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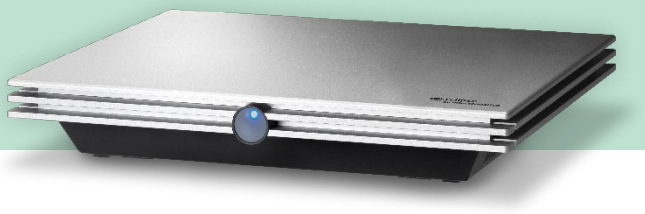
Technical Specifications

Eclipse



Interacoustics

D-0121111-I – 2025/11

Contents

Eclipse specifications

1.1 Eclipse software module overview

1.1.1 EP15/EP25/VEMP/Aided modules*

Test types/functionality:	EP15	EP25	VEMP	Aided Cortical
Click stimulus	x	x	x	
Broadband CE-Chirp® LS stimulus	Optional	x	Optional	
Narrow Band CE-Chirp® LS stimuli (0.5, 1, 2, 4 kHz)	Optional	x	Optional	
Tone Burst stimuli (0.25 – 8kHz)	x	x	x	
Recording window	15 and 30 ms	15 to 900 ms	150 ms	900 ms
ABR	x	x		
Rate Study	x	x	x	
ECochG	Optional	x		
MLR		x		
ALR		x		
MMN/P300		x		
eABR	x	x		
cVEMP / oVEMP	Optional	Optional	x	Optional
EMG controlled stimulus/recording			x	
EMG scaling (rectification)			x	
Patient EMG monitor/tone			x	
Aided Cortical	Optional	Optional	Optional	x
ManU-IRU stimuli				x
HD-Sounds				x
Ling stimuli				x

** Please refer to stimulus maximum intensity chapter for more details.*

1.1.2 TEOAE module

Test types/functionality:	TEOAE Module
Stimulus level	30 – 90 dB SPL
Non-linear click stimulus	x
Frequency range	500-5500Hz
Test time	5 seconds to 30 minutes
FFT display	x
Pass/refer bands	x
SNR value display	x
OAE level display	x
Automated screening (pass/refer) algorithm (protocol)	x
User definable pass/refer algorithm (protocol)	x

1.1.3 DPOAE module

Test types/functionality:	DPOAE Module
Stimulus level	30 - 80 dB SPL
Stimulus range	500 – 10000Hz
Test time	Min 2 sec – unlimited
DP-Gram	x
DP Input/Output	x
Normative data display option	x
Checkmark indication for SNR detection	x
User definable protocols	x
Manual test time override	x

1.1.4 ABRIS module

Functionality:	ABRIS Module
Stimulus type	Click
Stimulus rate	93 Hz
Stimulus intensity	30, 35, 40dB nHL
Test time	120 seconds (default)
Test montage	mastoid or nape
Test method	monaural
User customizable protocols	x
Password protection of test parameters	x

1.1.5 ASSR module

Functionality:	ASSR Module
Stimulus level	0 – 100 dB nHL
Narrow Band CE-Chirp® stimuli (0.5, 1, 2, 4 kHz)	x
Recording time	Up to 15 min per curve
Stimulus rate	40 or 90 Hz
Transducer options	Headphone, Inserts, Bone
nHL to eHL correction factors (Child/Adult)	x
Residual noise calculator	x
User customizable protocols	x
Noah 4 and higher compatibility	x

1.1.6 EP15/EP25/VEMP module stimulus maximum intensity

From software 4.5 the stimulus maximals are increased for all transducers.

Insert earphones and headphone can now go even louder.

To get the increased intensity maximals for bone conductor; Firstly, get the B81 BC, secondly ensure that the correct bone vibrator is chosen in the calibration setup to allow more output for the bone vibrator.
If it is a new transducer, always ensure that it is calibrated prior to use, follow the procedure as described in the service manual.

The below table is an overview of what the various transducers can minimum perform of intensity from software 4.5.
Individual systems may be able to perform even louder as this depends on the individual transducer sensitivity per frequency.

		ABR3A		DD45		DD45S		B81	
Stimulus		short 2-1-2	Long	short 2-1-2	Long	short 2-1-2	Long	short 2-1-2	Long
Burst	250	105	115	105	110	105	110	50	55
Burst	500	110	120	115	120	115	120	70	80
Burst	750	110	120	120	120	120	120	70	85
Burst	1000	110	120	120	120	120	120	75	90
Burst	1500	110	120	115	120	115	120	80	95
Burst	2000	110	120	115	120	110	120	75	90
Burst	3000	110	120	120	120	115	120	65	85
Burst	4000	105	120	115	120	110	120	65	80
Burst	6000	90	110	100	120	100	120	45	65
Burst	8000	70	95	95	120	90	115	35	60
CE-Chirp		100	105	110	110	110	110	70	70
Click		100	100	105	105	105	105	70	70
Click 200Hz-10kHz		95	95	105	105	105	105	70	70
NB CE-Chirp	500	105	105	115	115	115	115	60	60
NB CE-Chirp	1000	110	110	115	115	120	120	70	70
NB CE-Chirp	2000	105	105	115	115	110	110	70	70
NB CE-Chirp	4000	105	105	115	115	110	110	60	60

All above values are stimulus levels in dB nHL.

1.2 Included and optional parts

Included parts:

EP15/EP25/VEMP/ASSR/ABRIS/Aided
Eclipse
EPA Preamplifier[1]
EPA4 cable collector
USB cable
Power cable
LBK15 (only EP15, EP25, VEMP)
IP30 inserts phone including eartips
Neonatal Insert Ear tips
4.0 mm, 3.5 mm
Pediatric starter kit (EarTips)
Eartip adaptor and Tubekit.
ETB Standard surface Electrode Cables with Buttons
ETSE tab surface electrode kit.
Jumper Cable 125mm.
NuPrep gel 4oz/114g tube (SPG15)
Gauze Swabs
Disposable Snap electrodes[1]
Disposable tab electrodes[1].
Bridge & Implant Cleaners (Proxysoft)
Alcohol Pads
EP15/25/VEMP/Aided software
Instructions for Use Manual on USB
Additional Information Manual on USB

Aided:
Besides the above hardware, the following is also included:
SP90A active loudspeaker
Speaker cables
Loudspeaker stand
Ambient microphone
Microphone stand

EP25:
ECochG Starter Kit including cable, gel and 2 TM electrodes[1]

DPOAE
Eclipse
OAE Probe complete[1]
Power cable
USB cable
IA OAE Suite software
Ear Tip[1] Assortment Box
Cleaning tool
Probe tips[1]
Instructions for Use on USB
Additional Information Manual on USB

TEOAE
Eclipse
OAE Probe complete[1]
Power Cable
Country specific
USB connection cable
IA OAE Suite software
Assortment Box with ear tips[1] for OAE
Cleaning tool
Probe tips[1]
Instructions for Use Manual on USB
Additional Information Manual on USB

Optional parts:
OtoAccess® Database
Tranducers as headphone DD45s and bone conductor B81 are also available.
Refer to the current Sanibel Disposables & Accessories brochure (www.interacoustics.com) or contact your local distributor.

[1] Applied part according to IEC60601-1

1.3 Technical specifications

Technical specifications - Eclipse hardware

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 Annex I Approval of the quality system is made by TÜV – identification no. 0123	
Standards:	**Safety:**	IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Class I, Type BF) IEC 60601-2-40:2016 CAN/CSA-C22.2 No.60601-1:2014/A2-2022 ANSI/AAMI ES60601-1:2005/A2:2021
	EMC:	IEC 60601-1-2:2014+AMD1:2020
Power Supply:	**Input Volts:**	100 –240VAC, 50/60Hz.
	Consumption:	26W (0.3A Max)
	Safety marking	
Operating environment:	**Operating Temperature:**	15 – 35 °C (59 - 95°F)
	Rel. Humidity:	30 – 90%
	Ambient Pressure:	98kPa – 104kPa
Transport & Storage:	**Storage Temperature:** **Transport Temperature:** **Rel. Humidity:**	0°C – 50°C (32°F - 50°F) -20 – 50 °C (-4°F - 122°F) 10 – 95% (non condensing
Warm up time:		10 minutes at room temperature (20 °C) (68°F).
General		
PC control:	**USB:**	USB 1.1 or 2.0 for input/output for computer communication. Eclipse if fully operated from a PC
Construction:		Metal cabinet
Eclipse Dimensions		(L x W x H) 28 x 32 x 5.5 cm (11 x 12.6 x 2.2 Inches)
Eclipse Weight		2.5kg / 5.5 lbs excluding accessories

1.4 Technical specifications EP15/EP25/VEMP/Aided

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 Annex I Approval of the quality system is made by TÜV – identification no. 0123	
Standards:	**Test Signal:**	IEC 60645-3, 2007
	AEP	IEC 60645-7, 2009. Type 1
EPA Preamplifier:	**Two channels standard**	EPA4 Cable Collector (4 electrodes). Standard 50 cm. Option: 5 cm or 290 cm
	One Channel (optional)	EPA3 Cable Collector (3 electrodes). 50 cm
	Gain:	80 dB/60 dB (60dB = VEMP (-20dB))
	Frequency response:	0.5 – 11.3kHz
	CMR Ratio:	Minimum 100 dB. Typical 120 dB @55 Hz
	Noise (RTI)	=< 15 nV/√Hz
	Radio frequency immunity:	Typically 20 dB improvement over previous available designs
	Max input offset voltage:	2,5 V
	Input impedance:	>=10 MΩ/=< 170 pF
	Power from main unit:	Insulated power supply with 1500 V isolation. The signal is digitally/capacitive insulated.
Specifications as EPA4		
	Impedance measurement:	Selectable for each electrode
	Measurement frequency:	33 Hz
	Waveform:	Rectangular
	Measurement current:	19µA
	Range:	0.5 kΩ – 25 kΩ
Stimulus:	**Stimulus rate:**	0.1 to 80.1 stimuli per second in steps of 0.1.
	Envelopes/Windows:	Bartlett, Blackman, Gaussian, Hamming, Hanning, Rectangle and Manual (Rise/Fall and Plateau)
	Masking:	White noise. Calibrated and presented in peSPL.
	Transducer:	Insert phone, calibrated on an IEC 711 coupler. Headphone with independent calibration (optional) Bone conductor (optional) Free field loudspeaker (optional)
	Level:	20 – 135.5 dB peSPL, please refer to chapter stimulus maximum intensity for converted nHL as this depends on the frequency.
	Polarity:	Condensation, Rarefaction, Alternating.
	Click:	100 µs (200Hz -11kHz)
	Tone Burst Frequency:	250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000 and 8000 Hz.
	Tone Burst Stimulation Time:	Stimulation up to 780 ms
	NB CE-Chirp® LS Freq.:	500, 1000, 2000 and 4000 Hz
	Broadband CE-Chirp®: LS	200Hz -11kHz
	Relative Masking Level:	+30dB to -40 dB relative to stimulus level. The stimulus level is presented in nHL. The masking level is only presented in SPL, and can therefore not exceed the loudness of the stimulus. E.g. a stimulus presented at 100dBnHL, and relative masking level at 0dB would provide a masking level of 100dB peSPL. This would equal a level 75dBnHL. Maximum masking levels: Insert phones: 110dB SPL, relative levels 0 to -40. Headphones: 110dB SPL, relative levels 0 to -40. Insert phones: 110dB SPL, relative levels +60 to -40.
	Absolute Masking Level:	0dB to 110 dB SPL absolute level. The masking level is only presented in SPL, and can therefore not exceed the loudness of the stimulus. E.g. a stimulus presented at 100dBnHL, and relative masking level at 0dB would provide a masking level of 100dB peSPL. This would equal a level 75dBnHL. Maximum masking levels: Insert phones: 110dB SPL, relative levels 0 to -40. Headphones: 110dB SPL, relative levels 0 to -40. Insert phones: 110dB SPL, relative levels +60 to -40.
Recording:	**Analysis Time:**	-150 ms prior to stimuli and up to 1050 ms (license dependent).
	A/D Resolution:	16 bit.
	Sampling frequency	30 kHz
	Artifact Reject System:	Standard voltage based system

	Rejection levels:	Manual 0.2 - 640 µV input with 0.1uV steps.
	Anti-aliasing filter:	Internal filter in ADC
	Dots per Trace:	450 displayed.
	Low Pass Filter:	None or 17 – 12000 Hz, depending on the measurement type. 33 taps FIR Filter without wave peak latency displacement.
	High Pass Filter:	0.83 Hz to 500 Hz depending on the measurement type.
	DSP Low Pass Filter:	None, 100, 300, 750, 1k, 1,5k, 2k, 3k, 4k, 5k, 7,5k Hz
	DSP High Pass Filter:	0.5, 1.0, 3.3, 10, 33, 100 Hz
Display Gain:		General Display Gain. Applicable during testing. Single Curve Display Gain. Applicable during testing.
Controlled parameters:		Stimuli Rate, Number of stimuli, Polarity, Click, Tone Burst (Frequency, no. of sine waves, window), Stimulus intensity, Number of curves per intensity, Intensity (Ascending, Descending), Soft attenuator, Stimulus ear, Transducer, Masking level, Preliminary filter setting, Recording onset, Automatic next intensity (Wave repro level on screen), General Display Gain, Single Curve Display Gain, Baseline, Latency norm, Report templates, Print out, Manual stimulus to familiarization, Talk Forward.
Data collection:		Impedance test, Waveform buffer (A/B, Contra, Ipsi-Contra, A-B = Noise), Curve (Hide, Fixate, Merge, Delete), Online EEG, Waveforms storage in unlimited storage database.
Data Recovery:		Lost data due to crash of Windows® will in almost all cases be available upon re-establishing Windows® operation.

Note ! The transducer is dedicated to one Eclipse only! Calibration is stored on the Eclipse. Replacing the transducer will require new calibration of the transducer connected to the Eclipse.

1.4.1 peSPL to nHL correction values

Toneburst ECochG/ABR15/ABR30/AMLR/RATE STUDY/VEMP 0 dB 2-1-2 cycle linear envelope				Toneburst ALR/MMN dB 25-50-25 ms			
Hz	Insert phone	Headphone	Bone	Hz	Insert phone	Headphone	Bone
250	28.0	38.0	74.5	250	17.5	27.0	67.0
500	23.5	25.5	69.5	500	9.5	13.5	58.0
750	21.0	23.0	61.0	750	6.0	9.0	48.5
1000	21.5	21.5	56.0	1000	5.5	7.5	42.5
1500	26.0	23.0	51,5	1500	9.5	7.5	36.5
2000	28.5	24.5	47.5	2000	11.5	9.0	31.0
3000	30.0	26.5	46.0	3000	13.0	11.5	30.0
4000	32.5	32.0	52.0	4000	15.0	12.0	35.5
6000	36.5	37.5	60.0	6000	16.0	16.0	40.0
8000	41.0	41.5	65.5	8000	15.5	15.5	40.0
	ISO 389-6:2007				ISO 389-1:2000, ISO 389-2:1994, ISO 389-3:1994		

Click ECochG/ABR15/ABR30/AMLR/RATE STUDY/VEMP 0 dB				Click ALR/MMN 0 dB			
	Insert phone	Headphone	Bone		Insert phone	Headphone	Bone
Click	35.5	30.0	51.5	Click	35.5	30.0	51.5

NB CE-Chirp® LS ECochG/ABR15/ABR30/AMLR/RATE STUDY/VEMP 0 dB				NB CE-Chirp® LS ALR/MMN 0 dB			
Hz	Insert phone	Headphone	Bone	Hz	Insert phone	Headphone	Bone
500	25.5	27.5	74.0	500	25.5	27.5	74.0
1000	24.0	24.0	61.0	1000	24.0	24.0	61.0
2000	30.5	26.5	50.0	2000	30.5	26.5	50.0
4000	34.5	34.0	55.0	4000	34.5	34.0	55.0

CE-Chirp® LS ECochG/ABR15/ABR30/AMLR/RATE STUDY/VEMP 0 dB				CE-Chirp® LS ALR/MMN 0 dB			
	Insert phone	Headphone	Bone		Insert phone	Headphone	Bone
	31.5	26.5	51.0		31.5	26.5	51.0

Only tone burst correction values change for ALR & MMN testing. For Click and CE-Chirps® LS, the same correction is applied.

1.5 Technical specifications TEOAE

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 Annex I Approval of the quality system is made by TÜV – identification no. 0123	
Standards:	**Test signal**	IEC 60645-3:2007
	OAE	TEOAE IEC 60645-6:2022, Type 1 & 2 Otoacoustic emissions
Stimulus:	**Type:**	Click Non-linear
	Bandwidth:	500 – 5500 Hz
	Level:	30 to 90 dB peSPL, peak to peak calibrated, AGC controlled
	Level Step:	1 dB SPL
	Transducer:	Dedicated DPOAE/TEOAE probe (Accuracy 0.5 dB)
Recording:	**Analysis time:**	5 seconds to 30 minutes
	Sampling frequency	30 kHz
	A/D Resolution:	16 bit, 3.7 Hz resolution
	Artifact Reject System:	0 to +60 dB SPL or off Applicable during testing
	SNR Criteria:	Adjustable between 5 and 25 dB
Display gain:		
	General display gain:	Applicable during testing

OAE Probe Specifications:		
Probe:	**Application:**	TEOAE measurements
	Dimensions:	(W x D x H) 12 x 26 x 11 mm (exc. Eclipse)
	Weight:	3 g (exc. Cable, exc. Eclipse) 39 g (incl. cable, exc. Eclipse)
Cable:	**Length:**	2980 mm cable

Note! The OAE probe is dedicated to one Eclipse only! Calibration is stored on the Eclipse. Replacing the OAE transducer will require new calibration of the transducer connected to the Eclipse.

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

1.6 Technical specifications DPOAE

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 Annex I Approval of the quality system is made by TÜV – identification no. 0123	
Standards	**Test Signal:**	IEC 60645-1:2012 /ANSI S3.6
	OAE	DPOAE IEC 60645-6:2022, Type 2 Otoacoustic emissions
Stimulus:	**Frequency Range:**	500-10000 Hz
	Frequency Step:	25 Hz
	Level:	30 to 70 dB SPL
	Level Step:	1 dB SPL
	Transducer:	Dedicated DPOAE/TEOAE probe
Recording:	**Analysis time:**	minimum 2 sec to unlimited test time
	A/D Resolution:	16 bit, 3.7 Hz resolution
	Sampling frequency	30 kHz
	Artifact Reject System:	-30 to +30 dB SPL or off. Applicable during testing
	Stimulus Tolerance:	Adjustable between 1 and 10 dB
	SNR Criteria:	Adjustable between 3 and 25 dB
	Probe check window	256 points frequency response of the ear canal due to a click stimulus presented with a rate of 100 Hz at 80 dB SPL
	DP-Response window	4096 points frequency response
Display gain:		
	General display gain:	Applicable during testing

OAE Probe Specifications:		
Probe:	**Application:**	DPOAE measurements
	Dimensions:	(W x D x H) 12 x 26 x 11 mm (exc. Eclipse)
	Weight:	3 g (exc. Cable, exc. Eclipse) 39 g (incl. cable, exc. Eclipse)
Cable:	**Length:**	2980 mm cable

Note! The OAE probe is dedicated to one Eclipse only! Calibration is stored on the Eclipse. Replacing the OAE transducer will require new calibration of the transducer connected to the Eclipse.

DPOAE calibration:
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.

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.

1.7 Technical specifications ABRIS

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 Annex I Approval of the quality system is made by TÜV – identification no. 0123	
Standards:	**Test signal**	EC 60645-3:2007
	AEP	IEC 60645-7:2009 Type 2
EPA Preamplifier:	**Two channels standard:**	EPA4 Cable Collector (4 electrodes). Standard 50 cm. Option: 5 cm or 290 cm
	One Channel (optional):	EPA3 Cable Collector (3 electrodes). 50 cm
	Gain:	80 dB
	Frequency response:	0,5 – 11.3 kHz
	CMR Ratio:	Minimum 100 dB. Typical 120 dB @55 Hz
	Noise (RTI)	=< 15 nV/√Hz
	Radio frequency immunity:	Typically 20 dB improvement over previous available designs
	Max input offset voltage:	2,5 V
	Input impedance:	>=10 MΩ/ =<170 pF
	Power from main unit:	Insulated power supply with 1500 V isolation. The signal is digitally/capacitive insulated.
Specifications as EPA4 Impedance measurement:		
		Selectable for each electrode
	Measurement frequency:	33 Hz
	Waveform:	Rectangular
	Measurement current:	19µA
	Range:	0.5 kΩ – 25 kΩ
Stimulus:	**Stimulus rate:**	93 Hz
	Level:	30, 35, 40 dBnHL
	Click:	100 µs
Recording:	**Analysis time:**	120 seconds
	A/D resolution:	16 bit
	Sampling frequency	30 kHz
	Artifact rejection system:	Standard voltage based system
Display:		Stimulus level and type, Graph view
Security:		Password protection of test parameters possible.
Algorithmic Sensitivity:	**Click:**	99.99%
Specificity:	**Click:**	≥ 97%

1.8 Technical specifications ASSR

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 Annex I Approval of the quality system is made by TÜV – identification no. 0123.	
Standards:	**Test signal:**	IEC 60645-3:2007
	AEP	IEC 60645-7:2009, Type 1.
EPA Preamplifier:	**Two channels standard:**	EPA4 Cable Collector (4 electrodes). Standard 50 cm. Option: 5 cm or 290 cm
	One Channel (optional):	EPA3 Cable Collector (3 electrodes). 50 cm
	Gain:	80 dB
	Frequency response:	0,5 – 11.3 kHz
	CMR Ratio:	Minimum 100 dB. Typical 120 dB @55 Hz
	Noise (RTI)	=< 15 nV/√Hz
	Radio frequency immunity:	Typically 20 dB improvement over previous available designs
	Max input offset voltage:	2,5 V
	Input impedance:	>=10 MΩ/ =<170 pF
Impedance measurement:	**Waveform:**	Rectangular
	Measurement current:	19µA
	Range:	0.5 kΩ – 25 kΩ
Stimulus:	**Stimulus rate:**	40 or 90 Hz
	Transducer:	Ear Tone ABR insert phone, calibrated on an IEC 711 coupler. Headphone (optional) Bone conductor (optional)
	Level:	0 – 100 dB nHL in 5 dB steps.
	NB CE-Chirp® Freq.:	500, 1000, 2000, and 4000 Hz, both ears same time.
	Bandwidth:	1 octave ± ½ octave – 3 dB
	Masking:	White noise 0 – 100 dB SPL
	Analysis Time:	6 minutes to detect a ASSR signal – can be extended up to 15 minutes
Recording:	**Sampling frequency:**	30 kHz
	Artifact Reject System:	Standard voltage based system
	Gain:	74 – 110 dB. Auto or Manual selection.
	Channels:	2, with separate detection algorithm
	Algorithmic Sensitivity:	99% or 95% , false pass probability
	Rejection levels:	Manual 5, 10, 20, 40, 80, 160, 320, 640 µV input
	Anti- aliasing filter:	Analog 5kHz, 24 dB / octave
Display:		Independent control of up to 8 simultaneous stimuli (max 4 per ear)
Display Gain:		Independent start, stop control for each of the 8 stimuli
Controlled parameters:		Stimulus level control for each of the 8 stimuli
		False pass probability 1 or 5%
		Test protocols included for children and adult
NOAH:		NOAH 4 compatible

Note! The transducer is dedicated to one Eclipse only! Calibration is stored on the Eclipse. Replacing the transducer will require new calibration of the transducer connected to the Eclipse.

1.9 Electromagnetic Compatibility (EMC)

This section is valid for the Eclipse system including all variants.

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.

NOTICE: If Non-Medical Electronic Equipment (Typical information technology equipment) is attached, it is the responsibility of the operator to ensure that this equipment comply to applicable standards and the system as whole complies to the EMC requirements. Commonly used standards for EMC testing information technology equipment and similar equipment[2] are:

Emissions testing

EN 55032 (CISPR 32)	Electromagnetic Compatibility Of Multimedia Equipment – Emission Requirements
EN 61000.3.2	Electromagnetic compatibility (EMC) – Limits for harmonic current emissions (AC mains only, Equipment input current less than or equal to 16 A per phase)
EN 61000.3.3	Electromagnetic compatibility (EMC) – Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems (AC mains only, Equipment input current less than or equal to 16 A per phase)

[2] Products include personal computer, PC, tablet, laptop, notebook, mobile device, PDA, Ethernet hub, router, Wi-Fi, computer peripheral, keyboard, mouse, printer, plotter, USB storage, Hard drive storage, solid-state storage and many more.

Immunity testing

EN 55024 (CISPR 24) Information technology equipment – Immunity characteristics – Limits and methods of measurement

To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the following accessories specified in section 1.3 as applicable:

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 *Eclipse* is intended for use in the electromagnetic environment specified below. The customer or the user of the *Eclipse* should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ***Eclipse*** 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 ***Eclipse*** is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Complies Class A Category	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the *Instrument*.			
The ***Eclipse*** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ***Eclipse*** can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ***Eclipse*** 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 ***Eclipse*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***Eclipse*** 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 ***Eclipse***.
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 Line to line +2 kV Line to earth	+1 kV Line to line +2 kV Line to earth	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% *UT* (100% dip in *UT*) for 0.5 cycle, @ 0, 45, 90, 135, 180, 225, 270 and 315° 0% *UT* (100% dip in *UT*) for 1 cycle 40% *UT* (60% dip in *UT*) for 5 cycles 70% *UT* (30% dip in *UT*) for 25 cycles 0% *UT* (100% dip in *UT*) for 250 cycles	0% *UT* (100% dip in *UT*) for 0.5 cycle, @ 0, 45, 90, 135, 180, 225, 270 and 315° 0% *UT* (100% dip in *UT*) for 1 cycle 40% *UT* (60% dip in *UT*) for 5 cycles 70% *UT* (30% dip in *UT*) for 25 cycles 0% *UT* (100% dip in *UT*) for 250 cycles	Mains power quality should be that of a typical commercial or residential environment. If the user of the ***Eclipse*** requires continued operation during power mains interruptions, it is recommended that the ***Eclipse*** 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 Eclipse 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 ***Eclipse*** 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 ***Eclipse,*** 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
EPA Preamplifier	Interacoustics	-
EPA3 Cable Collector	Interacoustics	-
EPA4 Cable Collector	Interacoustics	-
LBK 15 Loop Back Box	Interacoustics	LBK15
IP30 insert earphones	Interacoustics	Insert earphone
EarTone ABR Insert Headphones	EarTone	EarTone ABR
Shielded Headphone	Interacoustics	Headphone
DT48A Headset	Interacoustics	DT48A
Bone Conductor	Radio Ear	Bone
OAE Probe	Interacoustics	-
Cochlear Nucleus Trigger Cable	Interacoustics	-

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
Mains Cable	2.0m	Unscreened
USB Cable	2.0m	Screened
EPA Preamplifier	2.5m	Screened
EPA3 Cable Collector	0.5m	Screened
EPA4 Cable Collector	50mm/0.5m/2.9m	Screened
LBK 15 Loop Back Box	2.0m	Screened
Insert earphones	2.9m	Screened
Shielded Headphone	2.9m	Screened
Bone Conductor	2.0m	Screened
OAE Probe	2.9m	Screened
Cochlear Trigger Cables	1.5m/5m	Screened