C – 50°C, - 4°F... + 122°F
	Short-term transport temperature (transit in between use):	-25 – 70°C, - 13°F... + 158°F
	Storage and Transport rel. Humidity:	Max 93% (non-condensing)
Altitude rating	Max. operating altitude:	2000 m / 6561 ft above sea level
Markings	IP marking is an ingress protection marking. The marking specifies the protection provided against ingress of particle matter and liquids. This instrument has different IP marking with the follow impact:	


IP02 IP20	IP02: To protect the instrument against rain and water always use the carrying bag during transport. IP20: This marking can be found on the instrument parts meaning that the parts are not protected against water NOTE: The charger, power supply and cradle are not to be used in home healthcare environments.
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General		
Dimensions Sera™		15.8 x 8.3 x 1,9 cm / 6.2 x 6.2 x 0.7 inches
Sera™ Weight		265 g / 0.5 lbs
User Interface:		Resistive Touch Screen
Display Size:		9.5 x 5.6 cm, color, 272 x 480 resolution
Data Interfaces:		Wireless Frequency range: 2402 – 2480 MHz Modulation types: GFSK, π/4-DQPSK and 8DPSK Radiated power: Up to +12 dBm
User Feedback:		Integrated speaker
Language Settings:		English, German, Spanish, French, Italian, Portuguese, Dutch, Polish, Finnish, Romanian, Russian, Chinese, Korean, Turkish, Norwegian, Japanese, Kazakh, Czech, Swedish and Ukrainian
Battery	Type:	Li-ion battery 44794; Capacity: 3.7V/3850 mAh
	Expected life time:	Depending on use – typically more than 3 years
Memory		1 GB (max. 250 Patient can be stored with 50 tests each)
Connector		Omnetics 12-pin connector
Preamplifier weight		85 g / 0.19 lbs
Preamplifier dimensions		8.5 x 0.5 x 2.5 cm / 3.4 x 0.2 x 0.9 inches

Printer		
Thermal printer (Optional)	Type:	HM-E200
	Connection:	Wireless
	Battery:	Rechargeable Li-polymer, DC 7.4 V, 1300 mAh
	Charger:	AC 100 – 240 V, ~50/60 Hz, 1.0 A
	Weight:	234 g / 8.3 oz
	Paper:	Thermal paper Thermal labels (103 per roll)
	Paper width:	58 mm (width) on thermal printer 56 mm x 60 mm (width x length) on label printer
	Printing time:	Max. 100mm/s. Printing time depends on the size of the used protocol.


ABRIS		
Preamplifier	One Channel:	3 electrodes, 51 cm, 20”
	Gain:	65 dB (72 dB nom.)
	Frequency response:	0,5 - 5000 Hz
	Noise:	<25 nV/√Hz
	CMR Ratio:	> 100 dB at 100 Hz
	Sample rate:	22.05 kHz
	Max input offset voltage:	2.5 V
	Input impedance:	10 MΩ/ 250 pF
	Power from main unit:	Isolated power supply

Electrical Impedance measurement	Measurement frequency:	33 Hz
	Waveform:	Rectangular
	Measurement current:	11.25 μ A
	Range:	0.5 k Ω – 50 k Ω \pm 10 %
Stimulus	Stimuli:	CE-Chirp® (200 Hz – 11 kHz), Click (200 Hz – 11 kHz)
	Stimulus rate:	90 Hz
	Transducers: (Calibrated to Standards)	IP30 insert phone IP30 EarCup OWA Probe SnapPROBE™
	Level:	25, 30, 35, 40, 45 dB nHL
	Bandwidth:	22.05 kHz
Recording	Analysis time:	3 minutes
	A/D resolution:	24 bit
	Artifact reject system:	Rejection level (Peak, Min RMS, Max RMS) & Clipping (Saturation)
Display		Transducer, test result bars, result symbols (pass/refer/incomplete), test time, artifact, electrode impedances.
Accuracy of Measurement	Algorithmic Sensitivity (default protocol):	>99.99 %  Please refer to the Sera™ Additional Information for further information about available test protocols, test protocol settings and sensitivity and specificity.

DPOAE		
Stimulus	Frequency range:	1500 to 6000 Hz
	Nominal frequency:	f2
	f2/f1 ratio:	1.22
	Level:	50 – 65 dB SPL
	Transducer:	SnapPROBE™ auto detection, auto calibrated Replaceable probe tip OWA Probe auto detection, auto calibrated Replaceable probe tip
Recording	Analysis time:	60 seconds
	A/D Resolution:	24 bit, 5.38 Hz resolution
	Artifact (noise) rejection system:	30 dB SPL
	Residual noise:	An RMS average measurement in the DP-bin frequency area (26 bins at frequencies < 2500 Hz & 60 bins \geq 2500 Hz).
	Test Pressure:	Ambient
Display		Transducer, test result bars, result symbols (pass/refer/incomplete), probe stability, test time, artifact.
Accuracy of Measurement:	Algorithmic Sensitivity (default protocol):	\geq 99.6 %  Please refer to the Sera™ Additional Information for further information about available test protocols, test protocol settings and sensitivity and specificity.

The Sera™ with DPOAE 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, 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.

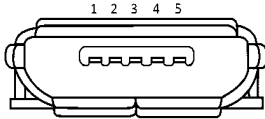
All protocols that include IEC in the name use the specified IEC calibration method.

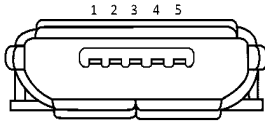
TEOAE		
Stimulus	Frequency range:	1500 to 4000 Hz
	Stimulus type:	Non-Linear (according to IEC 60645-6:2009)
	Level:	60 – 83 dBpe SPL, peak to peak calibrated, AGC controlled
	Click rate:	71/second
	Transducer:	SnapPROBE™ auto detection, auto calibrated Replaceable probe tip OWA Probe auto detection, auto calibrated Replaceable probe tip
Recording	Analysis time:	60 seconds
	Recording window:	2.5 – 14.1 ms
	A/D Resolution:	24 bit
	Artifact (noise) rejection system:	55 dB SPL
	Test pressure:	Ambient
	Residual noise:	An RMS value for each octave band, based on the Bayesian weighted average for the defined OAE time window.
Accuracy of Measurement	Algorithmic Sensitivity (default protocol):	≥ 99.6 %  Please refer to the Sera™ Additional Information for further information about available test protocols, test protocol settings and sensitivity and specificity.
Display		Transducer, test result bars, result symbols (pass/refer/incomplete), stimulus stability, test time, artifact.

Specification of input/output connections

	Sera™ ABR/OAE Connector for Probe, Pre-amplifier	Preamplifier, Probe, Transducer connector
Pin	Description	Description
1	CH1 out	CH1 out
2	CH1 GND	CH1 GND
3	DGND	DGND
4	GND A / GND Microphone	GND A / GND Microphone
5	Microphone – input / Analog balanced in	Microphone – input / Analog balanced in
6	Microphone + input / Analog balanced in	Microphone + input / Analog balanced in
7	Power supply +3/+5V	Power supply +3/+5V
8	CH2 out	CH2 out
9	CH2 GND	CH2 GND
10	I2C CLK	I2C CLK
11	I2C DATA	I2C DATA
12	I2C Interrupt	I2C Interrupt

Data input/output	
USB type A-B micro	USB port for communication

CRADLE CONNECTOR	CONNECTOR
MAINS	 <p>MICRO USB 5V/1.6A</p>

SERA™ CONNECTOR	MICRO USB (IN)
1	 <ul style="list-style-type: none"> 1. +5 VDC 2. NC 3. NC 4. NC 5. Ground

Calibration properties

Accuracy	
ABRIS	±2 dB for all stimulus types

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

Calibration reference values for the CE-Chirp® stimulus

Probe and insert stimuli are calibrated in SPL values using an ear simulator coupler made in accordance to IEC 60318-4.

Transducer	peRETSPL [dB re. 20 µPa]
RadioEar IP30 with ear tips	31.5 dB SPL
RadioEar IP30 with EarCups	58.5 dB SPL
OWA probe	35 dB SPL
SnapPROBE™	34.1 dB SPL

Reference values for the CE-Chirp® stimulus are Interacoustics standard values.

Calibration reference values for the click stimulus

Probe and insert stimuli are calibrated in SPL values using an ear simulator coupler made in accordance to IEC 60318-4.

Transducer	peRETSPL [dB re. 20 µPa]
RadioEar IP30 with ear tips	35 dB SPL
RadioEar IP30 with EarCups	61.5 dB SPL
OWA probe	33.5 dB SPL
SnapPROBE™	37.4 dB SPL

Coupler types used for calibration

ABRIS:

Probe and insert stimuli are calibrated in SPL values using an ear simulator coupler made in accordance with IEC 60318-4.

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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Appendix A: Stimulus

Another stimulus than specified in the standard IEC 60645-3 is used for some Automated ABR protocols. This CE-Chirp® stimulus has the same linear magnitude frequency response as the Click stimulus specified in the standard. However, it is designed as a sum of cosine functions in the frequency domain. The frequencies of the cosines are multiples of the stimulus repetition rate. With equal intensity for each frequency, to achieve the same linear magnitude frequency response. However, the phase of the cosine components is delayed according to the cochlear delay of the according frequency to achieve a more effective stimulus design. The frequency range of the stimulus is from 200 Hz up to 11 kHz.

Appendix B: Electromagnetic Compatibility (EMC)

This equipment is suitable in hospital and clinical 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.

NOTICE: ESSENTIAL PERFORMANCE for this equipment is defined by the manufacturer as:
This equipment 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.

Use of this equipment adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories 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 and cables can be found in this section.

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 equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result in improper operation.

This equipment complies with IEC60601-1-2:2014+AMD1:2020, emission class B group 1.

NOTICE: There are no deviations from the collateral standard and allowances uses.

NOTICE: All necessary instructions for maintenance comply with EMC and can be found in the general maintenance section in this instruction. No further steps required.
To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the following accessories as applicable:

Item	Manufacturer	Model
Preamplifier	Interacoustics	-
OWA Probe	RadioEar	-
Snap Probe	RadioEar	-
IP30 50Ohm stereo ID earphone	RadioEar	IP30
IP30 50Ohm earcup stereo ID headset	RadioEar	IP30

Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

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 (meter)	Screened (Yes/No)
Power Supply	1,5	N
Wireless charger/cradle	-	-
Audiometric Insert-Headsets (IP30)	0,25	Y
Ear Probes (OWA / Snap)	0,50	Partial
Preamplifier	1,15	Partial
Electrode cables	0,51	N

The use of the accessories, transducers, and cables with medical equipment/system other than this equipment may result in increased emissions or decreased immunity of the medical equipment/system.

Guidance and manufacturer's declaration - electromagnetic emissions

The Sera™ is intended for use in the electromagnetic environment specified below. The customer or the user of the Sera should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Sera 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 Sera is suitable for use in all commercial, industrial, business, and residential environments.
RF emissions CISPR 11	Class B	
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 Sera.

The Sera is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Sera can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Sera 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 Sera is intended for use in the electromagnetic environment specified below. The customer or the user of the Sera 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 Sera.
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 Sera requires continued operation during power mains interruptions, it is recommended that the Sera 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 Sera contains magnetically sensitive components or circuits, the proximity magnetic fields should be no higher than the test levels specified in Table 11

Note: *UT* is the A.C. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration — electromagnetic immunity

The Sera is intended for use in the electromagnetic environment specified below. The customer or the user of the Sera 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 Sera, 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	3 Vrms	$d = \frac{3,5}{V_{rms}} \sqrt{P}$
	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	$d = \frac{3,5}{V/m} \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \frac{7}{V/m} \sqrt{P} \quad 800 \text{ MHz to } 2,7 \text{ GHz}$ <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 meters (m).</p> <p>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> 
	10 V/m 80 MHz to 2,7 GHz Only for Home Healthcare environment	10 V/m (If Home Healthcare)	

NOTE 1 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 Sera is used exceeds the applicable RF compliance level above, the Sera should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Sera.

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