Technical Specifications

Titan





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Titan Specifications

1.1 Titan Software Module & Version Overview

1.1.1 IMP440 – Impedance Module

Test types/functionality:	Screener	Diagnostic	Clinical
Tympanometry 226Hz – Automatic (flexible start and stop pressure)	Х	Х	Х
Tympanometry 226Hz – Manual			х
Acoustic reflex with single intensities or reflex growth –	Х	Х	Х
ipsilateral (automatic)			
Acoustic reflex with single intensities or reflex growth -		Х	Х
contralateral (automatic)			
Manual control of all reflex functions	Х	Х	X
Reflex decay, automatic 10 dB above threshold or manually		Х	Х
controlled with stimulus duration of 10 up to 30 seconds			
Reflex latency, automatic 10 dB above threshold or manually			Х
controlled, first 300 ms from stimulus start			
ETF 1 – Non-perforated eardrum (William's test)		Х	Х
ETF 2 – Perforated eardrum (Toynbee test)			Х
ETF 3 – Patulous Eustachian tube (Sensitive baselinex			Х
tympanometry for 10 up to 60 seconds)			
High frequency probe tones (678, 800 & 1000 Hz)	Optional	Optional	Х
Wideband absorbance		Optional	Optional
Wideband 3D tympanometry		Optional	Optional
Wideband research module		Optional	Optional
User customizable protocols	Х	Х	Х
Protocol upload	Х	Х	Х
Client/session upload/download	Х	Х	Х
PC-controlled testing	Optional	Х	Х
Bluetooth	Х	Х	Х

1.1.2 ABRIS440 – Auditory Brainstem Response Infant Screening Module

Functionality:	Screener
Click stimulus	Х
CE-Chirp® stimulus	Х
Hi-Lo CE-Chirp® stimulus	Х
Stimulus intensity	30, 35, 40dB nHL
Bayesian weighted averaging	Х
Residual noise limit (as stop criteria)	Х
Test time	1 - 10 minutes (default = 3
	minutes)
Test montage	mastoid or nape
Test method	monaural or binaural
Enable pass/refer	Х
User customizable protocols	Х
Protocol upload	Х
Client/session upload/download	Х
PC-controlled testing	Х
Bluetooth	Х

1.1.3 DPOAE440 – Distortion Product Otoacoustic Emissions Module

Test types/functionality:	Screener	Clinical
Frequency range	500 – 6000 Hz	500 – 10000 Hz
Test points (frequencies)	Max 6 per test	Unlimited
DP-Gram	Х	х
DP Input/Output		х
Pressurized DPOAE	Optional	x
Enable pass/refer	Х	х
Normative data (view, edit, import, export)	Х	х
Manual testing (add test points, extend testing)		х
User customizable protocols	х	х
Protocol upload	х	х
Client/session upload/download	Х	х
PC-controlled testing	Optional	х
Bluetooth	Х	X

1.1.4 TEOAE440 – Transient Evoked Otoacoustic Emissions Module

Test types/functionality:	Screener	Clinical
Frequency range	1000 – 4500 Hz	500 – 5500 Hz
Test time	Max 6 minutes or 4500 sweeps	Unlimited
Stimulus intensity	60 – 84 dB SPL	30 – 90 dB SPL
Center band frequencies (1, 1.5, 2, 3, 4)	x	Х
Linear band frequencies (5 octave-wide bands 0.5 – 5.5 kHz)		Х
Custom band frequencies (user definable)		Х
Pressurized TEOAE	Optional	Х
FFT Display		Х
Enable pass/refer	Х	Х
Normative data (view, edit, import, export)	х	Х
Manual testing (extend testing)		Х
User customizable protocols	х	Х
Protocol upload	х	x
Client/session upload/download	х	Х
PC-controlled testing	Optional	Х
Bluetooth	Х	Х

1.2 Included and Optional Parts

The system consists of the following included and options parts:

IMP440

Included parts: Titan handheld unit with basic probe Power supply (with converter) BET55 Ear tips Lithium Battery 4 cavities (0.2, 0.5, 2 and 5cc) Titan PC suite with IMP440 Instructions for Use TCB Carrying Bag USB cable, USB adaptor

Included parts with diagnostic & clinical versions:

Cradle Clinical probe extension CIR55 contra insert headset OtoAccess™ database

Optional parts:

Short probe extension Sanibel MTP-II Thermal printer DD45C contra cup headset EARtone 3A insert headset for contra Cradle Clinical probe extension OtoAccess™ database WBT calibration kit

DPOAE440

Included parts: Titan handheld unit with basic probe Cradle Power supply (with converter) Clinical probe extension BET55 Ear tips Lithium Battery 4 cavities (0.2, 0.5, 2 and 5cc) Titan PC suite with DPOAE440 OtoAccess[™] database USB cable, USB adaptor Instructions for Use TCB Carrying Bag

Included parts with

screener version: Eartip 3-5mm flanged (25 pcs.) Eartip 4-7mm flanged (25 pcs.) Eartip 5-8mm flanged (25 pcs.)

Optional parts:

Short probe extension Sanibel MTP-II Thermal printer **Included parts:** Titan handheld unit with basic probe Cradle Power supply (with converter) PreAmplifier w/clothing clip & neckstrap Montage stickers Short extension cable ETSE tab surface electrode cables Pinch style electrode cables Sanibel tab surface electrodes (36 pcs.) Sanibel snap surface electrodes (36 pcs.) SPG15 preparation gel Alcohol pads, Gauze swabs USB cable, USB adaptor **BET55 Ear tips** Eartip 3-5mm flanged (25 pcs.) Eartip 4-7mm flanged (25 pcs.) Eartip 5-8mm flanged (25 pcs.) Lithium Battery 4 cavities (0.2, 0.5, 2 and 5cc) Titan PC suite with ABRIS440 OtoAccess[™] database Instructions for Use TCB Carrying Bag

ABRIS440

Optional parts:

EARtone ABR stereo ID earphones EarTone EarCup stereo ID transducer Sanibel MTP-II Thermal printer TDH39 Stereo ID headset DD45 stereo ID headset

TEOAE440

Included parts: Titan handheld unit with basic probe Cradle Power supply (with converter) Clinical probe extension BET55 Ear tips Lithium Battery 4 cavities (0.2, 0.5, 2 and 5cc) Titan PC suite with DPOAE440 OtoAccess[™] database USB cable, USB adaptor Instructions for Use TCB Carrying Bag

Included parts with screener version:

Eartip 3-5mm flanged (25 pcs.) Eartip 4-7mm flanged (25 pcs.) Eartip 5-8mm flanged (25 pcs.)

Optional parts:

Short probe extension Sanibel MTP-II Thermal printer

1.3 Titan Hardware – Technical Specifications

Medical CE-mark The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Mec Directive 93/42/EEC.				
		made by TÜV – identification no0123		
Standards	Safety:	IEC 60601-1, Internally powered, Type B and BF applied parts		
	EMC:	IEC 60601-1-2		
	Impedance:	IEC 60645-5/ANSI S3.39, Type 1		
	Test Signal:	IEC 60645-1/ANSI S3.6 , IEC 60645-3		
	OAE:	IEC 60645-6 2009, Type 2 Otoacoustic emissions		
	ABR:	IEC 60645-7 2009, Type 2		
Cradle	Safety:	IEC 60601-1, Class II		
	Power	Astrodyne ASA30M-0301 or UE24WCP		
	Mains voltages and frequencies:	100 – 240 VAC, 47 – 63 Hz		
	Consumption:	0.8 – 0.4 A		
Battery	Use only:	NP120 or CGA103450		
Operation environment	Temperature:	15 – 35 °C		
	Relative Humidity:	30 – 90%		
	Ambient Pressure:	98kPa – 104kPa		
	Warm-up Time:	1 minute		
Transport & Storage	Storage Temperature:	0°C – 50°C		
	Transport Temperature:	-20 – 50 °C		
	Rel. Humidity:	10 – 95%		
Impedance Measu	uring System			
Probe tone	Frequency:	Classic tympanometry: 226 Hz, 678 Hz, 800 Hz, 1000 Hz; pure tones; AGC controlled to protect for loud probe tone stimuli in small ear canals.		
	Level:	WBT: 226 Hz – 8000 Hz broadband stimulus, 21.5/sec. 226 Hz: 85 dB SPL (≈ 69 dB HL)		
		WBT: 96 dB peSPL (infant) / 100 dB peSPL (adult). (100 dB peSPL ≈ 65 dB nHL)		
Air pressure	Control:	Automatic.		
	Indicator:	Measured value is displayed on the graphical display.		
	Range:	-600 to +300 daPa.		
	Pressure limitation:	-750 daPa and +550 daPa.		
	Pressure change rate:	Minimum, medium, maximum or automatic with minimum speed at compliance peak. Selectable in the setup.		
Compliance	Range:	0.1 to 8.0 ml at 226 Hz probe tone (Ear volume: 0.1 to 8.0 ml) and 0.1 to 15 mmho at 678, 800 and 1000 Hz probe tone.		
Test types	Tympanometry	Automatic, where the start and stop pressure can be user- programmed in the setup function.		
		Manual control of all functions.		
	Eustachian tube function 1 – Non perforated eardrum	Williams test		
	Eustachian tube function 2 – Perforated eardrum	Toynbee test		
	Eustachian tube function 3 – Patulous Eustachian tube	Continuous sensitive impedance measurement for 30 up to 150 s.		
Indicators	Graphical display	Compliance is indicated as mI and pressure as daPa. In PC controlled mode admittance, susceptance and conductance can be printed. Stimulus level is indicated as dB Hearing Level.		
Memory	Tympanometry:	1 curve per ear per tympanometry test. 3 curves per ear per Eustachian tube function test. And theoretically an infinite number of tests per protocol.		
There is no deviation betwee	en static and dynamic mode.			
Reflex Functions				
Signal sources	Tone - Contra, Reflex:	250 500 1000 2000 2000 4000 6000 8000 11-		
orginal sources	Tone - Ipsi, Reflex:	250, 500, 1000, 2000, 3000, 4000, 6000, 8000 Hz.		
	NB noise - Contra, Reflex:	500, 1000, 2000, 3000, 4000 Hz. 250, 500, 1000, 2000, 3000, 4000, 6000, 8000 Hz.		

	NB noise - Ipsi, Reflex:	1000, 2000, 3000, 4000 Hz.		
	Noise - Contra, Reflex:	Wide Band, High Pass, Low Pass.		
	Noise - Ipsi, Reflex:	Wide Band, High Pass, Low Pass.		
Outputs	Contra Earphone:	TDH39 earphone, DD45 earphone, CIR55 insert and/or EARtone 3A insert for Reflex measurements.		
	Ipsi Earphone:	Probe earphone incorporated in the probe system for Reflex measurements.		
	Air:	Connection of the air system to the probe.		
Test types	Manual Reflex	Manual control of all functions.		
	Automated Reflex	Automatic reflexes:		
		- Single intensities		
		- Reflex growth		
	Reflex Decay	Automatic, 10 dB above threshold and manually controlled with stimulus durations of 10 to 30 s.		
	Reflex latency	Automated, first 300 ms from stimulus start.		

ABR Infant Scree	ening	
Preamplifier	One Channel:	3 electrodes. 50 cm Switchable: Software will automatically switch mastoid and ground if mastoid montage is used. So the user does not need to replace electrode during testing.
	Gain:	64 dB
	Frequency response:	0,5 - 5000 Hz
	Noise:	<25 nV/√Hz
	>90 dB.	
	Max input offset voltage:	2.5 V
	Input impedance:	10 MΩ/ 170 pF
	Power from main unit:	Isolated power supply
Electrical Impedance measurement	Measurement frequency:	33 Hz
	Waveform:	Rectangular
	Measurement current:	11.25 μA
	Range:	$0.5 \text{ k}\Omega - 25 \text{ k}\Omega \pm 10 \%$
Stimulus	Stimuli:	Click range (200 Hz -11 kHz) CE-Chirp® range (200 Hz – 11 kHz) HiLo CE-Chirp® range (Lo – up to 1.5 kHz) & (Hi – above 1.5 kHz)
	Stimulus rate:	90 Hz
	Transducers: (Calibrated to Standards)	EARTone ABR insert phone EARTone ABR for EarCup TDH 39 or DD45 head phone (Static force: 4,5N ± 0,5N IOW Probe
	Channels:	2
	Level:	30 dB nHL, 35 dB nHL, 40 dB nHL
	Bandwidth:	22.05 kHz
Recording	Analysis time:	1-10 min or Residual noise 5-80 nV
	A/D resolution:	24 bit
	Artifact reject system:	Rejection level (Peak, Min RMS, Max RMS) & Clipping (Saturation)
Display		Stimulus level and type, Bar and Graph view
		Basic and advanced view
Algorithmic Sensitivity	CE-Chirp®:	99.9%
Specificity	CE-Chirp®:	> 96%

DPOAE		
Stimulus	Frequency range:	500 to 10000 Hz
	Nominal frequency:	f2
	Frequency step:	25 Hz
	Level:	30 to 80 dB SPL (75 dB SPL for 6kHz and 65 dB SPL for 8kHz to 10kHz)
	Level Step:	1 dB
	Transducer:	IOW Probe auto detection, auto calibrated
Recording	Analysis time:	Minimum 2 seconds to unlimited time
	A/D Resolution:	24 bit, 5.38 Hz resolution
	Artifact rejection system:	-30 to +30 dB SPL or off
	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.
	DP-response window:	4096 points frequency response
	Residual noise:	A RMS average measurement in the DP-bin frequency area (26 bins at frequencies < 2500 Hz & 60 bins ≥ 2500 Hz).
Display	General display gain:	Applicable during testing
	Display:	Stimulus level and type, Bar and Graph view
Probe specifications	Titan IOW probe:	IMP, DPOAE, TEOAE and ABRIS capable
		Replaceable probe tip
Other		
Test Pressure		Ambient pressure.
		Tympanic peak pressure.

TEOAE					
Stimulus	Frequency range:	500 to 5500 Hz			
	Frequency step:	1 Hz (Custom bands)			
	Stimulus type:	Non-Linear and Linear (according to IEC 60645-3)			
	Level:	30 to 90 dB peSPL, peak to peak calibrated, AGC controlled			
	Level step:	1 dB			
	Click rate:	43 – 100 Hz			
	Stimulus tolerance:	Adjustable between 1 and 3 dB			
	Transducer:	IOW Probe auto detection, auto calibrated			
Recording	Analysis time:	5 seconds to unlimited time			
	A/D Resolution:	24 bit			
	Artifact rejection system:	0 to +60 dB SPL or off			
	SNR criteria:	Adjustable between 5 and 25 dB			
	TE criteria:	Band SNR, No. of Sweeps, Test time, Min Total OAE, Min Reproducibility - adjustable for use as test criteria			
Display	Stimulus time window:	128 points instant recording of first click in sequence of clicks			
	Probe check window:	256 points frequency response of the ear canal recorded click stimulus			
	Time recording window:	3-23 msec (max). A and B buffer time-samples @ sampling rate 11025 Hz			
	Wave reproducibility window:	Adjustable inside the recording window			
	Freq. response window:	256 points frequency response, bin spacing 43 Hz			
	Other information:	In ear status (active during test), Noise level, Tympanic peak pressure			
		Basic and Advanced view, FFT view, Test Summary view			
Probe specifications	Titan IOW probe:	IMP, DPOAE TEOAE and ABRIS capable			
		Replaceable probe tip			
Other					
Test Pressure		Ambient pressure or tympanic peak pressure found in IMP module			

General						
PC control	USB:	Input/output for computer communication. Titan can be fully operated from a PC. The measurements can then be followed on the PC screen. Data can be sent to and saved on the PC and stored in OtoAccess™. See separate section in Service Manual for programming details.				
Memory		Theoretically, an infinite amount of test results can be stored on the PC. The Titan hand held unit is delivered with a 8 GB memory card, enough for storing more than a quarter of a million tests.				
Thermal printer (Optional)	Туре:	Thermal (Bluetooth) printer with recording paper in rolls. Print on command through Bluetooth communication and through serial RS- 232.				
	Paper width:	57.5 ± 0.5 mm on thermal printer				
	Printing time:	Printing time depends on the size of the used protocol. For 2 tympanograms and 8 reflexes the thermal printer uses approximately 6s.				
Dimensions		6 x 6 x 28 cm / 2.4 x2.4 x11 inches				
Titan Weight		360 g / 0.8 lbs				
ABR/OAE/IMP PreAmplifier weight		120 g / 0.26 lbs				
ABR/OAE/IMP PreAmplifier dimensions		10.2 x 6.8 x 2.6 cm / 4 x 2.7 x 1 inches				
OAE/IMP shoulder box weight		64 g / 0.14lbs				
OAE/IMP shoulder box dimensions		6.5 x 3.5 x 1.8 cm / 2.6 x 1.4 x 0.7 inches				

Table 1: Frequencies and Intensity Ranges for IMP440

Titan Ma	ximums IMP										
	TDH39	TDH39		CIR55		EARtone 3A		IOW IPSI		DD45	
- Center	Reading		Reading		Reading		Reading		Reading		
- Freq.	Tone	NB	Tone	NB	Tone	NB	Tone	NB	Tone	NB	
_ [Hz]	[dB HL]	[dB HL]	[dB HL]	[dB HL]	[dB HL]	[dB HL]	[dB HL]	[dB HL]	[dB HL]	[dB HL]	
125	80	65	85	70	100	85	70	60	80	65	
250	100	85	100	85	110	100	85	75	100	85	
500	120	100	110	100	115	105	100	85	115	100	
750	120	105	110	105	120	110	100	85	120	105	
1000	120	105	115	105	120	110	105	90	120	105	
1500	120	105	115	105	120	110	110	90	115	100	
2000	120	105	115	105	120	110	105	90	115	100	
3000	120	105	115	105	120	110	95	90	125	105	
4000	120	105	110	100	120	105	100	85	115	105	
6000	120	100	95	95	105	100	85	80	110	90	
8000	105	95	80	85	90	85	80	75	105	95	
10000											
WB	-	120	-	120	-	120	-	105	-	125	
LP	-	120	-	120	-	120	-	110	-	120	
HP	-	120	-	120	-	120	-	105	-	130	

Table 2: Frequencies and Intensity Ranges for DPOAE440 Titan Maximums DPOAE

-	IOW IPSI Reading	IOW ch2 Reading	
Center Freq. [Hz]	Tone [dB SPL]	Tone [dB SPL]	
500	80	80	
750	80	80	
1000	80	80	
1500	80	80	
2000	80	80	
3000	80	80	
4000	80	80	
6000	75	75	
8000	65	65	
10000	65	65	

Titan Maximums TEOAE

Maximum TEOAE Click Intensity: 90 dB peSPL.

Titan Maximums ABRIS

Maximum ABRIS levels for Click and CE-Chirp® stimuli are limited to 30, 35 & 40 dBnHL for all transducers.

Specification of input/output connections

Specification o			
Inputs Patient response	Connector type Jack, 3,5mm 4- pole	Electrical properties Handheld switch: Pin 1: GND Pin 2: Signal Pin 3: Future use I/O Pin 4: Future use I/O	$3V$ through $10K\Omega$ is forced to ground when activated
Outputs			
Phones, Left/ Right	Jack, 3,5mm 4- pole	Voltage: Min. load impedance: Pin 1: CH1 GND Pin 2: CH1 OUT (left) Pin 3: CH2 OUT (right) Pin 4: CH1 GND	Up to 3V rms. by 10Ω load 8Ω Pin 3:
Phones,	Jack, 3,5mm 4-	Voltage:	Up to 3V rms. by 10Ω load
Contralateral	pole	Min. load impedance: Pin 1: CH1 GND Pin 2: CH1 OUT (left) Pin 3: CH2 OUT (right) Pin 4: CH1 GND	8Ω
Transducer	IA proprietary, 12-		CH1 out
Tranoducor	pole	Pin 2:	CH1 GND
	polo	Pin 3:	DGND
		Pin 4:	GND A / GND Microphone
		Pin 5:	Microphone – input / Analog balanced in
		Pin 6:	Microphone + input / Analog balanced in
		Pin 7:	Power supply +3/+5V
		Pin 8:	CH2 out
		Pin 9:	CH2 GND
		Pin 10:	I2C CLK
		Pin 11:	I2C DATA
		Pin 12:	I2C Interrupt
Data I/O			·
USB	USB type"B"	USB port for communication	

Calibration Properties

Calibration Propert	162	
Calibrated Transducers	Contralateral Earphone:	Telephonics TDH39 with a static force of 4.5N $\pm 0.5N$ and/or EARtone 3A and/or CIR55 insert phone
	Probe system:	Ipsilateral Earphone: is integrated in the probe system Probe frequency transmitter and receiver and pressure transducer is integrated in the probe system
Accuracy	General:	Generally the instrument is made and calibrated to be within and better than the tolerances required in the specified standards:
	Reflex Frequencies:	±1%
	Contralateral Reflex and Audiometer Tone Levels:	± 3 dB for 250 to 4000Hz and ± 5 dB for 6000 to 8000Hz
	Ipsilateral Reflex Tone Levels:	± 5 dB for 500 to 2000Hz and +5/-10 dB for 3000 to 4000Hz
	DPOAE Levels:	± 1.5 dB for 1000 to 4000Hz and ± 3 dB outside range
	TEOAE Levels:	±2 dB for click stimulus
	ABRIS Levels:	±2 dB for all stimulus types
	Pressure measurement :	$\pm 5\%$ or ± 10 daPa, whichever is greater
	Compliance measurement:	\pm 5% or \pm 0.1 ml, whichever is greater
Stimulus Presentation Control	Reflexes:	ON-OFF ratio = ≥ 70 dB Rise time = 27 ms
Control		Fall time = 24.6 ms
		A weighted SPL in Off = 31 dB

Impedance Calibration Properties

Probe tone	Frequencies:	226 Hz \pm 1%, 678 Hz \pm 1%, 800 Hz \pm 1%, 1000 Hz \pm 1%
	Level:	85 dB SPL ±1.5 dB measured in an IEC 60318-5 acoustic coupler. The level is constant for all volumes in the measurement range.
	Distortion:	Max 1% THD
Compliance	Range:	0.1 to 8.0 ml
	Temperature dependence:	-0.003 ml/°C
	Pressure dependence:	-0.00020 ml/daPa
	Reflex sensitivity: Reflex artifact level:	0.001 mI is the lowest detectable volume change ≥95 dB SPL (measured in the 711 coupler, 0.2 mI, 0.5 mI, 2.0 mI & 5.0 mI hardwalled cavities).
	Temporal reflex	Initial latency = $35 \text{ ms} (\pm 5 \text{ ms})$
	characteristics:	Rise time = 45 ms (\pm 5 ms)
		Terminal latency = $35 \text{ ms} (\pm 5 \text{ ms})$
		Fall time = 45 ms $(\pm 5 \text{ ms})$
		Overshoot = max. 1%
		Undershoot = max 1%
Pressure	Range:	Values between -600 to +300 daPa can be selected in the setup.
	Safety limits:	-750 daPa and +550 daPa, \pm 50 daPa

Reflex Calibration Standards and Spectral Properties:

Specifications for stimulus and audiometer signals are made to follow IEC 60645-5			
Pure tone:	ISO 389-1 for TDH39 and ISO 389-2 for CIR 55.		
Wide Band noise (WB): – Spectral properties:	Interacoustics Standard As "Broad band noise" specified in IEC 60645-5, but with 500 Hz as lower cut-off frequency.		
Low Pass noise (LP):	Interacoustics Standard		
 Spectral properties: 	Uniform from 500 Hz to 1600 Hz, ± 5 dB re. 1000 Hz level		
High Pass noise (HP):	Interacoustics Standard		
- Spectral properties:	Uniform from 1600 Hz to 10KHz, ± 5 dB re. 1000 Hz level		
Pure tone:	Interacoustics Standard.		
Wide Band noise (WB):	Interacoustics Standard		
- Spectral properties:	As "Broad band noise" specified in IEC 60645-5, but with 500 Hz as lower cut-off frequency.		
Low Pass noise (LP):	Interacoustics Standard		
- Spectral properties:	Uniform from 500 Hz to 1600 Hz, \pm 10 dB re. 1000 Hz level		
High Pass noise (HP):	Interacoustics Standard		
 Spectral properties: 	Uniform from 1600 Hz to 4000 Hz, \pm 10 dB re. 1000 Hz level		
General about levels:	The actual sound pressure level at the eardrum will depend on the volume of the ear. See Table 2 for details.		
	 Pure tone: Wide Band noise (WB): Spectral properties: Low Pass noise (LP): Spectral properties: High Pass noise (HP): Spectral properties: Pure tone: Wide Band noise (WB): Spectral properties: Low Pass noise (LP): Spectral properties: High Pass noise (LP): Spectral properties: 		

The risk of artifacts at higher stimulus levels in reflex measurements are minor and will not activate the reflex detection system

Table 3: Reference Values for Stimulus Calibration

Г			Reference Values for Stimulus Calibration									
	Freq.		Reference values for stimulus calibration [dB re. 20 µPa]					Variation Ipsi stimu levels for different volumes ear canal	llus of the	using		
									Relative to calibration performed an IEC 12	on	MX41/AR or PN51 cushion [dB]	
										coupler [dB]		
		ISO 389-1 (Interacoustics Standard)	ISO 389-2 (Interacoustics Standard)	ISO 382-2 (Interacoustics Standard)	Interacoustics Standard	Interacoustics Standard	Interacoustics Standard	Interacoustics Standard	ISO 389-4 (ISO 8798)	0.5 ml	1 ml	
		ISC Sta	Sta Sta	ISO (Inte Star	Into Sta	Into Sta	Into Sta	Into Sta	IS SI)			
	[Hz]	TDH39	EARtone 3A / ABR	CIR55	DD45		IOW Probe	IOW Probe NB	NB Stimulus Correction Values (except IOW probe)			
	125	45	26	26	47.5		41	43.5	4			3
	250	25.5	14	14	27		24.5	26.5	4			5
	500	11.5	5.5	5.5	13		9.5	17	4	9.7	5.3	7
	1000	7	0	0	6		6.5	10.5	6	9.7	5.3	15
	1500	6.5	2	2	8		5	12	6			21 (1600Hz)
ā	2000	9	3		8		12	11	6	11.7	3.9	26
DETCDI	3000	10	3.5		8		11	11	6	-0.8	-0.5	31 (3150Hz)
	4000	9.5	5.5		9 20 E		3.5	8	5	-1.6	-0.8	32
	6000	15.5	2	2	20.5		3	5.5	5			26 (6300Hz)
	8000	13	0	0	12		-5	-0.5	5			24
	WB	-8	-5		-8		-5			7.5	3.2	
	LP	-6	-7	-7	-6		-7			8.0	3.6	
	HP	-10	-8	-8	-10		-8			3.9	1.4	
	CE- Chirp	27.5	31.5		26	58.5	32					
	CE-	26.5	26.5		25.5	50	27.5					
	CE- Chirp High	28	31		28	58	32					
	Click	30.5	35		32.5	61.5	33.5					
L	* A II fiam	una in hal			Ctore	·	· .					

*All figures in bold are Interacoustics Standard values.

Coupler Types used for Calibration

IMP:

TDH39 is calibrated using a 6cc acoustic coupler made in accordance to IEC 60318-3, Ipsilateral earphone and probe tone are calibrated using a 2cc acoustic coupler made in accordance to IEC 60318-5 **ABRIS:**

Probe and insert stimuli are calibrated in SPL values using an ear simulator coupler made in accordance to IEC 60318-4. Headphones (TDH39 and DD45) stimuli are calibrated in SPL values using an artificial ear coupler according to IEC 60318-1.

DPOAE:

Probe stimuli L1 and L2 are calibrated individually in SPL values using the IEC 711 ear simulator coupler made in accordance to IEC 60318-4.

TEOAE:

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

General Information about Specifications

Interacoustics continuously strives to improve its products and their performance. Therefore the specifications can be subject to change without notice.

The performance and specifications of the instrument can only be guaranteed if it is subject to technical maintenance at least once per year. This should be carried out by a workshop authorized by Interacoustics.

Interacoustics puts diagrams and service manuals at the disposal of authorized service companies.

Enquiries about representatives and products may be sent to:

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Electromagnetic Compatibility (EMC) 1.4

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

The TITAN has been tested for EMC emissions and immunity as a standalone TITAN. Do not use the TITAN 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 TITAN is intended for use in the electromagnetic environment specified below. The customer or the user of the TITAN should				
assure that it is used in su	uch an environment.				
Emissions Test	Compliance	Electromagnetic environment - guidance			
RF emissions	Group 1	The TITAN uses RF energy only for its internal function.			
CISPR 11		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 TITAN is suitable for use in all commercial, industrial, business, and residential environments.			
Harmonic emissions	Complies				
IEC 61000-3-2	Class A Category				
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies				

Recommended separation	Recommended separation distances between portable and mobile RF communications equipment and the TITAN.					
The TITAN is intended for u	use in an electromagnetic environn	nent in which radiated RF disturbances	are controlled. The customer or the user of			
	the TITAN can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications					
			ower of the communications equipment.			
Rated Maximum output	Separation distance accordi	ng to frequency of transmitter				
power 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 m	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 applicabl	le to the frequency of the transmitte	er, where P is the maximum output pow	er rating of the transmitter in watts (W)			
according to the transmitter manufacturer						

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 TITAN is intended for use in the electromagnetic environment specified below. The customer or the user of the TITAN 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	+6 kV contact +8 kV air	+6 kV contact +8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	+2 kV for power supply lines +1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	+1 kV differential mode +2 kV common mode	+1 kV differential mode +2 kV common mode	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT	Mains power quality should be that of a typical commercial or residential environment. If the user of the <i>TITAN</i> requires continued operation during power mains interruptions, it is recommended that the <i>TITAN</i> be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.

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

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 TITAN , including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF	3 Vrms	3 Vrms	$d = 1, 2\sqrt{P}$
IEC / EN 61000-4-6	150kHz to 80 MHz		$d = 1, 2\sqrt{P}$ 80 MHz to 800
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	MHz
			$d = 2,3\sqrt{P}$ 800 MHz to 2,5
			GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture 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 eac frequency range (b)
			Interference may occur in the vicinity of equipment marked with the following symbol:
			(((•)))
NOTE 2 These guidelines objects and people.	,,	ectromagnetic propagation is affec	ted by absorption and reflection from structures,
AM and FM radio broadca	ast and TV broadcast cannot be pr	edicted theoretically with accuracy	ephones and land mobile radios, amateur radio, . To assess the electromagnetic environment due I field strength in the location in which the TITAN

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
Clinical Probe Extension	Interacoustics	-
Short Probe Extension	Interacoustics	-
ABRIS Preamplifier	Interacoustics	-
CIR55 Insert Phone	Interacoustics	CIR55
TDH39C Contra Headset	Interacoustics	TDH39C
DD45C Contra Headset	Interacoustics	DD45C
EARTone 3A with Minijack	Interacoustics	Ear3A
CIR55 Contra ID Earphone	Interacoustics	CIR55
TDH39C Contra ID Headset	Interacoustics	TDH39C
DD45C Contra ID Headset	Interacoustics	DD45C
EARTone 3A Contra ID Earphone	Interacoustics	Ear3A
TDH39 Stereo ID headset	Interacoustics	TDH39
DD45 Stereo ID headset	Interacoustics	TDH39
EARTone ABR Stereo ID Headset	Interacoustics	Ear3A
EarCup Stereo ID Headset	Interacoustics	Ear3A

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
PSU USB Adapter	0.1m	Screened
Clinical Probe Extension	2.0m	Unscreened
Short Probe Extension	0.4m	Unscreened
ABRIS Preamplifier	2.0m	Unscreened
CIR55 Insert Phone	0.4m	Screened
TDH39C Contra Headset	0.5m	Screened
DD45C Contra Headset	0.5m	Screened
EARTone 3A with Minijack	0.5m	Screened
CIR55 Contra ID Earphone	0.4m	Screened
TDH39C Contra ID Headset	0.5m	Screened
DD45C Contra ID Headset	0.5m	Screened
EARTone 3A Contra ID Earphone	0.5m	Screened
TDH39 Stereo ID headset	0.5m	Screened
DD45 Stereo ID headset	0.5m	Screened
EARTone ABR Stereo ID Headset	0.5m	Screened
EarCup Stereo ID Headset	0.5m	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 responses