

HANDHELD SCREENING TYMPANOMETER

TECHNICAL SPECIFICATIONS

DIMENSIONS AND WEIGHT

W x D x H: 4.5 in x 9 in x 2.8 in (11.5 cm x 23 cm x 7 cm)

Display: 128 x 64 px / 8 lines of 21 characters

Weight: 1.433 lb (650 g)

TYMPANOMETRY

Instrument Type: Meatus compensated tympanometer

Analysis Performed: Admittance peak level (in ml); Peak pressure of same; Gradient (in daPa); Ear canal volume (ECV) at 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 +/-10 daPa 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 daPa/sec; dependent on ear/cavity volume

Pressure Limits (Safety Cut Out): +600 to -800 daPa

REFLEX MEASUREMENTS

Measurement Modes: Ipsilateral

Reflex Tone Levels and Accuracy: 500 Hz, 1 kHz, 2 kHz, 4 kHz (+/-2%); Configurable over range 70 dB to 100 dBHL (4 kHz restricted to 95 dBHL) +/-3 dB, referenced to 2 ml calibration volume; Compensates for measured ear volume

Reflex Detection Threshold and Accuracy: 0.01 ml to 0.5 ml +/-0.01 ml configurable in 0.01 ml steps

Reflex Analysis: Reflex present/absent at each level tested; maximum amplitude of each reflex (seen on printed report & computer report); pressure at which reflex was performed

Pressure Used for Reflex Measurement: Pressure at Tympanogram peak, or 0 daPa

Reflex Tone Duration: 0.6 seconds

DATA MANAGEMENT

Number of Records Stored in Patient Database: 32 patients

Data Stored: Patient initials, tympanogram, reflex graphs, analysis, time/date, and test parameters

LANGUAGES

English, German, French, Spanish, Portuguese, or Italian

THERMAL PRINTER

Supported Printer: Sanibel MPT-II

Interface: Wired connection to cradle

INTERFACE TO COMPUTER

USB Version 1.1

ENVIRONMENTAL

Operating Temperature Range: +59° F (+15° C) to +95° F (+35° C)

Operating Humidity Range: 30% to 90% RH, non-condensing

Operating Atmospheric Pressure Range: 980 to 1040 mb, non-condensing

Transport and Storage Temperature Range: -68° F (-20° C) to +158° F (+70° C)

Transport and Storage Humidity Range: 10% to 90% RH, non-condensing

Transport and Storage Atmospheric Pressure Range: 900 to 1100 mb

POWER

Battery: NiMH rechargeable battery pack.

Interface: Wired connection to cradle

Main Power (To Cradle): 100 - 240 Vac; 50/60 Hz; 0.2 A

Number of Recordings with Full Charge: Up to 100

Auto Power-off Delay: 90 or 180 seconds

Idle Current: 70 mA

Current While Testing: 230 mA

QUALITY SYSTEM

Manufactured, designed, developed and marketed under ISO 13485 certified quality systems.

COMPLIANCE

- IEC 60601-1 (plus UL, CSA & EN deviations)
- IEC 60601-1-2
- IEC 60645-5, Type 2 Tympanometer
- CE Mark: To the EU Medical Device Directive