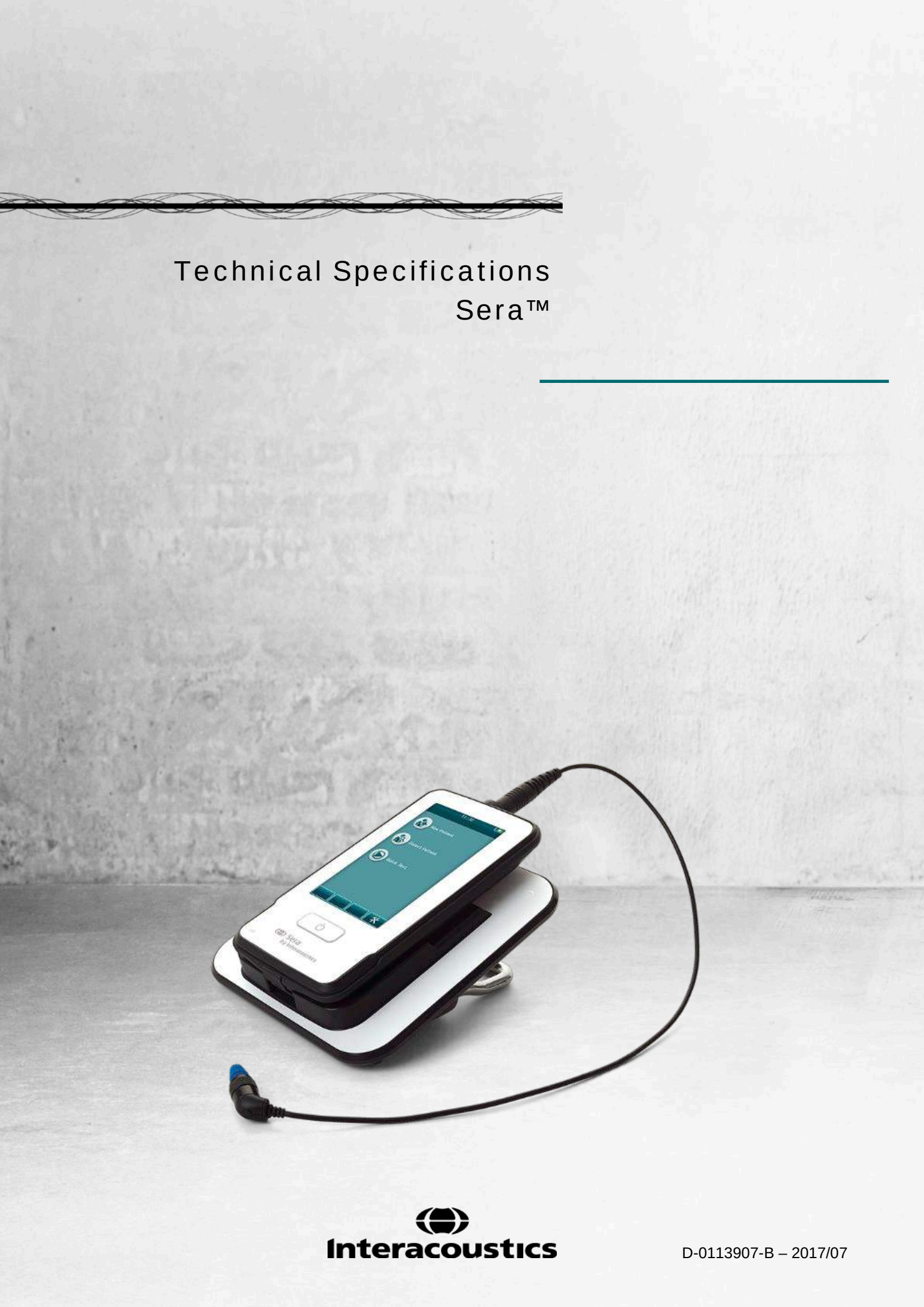
Technical Specifications
Sera™



Interacoustics

D-0113907-B – 2017/07

Included and Optional Parts

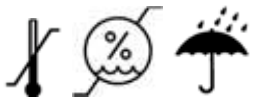
The system consists of the following included and optional parts:

Standard Components, General	Configurations	
	ABRIS	**ABRIS + OAE**
Sera™ handheld device	•	•
Sera™ cradle	•	•
Cradle power supply	•	•
Preamplifier[1]	•	•
USB Type A-B Micro cable	•	•
Carrying case	•	•
Cavity (0.2/0.5 cc)	•	•
Pinch clip cables for snap electrodes[1]	•	•
Instructions for Use	•	•
HearSIM™ software bundle	•	•
Sera™ Probe Tip Kit	Optional	•
Sera™ ADI Screening Eartip Kit	•	•
Sera™ Probe Cleaning Kit	•	•
IP/Probe Accessory Kit	•	•
EarCup Accessory Kit	Optional	Optional
Stylus Pen	•	•
Cleaning cloth for touchscreen	•	•
Neckstrap for preamplifier	•	•
Transducers		
OWA Probe 500 mm[1]	Optional	Optional
OWA Probe 1200 mm[1]	Optional	•
IP 30 (50 Ω) insert earphone with Eartip 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 MLP-II Kit (includes printer, power supply and 2 rolls of thermal label paper)	Optional	Optional

[1] Applied part according to IEC 60601-1

General Technical Specification

1.1 Sera™ Instrument – Technical Specifications

Medical CE-mark CE 0123	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 The Sera™ is an active, diagnostic medical product according to the class IIa of the EU medical directive 93/42/EEC.	
Standards	**Safety:**	IEC 60601-1:2012, Internally powered, Type B and BF applied parts
	EMC:	IEC 60601-1-2:2014 IEC 60601-2-40:2016
	Calibration:	ISO 389-2:1994 ISO 389-6:2007
	Test Signal:	IEC 60645-3:2007
	OAE:	IEC 60645-6:2009, Type 2
	ABR:	IEC 60645-7:2009, Type 2
Cradle	**Safety:** **Power** **Mains voltages and frequencies:** **Output:**	IEC 60601-1:2012, Class II UE08WCP-050160SPA Item number 8029254 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-condensating) 98 kPa – 104 kPa < 5 sec < 1 minute
Transport & Storage environment	**Storage Temperature:** **Transport Temperature:** **Storage and Transport rel. Humidity :**	0°C – 50°C, - 4°F... + 122°F -25 – 70°C, - 13°F... + 158°F Max 93% (non-condensating)
Altitude rating	**Max. operating altitude:**	2000 m / 6561 ft above sea level
Markings **IP02** **IP20**	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: 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.	

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:		Bluetooth® Transmit frequency: 2400 – 2483.5 MHz Modulation types: GFSK, π/4-DQPSK and 8DPSK Radiated power: 2.5 mW (Class 2)
User Feedback:		Integrated speaker
Language Settings:		English
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		OAE/Automated ABR
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:**	MLP II
	Connection:	Bluetooth®
	Battery:	Lithium Ion, DC 7.4 V, 1500 mAh
	Charger:	AC 100 – 250 V, ~50/60 Hz, 1.0 A
	Weight:	360 g / 12.7 oz
	Paper:	Thermal paper or label
	Paper width:	57.5 ± 0.5 mm (width) on thermal printer 57.5 ± 0.5 mm x 60 mm (width x length) on label printer
	Printing time:	Printing time depends on the size of the used protocol.

ABRIS		
Preamplifier	**One Channel:**	3 electrodes, 51 cm, 20''
	Gain:	72 dB
	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/ 170 pF
	Power from main unit:	Isolated power supply
Electrical Impedance measurement	**Measurement frequency:**	33 Hz
	Waveform:	Rectangular
	Measurement current:	11.25 µA
	Range:	0.5 kΩ – 25 kΩ ± 10 %
Stimulus	**Stimuli:**	CE-Chirp® range (200 Hz – 11 kHz)
	Stimulus rate:	90 Hz
	Transducers: (Calibrated to Standards)	IP30 insert phone IP30 EarCup OWA Probe
	Channels:	2
	Level:	35 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		Test result bars, result symbols (pass/refer/incomplete), test time, artifact, electrode impedances.
Accuracy of Measurement: using CE-Chirp®:	**Algorithmic Sensitivity: Specificity**	> 99.81% Please refer to the Sera™ Additional Information Manual for further information about Sensitivity and Specificity.

DPOAE		
Stimulus	**Frequency range:**	2000 to 5000 Hz
	Nominal frequency:	f2
	Level:	L1 = 65 dB SPL, L2 = 55 dB SPL
	Transducer:	OWA Probe auto detection, auto calibrated Replaceable probe tip
	Stimulus tolerance:	7 dB
Recording	**Analysis time:**	60 seconds
	A/D Resolution:	24 bit, 5.38 Hz resolution
	Artifact (noise) rejection system:	30 dB SPL
	SNR criteria:	Fixed at 6 dB
	Residual noise:	An RMS average measurement in the DP-bin frequency area (26 bins at frequencies < 2500 Hz & 60 bins ≥ 2500 Hz).
	Test Pressure:	Ambient
Display		Test result bars, result symbols (pass/refer/incomplete), test time, artifact.
Accuracy of Measurement:	**Algorithmic Sensitivity:**	> 99.73 % Please refer to the Sera™ Additional Information Manual for further information about Sensitivity and Specificity.

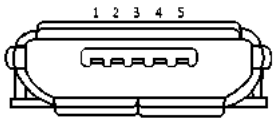
TEOAE		
Stimulus	**Frequency range:**	1500 to 4000 Hz
	Stimulus type:	Non-Linear (according to IEC 60645-3:2007)
	Level:	83 dB peSPL, peak to peak calibrated, AGC controlled
	Stimulus tolerance:	2 dB
	Click rate:	71/second
	Transducer:	OWA Probe auto detection, auto calibrated Replaceable probe tip
Recording	**Analysis time:**	60 seconds
	Recording window:	2.5 – 14.1 ms
	A/D Resolution:	24 bit
	Artifact (noise) rejection system:	55 dB SPL
	SNR criteria:	Fixed at 4 dB
	Test pressure:	Ambient
Accuracy of Measurement:	**Algorithmic Sensitivity:**	> 99.28 %  Please refer to the Sera™ Additional Information Manual for further information about Sensitivity and Specificity.
Display		Test result bars, result symbols (pass/refer/incomplete), test time, artifact.

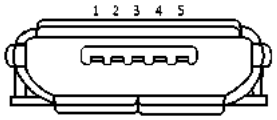
Specification of input/output connections

	Sera™ ABR/OAE Connector for Probe, Preamplifier	**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 I/O

USB USB type A-B micro USB port for communication

CRADLE CONNECTOR	
MAINS	 **MICRO USB 5V/1.6A**

SERA™ CONNECTOR			
		MICRO USB (IN)	
	1		1. +5 VDC 2. NC 3. NC 4. NC 5. Ground

Calibration reference values for CE-Chirp® stimulus

Radioear IP30 with Coupler IEC 60711.

Transducer	**peRETSPL [dB re. 20 µPa]**
RadioEar IP 30 with ear tips	31.5 dBSPL
RadioEar IP30 with EarCups	58.5 dBSPL

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

Coupler Types used for Calibration

ABRIS:
Probe and insert stimuli are calibrated in SPL values using an ear simulator coupler made in accordance to 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 to IEC 60318-4.
TEOAE:
Probe stimuli are calibrated in peSPL values using the IEC 711 ear simulator coupler made in accordance to 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:

Interacoustics A/S
Audiometer Allé 1
5500 Middelfart
Denmark
Tel.: +45 6371 3555
Fax: +45 6371 3522
E-mail: info@interacoustics.com
Web: www.interacoustics.com

Appendix A: Stimulus

Another stimulus than specified in the standard IEC 60645-3 is used. This CE-Chirp® stimulus has the same linear magnitude frequency response like 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 are delayed according to the cochlear delay of the according frequency in order 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)

Portable and mobile RF communications equipment can affect the ***Sera™*** . Install and operate the ***Sera™*** according to the EMC information presented in this chapter.

The ***Sera™*** has been tested for EMC emissions and immunity as a standalone ***Sera™***. Do not use the ***Sera™*** 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.

Cautions regarding 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.

Essential performance for this instrument is defined by the manufacturer as:

To generate and present stimulus signals in the audio range as specified in the applicable IEC 60645 series or ANSI standards in normal condition.

Absence of these performance features can lead to failure in diagnosis.

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.

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

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.
RF emissions CISPR 11	Class B	The ***Sera™*** 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 *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 2.5 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 ensure 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	+6 kV contact +8 kV air	+6 kV contact +8 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%.
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 differential mode +2 kV common mode	+1 kV differential mode +2 kV common mode	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	< 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 sec	< 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	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	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Note: *U*T 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
Conducted RF IEC / EN 61000-4-6 Radiated RF IEC / EN 61000-4-3	3 Vrms 150kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	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 $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz w $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 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 ***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.			

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.

All EMC tests shall be performed in both standard OAE and ABR protocol mode.

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 the EMC appendix of this instruction.

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.

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
Preamplifier	Interacoustics	-
OWA Probe	RadioEar	-
IP30 50Ohm stereo ID earphone	RadioEar	IP30
IP30 50Ohm earcup stereo ID headset	RadioEar	IP30

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:

EUT Support Equipment							
Item	**Manufacturer**	**Model**	**Cable**		**SIP/SOP**		**Serial no.**
			Length [meter]	Screened [Y/N]	Socket ID	Type	
Power Supply	UE / Fuhua	UE08WCP-050160SPA	-	-	Mains power	AC supply	-
			1,5	N	Micro USB on the wireless charger/cradle	DC supply	-
Wireless charger/cradle	Interacoustics	-	-	-	-	-	-
Audiometric Insert-Headset (50Ω)	Radioear	IP30	0,25	Y	On the preamp: Socket marked with ear symbol	Analog output Serial data	ID028384
Ear Probe	Interacoustics	OWA	0,48	Partial	On the preamp: Socket marked with ear symbol or top socket on the Sera™ device	Analog output Mic input Serial data	-
Preamp	Interacoustics	-	1,15	Partial	Top socket on the Sera™ device	Analog output Mic input Serial data	MA9017639
Electrode cables	Interacoustics	-	0,51	N	On the preamp: Colour marked sockets with head symbol	Analog input for Physiological signals	-