

Kamplex r16m - Tablet Tympanometer

GENERAL SPECIFICATIONS

DIMENSIONS AND WEIGHT

- L x W x H: 180x135x41mm
- Net weight: 570g
- Body material: self-extinguishing ABS UL 94 V0

TEST TYPES R16M

- Tympanometry, Reflexes, nr.1 Quick Test with editable protocols, High Frequency Tympanometry

TEST TYPES R16M-D

- Tympanometry, Reflexes, Decay with non acoustic monitor, nr.1 Quick Test with editable protocols, ETF for intact membrane and patulous ET, High Frequency Tympanometry

DISPLAY

- 7" TFT resistive touch screen display
- 800 by 480 resolution at 133px per inch (ppi) 262K colours

USER INTERFACE

- Intuitive icon system
- Internal patient database

REPORTS

- Data transfer to PC with Kamplex management data suite installed
- Dedicated report template

DATA TRANSFER TO PC

- Bluetooth 2.1

USB PORT

- No.1 USB host type A (pen drive connection for software upgrade)
- No.1 mini USB slave A

WINDOWS® COMPATIBLE SOFTWARE

- Kamplex MDS Management Data Suite

MAIN SYSTEM COMPONENTS

- Operative system: Microsoft® Windows® Embedded Compact
- CPU: TEGRA® 2 dual core @ 1Ghz



POWER

POWER SUPPLY

- Built-in 3,6V/3,1 Ah rechargeable lithium-ion battery
- External medical power supply/charger: Input 100 - 240 Vac / 0,3A - 50/60 Hz; Output +5 V dc / 2A

CONSUMPTION (WITH RECHARGEABLE BATTERY)

- Up to 2 hours of continuous testing
- Charge time with external medical power supply: up to 80% in 2 hours

ENVIRONMENTAL

TEMPERATURE

- Storage: -20° C up to +50° C
- Operating: +15° C up to +35° C
- Humidity: up to 90% (non condensing)
- Ambient pressure: from 700hPa up to 1060hPa

TYPANOMETRY OPERATING SPECIFICATIONS

PROBE TONE

- 226 Hz for traditional Y-curve tympanometry
- 1000 Hz for traditional Y-curve tympanometry with added "B" and "G" curve
- The probe is supplied in handheld mode

INTENSITY

- 226 Hz: 85dB SPL ± 2dB
- 1000 Hz: 75dB SPL ± 2dB
- Frequency Accuracy: ± 0,5%
- Harmonic distortion (THD): Less than 1%

ADMITTANCE MEASUREMENTS

- Compliance range at 226Hz: 0,05 up to 7ml
- Sensitivity scale: Auto Scales to appropriate range, available scale at 226Hz 1.5, 2, 5 and 7ml
- 1000 Hz: 0 to +25 mmho
- Sensitivity scale: Auto Scales to appropriate range, available scales 5, 10, 15, 20, 25 mmho

AIR PRESSURE

- Control: automatic
- Range: two selections available: +100/-200 daPa or +200/-400 daPa
- Pressure accuracy: ± 10 daPa or ± 10%
- Sweep rate: automatic adaptive speed control or fast (200 daPa/sec)
- Indicator: measured value is displayed on the graphical display
- Safety limitations: -750 up to +550 daPa

EUSTACHIAN TUBE FUNCTION

- ETF test for use with intact eardrums and patulous ET

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TYMPANOMETRY OPERATING SPECIFICATIONS

ACOUSTIC REFLEX TESTS

- Reflex test method: threshold and fixed level
- Stimulus duration: 0,5 or 1 sec.
- User selectable protocols for all test methods
- Ipsi or Contralateral stimulation for all reflex test
- Automated peak search functions available for Quick Test
- Reflex Decay: Manual
- Stimulus duration: 10 or 20 sec.

FREQUENCIES AND INTENSITY RANGES

- Ipsilateral:
 - pure tone level range (dB_{HL}) from 50 to 110
- Frequency: 500, 1000, 2000, 4000 Hz
- Accuracy: ±1%
- Harmonic distortion (THD): less than 3%
- Contralateral:
 - pure tone level range (dB_{HL}) from 50 to 115
- Frequency: 250, 500, 1000, 2000, 4000
- Accuracy: ±1%
- Calibration accuracy ±3 dB
- Level steps: 5 or 10 dB
- On/off ratio: 70 dB minimum

QUALITY SYSTEM

Manufactured, designed, developed and marketed under an ISO 13485, ISO 9001 certified quality system. Medical CE marks and FDA approval.

COMPLIANCE/REGULATORY STANDARDS

Designed, tested and manufactured to meet the European and international standards:

- MDD 93/42/EEC and update 2007/47/CEE:- Class IIa (as referred to in Annex IX, rule 10 of said MDD 93/42 EEC)
- Safety: IEC 60601-1, 3rd edition, Class II Type BF
- EMC: IEC 60601-1-2
- Impedance: IEC 60645-5 and ANSI S 3.39



STANDARD ACCESSORIES

- Probe HF
- Insert for Contra
- Kit of assorted ear tips; size from 6 mm up to 15 mm
- Calibration cavity
- Kamplex MDS Software
- Medical Power supply (100Vac – 240Vac)
- Carrying bag
- Charging Cradle
- Pen Drive (with Multilingual Quick user's handbook)
- Touch screen pen

OPTIONALS

- Headband Probe HF
- DD45 for Contra
- External USB Keyboard
- USB Videotoscope
- Wallmount kit
- Cloud datastorage account