

Technical Specifications Eclipse





Contents

1.1	Eclipse Software Module Overview	1			
	1.1.1 EP15/EP25/VEMP Modules 1.1.2 TEOAE25 Module 1.1.3 DPOAE20 Module 1.1.4 ABRIS Module 1.1.5 ASSR Module	2 2 2			
1.2	Included and Optional Parts	4			
1.3	Technical Specifications	5			
1.4	Technical Specifications EP15/EP25/VEMP	6 8			
1.5	Technical Specifications TEOAE25	9			
1.6	Technical Specifications DPOAE20	10			
1.7	Technical Specifications ABRIS	11			
1.8	Technical Specifications ASSR	12			
1.9	Electromagnetic Compatibility (EMC)				



1.1 Eclipse Software Module Overview

1.1.1 EP15/EP25/VEMP Modules

Test types/functionality:	EP15	EP25	VEMP
Stimulus level	0 – 100 dB nHL	0 – 100 dB nHL	0 – 100 dB nHL
Click stimulus	х	х	х
Broadband CE-Chirp® & CE-Chirp® LS stimuli	Optional	x	
Narrow Band CE-Chirp® & CE-Chirp® LS stimuli	Optional	x	
(0.5, 1, 2, 4 kHz)			
Tone Burst stimuli (0.25 – 4kHz)	x	x	x
Recording window	15 and 30 ms	Up to 980 ms	150 ms
ABR	x	x	
Rate Study	x	х	х
ECochG	Optional	x	Optional
MLR		х	
ALR		x	
MMN/P300		х	
eABR	x	x	
cVEMP / oVEMP	Optional	Optional	х
EMG controlled stimulus/recording			х
EMG scaling (rectification)			x
Patient EMG monitor/tone			x
Research module *	N/A	Optional	Optional

^{*} Research Module is a module license that enables the export of averaged curves, the data logging of individual sweeps and the import of WAV file stimuli. The exported data can be analyzed further in software such as MS Excel and Matlab programs. The research module includes the sound stimuli Da, Ga and Ba for ABR and MMN testing. Please refer to the Research module brochure or relevant chapter in the Instructions for Use manual for further information.

NB! Not all products are available in all countries. Please contact us for product availability in your country.



1.1.2 TEOAE25 Module

Test types/functionality:	TEOAE Module
Stimulus level	50 – 90 dB SPL
Linear click stimulus	X
Non-linear click stimulus	X
Stimulus bandwidth	400 – 4000 Hz
Test time	25 – 32000 sweeps
FFT display	X
1 kHz pass/refer bands, 1/3, 1/6, 1/12 octave band display	X
SNR value display	X
OAE level display	X
Automated screening (pass/refer) algorithm (protocol)	X
User definable pass/refer algorithm (protocol)	X
Password protection of test parameters	X

1.1.3 DPOAE20 Module

Test types/functionality:	DPOAE Module		
Stimulus level	30 - 75 dB SPL (70 dB for freq. above 6kHz)		
Stimulus range	500 – 8000 Hz		
Test time	Min 2 sec – unlimited		
DP-Gram	x		
DP Input/Output	x		
Normative data display option	x		
Checkmark indication for SNR detection	х		
User definable protocols	х		
Manual test time override	х		

1.1.4 ABRIS Module

1.1.4 ABRIS Module			
Test types/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)	х
Residual noise calculator	x
User customizable protocols	х
Noah 4 and higher compatibility	x

1.2 Included and Optional Parts

Included parts:

EPA Preamplifier Ecl	POAE20 clipse	Eclipse	Eclipse
	clipse		
FPA4 cable collector OA		EPA Preamplifier	EPA Preamplifier
	AE Probe complete	EPA4 cable collector	EPA4 cable collector
	ower cable	USB cable	USB cable
	SB cable	Power cable	Power cable
	POAE20 software	Insert phone including	Insert phone including
	ET25 Ear Tip	eartips	eartips
3 1	ssortment Box	Neonatal Insert Ear	Neonatal Insert Ear
	eaning tool	tips	tips
	obe tips	4.0 mm, 3.5 mm	4.0 mm, 3.5 mm
	toAccess™ Software	ETB Standard	ETB Standard
	structions for Use	Electrode Cables with	Electrode Cables with
	dditional Information	Buttons	Buttons
	anual	Pinch Clip Electrode	Pinch Clip Electrode
Cables		Cables	Cables
1 0	EOAE25	NuPrep gel 4oz/ 114 g	NuPrep gel 4oz/114g
,	clipse	tube (SPG15)	tube (SPG15)
	AE Probe complete	Gauze Swabs	Gauze Swabs
5	ower Cable	PEG15 Pregel foam	PEG15 Pregel foam
	ountry specific	snap electrodes (25	snap electrodes (25
	SB connection cable	pcs)	pcs)
	EOAE25 software	Alcohol Pads	Alcohol Pads
	ET25 Assortment Box	Ten20 Electrode	Ten20 Electrode
	th ear tips for OAE	Paste	Paste 8oz/228 g jar
	eaning tool	8oz/228 g jar	ASSR software
	obe tip	ABRIS software	OtoAccess™ software
	toAccess™ Software	OtoAccess™ software	Instructions for Use
	structions for Use	Instructions for Use	Manual on CD
	anual on CD	Manual on CD	Additional Information
	dditional Information	Additional Information	Manual on CD
Manual on CD Ma	anual on CD	Manual on CD	
EP25:			
ECochG Starter Kit			
including cable, gel and			
2 electrodes			

Optional parts:

Refer to the current Sanibel Disposables & Accessories brochure (<u>www.interacoustics.com</u>) or contact your local distributor.





1.3 Technical Specifications

Technical Specifications - Eclipse Hardware

Medical CE-mark:	The CE-mark indicates that	indicates that Interacoustics A/S meets the requirements of Annex II of the		
	Medical Device Directive 93/42/EEC.			
	Approval of the quality syste	em is made by TÜV – identification no. 0123.		
Standards:	Safety:	IEC 60601-1, Class I, Type BF and Type B		
	EMC:	IEC 60601-1-2		
Power Supply:	Input Volts:	100 –240V, 50/60Hz.		
	Consumption:	26 W (0.3A Max).		
	Safety:	IEC 60601-1 class I, UL2601		
Operating environment:	Operating Temperature:	15 – 35 °C (59 - 95°F)		
	Rel. Humidity:	30 – 90%		
Transport & Storage:	Storage Temperature:	0°C – 50°C (32°F - 50°F)		
	Transport Temperature:	-20 – 50 °C (-4°F - 122°F)		
	Rel. Humidity:	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		
Dimensions:		(L x W x H) 28 x 32 x 5.5 cm (11 x 12.6 x 2.2 Inches)		
Weight:	: 2.5kg / 5.5 lbs excluding accessories			



1.4 Technical Specifications EP15/EP25/VEMP

Medical CE-mark:	The CE-mark indicates that Int	eracoustics A/S meets the requirements of Annex II of the Medical				
	Device Directive 93/42/EEC.					
		is made by TÜV – identification no. 0123.				
	11 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2					
Standards:	Safety:	IEC 60601-1, Class I, Type BF and Type B				
	EMC:	IEC60601-1-2				
	Test Signal:	IEC 60645-3 Auditory test signals				
		IEC 60645-7, 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				
	Frequency response:	0,5 - 5000 Hz				
	CMR Ratio:	Minimum >118 dB. Typical 130 dB < 100 Hz				
	Radio frequency immunity:	Typically 25 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:	ncy: 33 Hz				
	Waveform:	Rectangular				
	Measurement current:	19μΑ				
	Range:	$0.5 \text{ k}\Omega - 25 \text{ k}\Omega$				
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:	Ear Tone ABR insert phone, calibrated on an IEC 711 coupler.				
		Headphone with independent calibration (optional)				
		Bone conductor (optional)				
	Level:	20 – 135.5 dB peSPL, (-10 – 100 dB nHL) in 1 dB steps.				
	Polarity:	Condensation, Rarefaction, Alternating.				
	Click:	100 μs (200Hz -11kHz)				
	Tone Burst Frequency:	250, 500, 750, 1000, 1500, 2000, 3000, and 4000 Hz.				
	Tone Burst Stimulation	Stimulation up to 780 ms				
	Time:					
NB CE-Chirp® LS Freq.: Broadband CE-Chirp®: LS Masking Level:		500, 1000, 2000 and 4000 Hz				
		200Hz -11kHz				
		+30dB to -40 dB relative to stimulus presented in peSPL.				
Recording:	Analysis Time:	-150 ms prior to stimuli and up to 1050 ms (license dependant).				
	A/D Resolution:	16 bit.				
	Sampling frequency	30 kHz				



	Artifact Reject System:	Standard voltage based system
	Rejection levels:	Manual 0.2 - 640 μV input wuth 0.1uV steps.
	Anti aliasing filter:	Analog 5kHz, 24 dB / octave
	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:	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.



1.4.1 peSPL to nHL Correction Values

Toneburst ECochG/ABR15/ABR30/AMLR/Neuro/VEMP 0 dB 2-2-2 cycle				Toneburst ALR/MMN dB 25-50-25 ms				
linear envelope					ALR/WIWIN	ub 25-50-25 II	iis	
Hz	Insert phone	Headphone	Bone	Hz	Insert phone	Headphone	Bone	
250	28	32	74.5	250	17.5	27	67	
500	23.5	23	69.5	500	9.5	13.5	58	
750	21	19	61	750	6	9	48.5	
1000	21.5	18.5	56	1000	5.5	7.5	42.5	
1500	26	21	51,5	1500	9.5	7.5	36.5	
2000	28.5	25	47.5	2000	11.5	9	31	
3000	30	25.5	46	3000	13	11.5	30	
4000	32.5	27.5	52	4000	15	12	35.5	
		1	SO 389-6:2007		ISO 389-1:20	000, ISO 389-2	2:1994, ISO 389- 3:1994	
	Click				Click			
ECo	ochG/ABR15/ABR30/	AMLR/Neuro/VE	MP 0 dB	ALR/MMN 0 dB				
	Insert phone	Headphone	Bone		Insert phone	Headphone	Bone	
Click	35.5	31	51.5	Click	35.5	31	51.5	
	NB CE-C	hirp® LS			NB CE	-Chirp® LS		
ECo	ochG/ABR15/ABR30/	AMLR/Neuro/VE	MP 0 dB	ALR/MMN 0 dB				
Hz	Insert phone	Headphone	Bone	Hz	Insert phone	Headphone	Bone	
500	25.5	25	74	500	25.5	25	74	
1000	24.0	21.0	61.0	1000	24.0	21.0	61.0	
2000	30.5	27	50	2000	30.5	27	50	
4000	34.5	29.5	55.0	4000	34.5	29.5	55.0	
CE-Chirp® LS				CE-Chirp® LS				
ECo	ECochG/ABR15/ABR30/AMLR/Neuro/VEMP 0 dB				ALR/I	MMN 0 dB		
	Insert phone	Headphone	Bone		Insert phone	Headphone	Bone	
	31.5	27.0	51.0		31.5	27.0	51.0	
Only toneburst correction values change for ALR & MMN testing.								

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



1.5 Technical Specifications TEOAE25

Medical CE-mark:	The Medical CE mark indicates that Interacoustics AS meets the requirements of Annex II of the				
	Medical Device Directive 93/42EEC. Approval of the quality system is made by TÜV –				
	identification no 0123.				
Standards:	Safety:	IEC 60601-1 (General safety) Class I, Type B			
	EMC	IEC 60601-1-2			
		IEC 60645-6, Type 1 & Type 2			
Stimulus:	Туре:	Click (Linear or Non-linear)			
	Bandwidth:	500 – 5500 Hz			
	Level:	50-90 dB SPL			
	Level Step:	1 dB SPL			
	Transducer:	Dedicated DPOAE/TEOAE25 probe (Accuracy 0.5 dB)			
Recording:	Analysis time:	25 to 32000 samples			
	Sampling frequency	30 kHz			
	A/D Resolution:	16 bit, 3.7 Hz resolution			
	Artifact Reject System:	25 – 55 dB SPL or off. Applicable during testing			
	SNR Criteria:	5 individual frequency bands can be set 1-30 dB SPL			
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	

TEOAE Calibration:

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



1.6 Technical Specifications DPOAE20

Medical CE-mark:	mark: The Medical CE mark indicates that Interacoustics AS meets the requirements of An			
	the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no 0123.			
Standards	Safety:	IEC 60601-1 (General safety) Class I, Type B		
	EMC	IEC 60601-1-2		
Stimulus:	Frequency Range:	500-8000 Hz		
	Frequency Step:	50 Hz		
	Level:	30-75 dB SPL (70 dB above 6kHz)		
	Level Step:	1 dB SPL		
	Transducer:	Dedicated DPOAE20/TEOAE25 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 – 30 dB SPL or off. Applicable during testing		
	Stimulus Tolerance:	Adjustable		
	SNR Criteria:	Adjustable		
	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	

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.



1.7 Technical Specifications ABRIS

Medical CE-mark:	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 no. 0123.			
Standards:	Safety:	IEC 60601-1, Class I, Type BF and Type B		
otanaar aor	EMC:	IEC 60601-1-2		
	LINO.	IEC 60645-3 Autitory test signals		
	Test signal	IEC 60645-7, Type 2		
EPA Preamplifier:		EPA4 Cable Collector (4 electrodes). Standard 50 cm. Option: 5		
LFA Freampliner.	Two channels standard:	cm or 290 cm		
	One Channel (antional)			
	One Channel (optional):	EPA3 Cable Collector (3 electrodes). 50 cm		
	Gain:	80 dB/60 dB		
	Frequency response:	0,5 - 5000 Hz		
	CMR Ratio:	Minimum >118 dB. Typical 130 dB < 100 Hz		
	Radio frequency	Typically 25 dB improvement over previous available designs		
	immunity:	Typically 25 db improvement ever provided available designs		
	Max input offset voltage:	2,5 V		
	Input impedance:	10 MΩ/ 170 pF		
	Dancer from main unit	Insulated power supply with 1500 V isolation. The signal is		
	Power from main unit:	digitally/capacitive insulated.		
Specifications as EPA4				
Impedance measurement:		Selectable for each electrode		
	Measurement frequency:	33 Hz		
	Waveform:	Rectangular		
	Measurement current:	19µA		
	Range:	$0.5 \text{ k}\Omega - 25 \text{ k}\Omega$		
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%		
opoundity.	J.IJKI	- 37 /0		



1.8 Technical Specifications ASSR

Medical CE-mark:	Interacoustics A/S meets the requirements of Annex II of the Medical . Approval of the quality system is made by TÜV – identification no.		
Standards:	0123. Safety	IEC 60601-1, Class I, Type BF and Type B	
	EMC:	IEC 60601-1-2	
	Test signal:	IEC 60645-3 Autitory test signals	
		IEC 60645-7, 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	
	Frequency response:	0,5 - 5000 Hz	
	CMR Ratio:	Minimum >118 dB. Typical 130 dB < 100 Hz	
	Radio frequency	Typically 25 dB improvement over previous available designs	
	immunity:		
	Max input offset voltage:	2,5 V	
	Input impedance:	10 MΩ/ 170 pF	
Impedance measurement:	Waveform:	Rectangular	
	Measurement current:	19µА	
	Range:	$0.5 \text{ k}\Omega - 25 \text{ k}\Omega$	
Stimulus:	Stimulus rate:	40 or 90 Hz	
	Transducer:	Ear Tone ABR insert phone, calibrated on an IEC 711 coupler.	
		HEADPHONE with independent calibration (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 compatible (NOAH 3.6 or higher) tested compability for NOAH 4.4, 4.3, 4.2, 4.1, 4.0 and 3.6	
		(Estimated Audiogram available for other NOAH modules)	



1.9 Electromagnetic Compatibility (EMC)

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

The Eclipse has been tested for EMC emissions and immunity as a standalone instrument. Do not use the Eclipse 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.

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	Not Applicable			
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable			

Recommended separation distances between portable and mobile RF communications equipment and the Eclipse

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	Separation distance according to frequency of transmitter [m]		
[W]	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.17\sqrt{P}$	$d = 1.17\sqrt{P}$	$d = 2.23\sqrt{P}$
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.

	er's Declaration - Electromagnetions in the electromagnetic environm		or the user of the Eclipse should assure that
it is used in such an environn			
Immunity Test	IEC 60601 Test level	Compliance	Electromagnetic Environment-Guidance
Electrostatic Discharge (ESD)	+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
IEC 61000-4-2			should be greater than 30%.
Electrical fast transient/burst	+2 kV for power supply lines	Not applicable	Mains power quality should be that of a typical commercial or residential
IEC61000-4-4	+1 kV for input/output lines	+1 kV for input/output lines	environment.
Surge	+1 kV differential mode	Not applicable	Mains power quality should be that of a typical commercial or residential
IEC 61000-4-5	+2 kV common mode		environment.
Voltage dips, short interruptions and voltage variations on power supply lines	< 5% <i>U</i> T (>95% dip in <i>U</i> T) for 0.5 cycle 40% <i>U</i> T	Not applicable	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
IEC 61000-4-11	(60% dip in <i>U</i> T) for 5 cycles 70% <i>U</i> T (30% dip in <i>U</i> T) for 25 cycles		recommended that the Eclipse be powered from an uninterruptable power supply or its battery.



	<5% <i>U</i> T (>95% dip in <i>U</i> T) for 5 sec		
Power frequency (50/60 Hz)	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical
IEC 61000-4-8			location in a typical commercial or residential environment.
Note: I/I is the A.C. mains voltage prior to application of the test level			

Guidance and manufacture	er's declaration — electromagnetic	immunity	
The Eclipse is intended for u	ise in the electromagnetic environme	nt specified below. The customer or	the user of the Eclipse should assure that
it is used in such an environ		L Commission of Level	Floring and the continuous and
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.
Conducted RF IEC / EN 61000-4-6	3 Vrms 150kHz to 80 MHz	3 Vrms	Recommended separation distance $d=1{,}2\sqrt{P}$
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,5 MHz	3 V/m	$d=1,2\sqrt{P}$ 80 MHz to
			$d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz
			Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> 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 Eclipse is used exceeds the applicable RF compliance level above, the Eclipse should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Eclipse (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
Insert Phones	Etymotic research	EarTone ABR
Headphone	Interacoustics	DD45s
Bone	Radio Ear	B71
OAE Probe	Interacoustics	Opt25
Cochlear Nucleus Trigger Cable	Interacoustics	Cochlear Nucleus
Optical USB 1.1 MED	Mailhaus	1.1 MED

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 phone	2.9m	Screened
Headphone	2.9m	Screened
Bone	2.0m	Screened
OAE Probe	2.9m	Screened
Cochlear Nucleus Trigger Cable	1.5m/5m	Screened

Essential performance

For this product the following is considered essential performance:

- To generate and present stimulus signals in the audio range as specified in the applicable IEC 60645 series in normal condition
- Record and store patient response

