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Technical Specifications

# Titan



D-01103650-G – 2019/04



**Interacoustics**



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# 1 Titan specifications

## 1.1 Titan software module & version overview

### 1.1.1 IMP440 – Impedance module

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



### 1.1.2 ABRIS440 – Auditory Brainstem Response Infant Screening Module

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



## 2 Included and optional parts

Standard Components, General	IMP440	ABRIS440	DPOAE440	TEOAE440
Titan handheld unit	•	•	•	•
Titan cradle	•*	•	•	•
Power supply (with converter)	•	•	•	•
Test cavities (0.2, 0.5, 2 & 5 cc)	•	•	•	•
Lithium battery (2x)	•	•	•	•
Carry bag	•	•	•	•
USB cable	•	•	•	•
USB adaptor	•	•	•	•
Titan Suite software bundle	•	•	•	•
OtoAccess® database	•*	•	•	•
Instructions for Use	•	•	•	•
Sanibel™ ADI Ear Tip Kit <sup>1</sup>	•	Optional	•	•
Pediatric ear tip kit <sup>2</sup>	n/a	Optional	•**	•**
Probe tip kit for IOW probe <sup>2</sup>	n/a	Optional	n/a	n/a
Probe tip kit for IOWA probe <sup>2</sup>	•	n/a	•	•
Titan probe floss kit	•	Optional	•	•
Accessory kit 1055 (for ABRIS) <sup>2</sup>	n/a	•	n/a	n/a
Neckstrap for preamplifier <sup>2</sup>	n/a	•	n/a	n/a
Preamplifier montage stickers	n/a	•	n/a	n/a
Use of disposable electrodes Quick Guide	n/a	•	n/a	n/a
Cleaning cloth	•	•	•	•
<b>Transducers</b>				
Clinical extension cable with IOWA probe <sup>2</sup>	•*	n/a	•	•
CIR55 contra insert (minijack) <sup>2 3</sup>	•*	n/a	n/a	n/a
Preamplifier <sup>1 2 3</sup>	n/a	•	n/a	n/a
Short extension cable <sup>2</sup>	Optional	•	Optional	Optional
IOW detachable probe <sup>2</sup>	•**	•	Optional	Optional
TDH39C contra cup headset (minijack) <sup>2</sup>	Optional	n/a	n/a	n/a
DD45C contra cup headset (minijack) <sup>2</sup>	Optional	n/a	n/a	n/a
E-A-RTONE 3A insert contra (minijack) <sup>2 3</sup>	Optional	n/a	n/a	n/a
IP30 insert contra (minijack) <sup>2</sup>	Optional	n/a	n/a	n/a
CIR55 <sup>2</sup> contra insert (ID plug) <sup>2</sup>	Optional	n/a	n/a	n/a
TDH39C contra cup headset (ID plug) <sup>2</sup>	Optional	n/a	n/a	n/a

<sup>1</sup> Applied part according to IEC 60601-1

<sup>2</sup> This part is not certified according to IEC 60601-1

\* Standard part for diagnostic or clinical versions only. May be optional for screener version.

\*\* Standard part for screener version only.



DD45C contra cup headset (ID plug) <sup>2</sup>	Optional	n/a	n/a	n/a
E-A-RTONE 3A insert contra (ID plug) <sup>2</sup>	Optional*	n/a	n/a	n/a
IP30 insert contra (ID plug) <sup>2</sup>	n/a	n/a	n/a	n/a
TDH39 stereo ID headset <sup>2</sup>	n/a	Optional	n/a	n/a
DD45 stereo ID headset <sup>2</sup>	n/a	Optional	n/a	n/a
E-A-RTONE EarCup stereo ID headset <sup>2</sup>	n/a	Optional	n/a	n/a
E-A-RTONE ABR stereo ID earphone <sup>2</sup>	n/a	Optional	n/a	n/a
IP30 EarCup stereo ID headset <sup>2</sup>	n/a	•	n/a	n/a
IP30 ABR stereo ID earphone <sup>2</sup>	n/a	Optional	n/a	n/a
Optional accessories or software				
WBT calibration kit	Optional	n/a	n/a	n/a
MPT-II thermal printer + paper kit	Optional	Optional	Optional	Optional
HiTrack Add-in for OtoAccess®	n/a	Optional	Optional	Optional



## 3 General technical specification

### 3.1 Titan hardware – technical specifications

<b>Medical CE-mark</b>	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no0123	
<b>Standards</b>	<b>Safety:</b>	IEC 60601-1: 2005, Internally powered, Type B and BF applied parts
	<b>EMC:</b>	IEC 60601-1-2: 2014
	<b>Impedance:</b>	IEC 60645-5:2004 /ANSI S3.39, Type 1
	<b>Test Signal:</b>	IEC 60645-1:2012 /ANSI S3.6 , IEC 60645-3: 2007
	<b>OAE:</b>	IEC 60645-6:2009, TEOAE Type 1 & 2 Otoacoustic emissions IEC 60645-6:2009, DPOAE Type 2 Otoacoustic emissions
	<b>ABR:</b>	IEC 60645-7: 2009, Type 2
	<b>FIPS:</b>	Complaint in accordance with FIPS PUB 140-2
<b>Cradle</b>	<b>Safety:</b> <b>Power</b> <b>Mains voltages and frequencies:</b> <b>Consumption:</b>	IEC 60601-1:2014, Class II Astrodyne ASA30M-0301 or UE24WCP 100 – 240 VAC, 47 – 63 Hz 0.8 – 0.4 A
<b>Battery</b>	<b>Use only:</b>	NP120 or CGA103450
<b>Operation environment</b>	<b>Temperature:</b>	15 – 35 °C
	<b>Relative Humidity:</b>	30 – 90%
	<b>Ambient Pressure:</b>	98kPa – 104kPa
	<b>Warm-up Time:</b>	1 minute
<b>Transport &amp; Storage</b>	<b>Storage Temperature:</b>	0°C – 50°C
	<b>Transport Temperature:</b>	-20 – 50 °C
	<b>Rel. Humidity:</b>	10 – 95%
<b>Impedance measuring system</b>		
<b>Probe tone</b>	<b>Frequency:</b>	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. WBT: 226 Hz – 8000 Hz broadband stimulus, 21.5/sec.
	<b>Level:</b>	226 Hz: 85 dB SPL (≈ 69 dB HL) WBT: 96 dB peSPL (infant) / 100 dB peSPL (adult). (100 dB peSPL ≈ 65 dB nHL)
<b>Air pressure</b>	<b>Control:</b>	Automatic.
	<b>Indicator:</b>	Measured value is displayed on the graphical display.
	<b>Range:</b>	-600 to +300 daPa.
	<b>Pressure limitation:</b> <b>Pressure change rate:</b>	-750 daPa and +550 daPa. Minimum, medium, maximum or automatic with minimum speed at compliance peak. Selectable in the setup.
<b>Compliance</b>	<b>Range:</b>	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.
<b>Test types</b>	<b>Tympanometry</b>	Automatic, where the start and stop pressure can be user-programmed in the setup function. Manual control of all functions.
	<b>Eustachian tube function 1 – Non perforated eardrum</b>	Williams test
	<b>Eustachian tube function 2 – Perforated eardrum</b>	Toynbee test
	<b>Eustachian tube function 3 – Patulous Eustachian tube</b>	Continuous sensitive impedance measurement for 30 up to 150 s.
	<b>Indicators</b>	<b>Graphical display</b>



<b>Memory</b>	<b>Tympanometry:</b>	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 between static and dynamic mode.		
<b>Reflex functions</b>		
<b>Signal sources</b>	<b>Tone - Contra, Reflex:</b>	250, 500, 1000, 2000, 3000, 4000, 6000, 8000 Hz.
	<b>Tone - Ipsi, Reflex:</b>	500, 1000, 2000, 3000, 4000 Hz.
	<b>NB noise - Contra, Reflex:</b>	250, 500, 1000, 2000, 3000, 4000, 6000, 8000 Hz.
	<b>NB noise - Ipsi, Reflex:</b>	1000, 2000, 3000, 4000 Hz.
	<b>Noise - Contra, Reflex:</b>	Wide Band, High Pass, Low Pass.
	<b>Noise - Ipsi, Reflex:</b>	Wide Band, High Pass, Low Pass.
	<b>Stimulus duration:</b>	750 ms (continuous)
<b>Outputs</b>	<b>Contra Earphone:</b>	TDH39 earphone, DD45 earphone, CIR55 insert and/or E-A-RTONE 3A/IP30 insert for Reflex measurements.
	<b>Ipsi Earphone:</b>	Probe earphone incorporated in the probe system for Reflex measurements.
	<b>Air:</b>	Connection of the air system to the probe.
<b>Test types</b>	<b>Manual Reflex</b>	Manual control of all functions.
	<b>Automated Reflex</b>	Automatic reflexes: - Single intensities - Reflex growth
	<b>Reflex Decay</b>	Automatic, 10 dB above threshold and manually controlled with stimulus durations of 10 to 30 s.
	<b>Reflex latency</b>	Automated, first 300 ms from stimulus start.

<b>ABR infant screening</b>		
<b>Preamplifier</b>	<b>One Channel:</b>	3 electrodes. 50 cm Switchable: Software will automatically switch mastoid and ground electrodes if the mastoid montage is used. The user does not need to change the electrodes during testing.
	<b>Gain:</b>	64 dB
	<b>Frequency response:</b>	0,5 - 5000 Hz
	<b>Noise:</b>	<25 nV/√Hz
	<b>CMR Ratio:</b>	>90 dB.
	<b>Max input offset voltage:</b>	2.5 V
	<b>Input impedance:</b>	10 MΩ/ 170 pF
	<b>Power from main unit:</b>	Isolated power supply
<b>Electrical Impedance measurement</b>	<b>Measurement frequency:</b>	33 Hz
	<b>Waveform:</b>	Rectangular
	<b>Measurement current:</b>	11.25 μA
	<b>Range:</b>	0.5 kΩ – 25 kΩ ± 10 %
<b>Stimulus</b>	<b>Stimuli:</b>	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)
	<b>Stimulus rate:</b>	90 Hz
	<b>Transducers: (Calibrated to Standards)</b>	E-A-RTONE ABR insert phone E-A-RTONE ABR for EarCup IP30 ABR insert phone IP30 ABR for EarCup TDH 39 or DD45 head phone (Static force: 4,5N ± 0,5N) IOW Probe
	<b>Level:</b>	30 dB nHL, 35 dB nHL, 40 dB nHL
	<b>Bandwidth:</b>	22.05 kHz
<b>Recording</b>	<b>Analysis time:</b>	1-10 min or Residual noise 5-80 nV
	<b>A/D resolution:</b>	24 bit
	<b>Artifact reject system:</b>	Rejection level (Peak, Min RMS, Max RMS) & Clipping (Saturation)
<b>Display</b>		Stimulus level and type, transducer, rejection level, electrode impedances, EEG/noise, bar or curve view, test time.
<b>Algorithmic Sensitivity</b>	<b>CE-Chirp®:</b>	99.9%
<b>Specificity</b>	<b>CE-Chirp®:</b>	> 96%





<b>DPOAE</b>		
<b>Stimulus</b>	<b>Frequency range:</b>	500 to 10000 Hz
	<b>Nominal frequency:</b>	f2
	<b>Frequency step:</b>	1 Hz
	<b>Level:</b>	30 to 80 dB SPL (75 dB SPL for 6kHz and 65 dB SPL for 8kHz to 10kHz)
	<b>Level Step:</b>	1 dB
	<b>Transducer:</b>	
<b>Recording</b>	<b>Analysis time:</b>	1 second to unlimited time
	<b>A/D Resolution:</b>	24 bit, 5.38 Hz resolution
	<b>Artifact rejection system:</b>	-30 to +30 dB SPL or off
	<b>Stimulus tolerance:</b>	Adjustable between 1 and 10 dB
	<b>SNR criteria:</b>	Adjustable between 3 and 25 dB
	<b>DP criteria:</b>	SNR, Min DP level, DP tolerance, Residual noise, mandatory points, DP reliability
	<b>Probe check window:</b>	256 points frequency response of the ear canal due to a click stimulus.
	<b>DP-response window:</b>	4096 points frequency response
<b>Display</b>	<b>Residual noise:</b>	A RMS average measurement in the DP-bin frequency area (26 bins at frequencies < 2500 Hz & 60 bins ≥ 2500 Hz).
	<b>Other information:</b>	In ear status (before/after test), noise rejection level, tympanic peak pressure
		Basic or advanced view of the DP-Gram, test summary table, point summary table
<b>Probe specifications</b>	<b>Titan IOWA probe:</b>	Clinical extension cable with fixed IOWA probe. Auto detection and auto calibrated. IMP, DPOAE and TEOAE capable
		Replaceable probe tip
<b>Test Pressure</b>		Ambient pressure Tympanic peak pressure (from IMP module)

<b>TEOAE</b>		
<b>Stimulus</b>	<b>Frequency range:</b>	500 to 5500 Hz
	<b>Frequency step:</b>	1 Hz (Custom bands)
	<b>Stimulus type:</b>	Non-Linear and Linear (according to IEC 60645-3)
	<b>Level:</b>	30 to 90 dB peSPL, peak to peak calibrated, AGC controlled
	<b>Level step:</b>	1 dB
	<b>Click rate:</b>	43.5 Hz or 80 Hz
	<b>Stimulus tolerance:</b>	Adjustable between 1 and 3 dB
	<b>Recording</b>	<b>Analysis time:</b>
<b>A/D Resolution:</b>		24 bit
<b>Artifact rejection system:</b>		0 to +60 dB SPL
<b>SNR criteria:</b>		Adjustable between 5 and 25 dB
<b>TE criteria:</b>		SNR, min sweeps, min Total OAE, min TE level, mandatory bands
<b>Stimulus time window:</b>		128 points instant recording of first click in sequence of clicks
<b>Probe check window:</b>		256 points frequency response of the ear canal recorded click stimulus
<b>Time recording window:</b>		4 – 23 msec (max). A and B buffer time-samples @ sampling rate 11025 Hz
<b>Freq. response window:</b>		256 points frequency response, bin spacing 43 Hz
<b>Residual noise:</b>		A RMS value for each octave band, based on the Bayesian weighted average for the defined OAE time window
<b>Display</b>	<b>Other information:</b>	In ear status (active before during & after test), noise rejection level, tympanic peak pressure
		Basic or advanced view, FFT view, test summary table. band summary table
<b>Probe specifications</b>	<b>Titan IOWA probe:</b>	Clinical extension cable with fixed IOWA probe. Auto detection and auto calibrated. IMP, DPOAE and TEOAE capable.
		Replaceable probe tip
<b>Test Pressure</b>		Ambient pressure Tympanic peak pressure (from IMP module)



<b>General</b>		
<b>PC control</b>	<b>USB:</b>	Titan can be fully operated from a PC via a USB connection.  Data can be stored on the device in handheld mode and transferred and saved on the PC in a database (OtoAccess® or Noah) via USB.
	<b>Wireless:</b>	Titan can be fully operated from a PC using a wireless connection..  Data can be stored on the device in handheld mode and transferred wirelessly and saved on the PC in a database (OtoAccess® or Noah).
<b>Memory</b>		The Titan includes a built-in 8 GB memory card. PC storage capacity is limited to the size of the database (OtoAccess® or Noah). It is recommended to store a maximum of 250 clients on the device.
<b>Thermal printer (Optional)</b>	<b>Type:</b>	Thermal printer with recording paper in rolls. Print on command through wireless communication or via a serial RS-232 connection.
	<b>Paper width:</b>	57.5 ± 0.5 mm on thermal printer
	<b>Printing time:</b>	Printing time depends on the size of the used protocol. For 2 tympanograms and 8 reflexes the thermal printer uses approximately 6s.
<b>User interface</b>	<b>Screen type:</b>	TFT with LED backlight
	<b>Display size:</b>	3.4 x 4.5 cm / 1.3 x 1.7 inches
<b>Dimensions</b>		6 x 6 x 28 cm / 2.4 x 2.4 x 11 inches
<b>Titan Weight</b>		360 g / 0.8 lbs
<b>Preamplifier weight</b>		120 g / 0.26 lbs
<b>Preamplifier dimensions</b>		10.2 x 6.8 x 2.6 cm / 4 x 2.7 x 1 inches
<b>Preamplifier cable length</b>		
<b>Short extension cable length</b>		40 cm / 15.7 inches
<b>Long extension cable shoulder box weight</b>		66 g / 0.14lbs
<b>Long extension cable shoulder box dimensions</b>		9.5 x 4.5 x 2.2 cm / 3.7 x 1.8 x 0.8 inches
<b>Long extension cable length</b>		234 cm / 92 inches



**Table 1: Frequencies and intensity ranges for IMP440**

Titan Maximums IMP										
Center Freq. [Hz]	TDH39		CIR55		E-A-RTONE 3A/IP30		IOW IPSI		DD45	
	Reading		Reading		Reading		Reading		Reading	
	Tone [dB HL]	NB [dB HL]	Tone [dB HL]	NB [dB HL]	Tone [dB HL]	NB [dB HL]	Tone [dB HL]	NB [dB HL]	Tone [dB HL]	NB [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	90	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		
Center Freq. [Hz]	IOWA IPSI Reading	IOWA ch2 Reading
	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 dB nHL for all transducers.



## Specification of input/output connections

### 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, Contralateral	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
Transducer	IA proprietary, 12-pole	Pin 1: Pin 2: Pin 3: Pin 4: Pin 5: Pin 6: Pin 7: Pin 8: Pin 9: Pin 10: Pin 11: Pin 12:	CH1 out CH1 GND DGND GND A / GND Microphone Microphone – input / Analog balanced in Microphone + input / Analog balanced in Power supply +3/+5V CH2 out CH2 GND I2C CLK I2C DATA I2C Interrupt
<b>Data I/O</b>			
USB	USB type"B"	USB port for communication	



## Calibration properties

<b>Calibrated Transducers</b>	Contralateral Earphone:	TDH39 or DD45 with a static force of 4.5N $\pm$ 0.5N and/or E-A-RTONE 3A/IP30 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
<b>Accuracy</b>	General:	Generally, the instrument is made and calibrated to be within and better than the tolerances required in the specified standards:
	Reflex Frequencies:	$\pm$ 1%
	Contralateral Reflex and Audiometer Tone Levels:	$\pm$ 3 dB for 250 to 4000Hz and $\pm$ 5 dB for 6000 to 8000Hz
	Ipsilateral Reflex Tone Levels:	$\pm$ 5 dB for 500 to 2000Hz and +5/-10 dB for 3000 to 4000Hz
	DPOAE Levels:	$\pm$ 1.5 dB for 1000 to 4000Hz and $\pm$ 3 dB outside range
	TEOAE Levels:	$\pm$ 2 dB for click stimulus
	ABRIS Levels:	$\pm$ 2 dB for all stimulus types
	Pressure measurement:	$\pm$ 5% or $\pm$ 10 daPa, whichever is greater
<b>Stimulus Presentation Control</b>	Compliance measurement:	$\pm$ 5% or $\pm$ 0.1 ml, whichever is greater
	Reflexes:	ON-OFF ratio = $\geq$ 70 dB Rise time = 27 ms Fall time = 24.6 ms A weighted SPL in Off = 31 dB

## Impedance calibration properties

<b>Probe tone</b>	Frequencies:	226 Hz $\pm$ 1%, 678 Hz $\pm$ 1%, 800 Hz $\pm$ 1%, 1000 Hz $\pm$ 1%
	Level:	85 dB SPL $\pm$ 1.5 dB measured in an IEC 60318-5 acoustic coupler. The level is constant for all volumes in the measurement range.
<b>Compliance</b>	Distortion:	Max 1% THD
	Range:	0.1 to 8.0 ml
	Temperature dependence:	-0.003 ml/ $^{\circ}$ C
	Pressure dependence:	-0.00020 ml/daPa
	Reflex sensitivity:	0.001 ml is the lowest detectable volume change
	Reflex artifact level:	$\geq$ 95 dB SPL (measured in the 711 coupler, 0.2 ml, 0.5 ml, 2.0 ml & 5.0 ml hardwalled cavities).
<b>Pressure</b>	Temporal reflex characteristics:	Initial latency = 35 ms ( $\pm$ 5 ms) Rise time = 45 ms ( $\pm$ 5 ms) Terminal latency = 35 ms ( $\pm$ 5 ms) Fall time = 45 ms ( $\pm$ 5 ms) Overshoot = max. 1% Undershoot = max 1%
	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:

<b>General</b>	Specifications for stimulus and audiometer signals are made to follow IEC 60645-5
<b>Contralateral Earphone</b>	Pure tone: ISO 389-1 for TDH39/DD45 and ISO 389-2 for CIR 55. 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, $\pm 5$ dB re. 1000 Hz level High Pass noise (HP): Interacoustics Standard – Spectral properties: Uniform from 1600 Hz to 10KHz, $\pm 5$ dB re. 1000 Hz level
<b>Ipsilateral Earphone</b>	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.

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 (impedance)**

	Freq.	Reference values for stimulus calibration [dB re. 20 µPa]							Variation of Ipsi stimulus levels for different volumes of the ear canal Relative to the calibration performed on an IEC 126 coupler [dB]		Sound attenuation values for TDH39 earphones using MX41/AR or PN51 cushion [dB]
		ISO 389-1 (Interacoustics Standard)	ISO 389-2 (Interacoustics Standard)	ISO 382-2 (Interacoustics Standard)	ISO389-1 Interacoustics Standard	Interacoustics Standard	Interacoustics Standard	ISO 389-4 (ISO 8798)	0.5 ml	1 ml	
	[Hz]	TDH39	E-A-R TONE 3A/ IP30 insert	CIR55	DD45	IOW/ IOWA Probe	IOW/ IOWA Probe NB	NB stimulus correction values (except IOW/IOWA probe)			
RETSPL	125	45	26	26	47.5	<b>41</b>	<b>43.5</b>	4			3
	250	25.5	14	14	27	<b>24.5</b>	<b>26.5</b>	4			5
	500	11.5	5.5	5.5	13	<b>9.5</b>	<b>17</b>	4	9.7	5.3	7
	1000	7	0	0	6	<b>6.5</b>	<b>10.5</b>	6	9.7	5.3	15
	1500	6.5	2	2	8	<b>5</b>	<b>12</b>	6			21 (1600Hz)
	2000	9	3	3	8	<b>12</b>	<b>11</b>	6	11.7	3.9	26
	3000	10	3.5	3.5	8	<b>11</b>	<b>11</b>	6	-0.8	-0.5	31 (3150Hz)
	4000	9.5	5.5	5.5	9	<b>3.5</b>	<b>8</b>	5	-1.6	-0.8	32
	6000	15.5	2	2	20.5	<b>3</b>	<b>5.5</b>	5			26 (6300Hz)
	8000	13	0	0	12	<b>-5</b>	<b>-0.5</b>	5			24
	WB	<b>-8</b>	<b>-5</b>	<b>-5</b>	<b>-8</b>	<b>-5</b>			7.5	3.2	
	LP	<b>-6</b>	<b>-7</b>	<b>-7</b>	<b>-6</b>	<b>-7</b>			8.0	3.6	
	HP	<b>-10</b>	<b>-8</b>	<b>-8</b>	<b>-10</b>	<b>-8</b>			3.9	1.4	

*All figures in bold are Interacoustics Standard values.*

**Table 4: Reference values for stimulus calibration (ABR)**



	Stimulus	Reference values for stimulus calibration [dB re. 20 µPa]				
		Interacoustics Standard Values				
		TDH39	E-A-RTONE ABR /IP30 inserts	DD45	E-A-RTONE ABR /IP30 EarCups	IOW Probe
<b>peRETSPL</b>	CE-Chirp®	27.5	31.5	26	58.5	32
	CE- Chirp® Low	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

## 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:

Interacoustics A/S	Phone:	+45 63713555
Audiometer Allé 1	Fax:	+45 63713522
5500 Middelfart	E-mail:	<a href="mailto:info@interacoustics.com">info@interacoustics.com</a>
Denmark	http:	<a href="http://www.interacoustics.com">www.interacoustics.com</a>





### 3.2 Electromagnetic compatibility (EMC)

- This instrument is suitable in hospital environments except for near active HF surgical equipment and RF shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.
- Use of this instrument adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this instrument and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. The list of accessories, transducers and cables can be found in this appendix.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this instrument, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

#### NOTICE

- ESSENTIAL PERFORMANCE for this instrument is defined by the manufacturer as:

This instrument 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. There are no deviations from the collateral standard and allowances uses.
- This instrument is in compliance with IEC60601-1-2:2014, emission class B group 1.

NOTICE: There are no deviations from the collateral standard and allowances uses.

NOTICE: All necessary instruction for maintaining compliance with regard to EMC can be found in the general maintenance section in this instruction. No further steps required.



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

Recommended separation distances between portable and mobile RF communications equipment and the <b>TITAN</b> .			
The <b>TITAN</b> is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the <b>TITAN</b> can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the <b>TITAN</b> as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.


**Note 1** At 80 MHz and 800 MHz, the higher frequency range applies.

**Note 2** These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The <b>TITAN</b> is intended for use in the electromagnetic environment specified below. The customer or the user of the <b>TITAN</b> 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	< 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 <b>TITAN</b> requires continued operation during power mains interruptions, it is recommended that the <b>TITAN</b> be powered from an uninterruptable power supply or its battery.



	(>95% dip in <i>UT</i> ) for 5 sec		
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.
<b>Note:</b> <i>UT</i> is the A.C. mains voltage prior to application of the test level.			

<b>Guidance and manufacturer's declaration — electromagnetic immunity</b>			
The <b>TITAN</b> is intended for use in the electromagnetic environment specified below. The customer or the user of the <b>TITAN</b> 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>TITAN</b> , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  Recommended separation distance $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 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:  
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	
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 <b>TITAN</b> is used exceeds the applicable RF compliance level above, the <b>TITAN</b> should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the <b>TITAN</b> . <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
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
E-A-RTONE 3A with Minijack	Interacoustics	Ear3A
CIR55 Contra ID Earphone	Interacoustics	CIR55
IP30 contra with minijack	Interacoustics	IP30
TDH39C Contra ID Headset	Interacoustics	TDH39C
DD45C Contra ID Headset	Interacoustics	DD45C
E-A-RTONE 3A Contra ID Earphone	Interacoustics	Ear3A
TDH39 Stereo ID headset	Interacoustics	TDH39
DD45 Stereo ID headset	Interacoustics	TDH39
IP30 contra ID earphone	Interacoustics	IP30
E-A-RTONE ABR Stereo ID Headset	Interacoustics	Ear3A
EarCup Stereo ID Headset	Interacoustics	Ear3A
IP30 Earcup stereo ID headset	Interacoustics	IP30
IP30 ABR stereo ID earphone	Interacoustics	IP30

Conformance to the EMC requirements as specified in IEC 60601-1-2 is ensured if the cable types and cable lengths are as specified below:

Description	Length	Screened?
Mains Cable	2.0m	Unscreened
USB Cable	2.0m	Screened
PSU USB Adapter	0.1m	Screened
Clinical Extension Cable	2.4m	Unscreened
Short Extension Cable	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
E-A-RTONE 3A with Minijack	0.5m	Screened
IP30 contra 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
E-A-RTONE 3A Contra ID Earphone	0.5m	Screened
IP30 contra ID earphone	0.5m	Screened
TDH39 Stereo ID headset	0.5m	Screened
DD45 Stereo ID headset	0.5m	Screened
E-A-RTONE ABR Stereo ID Headset	0.5m	Screened
E-A-RTONE EarCup Stereo ID Headset	0.5m	Screened
IP30 EarCup stereo ID headset	0.5m	Screened
IP30 ABR stereo ID earphone	0.5m	Screened