CE 0123   LLOYD'S REGISTER QUALITY ASSURANCE · ISO 13485   **FDA**

PURE TONE AUDIOMETER FOR OCCUPATIONAL HEALTH

hearTest Occ Health is a certified tablet-based audiometry solution with cloud data management for seamless occupational hearing care.

This portable and robust solution provides the same attenuation as a single-wall sound booth.

hearTest™
occ health

COMPLIES TO INTERNATIONAL STANDARDS

hearTest
OCC HEALTH

- **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

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

REGISTRATIONS & CERTIFICATIONS

**UNITED STATES
(FDA REGISTERED)**

Registration nr: 3014337591

**EUROPE
(CE CERTIFIED)**

LRQ00001888/B

**AUSTRALIA
(TGA CERTIFIED)**

ARTG identifier: 321961

FEATURES & BENEFITS

OCCUPATIONAL HEALTH REPORTING

Advanced occupational health reports for medical and legal requirements. Saves time and paperwork.

PLH CALCULATION

Percentage of hearing loss (PLH) calculated in-app and in the cloud.

STANDARD PROTOCOLS SPECIFIED PER TERRITORY

Best practice audiometry protocols, with flexible customisation.

BASELINE AND STS REPORTING

Baseline audiogram with standard threshold shift (STS) reporting.

AMBIENT NOISE ATTENUATION

Insert earphones with ear defenders, offer superior noise attenuation equivalent to a single-wall sound booth.

RELIABILITY WARNINGS

False response count and response times referenced to normative data.

ENVIRONMENTAL NOISE WARNING

Real-time monitoring of noise to alert users of noise concerns.

SIGNATURE

Persons being tested can sign for consent on the screen using the digital interface.

MOBILE SOLUTION

Tablet-based solution offers robust portability. Advanced test results viewed in-app and in the cloud.

INTEGRATION OF VIDEO-OTOSCOPY

hearScope integrates seamlessly to include eardrum images on patient records.

Available in **English, Spanish & French**

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HARDWARE

INSERT HARDWARE

Samsung Tab A7, IP30 insert earphones, ear defenders, 500 disposable foam tips in various sizes, v3 DAC & carry case

OVER EAR HARDWARE

Samsung Tab A7, RadioEar DD450 headphones, v3 DAC & carry case

PROTOCOLS

Frequency range	• Insert: 125 - 8,000 Hz • Over ear: 125 - 16,000 Hz
Testing protocol	Shortened Threshold Ascending method
Pre-tone waiting period	Randomised between 1,500 - 4,000 ms
Person response window after tone	Adjustable between 1,500 - 4,000 ms
Optionals	Self-test / test operator mode
Additional features	• On-screen patient signature • Add otoscopy images to test

OCCUPATIONAL HEALTH PROTOCOLS PRE-PROGRAMMED AND AVAILABLE FOR SELECTION

- OSHA - Baseline and annual audiometric testing
- NAL 80 - Baseline, periodic and exit audiometry protocols
- SANS 10083 - Occupational health baseline, monitoring and exit protocol

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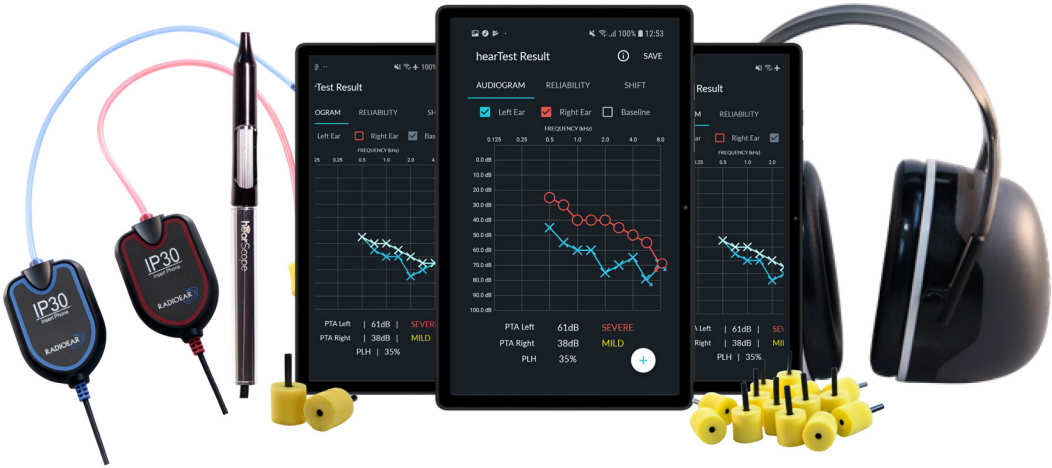
TECHNICAL SPECIFICATIONS AND PERFORMANCE

Carry case dimensions • Includes a handle • Includes a shoulder strap	• 35 cm x 26 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	• IP68 • 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

TONE SPECIFICATIONS

Type	Pure tone
Frequencies *Headphone dependant	125, 250, 500, 750, 1000, 1,500, 2,000, 3,000, 4,000, 6,000, 8,000, 10,000, 12,500, 16,000
Rise / fall time	35 ms
Total harmonic distortion	<2%
Intensity range *With DAC: From -10 dB HL	Insert: 125 Hz: -10 to 80 dB HL 250 Hz: -10 to 90 dB HL 500 to 4,000 Hz: -10 to 100 dB HL 6,000 and 8.000 Hz: -10 to 80 dB HL Over ear: 125 Hz: -10 to 75 dB HL 250 Hz: -10 to 90 dB HL 750 to 4,000 Hz: -10 to 95 dB HL 6,000 and 8,000 Hz: -10 to 90 dB HL 10,000 Hz: -10 to 80 dB HL 12,500 Hz: -10 to 75 dB HL 16,000 Hz: -10 to 55 dB HL

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HEADPHONE SPECIFICATIONS

RETSPL: (determined using an IEC 60318-1 ear simulator)	Frequency [Hz]	IP30 P5011 [dB] *Referenced to 0 dB HL testing from 500 Hz and up	Insert Insert earphones covered by 3M circumaural ear defenders	DD450 [dB] *Referenced to 0 dB HL testing from 500 Hz and up	Over ear
		MPANL	RETSPL	MPANL	RETSPL
	125	83	28	64	30.5
	250	70	17.5	50	18
	500	57	9.5	38	11
	750		6		6
	1,000	50	5.5	38	5.5
	1,500		9.5		5.5
	2,000	44	11.5	37	4.5
	3,000		13		2.5
	4,000	55	15	51	9.5
	6,000		16		17
	8,000	56	15.5	56	17.5
	10,000				22
	12,500				27.5
	16,000				56

Attenuation similar to a single-wall sound booth