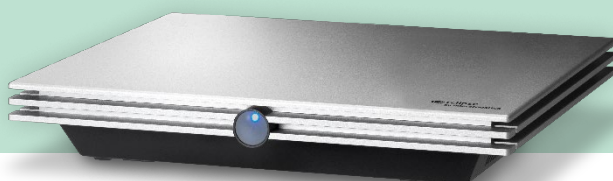


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Technical Specifications

# Eclipse



D-012111-G – 2024/02

# Contents

1.1	Eclipse software module overview .....	1
1.1.1	EP15/EP25/VEMP modules .....	1
1.1.2	TEOAE module .....	2
1.1.3	DPOAE module.....	2
1.1.4	ABRIS module .....	2
1.1.5	ASSR module .....	3
1.1.6	EP15/EP25/VEMP module stimulus maximum intensity .....	4
1.2	Included and optional parts .....	5
1.3	Technical specifications .....	6
1.4	Technical specifications EP15/EP25/VEMP .....	7
1.4.1	peSPL to nHL correction values .....	9
1.5	Technical specifications TEOAE .....	9
1.6	Technical specifications DPOAE.....	11
1.7	Technical specifications ABRIS .....	12
1.8	Technical specifications ASSR .....	13
1.9	Electromagnetic Compatibility (EMC) .....	14



# Eclipse specifications

## 1.1 Eclipse software module overview

### 1.1.1 EP15/EP25/VEMP modules\*

Test types/functionality:	EP15	EP25	VEMP
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 980 ms	150 ms
ABR	x	x	
Rate Study	x	x	x
ECochG	Optional	x	Optional
MLR		x	
ALR		x	
MMN/P300		x	
eABR	x	x	
cVEMP / oVEMP	Optional	Optional	x
EMG controlled stimulus/recording			x
EMG scaling (rectification)			x
Patient EMG monitor/tone			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 maximums are increased for all transducers.

Insert earphones and headphone can now go even louder.

To get the increased intensity maximums 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.

Stimulus		ABR3A		DD45		DD45S		B81	
		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

Eclipse  
EPA Preamplifier<sup>1</sup>  
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  
PEG15 Pregel foam snap electrodes (25 pcs) 1  
Disposable Snap electrodes<sup>1</sup>.  
Disposable tab electrodes<sup>1</sup>.  
Bridge & Implant Cleaners (Proxysoft)  
Alcohol Pads  
EP15/25/VEMP software  
Instructions for Use Manual on USB  
Additional Information Manual on USB

#### EP25:

ECochG Starter Kit including cable, gel and 2 TM electrodes<sup>1</sup>

### Optional parts:

OtoAccess® Database

Transducers as headphone DD45s and bone conductor B81 are also available.

Refer to the current Sanibel Disposables & Accessories brochure ([www.interacoustics.com](http://www.interacoustics.com)) or contact your local distributor.

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<sup>1</sup> Applied part according to IEC60601-1

#### DPOAE

Eclipse  
OAE Probe complete<sup>1</sup>  
Power cable  
USB cable  
IA OAE Suite software  
Ear Tip<sup>1</sup> Assortment Box  
Cleaning tool  
Probe tips<sup>1</sup>  
Instructions for Use on USB  
Additional Information Manual on USB


#### TEOAE

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



### 1.3 Technical specifications

#### Technical specifications - Eclipse hardware

<b>Medical CE-mark:</b>	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	
<b>Standards:</b>	<b>Safety:</b>	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
	<b>EMC:</b>	IEC 60601-1-2:2014+AMD1:2020
<b>Power Supply:</b>	<b>Input Volts:</b>	100 –240VAC, 50/60Hz.
	<b>Consumption:</b>	26W (0.3A Max)
	<b>Safety marking</b>	
<b>Operating environment:</b>	<b>Operating Temperature:</b>	15 – 35 °C (59 - 95°F)
	<b>Rel. Humidity:</b>	30 – 90%
	<b>Ambient Pressure:</b>	98kPa – 104kPa
<b>Transport &amp; Storage:</b>	<b>Storage Temperature:</b>	0°C – 50°C (32°F - 50°F)
	<b>Transport Temperature:</b>	-20 – 50 °C (-4°F - 122°F)
	<b>Rel. Humidity:</b>	10 – 95% (non condensing)
<b>Warm up time:</b>		10 minutes at room temperature (20 °C) (68°F).
<b>General</b>		
<b>PC control:</b>	<b>USB:</b>	USB 1.1 or 2.0 for input/output for computer communication. Eclipse if fully operated from a PC
<b>Construction:</b>		Metal cabinet
<b>Eclipse Dimensions</b>		(L x W x H) 28 x 32 x 5.5 cm (11 x 12.6 x 2.2 Inches)
<b>Eclipse Weight</b>		2.5kg / 5.5 lbs excluding accessories





## 1.4 Technical specifications EP15/EP25/VEMP

<b>Medical CE-mark:</b>	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		
<b>Standards:</b>	<b>Test Signal:</b>	IEC 60645-3, 2007	
	<b>AEP</b>	IEC 60645-7, 2009. Type 1	
<b>EPA Preamplifier:</b>	<b>Two channels standard</b>	EPA4 Cable Collector (4 electrodes). Standard 50 cm. Option: 5 cm or 290 cm	
	<b>One Channel (optional)</b>	EPA3 Cable Collector (3 electrodes). 50 cm	
	<b>Gain:</b>	80 dB/60 dB (60dB = VEMP (-20dB))	
	<b>Frequency response:</b>	0.5 – 11.3kHz	
	<b>CMR Ratio:</b>	Minimum 100 dB. Typical 120 dB @55 Hz	
	<b>Noise (RTI)</b>	=< 15 nV/√Hz	
	<b>Radio frequency immunity:</b>	Typically 20 dB improvement over previous available designs	
	<b>Max input offset voltage:</b>	2,5 V	
	<b>Input impedance:</b>	>=10 MΩ/=< 170 pF	
	<b>Power from main unit:</b>	Insulated power supply with 1500 V isolation. The signal is digitally/capacitive insulated.	
<b>Specifications as EPA4</b>	<b>Impedance measurement:</b>	Selectable for each electrode	
	<b>Measurement frequency:</b>	33 Hz	
	<b>Waveform:</b>	Rectangular	
	<b>Measurement current:</b>	19μA	
	<b>Range:</b>	0.5 kΩ – 25 kΩ	
<b>Stimulus:</b>	<b>Stimulus rate:</b>	0.1 to 80.1 stimuli per second in steps of 0.1.	
	<b>Envelopes/Windows:</b>	Bartlett, Blackman, Gaussian, Hamming, Hanning, Rectangle and Manual (Rise/Fall and Plateau)	
	<b>Masking:</b>	White noise. Calibrated and presented in peSPL.	
	<b>Transducer:</b>	Insert phone, calibrated on an IEC 711 coupler. Headphone with independent calibration (optional) Bone conductor (optional)	
	<b>Level:</b>	20 – 135.5 dB peSPL, please refer to chapter stimulus maximum intensity for converted nHL as this depends on the frequency.	
	<b>Polarity:</b>	Condensation, Rarefaction, Alternating.	
	<b>Click:</b>	100 μs (200Hz -11kHz)	
	<b>Tone Burst Frequency:</b>	250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000 and 8000 Hz.	
	<b>Tone Burst Stimulation Time:</b>	Stimulation up to 780 ms	
	<b>NB CE-Chirp® LS Freq.:</b>	500, 1000, 2000 and 4000 Hz	
	<b>Broadband CE-Chirp®: LS</b>	200Hz -11kHz	
	<b>Relative Masking Level:</b>	+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.	
	<b>Absolute Masking Level:</b>	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.	
	<b>Recording:</b>	<b>Analysis Time:</b>	-150 ms prior to stimuli and up to 1050 ms (license dependent).
		<b>A/D Resolution:</b>	16 bit.
<b>Sampling frequency</b>		30 kHz	
<b>Artifact Reject System:</b>		Standard voltage based system	
<b>Rejection levels:</b>		Manual 0.2 - 640 μV input with 0.1uV steps.	



	<b>Anti-aliasing filter:</b>	Internal filter in ADC
	<b>Dots per Trace:</b>	450 displayed.
	<b>Low Pass Filter:</b>	None or 17 – 12000 Hz, depending on the measurement type. 33 taps FIR Filter without wave peak latency displacement.
	<b>High Pass Filter:</b>	0.83 Hz to 500 Hz depending on the measurement type.
	<b>DSP Low Pass Filter:</b>	None, 100, 300, 750, 1k, 1,5k, 2k, 3k, 4k, 5k, 7,5k Hz
	<b>DSP High Pass Filter:</b>	0.5, 1.0, 3.3, 10, 33, 100 Hz
<b>Display Gain:</b>		General Display Gain. Applicable during testing. Single Curve Display Gain. Applicable during testing.
<b>Controlled parameters:</b>		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.
<b>Data collection:</b>		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.
<b>Data Recovery:</b>		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

<b>Medical CE-mark:</b>	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	
<b>Standards:</b>	<b>Test signal</b>	IEC 60645-3:2007
	<b>OAE</b>	TEOAE IEC 60645-6:2022, Type 1 & 2 Otoacoustic emissions
<b>Stimulus:</b>	<b>Type:</b>	Click Non-linear
	<b>Bandwidth:</b>	500 – 5500 Hz
	<b>Level:</b>	30 to 90 dB peSPL, peak to peak calibrated, AGC controlled
	<b>Level Step:</b>	1 dB SPL
	<b>Transducer:</b>	Dedicated DPOAE/TEOAE probe (Accuracy 0.5 dB)
<b>Recording:</b>	<b>Analysis time:</b>	5 seconds to 30 minutes
	<b>Sampling frequency</b>	30 kHz
	<b>A/D Resolution:</b>	16 bit, 3.7 Hz resolution
	<b>Artifact Reject System:</b>	0 to +60 dB SPL or off Applicable during testing
	<b>SNR Criteria:</b>	Adjustable between 5 and 25 dB
<b>Display gain:</b>	<b>General display gain:</b>	Applicable during testing

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

<b>Medical CE-mark:</b>	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	
<b>Standards</b>	<b>Test Signal:</b>	IEC 60645-1:2012 /ANSI S3.6
	<b>OAE</b>	DPOAE IEC 60645-6:2022, Type 2 Otoacoustic emissions
<b>Stimulus:</b>	<b>Frequency Range:</b>	500-10000 Hz
	<b>Frequency Step:</b>	25 Hz
	<b>Level:</b>	30 to 70 dB SPL
	<b>Level Step:</b>	1 dB SPL
	<b>Transducer:</b>	Dedicated DPOAE/TEOAE probe
<b>Recording:</b>	<b>Analysis time:</b>	minimum 2 sec to unlimited test time
	<b>A/D Resolution:</b>	16 bit, 3.7 Hz resolution
	<b>Sampling frequency</b>	30 kHz
	<b>Artifact Reject System:</b>	-30 to +30 dB SPL or off. Applicable during testing
	<b>Stimulus Tolerance:</b>	Adjustable between 1 and 10 dB
	<b>SNR Criteria:</b>	Adjustable between 3 and 25 dB
	<b>Probe check window</b>	256 points frequency response of the ear canal due to a click stimulus presented with a rate of 100 Hz at 80 dB SPL
	<b>DP-Response window</b>	4096 points frequency response
<b>Display gain:</b>	<b>General display gain:</b>	Applicable during testing

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

<b>Medical CE-mark:</b>	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	
<b>Standards:</b>	<b>Test signal</b>	EC 60645-3:2007
	<b>AEP</b>	IEC 60645-7:2009 Type 2
<b>EPA Preamplifier:</b>	<b>Two channels standard:</b>	EPA4 Cable Collector (4 electrodes). Standard 50 cm. Option: 5 cm or 290 cm
	<b>One Channel (optional):</b>	EPA3 Cable Collector (3 electrodes). 50 cm
	<b>Gain:</b>	80 dB
	<b>Frequency response:</b>	0,5 – 11.3 kHz
	<b>CMR Ratio:</b>	Minimum 100 dB. Typical 120 dB @55 Hz
	<b>Noise (RTI)</b>	=< 15 nV/√Hz
	<b>Radio frequency immunity:</b>	Typically 20 dB improvement over previous available designs
	<b>Max input offset voltage:</b>	2,5 V
	<b>Input impedance:</b>	>=10 MΩ/ =<170 pF
	<b>Power from main unit:</b>	Insulated power supply with 1500 V isolation. The signal is digitally/capacitive insulated.
<b>Specifications as EPA4 Impedance measurement:</b>		Selectable for each electrode
	<b>Measurement frequency:</b>	33 Hz
	<b>Waveform:</b>	Rectangular
	<b>Measurement current:</b>	19μA
	<b>Range:</b>	0.5 kΩ – 25 kΩ
<b>Stimulus:</b>	<b>Stimulus rate:</b>	93 Hz
	<b>Level:</b>	30, 35, 40 dBnHL
	<b>Click:</b>	100 μs
<b>Recording:</b>	<b>Analysis time:</b>	120 seconds
	<b>A/D resolution:</b>	16 bit
	<b>Sampling frequency</b>	30 kHz
	<b>Artifact rejection system:</b>	Standard voltage based system
<b>Display:</b>	Stimulus level and type, Graph view	
<b>Security:</b>	Password protection of test parameters possible.	
<b>Algorithmic Sensitivity:</b>	<b>Click:</b>	99.99%
<b>Specificity:</b>	<b>Click:</b>	≥ 97%



## 1.8 Technical specifications ASSR

<b>Medical CE-mark:</b>	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.	
<b>Standards:</b>	<b>Test signal:</b>	IEC 60645-3:2007
	<b>AEP</b>	IEC 60645-7:2009, Type 1.
<b>EPA Preamplifier:</b>	<b>Two channels standard:</b>	EPA4 Cable Collector (4 electrodes). Standard 50 cm. Option: 5 cm or 290 cm
	<b>One Channel (optional):</b>	EPA3 Cable Collector (3 electrodes). 50 cm
	<b>Gain:</b>	80 dB
	<b>Frequency response:</b>	0,5 – 11.3 kHz
	<b>CMR Ratio:</b>	Minimum 100 dB. Typical 120 dB @55 Hz
	<b>Noise (RTI)</b>	=< 15 nV/√Hz
	<b>Radio frequency immunity:</b>	Typically 20 dB improvement over previous available designs
	<b>Max input offset voltage:</b>	2,5 V
<b>Impedance measurement:</b>	<b>Input impedance:</b>	>=10 MΩ/ =<170 pF
	<b>Waveform:</b>	Rectangular
	<b>Measurement current:</b>	19μA
<b>Stimulus:</b>	<b>Range:</b>	0.5 kΩ – 25 kΩ
	<b>Stimulus rate:</b>	40 or 90 Hz
	<b>Transducer:</b>	Ear Tone ABR insert phone, calibrated on an IEC 711 coupler. Headphone (optional) Bone conductor (optional)
	<b>Level:</b>	0 – 100 dB nHL in 5 dB steps.
	<b>NB CE-Chirp® Freq.:</b>	500, 1000, 2000, and 4000 Hz, both ears same time.
	<b>Bandwidth:</b>	1 octave ± ½ octave – 3 dB
	<b>Masking:</b>	White noise 0 – 100 dB SPL
	<b>Analysis Time:</b>	6 minutes to detect a ASSR signal – can be extended up to 15 minutes
<b>Recording:</b>	<b>Sampling frequency:</b>	30 kHz
	<b>Artifact Reject System:</b>	Standard voltage based system
	<b>Gain:</b>	74 – 110 dB. Auto or Manual selection.
	<b>Channels:</b>	2, with separate detection algorithm
	<b>Algorithmic Sensitivity:</b>	99% or 95% , false pass probability
	<b>Rejection levels:</b>	Manual 5, 10, 20, 40, 80, 160, 320, 640 μV input
	<b>Anti-aliasing filter:</b>	Analog 5kHz, 24 dB / octave
<b>Display:</b>	Independent control of up to 8 simultaneous stimuli (max 4 per ear)	
<b>Display Gain:</b>	Independent start, stop control for each of the 8 stimuli	
<b>Controlled parameters:</b>	Stimulus level control for each of the 8 stimuli	
	False pass probability 1 or 5%	
	Test protocols included for children and adult	
<b>NOAH:</b>	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<sup>2</sup> 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)

<sup>2</sup> 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 <i>Eclipse</i> is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>Eclipse</i> should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The <i>Eclipse</i> 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 <i>Eclipse</i> is suitable for use in all commercial, industrial, business, and residential environments.
RF emissions CISPR 11	Class B	
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 <i>Instrument</i> .			
The <i>Eclipse</i> is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the <i>Eclipse</i> can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the <i>Eclipse</i> 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. <b>Note 1</b> At 80 MHz and 800 MHz, the higher frequency range applies. <b>Note 2</b> 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.


<b>Immunity Test</b>	<b>IEC 60601 Test level</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
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 <b>Eclipse</b> .
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% <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	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	Mains power quality should be that of a typical commercial or residential environment. If the user of the <b>Eclipse</b> requires continued operation during power mains interruptions, it is recommended that the <b>Eclipse</b> be powered from an uninterruptible 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 <b>Eclipse</b> 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
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 <b>Eclipse</b> , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  <b>Recommended separation distance:</b>  $d = \frac{3,5}{V_{rms}} \sqrt{P}$
	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	$d = \frac{3,5}{V/m} \sqrt{P}$ 80 MHz to 800 MHz
	10 V/m 80 MHz to 2,7 GHz Only for Home Healthcare environment	10 V/m (If Home Healthcare)	$d = \frac{7}{V/m} \sqrt{P}$ 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, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>  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.

<sup>a</sup>) 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**.

<sup>b</sup>) 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