
CE 0123

**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<br>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 COMPLIANT)

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***

**hearTest Occ Health can be provided in these languages on request.*

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# HARDWARE

### INSERT HARDWARE

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

### OVER EAR HARDWARE

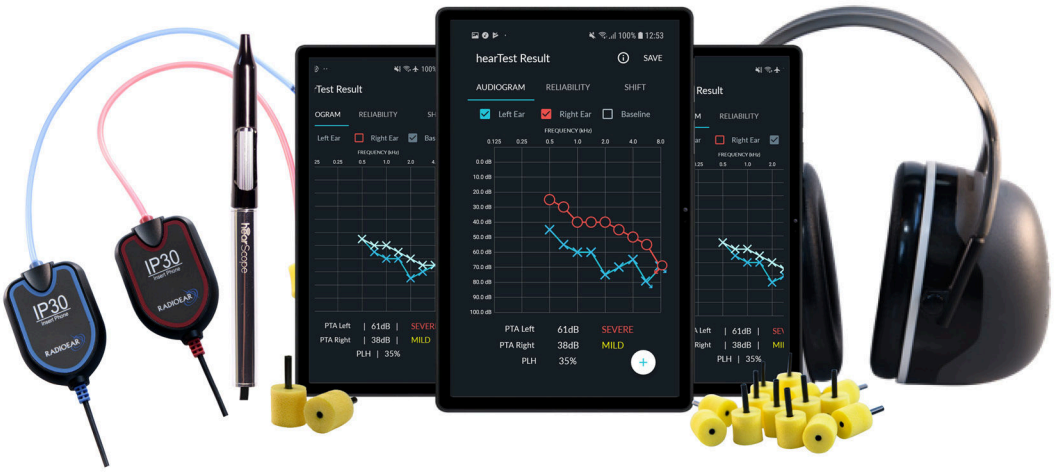
Samsung Tab A, RadioEar DD450 headphones, v3 DAC & carry case

# PROTOCOLS

| | |
|---|---|
| Frequency range | • Insert: 125 - 8,000 Hz<br>• 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<br>• 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

| | |
|---|---|
| Carry case dimensions<br>• Includes a handle<br>• Includes a shoulder strap | • 35 cm x 26 cm x 12 cm<br>• 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<br>• IEC 60601-1-2<br>• IEC 62304 |
| Medical device class | Class IIa |
| Degree of protection (electric shock) | Type B applied part |
| Warm up time | None |
| Protection against ingress (IP):<br>• Tablet<br>• Headphones | • IP68<br>• Not specified |
| Usage environment | Professional healthcare environment |
| Operating temperature<br>Humidity<br>Ambient pressure | • 15 to 35 °C<br>• 30 to 90 %RH Non-Condensing<br>• 98 to 104 kPa |
| Shipping and storage conditions<br>Temperature<br>Humidity<br>Ambient pressure | • 0 to 30 °C<br>• 30 to 60% Non-Condensing<br>• 70 to 106 kPa |

# TONE SPECIFICATIONS

| | |
|---|---|
| Type | Pure tone |
| Frequencies<br>**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<br>**With DAC: From -10 dB HL* | Insert:<br>125 Hz: -10 to 80 dB HL<br>250 Hz: -10 to 90 dB HL<br>500 to 4,000 Hz: -10 to 100 dB HL<br>6,000 and 8.000 Hz: -10 to 80 dB HL<br><br>Over ear:<br>125 Hz: -10 to 75 dB HL<br>250 Hz: -10 to 90 dB HL<br>750 to 4,000 Hz: -10 to 95 dB HL<br>6,000 and 8,000 Hz: -10 to 90 dB HL<br>10,000 Hz: -10 to 80 dB HL<br>12,500 Hz: -10 to 75 dB HL<br>16,000 Hz: -10 to 55 dB HL |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# HEADPHONE SPECIFICATIONS

| | | IP30 P5011 [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 | |
|---|---|---|---|---|---|
| | | Insert Insert earphones covered by 3M circumaural ear defenders | | Over ear | |
| | Frequency [Hz] | MPANL | RETSPL | MPANL | RETSPL |
| **RETSPL:** (determined using an IEC 60318-1 ear simulator) | 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 | | | |