# heoroAE

## hearOAE is FDA cleared

## NextGen OAE Testing Digital precision, effortless simplicity



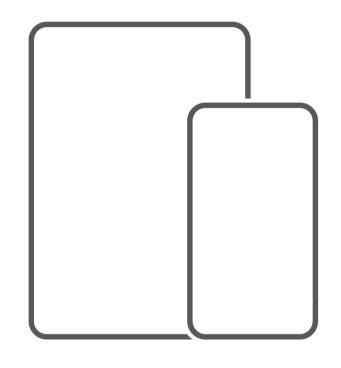
Lead the way in the auditory healthcare landscape, with hearOAE - an innovative app-based OAE solution that operates on smartphones and tablets.

hearOAE creates a seamless experience for OAE testing in various settings and is available as either:

A DP and TE screening only device, or
A DP and TE screening and diagnostic device.

In addition, the cloud data management integration enables you to access your data securely from anywhere, any time.

## Features and benefits for precision OAE testing



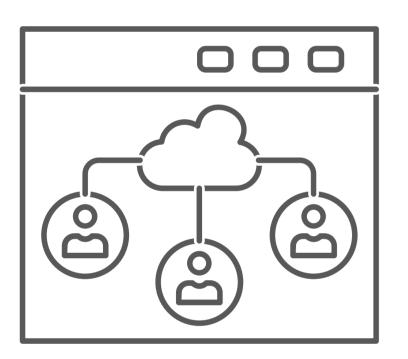
## Smart device compatibility

Unlock convenience with our intuitive smartphone- and tablet-based OAE device with Bluetooth<sup>®</sup> functionality.



#### **Multi-functionality**

Perform OAE, pure tone and digits-in-noise tests with the same hearX<sup>®</sup> smart device.



## Cloud-based data management

Simplify your workflow with real-time, secure cloud-based referral and data management, monitoring and reporting, included free of charge during your first year.

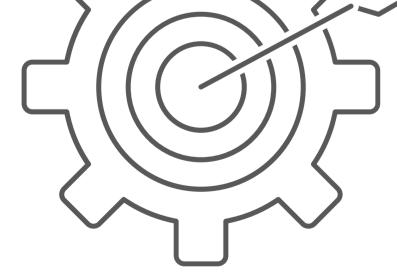


#### Ease of use

Conduct patient-focused testing with our intuitive app design, easy navigation, and clearly-presented test results.



Rapid and non-invasive screening method to determine cochlear function which can quickly provide objective measurements, allowing for efficient screening of large groups, such as newborns or school children.





## **Compliance and security**

hearX<sup>®</sup> is SOC 2<sup>®</sup> compliant, which validates our commitment to critical security standards to secure and protect customer data.





## hearOAE components

1.	Use your Android d	evice to connect the app to the hearOAE device via Blueto	oth <sup>®</sup> .
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2. Use the set protocols or create your own TEOAE and DPOAE testing protocols with the app.

## hearOAE app

- 3. Verify probe functionality with the 'Probe Check' feature.
- Control TEOAE and DPOAE tests, including pre-test functions like 'Probe Fit' and in-ear 4. calibration.
- Get instant, clear feedback through tables, figures, and graphs during and after the test. 5.
- The hearOAE device contains hardware and software that can generate and process signals 1.

hearOAE device	<ul> <li>and measure the results.</li> <li>2. It also contains: <ul> <li>A rechargeable Lithium-Ion battery to power the device,</li> <li>3 light indicators to display the device status.</li> <li>A push button with a power symbol for easy on/off control.</li> </ul> </li> <li>3. Test results are communicated to the smart device via Bluetooth, and displayed on the smart device screen.</li> </ul>
Probe	<ol> <li>The probe contains speakers and a microphone that produce the test stimuli and measure the sound pressure level (SPL) presented in the ear canal.</li> <li>The probe also has a removable probe coupler with ear tips that fit onto the coupler.</li> </ol>





### Smart device

Samsung smart device (including charge adapter and USB-C charging cable).



#### hearOAE device

The same charging cable can be used for smart device.





## hearOAE probe



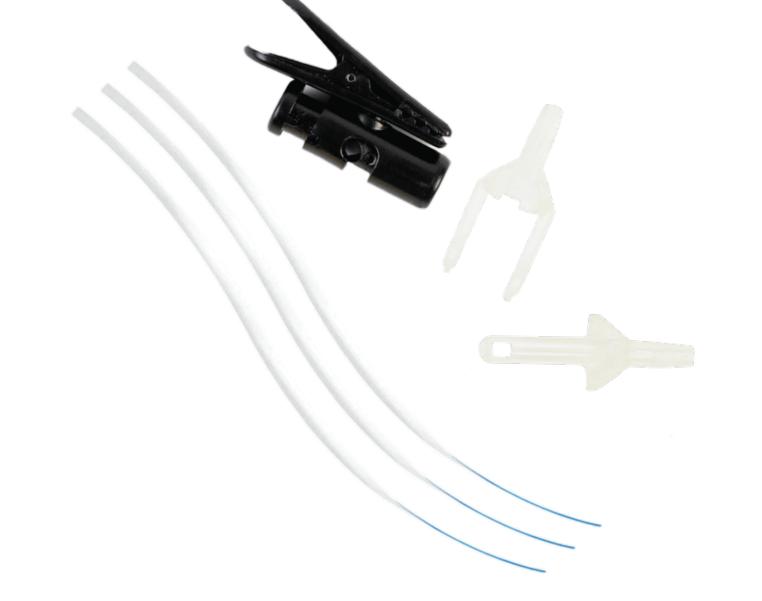




## Starter kit includes







### Ear tips

## 5 x probe couplers

#### Accessories

Cleaning lineCable clip

Sanibel ADI assortment box

Please note:

Only use the Sanibel ADI series of ear tips.

Different colors and shapes represent different sizes.

Ear tips are for single patient use.

Printed Quick Start Guide (QSG)

Please note: Cleaning lines are for single patient use.

## Packaging specifications

Dimensions	350 x 270 x 120 mm
<b>Net weight</b> (Contents: Smart device, probe, hearOAE device and charger)	< 1 Kg

<b>Shipping weight</b> (Quantity=1)	1 Kg
Power source	Internally powered
Safety and design standards	IEC 60645-6 ; IEC 60601-1-2 ; IEC 62304
Degree of protection (Electric shock)	Type B applied part
Warm-up time	None
Usage environment	Professional healthcare environment

<b>Operating environmental conditions</b> Temperature Humidity Ambient pressure	15°C to 35°C 30 to 90 %RH (Non-condensing) 98 to 104 kPa
Transport and storage conditions	
Temperature Humidity Ambient pressure	5°C to 40°C 10 to 90 %RH (Non-condensing) 50 to 110 kPa





## Minimum smart device specifications

Power supply Non-removable Lithium-Ion rechargeable battery

**Battery capacity** 3000 mAh

**Expected battery lifetime** 2 years of regular use

> **Battery indicator** Battery level is indicated on the device screen

Battery replacement	Please contact the seller for any replacements
Dimensions and weight	4.7 inch display 150 grams
User interface	Android 10
Interfaces	USB-C Port: The smart device features a USB-C port for data transfer, charging, and accessory connectivity.
Wireless communication protocols	<b>Wi-Fi:</b> The device supports high-speed wireless internet connectivity through the Wi-Fi protocol, enabling access to online resources, cloud services, and remote communication.

Bluetooth<sup>®</sup> Low Energy (BLE): The Bluetooth<sup>®</sup> technology allows wireless pairing to the hearOAE device

## Probe specifications

Type of OAE	Distortion Product Otoacoustic Emissions (DPOAE) Transient Evoked Otoacoustic Emissions (TEOAE)
Stimulus frequency range	<b>DPOAE:</b> 700 to 8000 Hz <b>TEOAE:</b> 1000 to 4000 Hz
Stimulus level range	DPOAE: 30 to 75 dB SPL TEOAE: 60 to 86 dB SPL
	Drivers: Knowles FD series

Transducers	Microphone: Knowles EM series
Cable length	1.2 meters
Weight	30 grams
Interfaces	<b>8-pin circular push-pull:</b> The probe is equipped with an 8-pin connector designed for a secure physical connection to a compatible hearOAE device. This connection ensures data transmission and facilitates accurate measurements.





## hearOAE device specifications

Battery capacity4.2 V 2200 mAh Li-ionComplies with IEC 62133-2:2017

Expected battery lifetime 2 years of regular use

Number of tests per full battery charge ~ 200

Charging port USB-C

Probe connector 8-pin circular push-pull

### **Dimensions** 146 x 88 x 33 mm

Weight 300 grams

## Ingress Protection (IP) IP30

**USB-C port:** The hearOAE device features a USB-C port for charging. Note: The port is exclusively intended for charging purposes and does not support data transfer or other functionalities.

## Interfaces

8-pin circular push-pull: The device is equipped with an 8-pin connector designed for a secure physical connection to a compatible probe. This connection ensures data transmission and facilitates accurate measurements.
Bluetooth Low Energy (BLE): The Bluetooth technology allows wireless pairing to the hearOAE device

## Wireless communication protocols

**Bluetooth<sup>®</sup> Low Energy (BLE):** The Bluetooth<sup>®</sup> technology allows wireless pairing with the smart device for interaction and data exchange.

#### \*Disclaimer

The intended user population consists of trained personnel, such as audiologists, ENT surgeons, medical doctors, hearing healthcare professionals or other personnel with a similar level of education. This instrument should not be used by personnel who do not have the necessary knowledge and training to understand its intended use and how the results should be interpreted. hearX does not accept any liability regarding any misuse or improper application of this instrument by unauthorized personnel. Limited quantities available.



