

Type identification

MADSEN Zodiac Diagnostic/Clinical is type 1096 from Natus Medical Denmark ApS

Feature table

	Quick Check	Diagnostic	Clinical
Tympanometry, auto	X	X	X
Tympanometry, manual		X	X
Tymp History	X	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-I (Intact)		X	X
ETF-P (Perforated)			X
B & G tympanograms			X
Admittance Recorder			X

Compliance measuring system

Probe tone:	226 Hz at 85 dB SPL \pm 3 dB 678 Hz at 72 dB SPL \pm 3 dB 800 Hz at 70.5 dB SPL \pm 3 dB 1000 Hz at 69 dB SPL \pm 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:	\pm 0.5%
Range:	0.2 ml to 5.0 ml \pm 5% or 0.05 ml whichever is greater * 5.0 ml to 8.0 ml \pm 15% * * The accuracy stated requires that calibration has been performed at the altitude where the device is to be put into operation

Acoustic reflex

Sensitivity

Reflex Threshold and Reflex Decay:	0.01, 0.02, 0.03, 0.04 or 0.05 mmho
Reflex Screening:	0.04 mmho
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:	\pm 0.5%
Range:	BBN, LPN, HPN at 50 to 110 dB SPL * \pm 3 dB * measured in the respective couplers

	Contralateral insert phone:	Contralateral TDH-39 phone:
Range:	500 Hz at 50 to 115 dB HL \pm 3 dB 1000 Hz at 50 to 120 dB HL \pm 3 dB 2000 Hz at 50 to 120 dB HL \pm 3 dB 4000 Hz at 50 to 120 dB HL \pm 3 dB	500 Hz at 50 to 115 dB HL \pm 3 dB 1000 Hz at 50 to 120 dB HL \pm 3 dB 2000 Hz at 50 to 115 dB HL \pm 3 dB 4000 Hz at 50 to 115 dB HL \pm 3 dB
THD:	< 5% for levels below 110 dB HL < 10% for levels above 110 dB HL	< 2.5 % for levels below 110 dB HL < 5 % for levels above 110 dB HL

Ipsilateral Stimulation

Tone:	500 Hz, 1000 Hz, 2000 Hz, 4000 Hz
Frequency accuracy:	\pm 0.5%
Range:	BBN, LPN, HPN at 50 to 110 dB SPL * \pm 3 dB (* measured in calibration coupler)
Screening range:	BBN at 50 to 90 dB SPL * \pm 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 \pm 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 \pm 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 \pm 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 \pm 5 dB.

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 \pm 6 dB tolerance.
Level:	Overall noise level is indicated in dB HL. Tolerance \pm 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 \pm 6 dB tolerance.
Level:	Noise level is indicated in dB HL. Tolerance \pm 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 \pm 20% in 20% to 80% of the total pressure range
Pressure accuracy:	\pm 10% or \pm 10 daPa, whichever is greatest For probe tones above 226 Hz and volumes below 0.7 cc, additional \pm 10 daPa can occur.
Pump measure direction:	Positive to negative or negative to positive
Safety:	Separate safety +530 daPa and -730 daPa \pm 70 daPa
Graph units	
Unit of admittance graph Y-axis:	ml, cc, mmho, μ l
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
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	
Power consumption:	< 70 VA
Operating environment	
Temperature:	+15°C to +35°C (59°F to +95°F)
Air humidity:	10 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.
Storage 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 (Stand-alone)	
Printer:	Built-in printer. Prints 832 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	
Standards	
Safety:	IEC 60601-1:2005+AMD1:2012 EN 60601-1:2006+A1:2013 ANSI/AAMI ES60601-1:2005 + A1:2012 CAN/CSA-C22.2 NO. 60601-1:14 Class II, externally powered, Type BF, IPX0
EMC:	IEC 60601-1-2:2007 and EN 60601-1-2:2007 IEC 60601-1-2:2014 and EN 60601-1-2:2015
Impedance/Admittance:	Clinical/Diagnostic: EN 60645-5:2005 Type 1, ANSI S3.39 1987 (R2012) Type 1
Power supply:	Class I, externally powered supply
System requirements	
For system requirements, please refer to the OTSuite data sheet.	

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