r35c PT

FULL COMPREHENSIVE CLINICAL
COMBINED MULTIFREQUENCY MIDDLE EAR ANALYZER

PRODUCT SPECIFICATIONS

Please contact Resonance should you have any questions:
support@resonance-audiology.com

GENERAL SPECIFICATION

DIMENSIONS AND WEIGHT
- L x W x H: 370 x 290 x180 mm
- Net weight: 3.5 kg

TEST TYPES
- Tympanometry: Automatic Tympanometry, Acoustic Reflex, Reflex Decay, nr. 3 Quick tests, Acoustic Reflex Latency Test (ARLT), ETF (Intact, Perforated and Patulous), Special tests (Growth-DLI and Non-acoustic), Multifrequency Tympanometry
- Audiometry: Pure Tone test, Autothreshold, ABLB, Speech Test, Stenger, DLI, SISI, Bekesy, Tone Decay, MLB, Multifrequency, GAP, DLF

DISPLAY
- 7" TFT Color display

USER INTERFACE
- Multilingual

PRINTER
- Built-in fast thermal printer with paper width: 112 mm supplied as standard part

REPORTS
- Printed on thermal printer
- .pdf report created directly from the device and stored on USB Pen drive with possibility to add patient data and tests comments via the USB Keyboard (optional)
- Data transfer to PC using Resonance Management Data Suite

"CHILDREN" FEATURE
- To help keep the child distracted while running screening "Quick Check" or "Tympanometry HF", a series of animated images appears on the color display

DATA TRANSFER TO PC
- Via cable through USB port

COMMUNICATION PORT
- Nr.1 USB host type A
- Nr.1 USB slave type B

WINDOWS® COMPATIBLE SOFTWARE
- Resonance MDS Management Data Suite

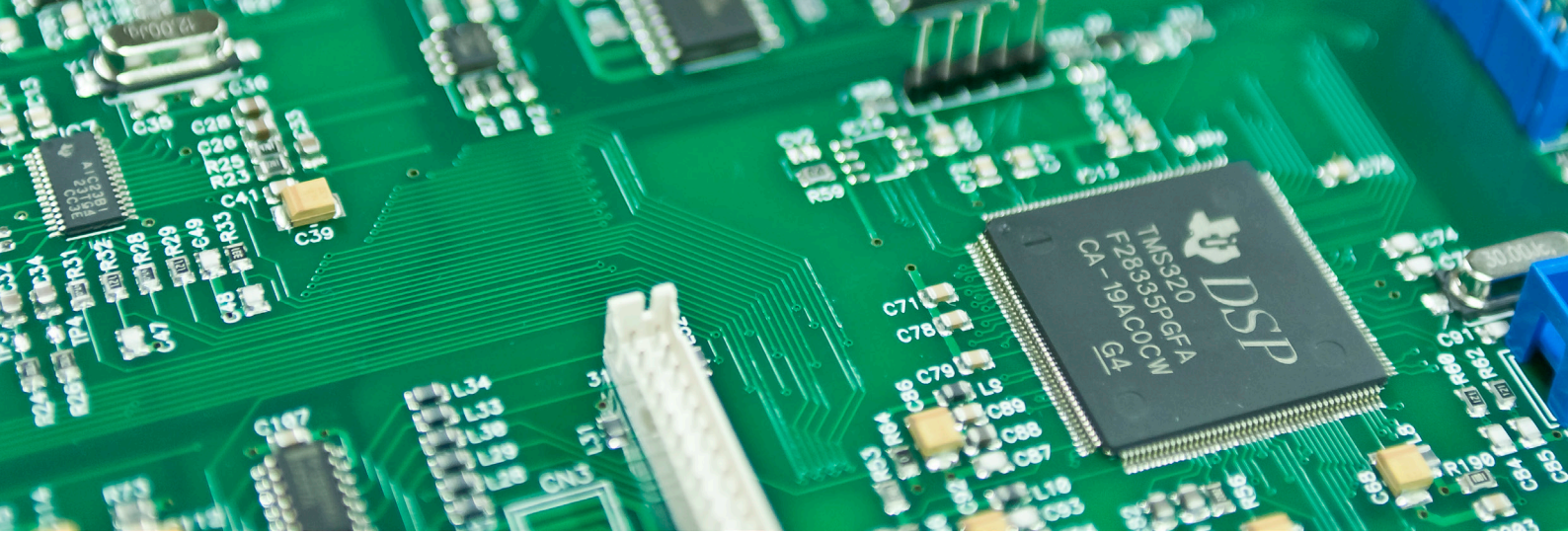
POWER

POWER SUPPLY
- 110 - 240 V AC 50/60 Hz 40 VA
- Fuses: 2 x T 1 A L 250 V

CONSUMPTION
- Max current 0.15 A
- Power consumption 40 VA

ENVIRONMENTAL

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



TYMPANOMETRY OPERATING SPECIFICATIONS

PROBE TONE
- 226 Hz for Admittance (Y) curve tympanometry
- 1000 Hz for Admittance (Y) curve tympanometry with added Susceptance (B) and Conductance (G) curves

INTENSITY
- 226 Hz: 85 dB SPL ± 2 dB
- 678, 800 and 1000 Hz: 75 dB SPL ± 2 dB
- Frequency Accuracy: ± 0.5%
- Harmonic distortion: Less than 1%

ADMITTANCE MEASUREMENTS
- Compliance range at 226 Hz: 0.05 up to 7 ml
- 678, 800 and 1000 Hz: 0 to +25 mmho
- Sensitivity scale: Autoscale to appropriate range; available scale at 226 Hz: 1.5, 2, 5 or 7 ml
- Sensitivity scale HF: Autoscale to appropriate range, available scales at 678, 800 and 1000 Hz: 5, 10, 15, 20, 25 mmho

AIR PRESSURE
- Control: Automatic and Manual
- Range: from +400 up to -600 daPa adjustable in 50 daPa steps
- Pressure accuracy: +/- 10 daPa or +/- 10%
- Sweep rate: 50, 100, 200, 300 daPa/sec and automatic
- Indicator: Measured value is displayed
- Safety limitations: -800 up to +600 daPa

EUSTACHIAN TUBE FUNCTION
- ETF test for use with both intact and perforated eardrums
- Available also test for patulous tympanic membrane

ACOUSTIC REFLEX TESTS
- Reflex test method: Threshold , Automatic, Manual
- Stimulus duration: 0.5, 1 or 2 sec.
- User selectable protocols for all test methods
- Ipsi or Contralateral stimulation for all reflex test
- Automated peak search functions available for all test methods
- Manual Reflex: Pump manual control of all stimuli
- Reflex Decay: Threshold, Automatic, Manual
- Stimulus duration: 10 or 20 sec.
- ARLT: Threshold, Automatic, Manual
- Stimulus duration: 1 sec. fixed
- Non-acoustic: 10/20 sec.

FREQUENCIES AND INTENSITY RANGES
Ipsilateral:
- Pure tone level range (dB HL) from 50 to 110
- Noise level range (dB SPL) from 50 to 100
- Frequency: 500, 1000, 2000, 3000, 4000 Hz
- Noise: BBN, HP or LP
- Frequency accuracy: ±1%
- Harmonic distortion (THD): less than 3%

Contralateral:
- Pure tone level range (dB HL) from 50 to 120
- Noise level range (dB SPL) from 50 to 115
- Frequency: 250, 500, 1000, 2000, 3000, 4000, 6000, 8000 Hz
- Noise: BBN, HP or LP
- Frequency accuracy: ±1%
- Calibration accuracy ±3 dB
- Level steps: 1, 2, 5 or 10 dB
- On/Off ratio: 70 dB minimum

AUDIOMETRY OPERATING SPECIFICATIONS

RANGE
- Frequency range:
  125 - 8000 Hz (with DD45)
  125 - 12500 Hz (with HDA280)
  250 - 8000 Hz (with B71W)
- Range stimuli level -10 up to 120 dB HL

ACCURACY
- Frequency < 0.5%
- Distortion < 1%
- Attenuator linearity 1 dB per 5 dB step, max 3 dB whole range

TYPE OF SIGNALS
- Pure tone: sine wave 125 to 8KHz signal (to 12.5 KHz for HDA280 phones)
- Warble: ± 5% frequency sine wave modulated, modulation: sine wave 5 Hz
- Narrow band noise: 24 dB/oct filtered noise
- Speech noise: 1 kHz 12 dB/oct filtered noise
- White noise
- External signal
- External mike
- Speech material recorded on SD card
- Master Hearing Aid: 1 KHz 6, 12, 18, 24 dB High pass filters
- On/Off rise – fall time: 40msec

OUTPUT TRANSDUCERS
- ACR, ACL: 10 ohm DD45 matched pair earphone, alternatively HDA280 Sennheiser. IP30 Insert earphones (optional)
- BC: B71W Radioear; B81 (optional)
- INSERT: Insert transducer
- Free field output: 600 ohm impedance

STIMULUS PRESENTATION MODALITY
- Presentation: Normal, Reverse, Extended (present tone for 1 second from 20 dB below the maximum level)
- Modality: Continuous, Pulsed (rate 0.5, 1 and 2 Hz), Alternated (ABLB and MLB 0.5, 1 and 2 Hz)
- DLI increment levels:
  0.1 dB in steps of 0.1 dB up to 1.0 dB; 1.5, 2, 3, 4, 5 dB
- DLI increment recurrence rates: 0.5 Hz, 1 Hz, 2 Hz
- SISI increment recurrence rates:
  0.2 Hz, 0.5 Hz, random. Time on 300 ms
- SISI increment level: 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5 dB
- Bekesy: mode sweep and fixed; Continuous, Pulsed and LOT; exam duration 30 sec and 60 sec.

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 its revised versions: Class IIa (as referred to in Annex IX, rule 10 of said MDD 93/42 EEC)
- Safety: IEC 60601-1, 3rd edition, Class 1 Type B
- EMC: IEC 60601-1-2
- Impedance: IEC 60645-5/ANSI S.3.39 Type 1
- Audiometer: to IEC 60645-1; IEC 60645-2 and ANSI S3.6, Type 1A

STANDARD ACCESSORIES
- Probe HF
- Headband and probe handle
- Probe cleaning tool kit
- DD45 for Contra
- Kit of assorted ear tips; size from 6 mm up to 15 mm
- Calibration cavity with probe holder
- Built-in fast thermal printer
- Thermal paper roll
- Device dust cover
- Multilingual Quick user's handbook
- Pen Drive
- Resonance® MDS software with NOAH® module included (demo version)
- Power supply cable (110 – 220 V)
- Spare fuse
- DD45, ADC or HDA280 headset for audiometry testing
- B71W bone conductor
- Patient microphone (talk back)
- Patient response pushbutton
- SD-card with Multilanguage speech material
- Insert-Transducer (for bone conductor masking and contralateral reflex)
- Operator headset with microphone and speaker (talk over and monitor)

OPTIONALS
- Kit of assorted silicone ear tips "MS" shape size from 8 mm up to 16 mm
- External USB Keyboard
- Carrying bag
- TDH39 for Contra
- TDH39 headset
- Pediatric Headset (AC or BC)
- ADC Audiocups Noise reducing headset enclosures
- Goose-neck microphone
- IP30 insert earphones
- B81 High Output Bone Conductor
- Silent cabin cables
- Free field loudspeaker
- Additional patient response pushbutton
- MDS software license
- Quick-SIN test

Datasheet: REV OCTOBER 2017