CE 0123

SMARTPHONE AUDIOMETER

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

hearTest

HEARTEST

COMPLIES TO INTERNATIONAL STANDARDS

- **IEC 60645-1 -** Equipment for pure-tone audiometry (type 4 audiometer)
- **ANSI S3.6 -** Specification for audiometers (type 4 audiometer)
- **ISO 8253-1 -** Pure-tone air conduction audiometric test methods
- **ISO 389 series -** Reference zero 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)

Registration nr: 3014337591

EUROPE
(CE)

LRQ00001888/B

AUSTRALIA
(TGA)

ARTG identifier: 321961

FEATURES

CLINICALLY VALID TESTS

Evidence-based, validated audiometer calibrated to ISA/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*

Test up to 16 000Hz

* Available with specific headphones at an additional software 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

Onscreen capture of patient signature which is included on hearing result report.

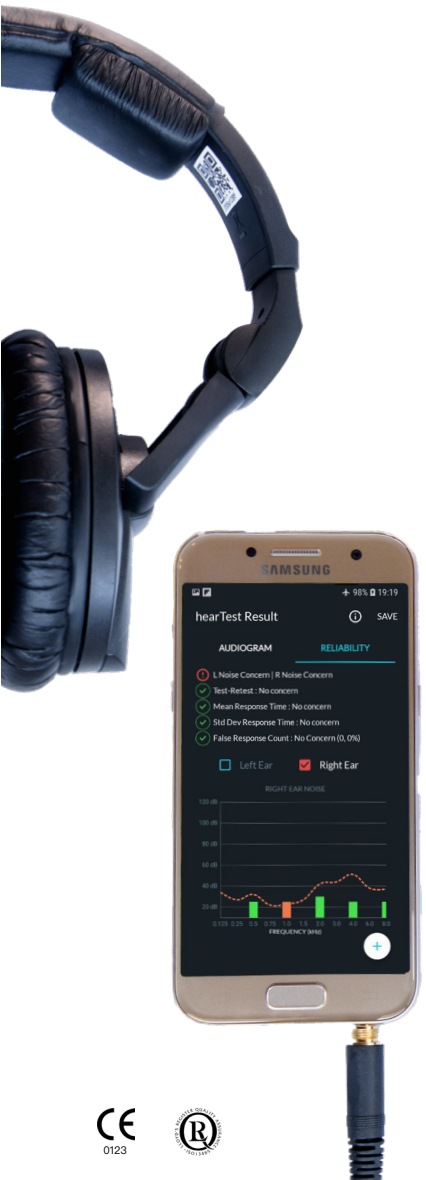
DOWNLOADABLE REPORTS

Hearing test results available for download from mHealth Studio Cloud

PROTOCOLS

Frequency range	125 - 16 000 Hz (Headphone specific)
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)
Testing method	• Shortened Threshold Ascending • Intelligent Optimised Shortened Threshold Ascending • Fast 5 • Fast 10
Adjustable minimum testing intensity	Sennheiser HD 280 Pro, Minimum 0dB Sennheiser HDA 300, Minimum 0dB RadioEar IP30, Minimum -10dB
Adjustable maximum pre-tone waiting period	1 500ms - 4000 ms
Adjustable response window after tone	1 500ms - 4000 ms
Optional settings	• Test paradigm - Self-test / test operator mode • Narrow band masking enabled (Occurs when tone above 40dB)

TECHNICAL SPECIFICATIONS AND PERFORMANCE



Dimensions	26cm x 18cm x 9.5cm
Net weight (contents: smartphone, headphones, and charger)	< 1 kg
Shipping weight	2 kg
Power source	Internally Powered
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): - Smartphone - 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
Storage temperature	-20 to 50 °C

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TONE

Type	Pure Tone with optional masking
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 000Hz (EHF with HDA300 headphones only)
Rise / Fall time	35 ms (-20 dBFS to -1 dBFS and vice versa)
Intensity range	**Sennheiser HD280 Pro (circumaural):** 0 to 90 dB HL from 125 - 8 000 Hz **Sennheiser HDA300 (circumaural):** 0 to 90 dB HL from 125 Hz - 16 000 Hz (4000 Hz - 85 dB HL, 6 000 Hz - 80 dB HL, 8 000 Hz - 75 dB HL, 10 000 Hz - 65 dB HL, 12 500 Hz - 60 dB HL, 16 000 Hz - 40 dB HL) **RadioEar IP30 (insert earphones):** -10 to 90 dB HL from 125 - 8 000 Hz (6000 Hz - 80 dB HL; 8 000 Hz - 70 dB HL)
Accuracy	>99%
SPL accuracy	Within 3 dB across all frequencies

HEADPHONE SPECIFICATIONS

		HD 280 Pro		HDA 300[1]		IP30 P5011	
		Circumaural		Circumaural		Insert (with 3M Peltor earmuff)	
	Frequency [Hz]	MPANL	RETSPL	MPANL	RETSPL	MPANL	RETSPL
RETSPL: (determined using an IEC 60318-1 ear simulator)	125	41	37.2	48	26.2	83	28
	250	30	13.5	37	20.1	70	21.5
	500	27	6.8	22	8.6	57	9.5
	750	-	1.8	-	5.1	50	-
	1000	31	1.4	23	2.7	44	5.5
	1 500	-	3.7	-	3.2	50	-
	2 000	44	1.9	42	0.5	55	11.5
	3 000	-	-3.9	-	-1.6	60	-
	4 000	43	2.2	46	0.1	56	15
	6 000	-	16	-	20.9	83	16
	8 000	32	29.4	32	23.1	70	15.5
	10 000	-	-	-	18.5	-	-
	12 500	-	-	-	27	-	-
	16 000	-	-	-	47.7	-	-

MPANL - maximum permissible ambient noise level for testing down to 0 dB
RETSPL - reference equivalent threshold sound pressure level

1 Sennheiser (2013). HDA 300 - Reference of measurements. https://assets.sennheiser.com/global-downloads/file/4745/HDA300_References_1018.pdf

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