

CE
0088



hearTest™ is a world-first certified digital audiometry solution using a smartphone and cloud data management for comprehensive occupational healthcare.

hearTest™ occupational health solution provides the same attenuation as a single-wall sound booth.

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

HEARTEST REGISTRATIONS AND CERTIFICATIONS



UNITED STATES
(FDA REGISTERED)

Registration nr: 3014337591



EUROPE
(CE)

LRQ00001888/B



AUSTRALIA
(TGA)

ARTG identifier: 321961

HEARTEST OCC HEALTH FEATURES



AMBIENT NOISE ATTENUATION

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



STANDARD PROTOCOLS SPECIFIED PER TERRITORY

Best practice audiometry protocols, with flexible customisation.



RELIABILITY WARNINGS

False response count and response times referenced to normative data.



PLH CALCULATION

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



BASELINE AND STS REPORTING

Baseline audiogram with standard threshold shift reporting.



INTEGRATION OF VIDEO-OTOSCOPY

hearScope integrates seamlessly to include eardrum images on patient records.



SIGNATURE

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



OCCUPATIONAL HEALTH REPORTING

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



ENVIRONMENTAL NOISE WARNING

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



MOBILE SOLUTION

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

PROTOCOLS

Frequency Range	125 - 8000 Hz
Testing protocol	Shortened Threshold Ascending method
Pre-tone waiting period	Randomised between 1500 - 4000ms
Person response window after tone	Adjustable between 1500 - 4000ms
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

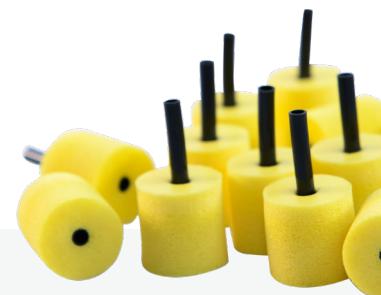
TECHNICAL SPECIFICATIONS AND PERFORMANCE

Dimensions	26cm x 18cm x 9.5cm
Net Weight (Contents: Smartphone, headphones, and charger)	< 1 kg
Shipping weight (Quantity=1)	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 oC 30 to 90 %RH Non-Condensing 98 to 104 kPa
Storage temperature	-20 to 50 oC



TONE

Type	Pure Tone
Frequencies	125, 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000 Hz
Rise / Fall time	35 ms (-20 dBFS to -1 dBFS and vice versa)
Intensity Range	0 - 95 dB HL (6000 Hz - 80 dB HL; 8000 Hz - 70 dB HL)



HEADPHONE SPECIFICATIONS

RETSPL: (determined using an IEC 60318-1 ear simulator)		HDA 300 ¹ [dB]		IP30 P5011	
		Circumaural		Insert (with 3M Peltor earmuff)	
	Frequency [Hz]	Passive attenuation	RETSPL	Passive attenuation	RETSPL
	125	12.4	26.2	34	28
	250	12.7	20.1	36	21.5
	500	9.4	8.6	42	9.5
	1000	12.8	2.7	41	5.5
	2000	15.1	0.5	39	11.5
	4000	28.8	0.1	50	15
	6000	-	20.9	50	16
	8000	26.2	23.1	44	15.5
				Attenuation similar to a single-wall sound booth	



**IP30 P5011 &
3M PELTOR EARMUFF**

SENHEISER HDA 300



¹Sennheiser (2013). HDA 300 - Reference of measurements. https://en-ie.sennheiser.com/global-downloads/file/4745/HDA300_References.pdf