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Technical Specifications

MT10



D-0108724-D – 2023/06



Included and optional parts

Included Parts MT10:

MT10 Tympanometer ^{1 2}
4 x 1.5V 'AA' Batteries
Instructions for Use Calibration certificate
Warranty card

Additional Parts:

4 in 1 test cavity assembly
Carrying case
Portable thermal printer
2 rolls of thermal paper
Diagnostic Suite and OtoAccess®
Infra-red USB Adapter
Additional probe tip
Additional sets of ear tips ¹

¹ Applied part according to IEC60601-1

² The probetip of MT10 is considered applied part by definition, whereas the remaining part of the device may unintentionally come into contact with the patient (clause 4.6)



General technical specifications

Tympanometry	
Instrument type	Screening tympanometer
Analysis performed	Compliance peak level (in ml). Pressure of same; Gradient (in daPa); Ear Canal Volume (ECV) @ 200 daPa
Probe tone levels and accuracy	226 Hz +/-2%; 85 dB SPL +/-2 dB over range 0.2 ml to 5 ml
Pressure levels and accuracy	+200 daPa to -400 daPa +/-10d aPa or +/-10% (whichever is larger) over range
Ear volume measurement range and accuracy	0.2 ml to 5 ml +/-0.1 ml or +/-5% (whichever is larger) over entire range
Sweep speed	Typically 200-300 daPa/sec; dependent on ear and cavity volume
Pressure limits (safety cutout)	+600 to -800 daPa
Number of samples stored	100 per tympanogram

Optional: reflex measurements	
Measurement modes	Ipsilateral optional
Reflex tone levels and accuracy	500 Hz, 1 kHz, 2 kHz, 4 kHz Frequency +/-2%, configurable over range 70 dB to 100 dB HL (4 kHz restricted to 95 dBHL) +/-2 dB, referenced to 2 ml calibration volume; Compensates for measured ear volume
Reflex measurement range and accuracy	0.01 ml to 0.5 ml +/-0.01 ml configurable in 0.01 ml steps.
Number of reflex levels	Four: 100 dB with 5 dB or 10 dB steps; 95 dB, 90 dB or 85 dB with 5 dB steps
Reflex analysis	Reflex pass/fail at each level tested; Maximum amplitude of each reflex (seen on printed report and PC report); Pressure at which reflex was performed.
Pressure used for reflex measurement	Pressure at Tympanogram peak, or 0 daPa (Always and Prompt Before Each Test modes)
Reflex level cut-off	Optionally, Auto-stop when reflex found
Reflex threshold detection	Configurable 0.01-0.50 ml in 0.01 ml increments
Reflex tone duration	0.6 seconds
Number of records stored in Patient Database	30
Data storage	Any recording can be stored once the tympanogram is viewed. Patient Initials (A-Z, 0-9, "-") must be entered before storage.
Data held	Patient Initials, Tympanogram and Reflex graphs and analysis for Left Ear and/or Right Ear, Time and Date of recording, which ears were tested, whether or not the record has been printed and /or sent to a PC, parameters printed and/or sent to a PC, parameters used for analysis, 128 bit Globally Unique Identifier (GUID).
Display mode	Records listed in reverse chronological order (latest first), with indication of date stored as described above.



Real time clock	
Time stamps	Time and date stamp applied to all recordings, and to the last calibration date
Backup power supply	>30 days without main batteries fitted

Languages	
Operating languages	English, German or French

Printing	
Supported printer	Sanibel MPTII.
Interface	Infra-red, IrDA hardware, 9600 baud.
Information printed	Space for patient and clinician's details, Tympanogram analysis parameters, Tympanogram, Reflex analysis parameters, Reflex graph, Serial Number of device, Last and Next Due Calibration dates.

Serial interface to PC	
Interface	OBEX (Object Exchange) service running on top of IrDA stack. Auto-selects rate between 9600 – 115200 baud
Information sent	Patient header, full left or right ear data

Power supply	
Battery types	4 Alkaline AA Cells or; 4 NIMH rechargeable batteries which must be larger than 2.3 Ah capacity
Warm-up period	None at room temperature
Number of recordings from one set of cells	Approx. 200 (Alkaline AA)
Auto power-off delay	90 or 180 seconds
Idle current	70 mA
Current while testing	230 mA

Physical	
Display	128x64 pixels / 8 lines of 21 characters
Dimensions	190 mm long x 80 mm wide x 40 mm high excluding probe 225 mm long including probe.
Weight (without batteries)	285 g
Weight (with batteries)	380 g

Environmental	
Operating temperature range	+15°C - +35°C
Operating humidity range	30% to 90% RH, non-condensing
Operating atmospheric pressure range	980 to 1040 mb
Storage temperature range	-20°C to +50°C
Storage humidity range	10% to 95% RH, non-condensing. Keep dry
Storage atmospheric pressure range	900 to 1100 mb

Standards conformance	
Safety	IEC 60601-1 ANSI/AAMI ES60601-1, CAN-CSA C22.2 No 60601-1
EMC	IEC 60601-1-2+AMD1:2020
Performance	IEC 60645-5, Type 2 Tympanometer
CE mark	To the EU Medical Device Directive.