PURE TONE CLINICAL AUDIOMETER

hearTest is a world-first certified digital audiometry solution that uses a tablet linked to a cloud data management platform for comprehensive audiometry.

hearTest

COMPLIES TO INTERNATIONAL STANDARDS

- **IEC 60645-1 -** Equipment for pure tone audiometry
- **ANSI S3.6 -** Specification for audiometers
- **ISO 8253-1 -** Pure tone air conduction audiometric test methods
- **ISO 389 series -** reference threshold levels for the calibration of audiometric equipment

United States of America	29 CFR PART 1910.95
Australia and New Zealand	AS/NZS 1269.4
South Africa	SANS 10083 SANS 10154-1

REGISTRATIONS AND CERTIFICATIONS

UNITED STATES
(FDA COMPLIANT)

Registration no: 3014337591

EUROPE
(CE CERTIFIED)

Certification no: G10 105532 0003 Rev. 00

AUSTRALIA
(TGA CERTIFIED)

ARTG identifier: 321961

BENEFITS & FEATURES

CLINICALLY VALID TESTS

Evidence-based, validated audiometer calibrated to ISO/ANSI/SANS standards.

AUDIOGRAM RESULT

Audiogram with pure tone average and degree of loss classification.

COST-EFFECTIVE

Accurate testing at a fraction of the cost.

ENVIRONMENTAL NOISE WARNING

Pre-test and real-time noise monitoring for environmental noise concerns.

TIME-EFFICIENT

Automated testing within minutes and pre-programmed test sequences for improved efficiency.

EASY-TO-USE, ADJUSTABLE PROTOCOLS

Best practice pure tone audiometry protocols for varied contexts.

EXTENDED HIGH FREQUENCY TESTING*

Determining threshold shift in the high frequency range.

*Available with RadioEar DD450 headphones and the addition of the DAC, at an additional cost.

CONDITIONING

Pre-test conditioning functionality to facilitate the testing process with talk-forward features.

NARROW BAND MASKING

Automatic masking feature across all frequencies.

QUALITY CONTROL

Smart features to ensure on-site quality control and test reliability.

DIGITAL DATA MANAGEMENT

Patient, test and facility data consolidated instantly on a secure online database.

INTEGRATION OF VIDEO-OTOSCOPY

hearScope integrates seamlessly to include eardrum images on patient test results.

PATIENT SIGNATURE

On-screen capture of patient signature which is included on hearing result report.

DOWNLOADABLE REPORTS

Hearing test results available for download from mHealth Studio Cloud.

Available in **English, Spanish & French***

*hearTest can be provided in these languages on request.

CE 0123

HARDWARE

DIAGNOSTIC HARDWARE SET A
Test down to 10 dB HL

Samsung Tab A, Sennheiser HD 280 Pro headphones & carry case

DIAGNOSTIC HARDWARE SET B
Test down to -10 dB HL

Samsung Tab A, Sennheiser HD 280 Pro headphones, v3 DAC & carry case

DIAGNOSTIC HARDWARE SET C
Test down to -10 dB HL

Samsung Tab A, RadioEar DD450 headphones, v3 DAC & carry case

PROTOCOLS

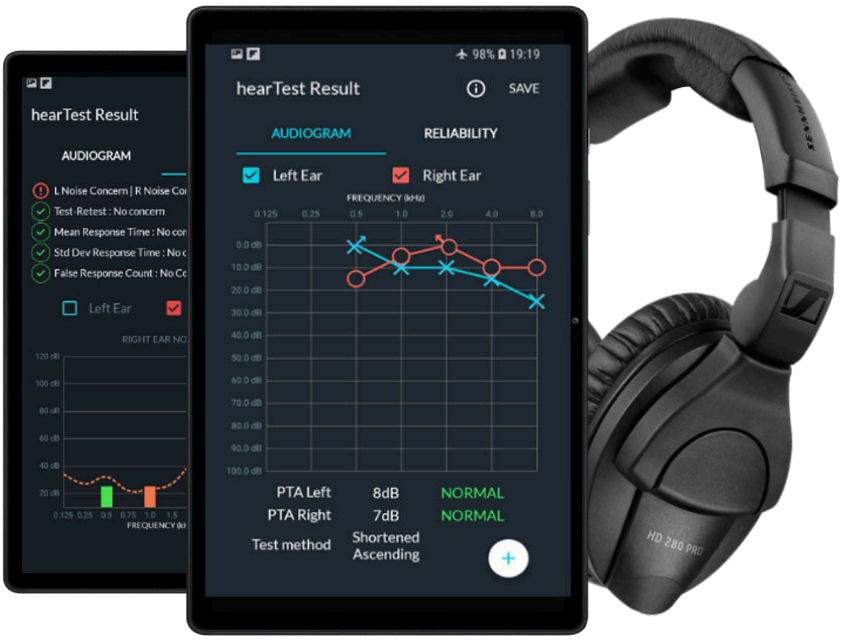
Frequency range	• Set A: 125 - 8,000 Hz • Set B: 125 - 8,000 Hz • Set C: 125 - 16,000 Hz
Testing protocol	• Custom protocol setup possible • Default protocol (500, 1,000, 2,000, 4,000, 8,000 Hz) • Daily check protocol (500, 1,000, 2,000, 4,000, 8,000 Hz)
Threshold seeking methods	• Shortened Ascending (ISO 8253-1:2010) • Intelligent Optimisation (Fast) • Intelligent Optimisation (Fastest)
Adjustable minimum testing intensity	• Set A: Minimum 10 dB HL • Set B: Minimum - 10 dB HL • Set C: Minimum - 10 dB HL
Adjustable response window after tone	1,500 ms - 4,000 ms
Adjustable maximum pre-tone waiting period	1,500 ms - 4,000 ms
Optional settings	• Test paradigm: self-test / test operator mode • Narrow band automated masking enabled (with tones above 40 dB)

TECHNICAL SPECIFICATIONS AND PERFORMANCE

Carry case dimensions • Includes a handle • Includes a shoulder strap	• 35 cm x 27 cm x 12 cm • 13.77 inch x 10.23 inch x 4.72 inch
Net weight (contents: tablet, headphones, and charger)	< 1 kg
Shipping weight (quantity=1)	2 kg
Safety and design standards	• IEC 60645-1 • IEC 60601-1-2 • IEC 62304
Medical device class	Class IIa
Degree of protection (electric shock)	Type B applied part
Warm up time	None
Protection against ingress (IP): • Tablet • Headphones	• IP 68 • Not specified
Usage environment	Professional healthcare environment
Operating temperature Humidity Ambient pressure	• 15 to 35 °C • 30 to 90 %RH Non-condensing • 98 to 104 kPa
Shipping and storage conditions Temperature Humidity Ambient pressure	• 0 to 30 oC • 30 to 60% Non-Condensing • 70 to 106 kPa

TONE SPECIFICATIONS

Type	Pure tone
Frequencies	125, 250, 500, 750, 1,000, 1,500, 2,000, 3,000, 4,000, 6,000, 8,000 Hz 10,000, 12,500, 16,000 Hz
Rise / fall time	35 ms (-20 dBFS to -1 dBFS and vice versa)
Intensity range	Set A: Sennheiser HD 280 Pro 125 Hz 65 dB HL 250 Hz 80 dB HL 500 to 3000 Hz 90 dB HL 4000 Hz 85 dB HL 6000 Hz 80 dB HL 8000 Hz 70 dB HL *Note: ranges paired Tab A (T510/5) & Tab A7 Set B: Sennheiser HD 280 Pro 125 Hz 75 dB HL 250 Hz 90 dB HL 500 Hz 95 dB HL 750 to 4000 Hz 100 dB HL 6000 Hz 95 dB HL 8000 Hz 90 dB HL *Note: ranges paired with USB DAC v3 Set C: RadioEar DD450 125 Hz: 75 dB HL 250, 6,000 and 8,000 Hz: 90 dB HL 500 to 4,000 Hz: 95 dB HL 10,000 Hz: 80 dB HL 12,500 Hz: 75 dB HL 16,000 Hz: 55 dB HL *Note: ranges paired with USB DAC v3



HEADPHONE SPECIFICATIONS

		HD 280 Pro [dB] *Referenced to 0 dB HL testing from 500 Hz and up		DD450 [dB] *Referenced to 0 dB HL testing from 500 Hz and up	
	Frequency [Hz]	MPANL	RETSPL	MPANL	RETSPL
RETSPL: (for IEC 60318-1 ear simulator)	125	41	37.2	64	30.5
	250	30	13.5	51	18
	500	27	6.8	38	11
	750	-	1.8	-	6
	1,000	31	1.4	38	5.5
	1,500	-	3.7	-	5.5
	2,000	44	1.9	37	4.5
	3,000	-	-3.9	-	2.5
	4,000	43	2.2	51	9.5
	6,000	-	16	-	17
	8,000	32	29.4	56	17.5
	10,000	-	-	-	22
	12,500	-	-	-	27.5
	16,000	-	-	-	56