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Technical Specifications

Titan



D-0103650-L - 2023/03



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
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 baselinetympanometry 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

1.1.3 DPOAE440 – Distortion Product Otoacoustic Emissions Module

Test types/functionality:	Screener	Clinical
Tympanometry 226Hz	X	x
Tympanometry 1000Hz		Optional
Frequency range	500-6000 Hz	500 – 10000 Hz
Test points (frequencies)	Max 6 per test	Unlimited
DP-Gram	x	x
DP Input/Output		x
Pressurized DPOAE	Optional	x
Enable pass/refer	x	x
Normative data (view, edit, import, export)	x	x
Manual testing (add test points, extend testing)		x
User customizable protocols	x	x
Protocol upload	x	x
Client/session upload/download	x	x
PC-controlled testing	Optional	x
Bluetooth	x	x



1.1.4 TEOAE440 – Transient Evoked Otoacoustic Emissions Module

Test types/functionality:	Screeener	Clinical
Tympanometry 226Hz	x	x
Tympanometry 1000Hz		Optional
Frequency range	1000 – 4500 Hz	500 – 5500 Hz
Test time	Max 6 minutes or	Unlimited
Stimulus intensity SA	60 – 84 dB SPL	3
Center band frequencies (1, 1.5, 2, 3, 4)	x	x
Custom band frequencies (user definable)		x
Pressurized TEOAE	Optional	x
FFT Display		x
Enable pass/refer	x	x
Normative data (view, edit, import, export)	x	x
Manual testing (extend testing)		x
User customizable protocols	x	x
Protocol upload	x	x
Client/session upload/download	x	x
PC-controlled testing	Optional	x
Bluetooth	x	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	•	•	•	•
Instructions for Use	•	•	•	•
Sanibel™ ADI Ear Tip Kit ¹	•	Optional	•	•
Pediatric ear tip kit	n/a	Optional	•**	•**
Probe tip kit for IOW probe	n/a	Optional	n/a	n/a
Probe tip kit for IOWA probe	•	n/a	•	•
Titan probe floss kit	•	Optional	•	•
Accessory kit 1055 (for ABRIS)	n/a	•	n/a	n/a
Neckstrap for preamplifier	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	•	•	•	•
Transducers				
Clinical extension cable with IOWA probe ²	•*	n/a	•	•
Preamplifier ¹	n/a	•	n/a	n/a
Short extension cable	Optional	•	Optional	Optional
IOW detachable probe	•**	•	Optional	Optional
TDH39C contra cup headset (minijack)	Optional	n/a	n/a	n/a
DD45C contra cup headset (minijack)	Optional	n/a	n/a	n/a
E-A-RTONE 3A insert contra (minijack)	Optional	n/a	n/a	n/a
IP30 insert contra (minijack) ²	Optional	n/a	n/a	n/a
TDH39C contra cup headset (ID plug)	Optional	n/a	n/a	n/a
DD45C contra cup headset (ID plug)	Optional	n/a	n/a	n/a
E-A-RTONE 3A insert contra (ID plug)	Optional*	n/a	n/a	n/a
IP30 insert contra (ID plug) ²	n/a	n/a	n/a	n/a
E-A-RTONE EarCup stereo ID headset	n/a	Optional	n/a	n/a

¹ Applied part according to IEC 60601-1



E-A-RTONE ABR stereo ID earphone	n/a	Optional	n/a	n/a
IP30 EarCup stereo ID headset	n/a	•	n/a	n/a
IP30 ABR stereo ID earphone	n/a	Optional	n/a	n/a
Optional accessories and software				
WBT calibration kit	Optional	n/a	n/a	n/a
HM-E200 thermal printer + paper kit	Optional	Optional	Optional	Optional
OtoAccess® Database	Optional	Optional	Optional	Optional



3 General technical specifications

3.1 Titan hardware – technical specifications

The Titan with DPOAE440 uses an improved method of stimuli level control, which more accurately delivers the specified intensity in the full range of ear canals, from infants to adults. The applicability of the IEC 60645-6 standard is currently limited to adult ears. Therefore, in order to better serve a market with a product that provides more accurate stimulus levels to a wide range of ear canal volumes (specifically infants), we have elected to utilize a more comprehensive calibration procedure for DPOAEs that is outside the scope of IEC 60645-6 for some protocols.

This improved method of stimulus control is enabled when the “Use Microphone compensation” checkbox is checked. To use the IEC60645-6 calibration method, uncheck the “Use Microphone compensation” in the Advanced tab of the protocol setup.

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:	43.5 Hz or 80 Hz
	Stimulus tolerance:	Adjustable between 1 and 3 dB
Recording	Analysis time:	30 seconds to 30 minutes or 300 to 30000 sweeps
	A/D Resolution:	24 bit
	Artifact rejection system:	0 to +60 dB SPL
	SNR criteria:	Adjustable between 5 and 25 dB
	TE criteria:	SNR, min sweeps, min Total OAE, min TE level, mandatory bands
	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:	4 – 23 msec (max). A and B buffer time-samples @ sampling rate 11025 Hz
	Freq. response window:	256 points frequency response, bin spacing 43 Hz
	Averaging method:	Bayesian weighted averaging
	Residual noise:	A RMS value for each octave band, based on the Bayesian weighted average for the defined OAE time window
Display	Other information:	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
Probe specifications	Titan IOWA probe:	Clinical extension cable with fixed IOWA probe. Auto detection and auto calibrated. IMP, DPOAE and TEOAE capable.
		Replaceable probe tip
Test Pressure		Ambient pressure Tympanic peak pressure (from IMP module)



General		
PC control	USB:	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® Database or Noah) via USB.
	Wireless:	Titan can be fully operated from a PC via 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® Database or Noah).
Memory		The Titan includes a built-in 8 GB memory card. PC storage capacity is limited to the size of the database (OtoAccess ® Database or Noah). It is recommended to store a maximum of 250 clients on the device.
Thermal printer (Optional)	Type:	Thermal printer with recording paper in rolls. Print on command through wireless communication printer.
	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.
User interface	Screen type:	TFT with LED backlight
	Display size:	3.4 x 4.5 cm/1.3 x 1.7 inches
Dimensions		6 x 6 x 28 cm / 2.4 x 2.4 x 11 inches
Titan Weight		360 g / 0.8 lbs
Preamp weight		120 g / 0.26 lbs
Preamp dimensions		10.2 x 6.8 x 2.6 cm / 4 x 2.7 x 1 inches
Short extension cable length		40 cm/15.7 inches
Long extension cable shoulder box weight		66 g/0.14lbs
Long extension cable shoulder box dimensions		9.5 x 4.5 x 2.2 cm/3.7 x 1.8 x 0.8 inches
Long extension cable length		234 cm/92 inches



Table 1: Frequencies and intensity ranges for IMP440

Titan Maximums IMP								
Center Freq. [Hz]	TDH39		E-A-RTONE 3A/IP30		IOW IPSI		DD45	
	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]
125	80	65	100	85	70	60	80	65
250	100	85	110	100	85	75	100	85
500	120	100	115	105	100	85	115	100
750	120	105	120	110	100	85	120	105
1000	120	105	120	110	105	90	120	105
1500	120	105	120	110	110	90	115	100
2000	120	105	120	110	105	90	115	100
3000	120	105	120	110	95	90	125	105
4000	120	105	120	105	100	90	115	105
6000	120	100	105	100	85	80	110	90
8000	105	95	90	85	80	75	105	95
10000								
WB	-	120	-	120	-	105	-	125
LP	-	120	-	120	-	110	-	120
HP	-	120	-	120	-	105	-	130

Table 2: Frequencies and Intensity Ranges for DPOAE440

Titan Maximums DPOAE		
Center Freq. [Hz]	IOWA IPSI	IOWA ch2
	Reading	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

Data I/O

USB	USB type" B"	USB port for communication
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Calibration properties

Calibrated Transducers	Contralateral Earphone:	TDH39 or DD45 with a static force of 4.5N ±0.5N and/or E-A-RTONE 3A/IP30
	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:	±5% or ±10 daPa, whichever is greater
	Compliance measurement:	±5% or ±0.1 ml, whichever is greater
Stimulus Presentation Control	Reflexes:	ON-OFF ratio = ≥ 70 dB Rise time = 27 ms Fall time = 24.6 ms A weighted SPL in Off = 31 dB

Impedance calibration properties



Probe tone	Frequencies:	226 Hz ± 1%, 678 Hz ± 1%, 800 Hz ± 1%, 1000 Hz ± 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:	0.001 ml is the lowest detectable volume change
	Reflex artifact level:	≥95 dB SPL (measured in the 711 coupler, 0.2 ml, 0.5 ml, 2.0 ml & 5.0 ml hardwalled cavities).
	Temporal reflex characteristics:	Initial latency = 35 ms (±5 ms) Rise time = 45 ms (±5 ms) Terminal latency = 35 ms (±5 ms) Fall time = 45 ms (±5 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, ±50 daPa

Reflex calibration standards and spectral properties:

General Contralateral Earphone	Specifications for stimulus and audiometer signals are made to follow IEC 60645-5
	Pure tone: ISO 389-1 for TDH39/DD45
	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.
Ipsilateral Earphone	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
Ipsilateral Earphone	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, ±10 dB re. 1000 Hz level
	High Pass noise (HP): Interacoustics Standard
– Spectral properties: Uniform from 1600 Hz to 4000 Hz, ±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)		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		DD45	IOW/ IOWA Probe	IOW/ IOWA Probe NB	NB stimulus correction values (except IOW/IOWA probe)			
125	45	26		47.5	41	43.5	4			3
250	25.5	14		27	24.5	26.5	4			5
500	11.5	5.5		13	9.5	17	4	9.7	5.3	7
1000	7	0		6	6.5	10.5	6	9.7	5.3	15
1500	6.5	2		8	5	12	6			21 (1600Hz)
2000	9	3		8	12	11	6	11.7	3.9	26
3000	10	3.5		8	11	11	6	-0.8	-0.5	31 (3150Hz)
4000	9.5	5.5		9	3.5	8	5	-1.6	-0.8	32
6000	15.5	2		20.5	3	5.5	5			26 (6300Hz)
8000	13	0		12	-5	-0.5	5			24
WB	-8	-5		-8	-5			7.5	3.2	
LP	-6	-7		-6	-7			8.0	3.6	
HP	-10	-8		-10	-8			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
peRETSPL	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

5500 Middelfart

Denmark

E-mail:

info@interacoustics.com

http:

www.interacoustics.com



3.2 Electromagnetic compatibility (EMC) and EMF exposure

- 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 in improper operation.

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+AMD1:2020, 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 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.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The TITAN 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 TITAN 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 TITAN .			
The TITAN is intended for use in an electromagnetic environment 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 equipment (transmitters) and the TITAN as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
Note 2 These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			



Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The 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	+8 kV contact +15 kV air	+8 kV contact +15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Immunity to proximity fields from RF wireless communications equipment IEC 61000-4-3	Spot freq. 385-5.785 MHz Levels and modulation defined in table 9	As defined in table 9	RF wireless communications equipment should not be used close to any parts of the TITAN .
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	Not applicable +1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	+1 kV line to line +2 kV line to earth	Not applicable	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	0% UT (100% dip in UT) for 0.5 cycle, @ 0, 45, 90, 135, 180, 225, 270 and 315° 0% UT (100% dip in UT) for 1 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles 0% UT (100% dip in UT) for 250 cycles	Not applicable	Mains power quality should be that of a typical commercial or residential environment. If the user of the TITAN requires continued operation during power mains interruptions, it is recommended that the TITAN be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Radiated fields in close proximity — Immunity test IEC 61000-4-39	9 kHz to 13.56 MHz. Frequency, level and modulation defined in AMD 1: 2020, table 11	As defined in table 11 of AMD 1: 2020	If the TITAN contains magnetically sensitive components or circuits, the proximity magnetic fields should be no higher than the



			test levels specified in Table 11
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Note: *UT* is the A.C. mains voltage prior to application of the test level.

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 / 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 TITAN , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \frac{3,5}{V_{rms}} \sqrt{P}$
	6 Vrms In ISM bands (and amateur radio bands for Home Healthcare environment.)	6 Vrms	
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,7 GHz	3 V/m	$d = \frac{3,5}{v/m} \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \frac{7}{v/m} \sqrt{P} \quad 800 \text{ MHz to } 2,7 \text{ GHz}$ 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
	10 V/m 80 MHz to 2,7 GHz Only for Home Healthcare environment	10 V/m (If Home Healthcare)	



		Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 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 TITAN is used exceeds the applicable RF compliance level above, the TITAN should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the TITAN . 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
Clinical Probe Extension	Interacoustics	-
Short Probe Extension	Interacoustics	-
ABRIS Preamplifier	Interacoustics	-
TDH39C Contra Headset	Interacoustics	TDH39C
DD45C Contra Headset	Interacoustics	DD45C
E-A-RTONE 3A with Minijack	Interacoustics	Ear3A
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
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
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



Compliance with the EMF exposure guidelines as specified by ICNIRP, (HEALTH PHYSICS 96(4):504-514; 200) is ensured when using the following accessories:

The accessories are classified (EMF level) according to the maximum strength of the permanent magnetic field.

Patients having magnetically programmable cerebral shunts must observe the precautions stated by the manufacturer of the shunt if the accessories with a HIGH magnetic field are used. No special precautions are necessary with accessories which emit a LOW magnetic field.

ITEM	MANUFACTURER	MODEL	EMF level
Clinical Probe Extension	Interacoustics	-	LOW
Short Probe Extension	Interacoustics	-	LOW
ABRIS Preamplifier	Interacoustics	-	LOW
TDH39C Contra Headset	Interacoustics	TDH39C	HIGH
DD45C Contra Headset	Interacoustics	DD45C	HIGH
E-A-RTONE 3A with Minijack	Interacoustics	Ear3A	LOW
IP30 contra with minijack	Interacoustics	IP30	LOW
TDH39C Contra ID Headset	Interacoustics	TDH39C	HIGH
DD45C Contra ID Headset	Interacoustics	DD45C	HIGH
E-A-RTONE 3A Contra ID Earphone	Interacoustics	Ear3A	LOW
TDH39 Stereo ID headset	Interacoustics	TDH39	HIGH
DD45 Stereo ID headset	Interacoustics	TDH39	HIGH
IP30 contra ID earphone	Interacoustics	IP30	LOW
E-A-RTONE ABR Stereo ID Headset	Interacoustics	Ear3A	LOW
EarCup Stereo ID Headset	Interacoustics	Ear3A	LOW
IP30 Earcup stereo ID headset	Interacoustics	IP30	LOW
IP30 ABR stereo ID earphone	Interacoustics	IP30	LOW