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Technical Specifications

# AT235



D-0105062-H – 2021/09



## License overview

International configuration AT235		
	Standard	Standard + H
<b>Licenses Tympanometry</b>		
Test:		
Tymp 226 Hz	x	x
Tymp 678, 800 & 1000 Hz		x
Manual tympanometry		x
Reflex Ipsilateral	x	x
Reflex Contralateral	x	x
ETF 1 test non-perforated tympanic membrane	x	x
EFT 2 test perforated tympanic membrane	x	x
EFT 3 patulous tympanic membrane		x
Reflex Decay	x	x
Reflex Latency		x
Pure tone audiometry	x	x
Modified Hughson Westlake audiometry test	x	x
Tympanogram transfer	Optional	Optional



## Languages supported in IMP and AUD

	Chinese	Czech	English	Finnish	French	German	Greek	Italian	Japanese	Korean	Norwegian	Polish	Portuguese	Russian	Spanish	Turkish
<b>IMP</b>																
MT10			X		X	X										
Existing AT235			X			X										
New AT235	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Existing AA222			X			X										
New AA222	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Titan	X	X	X		X	X		X	X	X			X	X	X	
<b>AUD</b>																
AS608			X		X	X									X	
AD226	X		X		X	X		X				X	X	X	X	X
AD629 / AD229	X*	X*	X	X*	X	X	X*	X	X*	X*	X*	X	X*	X*	X	X
AC40	X*	X*	X	X*	X	X	X*	X	X*	X*	X*	X	X*	X*	X	X
<b>Suites</b>																
Titan suite	X	X	X		X	X		X	X			X	X	X	X	X
DS	X	X	X		X	X	X	X	X	X		X	X	X	X	X



## Included and optional parts

### Included Parts:

- AT235 instrument
- Clinical probe system<sup>1</sup>
- Diagnostic probe system<sup>1,2</sup>
- Power supply unit UES65-240250SPA3
- Contralateral headphone1
- CAT50 (Option)
- DD65v2 Audiometric headset
- Patient response (Option)
- Printer kit (Option)
- Wall mounting kit (Option)
- Cleaning cloth
  
- Assortment bag BET55


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

<sup>2</sup> One can be selected.



## General technical specifications

General		
Medical CE-mark:	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no0123.	
Standards:	Safety:	IEC 60601-1, Class I, Type B applied parts
	EMC:	IEC 60601-1-2
	Impedance:	IEC 60645-5 (2004)/ANSI S3.39 (2012), Type 1
	Audiometer:	IEC60645-1 (2017)/ANSI S3.6 (2018), Type 4
Operation environment:	Temperature:	15° – 35 °C
	Relative humidity:	30 – 90%
	Ambient pressure:	98 kPa – 104 kPa
	Warm-up time:	1 minute
Display	10 inch high resolution color display 1024x600	
Transport & storage:	Storage temperature:	0° – 50°C
	Transport temperature:	-20° – 50 °C
	Relative humidity:	10 – 95%
Internal storage	500 clients and 50.000 sessions	
Internal battery	CR2032 3 V, 230 mAh, Li. Not serviceable by user	
PC control:	USB:	Input/output for computer communication Data can be sent to and saved on the PC and stored in OtoAccess® (Diagnostic Suite sync module is required).
	Thermal printer (Optional):	Type: MPT-III Thermal MPT-III printer with recording paper in rolls Print on command via USB
Power supply 	UES65-240250SPA3	Use only specified power supply unit UES65-240250SPA3 type Input: 100-240 VAC 50-60 Hz, 2,0 A Output: 24.0 VDC
Dimensions	H x W x L:	29 x 38 x 7,5 cm
AT235 weight	2.5 kg	

Impedance measuring system		
Probe tone:	Frequency: Level:	226 Hz, 678 Hz, 800 Hz, 1000 Hz; pure tones; ±1% 85 dB SPL (≈ 69 dB HL) ±1.5 dB
Air pressure:	Control:	Automatic.
	Indicator:	Measured value is displayed on the graphical display
	Range:	-600 to +400 daPa. ±5%
	Pressure limitation:	-750 daPa and +550 daPa
Compliance:	Pump speed:	Automatic, Fast 300 daPa/s, Medium 200 daPa/s, Slow 100 daPa/s, Very slow 50 daPa/s.
	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. All ±5%
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



<b>Reflex functions</b>		
Signal sources:	Tone - Contra, Reflex:	250, 500, 1000, 2000, 3000, 4000, 6000, 8000 Hz, Wide Band, High and Low pass
	Tone - Ipsi, Reflex:	500, 1000, 2000, 3000, 4000 Hz wide band, high and low pass
	NB noise – Contra, Reflex:	250, 500, 1000, 2000, 3000, 4000, 6000, 8000 Hz
	NB noise – Ipsi, Reflex:	1000, 2000, 3000, 4000 Hz
	Stimulus duration:	750 ms
	Reflex acceptance:	Adjustable between 2% and 6%, or 0.05 – 0.15 ml change of ear canal volume
	Intervals:	Down to 1 dB step size.
	Intensity max:	90, 100, 120 dBHL.
Outputs:	Contra Earphone:	TDH39 earphone, DD45 earphone, CIR insert and/or EARtone 3A insert for Reflex measurements.
	Ipsi Earphone:	Probe earphone incorporated in the probe system for Reflex measurements
	Probe connection:	Connection of the electrical and air system to the probe
Test types:	Manual reflex:	Manual control of all functions.
	Automated Reflex	Single intensities Reflex growth
	Reflex decay:	Automatic, 10 dB above threshold and manually controlled with stimulus durations of 10
	Reflex latency:	Automated, first 300 ms from stimulus start

<b>Audiometer functions</b>		
Signals:	Frequencies Hz:	Intensities dB HL:
	125	-10 to 70
	250	-10 to 90
	500	-10 to 100
	1000	-10 to 100
	2000	-10 to 100
	3000	-10 to 100
	4000	-10 to 100
	6000	-10 to 100
8000	-10 to 90	
Test types	Auto threshold determination (Modified Hughson Westlake) Auto testing: duration 1-2 s adjusted in 0.1 s intervals	



## Calibration properties

Calibrated transducers:	Contralateral earphone:	Telephonics TDH39/DD45 with a static force of 4.5N 0.5N, IP30 and/or IP30 single contra
	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 4000 Hz and 5 dB for 6000 to 8000 Hz
	Ipsilateral reflex tone levels:	5 dB for 500 to 2000 Hz and +5/-10 dB for 3000 to 4000 Hz
	Pressure measurement: Compliance measurement:	5% or 10 daPa, whichever is greater 5% or 0.1 ml, whichever is greater
Stimulus presentation control:	Reflexes:	ON-OFF ratio ≥ 70 dB Rise time = 20 ms Fall time = 20 ms A weighted SPL in Off = 31 dB
<b>Impedance calibration properties</b>		
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: Reflex artifact level:	0.001 ml is the lowest detectable volume change ≥95 dB SPL (measured in the 711 coupler, 0.2 ml, 0.5 ml, 2.0 ml & 5.0 ml hard walled cavities)
	Temporal reflex characteristics: (IEC60645-5 clause 5.1.6)	Initial latency = 35 ms (5 ms) Rise time = 42 ms (5 ms) Terminal latency = 23 ms (5 ms) Fall time = 44 ms (5 ms) Overshoot = max. 1% Undershoot = max. 1%
Pressure:	Range:	Values between -600 to +400 daPa can be selected in the setup.
	Safety limits:	-750 daPa and +550 daPa, 50 daPa
Barometric pressure:	The barometer pressure changes influence on the impedance measurement in the specified range (97300 – 105300 Pascal).	Admittance can vary inside: ± 4% The pressure accuracy is: ±10 daPa or 10%, whichever is greater



Height above sea level:	The pressure sensor used, is a differential/gauge type, which means, it measure the pressure difference and therefore not affected of the height above sea level.					
	<b>Probe tones</b>	<b>0 meters</b>	<b>500 meters</b>	<b>1000 meters</b>	<b>2000 meters</b>	<b>4000 meters</b>
	226 Hz	1.0 mmho	1.06 mmho	1.13 mmho	1.28 mmho	1.65 mmho
	678 Hz	3.0 mmho	3.19 mmho	3.40 mmho	3.85 mmho	4.95 mmho
	800 Hz	3.54 mmho	3.77 mmho	4.01 mmho	4.55 mmho	5.84 mmho
	1000 Hz	4.42 mmho	4.71 mmho	5.01 mmho	5.68 mmho	7.30 mmho
	The pressure accuracy is: $\pm 10$ daPa or 10%, whichever is greater. To minimize the influence of temperature, barometer pressure, humidity and height above sea level, it always recommended to calibrate the unit in the local positions.					
Temperature	The temperature have no theoretic impact on the impedance calculation, but the temperature has influence on the electronic circuits. This temperature influence for the standard specified temperature range (15-35 °C) is inside: Admittance can vary inside: $\pm 5\%$ , $\pm 0.1 \text{ cm}^3$ , $\pm 10^{-9} \text{ m}^3/\text{Pa}\cdot\text{s}$ , whichever is greater.					
<b>Reflex calibration standards and spectral properties:</b>						
General:	Specifications for stimulus and audiometer signals are made to follow IEC 60645-5					
Contralateral earphone:	Pure tone:	ISO 389-1 for TDH39 and ISO 389-9 for IP30				
	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): Spectral properties:	Interacoustics Standard Uniform from 500 Hz to 1600 Hz, 5 dB re. 1000 Hz level				
	High Pass noise (HP): Spectral properties:	Interacoustics Standard Uniform from 1600 Hz to 10KHz, 5 dB re. 1000 Hz level				
Ipsilateral Earphone:	Pure tone:	Interacoustics Standard				
	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): Spectral properties:	Interacoustics Standard Uniform from 500 Hz to 1600 Hz, 10 dB re. 1000 Hz level				
	High Pass noise (HP): Spectral properties:	Interacoustics Standard 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.				
The risk of artifacts at higher stimulus levels in reflex measurements are minor and will not activate the reflex detection system						





**Reference values for stimulus calibration**

Freq.	Reference Equivalent Threshold Sound Level (RETSPL) [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/DD45 earphones using MX41/AR or PN51 cushion [dB]
	ISO 389-1 (Interacoustics Standard)	ISO 389-9 (Interacoustics Standard)	Interacoustics Standard	Interacoustics Standard	Interacoustics Standard	Interacoustics Standard	ISO 389-4 (ISO 8798)	0.5 ml	1 ml	
[Hz]	TDH39	IP30	DD65 v2	DD45	Probe	NB Stimulus Correction Values				
125	45	26	30,5	47.5	41	4			3	
250	25.5	14	17	27	24.5	4			5	
500	11.5	5.5	8	13	9.5	4	9.7	5.3	7	
1000	7	0	4,5	6	6.5	6	9.7	5.3	15	
1500	6.5	2	2,5	8	5	6			21 (1600 Hz)	
2000	9	3	2,5	8	12	6	11.7	3.9	26	
3000	10	3.5	2	8	11	6	-0.8	-0.5	31 (3150 Hz)	
4000	9.5	5.5	9,5	9	3.5	5	-1.6	-0.8	32	
6000	15.5	2	21	20.5	3	5			26 (6300 Hz)	
8000	13	0	21	12	-5	5			24	
RETSPL	WB	-8	-5	-8	-8	-5		7.5	3.2	
	LP	-6	-7	-6	-6	-7		8.0	3.6	
	HP	-10	-8	-10	-10	-8		3.9	1.4	

\*All figures in bold are Interacoustics Standard values.



**Reference equivalent threshold values for transducers**

**Impedance - frequencies and intensity ranges**

<b>AT235 Maximums IMP</b>										
	TDH39		DD65v2		IP30		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	75	60
250	100	85	100	85	110	100	85	75	100	85
500	120	100	110	95	115	105	100	85	120	100
750	120	105	115	100	120	110	100	85	120	105
1000	120	105	115	100	120	110	105	90	120	105
1500	120	105	115	100	120	110	110	90	120	100
2000	120	105	115	95	120	110	105	90	120	100
3000	120	105	115	100	120	110	95	90	120	105
4000	120	105	110	95	120	105	100	85	120	105
6000	120	100	100	85	105	100	85	80	110	90
8000	105	95	95	70	90	85	80	75	105	95
10000										
WB	-	115	-	115	-	115	-	95	-	120
LP	-	120	-	115	-	120	-	100	-	120
HP	-	115	-	115	-	120	-	95	-	120