MADSEN® Zodiac

TECHNICAL SPECIFICATIONS
Diagnostic / Clinical

Type identification

MADSEN Zodiac is type 1096 from GN Otometrics A/S

Feature table

	Quick Check	Diagnostic	Clinical
Tympanometry, auto	X	X	X
Tympanometry, manual		X	X
Probe tone, 226 Hz	X	X	X
Probe tone, 1000 Hz		X	X
Probe tone, 678 and 800 Hz			X
Reflex Screening	X	X	X
Reflex Threshold (Ipsi/Contra)		X	X
Reflex Decay		X	X
ETF-P (Perforated)			X
Admittance Recorder			X
B & G tympanograms			X

Compliance measuring system

Probe tone:	226 Hz at 85 dB SPL ± 3 dB 678 Hz at 72 dB SPL ± 3 dB 800 Hz at 70.5 dB SPL ± 3 dB 1000 Hz at 69 dB SPL ± 3 dB
Dynamic probe tone level:	The probe tone level will be compensated to accommodate varying ear canal volumes. The output level will be decreased in volumes < 1.7 ml The output level will be increased in volumes > 2.3 ml
THD:	< 1% in 2 cc
Frequency accuracy:	± 0.5%
Range:	0.2 ml to 5.0 ml ± 5% or 0.05 ml which ever is greater * 5 ml to 8.0 ml ± 15% * * The accuracy stated requires that calibration has been performed at the altitude where the device is to be put into operation

Acoustic reflex

Step size dB:	Diagnostic: 5, 10 dB Clinical: 1, 2, 5, 10 dB

Contralateral Stimulation

Pure tones:	500 Hz, 1000 Hz, 2000 Hz, 4000 Hz
Frequency accuracy:	± 0.5%
Noise:	White Noise according to IEC 1027 and ANSI S3.39 Low Pass 400 to 1600 Hz. High Pass 1600 to 4000 Hz. Roll off > 12 dB/Octave.
Range:	BBN, LPN, HPN at 50 to 110 dB SPL * ±3 dB * measured in the respective couplers
Contralateral insert phone:	
Range:	500 Hz at 50 to 115 dB HL ± 3 dB 1000 Hz at 50 to 120 dB HL ± 3 dB 2000 Hz at 50 to 120 dB HL ± 3 dB 4000 Hz at 50 to 120 dB HL ± 3 dB
THD:	< 5% for levels below 110 dB HL < 10% for levels above 110 dB HL

Ipsilateral Stimulation

Tone:	500 Hz, 1000 Hz, 2000 Hz, 4000 Hz
Frequency accuracy:	± 0.5%
Noise:	Roll off > 12 dB/Octave
Range:	BBN, LPN, HPN at 50 to 110 dB SPL * ±3 dB * measured in calibration coupler
Screening range:	BBN at 50 to 90 dB SPL * ±3 dB * measured in calibration coupler
Step size dB:	1, 2, 5, 10 dB
Decay range:	50 to 100 dB HL* * artifacts may start to occur at levels above 95 dB HL in 0.5 cc.

Lowpass noise

Contralateral TDH-39 headphone	
Band limit:	1600 Hz (nominal -3 dB point)
Slope:	The slope is between -12 and -18 dB/octave above 1600 Hz, with an additional ±6 dB tolerance. Above 8500 Hz, the spectrum level remains below -34 dB re. 1600 Hz level.
Level:	Noise level is indicated in dB HL. Tolerance ±5 dB.
Contralateral insert earphone and ipsilateral probe	
Bandwidth:	1600 Hz (nominal -3 dB point)
Slope:	The slope is between -12 and -18 dB/octave above 1600 Hz, with an additional ±6 dB tolerance. Above 8500 Hz, the spectrum level remains below -34 dB re. 1600 Hz level.
Level:	Noise level is indicated in dB HL. Tolerance ±5 dB.

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Highpass noise	
Contralateral TDH-39 headphone	
Band limit:	1600 Hz (nominal -3 dB point)
Slope:	The slope is between +12 and +18 dB/octave below 1600 Hz, with an additional ±6 dB tolerance. Below 100 Hz, the spectrum level remains below -38 dB re. 1600 Hz level.
Level:	Overall noise level is indicated in dB HL. Tolerance ±5 dB.
Contralateral insert earphone and ipsilateral probe	
Bandwidth:	1600 Hz (nominal -3 dB point)
Slope:	The slope is between -12 and -18 dB/octave above 1600 Hz, with an additional ±6 dB tolerance. Above 8500 Hz, the spectrum level remains below -38 dB re. 1600 Hz level.
Level:	Noise level is indicated in dB HL. Tolerance ±5 dB.
Air pressure system	
Range:	Normal +200 to -400 daPa/s, Extended +400 to -600 daPa/s
Pressure sweep rate:	50, 100, 200, 400, 600 daPa/s ± 20% in 20% to 80% of the total pressure range
Pressure accuracy:	± 10% or ± 10 daPa, whichever is greatest For probe tones above 226 Hz and volumes below 0.7 cc, additional ± 10 daPa can occur.
Pump measure direction:	Positive to negative or negative to positive
Safety:	Separate safety +530 daPa and -730 daPa ±70 daPa Software safety +450 daPa and -650 daPa ±70 daPa.
Graph units	
Unit of admittance graph Y-axis::	ml, cc, mmho, µl
Unit of graph X-axis:	daPa, sec
Device display	
Display:	7 inch, 15:9 WVGA
Resolution:	800 x 480 pixel
USB port connector	
Type:	USB device port
Compatible:	USB 2.0
Power supply	
External power supply	XP Power, type AFM60US24
Output:	24 V, 2.5 A
Input:	100-240 V AC, 50-60 Hz, 1.5 A
Power consumption	
	< 60 VA
Operating environment	
Temperature:	+15°C to +35°C (59°F to +95°F) **Caution** - Operation in temperatures exceeding -20°C (-4°F) or +60°C (140°F) may cause permanent damage to the device.
Air humidity:	30 to 90%, non-condensing
Air pressure:	600 hPa to 1060 hPa
Warm-up time:	< 10 min. If stored in conditions not within specified operating environment conditions, the device must warm up for 24 hour before being put into operation.
Storing and handling	
Temperature:	-20°C to +60°C (-4°F to +140°F)
Relative humidity:	< 90 %, non-condensing
Air pressure:	500 hPa to 1060 hPa
Dimensions (HxWxD)	
Stand-alone version:	190 mm x 248 mm x 261 mm (7.5" x 9.8" x 10.3")
PC-based version:	100 mm x 240 mm x 240 mm (3.9" x 9.4" x 9.4")
Probe dimensions (HxWxD)	
Quick Check probe:	28 mm x 22 mm x 100 mm (1.1" x 0.9" x 3.9")
Diagnostic probe:	10 mm x 10 mm x 25 mm (0.4" x 0.4" x 1.0")
Weight	
Stand-alone version:	2.65 kg/5.85 lb
PC-based version:	1.65 kg/3.64 lb
Optional features	
Printer:	Built-in printer. Prints 600 dot line/s on 112 mm paper width
2 cc coupler	

Calibration

Equipment should be calibrated regularly according to EN 60645-5 and ANSI S3.39

Essential performance

MADSEN Zodiac has no essential performance and accordingly, the applicable requirements are as stated in the following:

1. Impedance/admittance as defined by EN 61027 Type 1, ANSI S3.39 Type 1.
2. Basic safety as defined by IEC 60601-1.

All information required by IEC 60601-1-2:2007, #5.2.2.1#5.2.2.10 is available in the MADSEN Zodiac User Guide.

Standards	
Safety:	IEC 60601-1, UL 2601-1, CAN/CSA - C22.2 NO 601.1-90 ANSI/AAMI ES60601-1 + AMD 1, CAN/CSA-C22.2 No. 60601-1 MADSEN Zodiac: EN 60601-1, Class II, externally powered, Type BF, IPX0
EMC:	EN 60601-1-2
Impedance/Admittance:	Clinical/Diagnostic: EN 60645-5 Type 1, ANSI S3.39 Type 1 Quick Check: EN 60645-5 Type 2, ANSI S3.39 Type 2
Power supply:	Class I externally powered supply

System requirements

For system requirements, please refer to the OTOsuite data sheet.

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