HOAE-MN-01 HEAROAE IFU V1.1L

Date updated: 03/20/2025

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REVISION HISTORY

REVISION	DATE	DESCRIPTION
v1.0	31 Oct 2024	Document started
v1.1	14 Feb 2025	GTM Application version updates

INTRODUCTION

This manual provides instructions for use (IFU) for hearOAE®. The purpose of hearOAE is to provide an affordable and reliable solution to measure and report on Otoacoustic Emissions. hearOAE is able to conduct Transient Evoked Otoacoustic Emissions (TEOAE) and Distortion Product Otoacoustic Emissions (DPOAE) screening and diagnostic tests for infants, children, and adults.

The hearOAE Instructions for Use is available in paper format upon request within 7 days.

1. INTENDED USE

Intended use: hearOAE is intended to be used by hearing healthcare professionals in the audiologic evaluation and documentation of ear function and ear disorders using Transient Evoked Otoacoustic Emissions (TEOAEs) and Distortion Product Otoacoustic Emissions (DPOAEs). The target population for the hearOAE includes all ages.

Intended user: 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.

2. GENERAL INFORMATION

hearOAE is designed and verified according to EN 60645-6: 2022 as a type 1 diagnostic OAE instrument. hearOAE provides two test modalities, namely transient evoked OAE (TEOAE) and distortion product OAE (DPOAE).

TEOAEs are low-level sounds emitted from the cochlear outer hair cells, subsequent to stimulation of the cochlea from click stimuli. hearOAE generates a series of clicks over a broad frequency range which is presented into the outer ear canal. The click stimuli alternate in level and polarity which gives rise to the non-linear response quantifying the OAE. Outer hair cell function is estimated across a limited range of frequencies, from 1kHz to 4kHz.

DPOAEs are low-level sounds emitted from cochlear hair cells in response to two closely presented stimulating tones at different frequencies (f1 and f2). The result is a distortion product tone at the specific test frequency (2f1-f2). hearOAE presents a sequence of tones directed into the outer ear canal and measures the DPOAE produced by the cochlear outer hair cells. Cochlear function is estimated across a larger range of frequencies, from 700Hz to 8kHz.

The hearOAE instrument is designed to be a screening and diagnostic device for hearing loss. Sensitivity and specificity of this type of instrument are based on the test characteristics defined by the user, and may vary depending on environmental and operating conditions. The presence of otoacoustic emissions suggests normal outer hair cell function, which in turn correlates to normal hearing sensitivity. In the case that a screening test was performed, a PASS result using this instrument is not an indication that the full auditory system is normal. Thus, a PASS result should not be allowed to override other indications that hearing is not normal. A full audiologic evaluation should be administered if concerns about hearing sensitivity persist. A REFER test result should not be assumed to be an indicator of a lack of auditory function; however, it should be followed with full audiologic diagnostic testing.

2.1 HEAROAE COMPONENTS

hearOAE consists of three main components listed below:

1. hearOAE Application (available on supported Android devices supplied by hearX SA)
2. hearOAE Device
3. hearOAE Probe

hearOAE Application: The app is operated on an Android smart device that uses Bluetooth connectivity to communicate to the hearOAE Device. The hearOAE App enables the user to choose and set up testing protocols for both TEOAE and DPOAE. The App further enables the checking of the probe functionality, namely “Probe Check”. The App controls the start and stop

of a TEOAE and DPOAE test including pre-test functions such as Probe Fit and in-ear calibration. The App provides feedback during and after the test in the form of tables, figures and graphs.

hearOAE Device: The hearOAE Device consists of hardware and software for generating the test signals and measuring the responses. The hearOAE Device has the ability to generate, measure and process signals. The hearOAE Device also contains a rechargeable lithium-ion battery to power the device. The instrument uses three light indicators to provide a visual display of the status of the hearOAE Device to the user. A push button is located on the case of the hearOAE Device to allow the user to switch it on or off signified by a Power symbol. Test results are communicated via Bluetooth to the hearOAE Smart device to be displayed on the Smart device screen to the user.

hearOAE Probe: The probe houses speakers and a microphone that produce the test stimuli and measure the sound pressure level (SPL) present in the ear canal. The hearOAE Probe has a removable probe coupler with ear tips which fit onto the probe coupler.

3. WHAT'S IN THE BOX?

3.1. HARDWARE

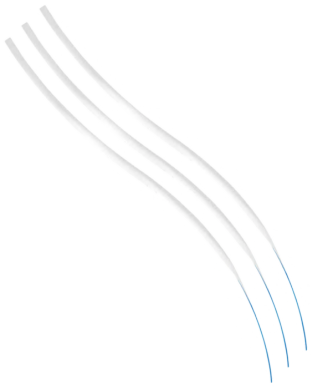
1. Smart device: **Samsung Smart Device** (including charge adapter and USB-C charging cable)	

2. hearOAE Device (including charge adapter and USB-C charging cable)	

3. hearOAE Probe	
4. Hardcover Carry Case	

3.2. STARTER KIT

1. Ear Tips Sanibel ADI Assortment box (Ear tips are single patient use)	Please note: Only use the Sanibel ADI series of ear tips. Different colors and shapes represent different sizes. 
2. Probe Coupler (quantity: 5)	

3. Extras (Cleaning floss are single patient use)	• Accessory Case  • Cleaning Floss  • Cable clip • Printed Quick Start Guide (QSG)

4. IMPORTANT SAFETY WARNINGS

hearOAE should only be used by persons who have received adequate training and/or have thoroughly read through this IFU. hearOAE should only be used with the provided smart device, hearOAE Probe and hearOAE Device issued from hearX. This instrument has been calibrated with a standard ear simulator to ensure that tests conducted are reliable. Please note that if a sound or tone is presented at a loud level, discomfort may be caused to exposed persons.

Refer to the **Maintenance and Cleaning** section of this manual for the proper cleaning procedure of the device and its accessories. The instrument must be stored and operated within the specified temperature, pressure, and humidity ranges (see **Operating Environmental Conditions 12.2**).

Do not attempt to open, modify, or service any part of the device. The device must be returned to the manufacturer or distributor for all servicing requirements. Should the device or any of its parts be opened, the warranty of the product will be voided. Please be cautious of the fact that the device consists of various electronics that are sensitive to mechanical damage (due to e.g. vibrations, electrostatic discharge, dropping the device, etc.). As such, the device should be handled with care. If the device has been damaged, return it to the manufacturer for repair.

When unpacking hearOAE, carefully check the equipment for any visible damage. Should any of the equipment show visible damage, please return the content to the seller. Ensure that the device is stored in a place of safety to avoid theft or the device being used by unauthorized persons.

4.1. SAFETY PRECAUTIONS

- General safety precautions must be followed when operating electrical equipment. Failure to observe these precautions could result in damage to the equipment and injury to the operator or patient.
- The employer should instruct each employee in the recognition and avoidance of unsafe conditions, and the regulations applicable to his or her work environment, to control or eliminate any hazards or other exposure to illness or injury.
- It is understood that safety rules within individual organizations vary. If a conflict exists between the material contained in this manual and the rules of the organization using this instrument, the more stringent rules should take precedence.
- The hearOAE is intended to be used by Audiologists, ENT surgeons, hearing healthcare professionals and/or technicians who have been trained with the use of the device.

4.2. CAUTIONS

- This product and its components will perform reliably only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and/or inserts. A defective product should not be used. Make sure all connections to external accessories are snug and secured properly. Parts that may be broken or missing, or are visibly worn, distorted or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from hearX.
- This product should not be used in the presence of fluid that can come into contact with any of the electronic components, probe transducers or cables. Should the user suspect fluids have contacted the system components or accessories, the unit should not be used until deemed safe by a hearX service technician.
- Do not use the device in the presence of flammable gaseous mixtures. Users should consider the possibility of explosions or fire when using this device in close proximity to flammable anesthetic gases.
- Do not use hearOAE in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc.
- Equipment is not user repairable. As such repairs and battery replacements must be performed by a qualified service representative only.
- The equipment/system may cause radio interference, or may disrupt the operation of nearby equipment. It may thus be necessary to take mitigation measures, such as reorienting or relocating the hearOAE Device, or shielding the testing location.
- Never insert the probe tube into the ear canal without affixing an ear tip.
- Only use the disposable ear tips designed for use with this instrument.

4.3. WARNINGS

4.3.1 ELECTRIC SHOCK HAZARDS

Do not open the case of the hearOAE Device. Refer servicing to qualified personnel.

4.3.2 EXPLOSION

This system is not explosion proof. Do not use in the presence of flammable anesthetics or other gases.

4.3.3 CHOKING HAZARD

The hearOAE probe uses small parts that present a choking hazard. Keep the ear tips and probe couplers out of reach from infants and children.

4.3.4 BATTERY/GENERAL SAFETY

This instrument contains a rechargeable lithium-ion battery. The battery is not user-replaceable and must be returned to an authorized hearX service location for repair. Refer to the **Recycling/Disposal** section for information on the disposal of lithium-ion batteries.

4.3.4.1 RECYCLING/ DISPOSAL

Many local laws and regulations require special procedures to recycle or dispose of electrical equipment related waste including batteries, printed circuit boards, electronic components, wiring, and other elements of electronic devices. Follow all your respective local laws and regulations for the proper disposal of batteries and any other parts of this system.

Batteries may explode or cause burns, if disassembled, crushed, or exposed to fire or high temperatures.

The do's and don'ts of battery disposal:

- Don't dispose of large amounts of lithium-ion batteries in household waste.
- Do try and opt for recycling, even if the battery is suitable for household waste.
- Never dispose of batteries in a fire, this is incredibly dangerous and could result in explosions.
- Do find a recycling or collection service, or get in touch with your local council to find out more.

4.3.5 GENERAL

This device contains minimal traces of lead within its internal components, which should not present any risk to the user when used as intended. Disposal of the device should be carried out in accordance with the relevant regulations in each territory regarding devices containing lead.

The device is not designed to be opened. However, in the unlikely event that it is unintentionally exposed or opened, individuals who come into contact with the internal components should wash their hands thoroughly with soap and water. The device should then be disposed of according to local regulations for lead-containing devices, or it can be returned to hearX for appropriate disposal.

For safe and effective use, please ensure careful review of all provided instructions.

4.3.6 CYBERSECURITY

To ensure the ongoing security, optimal performance, and technological currency of the hearOAE medical device, it is imperative to follow these comprehensive guidelines for device maintenance, cybersecurity, and firmware/software updates. The device seamlessly integrates with an Android smart device, utilizing a locked-down environment managed by Mobile Device Management (MDM), particularly the Knox platform, to bolster security measures. hearX oversees the upkeep of the Android device, ensuring timely updates, security patches, and antivirus software installations remotely through the MDM. This proactive approach helps maintain the device's cybersecurity posture. To uphold the device's overall security, it is recommended to restrict the use of the Android smart device solely for its intended medical purposes, avoiding unnecessary installations or modifications. Additionally, restrict network connections to trusted and secure networks to minimise exposure to potential threats. Furthermore, please note that firmware updates, which are essential for continuous enhancement, require the device to be returned to an approved hearX distributor. This controlled process guarantees accurate and secure firmware updates by authorized professionals, ensuring the device's technological currency and optimal performance. By adhering to these measures and collaboration with the supplier, you contribute significantly to the device's resilience against cyber risks, ensure its continued reliability in delivering accurate and timely results, and allow for future technological advancements. Your diligence is greatly valued and ensures the device's long-term functionality.

4.3.6.1 HOW TO ENSURE SAFE CYBERSECURITY PRACTICES:

To ensure the secure and reliable use of the hearOAE medical device, it is essential for users and user facilities to implement the following security actions:

1. Network Connectivity: Only connect the device to trusted and secure networks. Avoid connecting the device to public or unsecured networks to minimize the risk of unauthorised access or data breaches.

2. Access Control: Restrict access to the Android smart device, ensuring it is used solely for the intended medical purposes. Do not install or modify any applications that are not directly related to the device's medical functions.
3. Device Physical Security: Keep the Android smart device and the hearOAE medical device in a secure and controlled environment. Prevent unauthorized access to the device, which may compromise its security.
4. Firmware Updates: Promptly return the device to an approved hearX distributor for firmware updates. This controlled process ensures that only authorised professionals apply accurate and secure firmware updates, maintaining the device's technological currency and optimal performance.
5. Use of Approved Accessories: Only use accessories that have been approved by hearX. Using unauthorised accessories may compromise the device's security, functionality, and accuracy.
6. User Account Management: If applicable, manage user accounts on the Android smart device with utmost care. Use strong and unique passwords for any accounts associated with the device, and promptly revoke access for any individuals who no longer require it.
7. User Training: Provide thorough training to authorised users on the secure operation of the device. Ensure that users are aware of potential security risks and the steps to take to mitigate them.
8. Regular Monitoring: Routinely monitor the device's performance and any security alerts provided by hearX. Report any unusual or suspicious activities to the appropriate personnel.

5. SETTING UP YOUR DEVICE

5.1 UNPACKING AND INSPECTION

When the device is received, check the package for rough handling and damage. If the case is damaged, it should be kept until the contents have been checked mechanically and electrically. The user needs to report any missing or malfunctioning parts immediately, by sending an email with a description of the malfunction to *support@hearxgroup.com*. Make sure to keep the packaging and its contents, as it will be required for inspection and the insurance claim.

Please refer to the **Warranty** Section in this document for more information.

5.2 MARKINGS

	Manufacturer name and address
	Distributor name and address
	Type B applied part. A part which provides protection against electric shock, particularly regarding allowable patient leakage current and patient auxiliary current. The applied part is the assembled probe with cable.
	Follow instructions for use.
	Medical device.

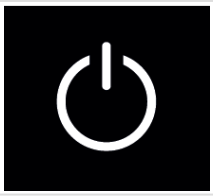
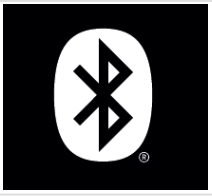
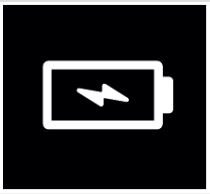
SN	This symbol will be followed by the manufacturer's serial number.
UDI	Unique device identifier.
	Not for general waste.
	Device is fragile.
	Keep product dry.
	Caution, consult instructions for use.
	Date of manufacture.
FC	Federal Communications Commission.
	Bluetooth enabled.
	Do not reuse.

5.3 HARDWARE INSTALLATION

5.3.1 HEAROAE DEVICE INDICATOR AND STATES

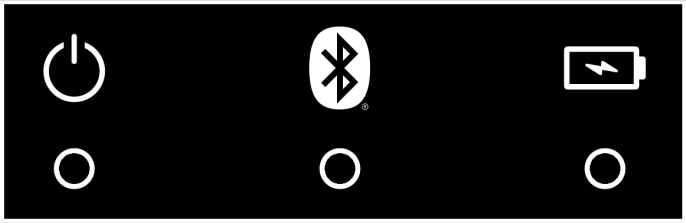
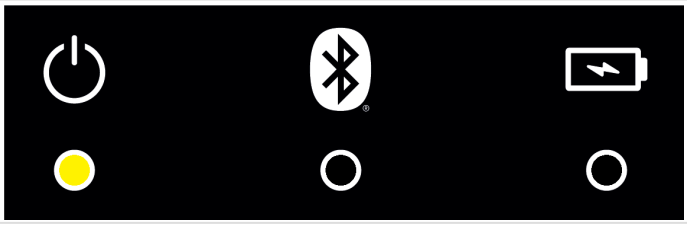
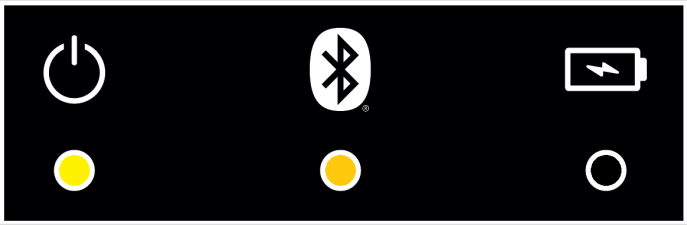
The hearOAE Device has three light indicators. The one on the left is the “Power Mode” indicator, the one in the middle the “Bluetooth mode” indicator and the one on the right the “Charging mode” indicator.

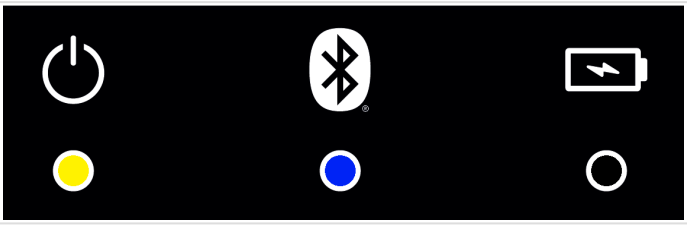
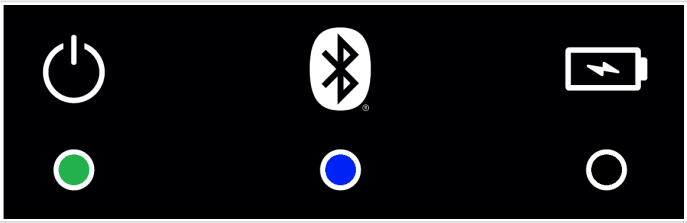
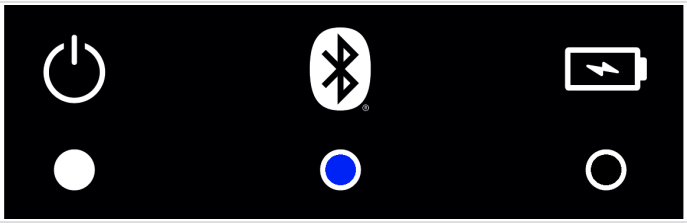
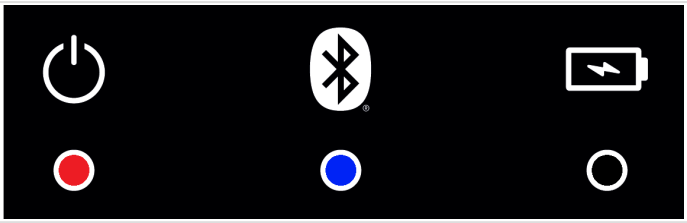
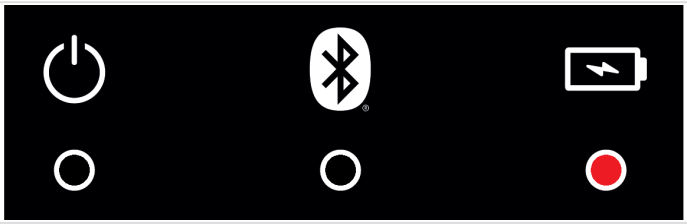
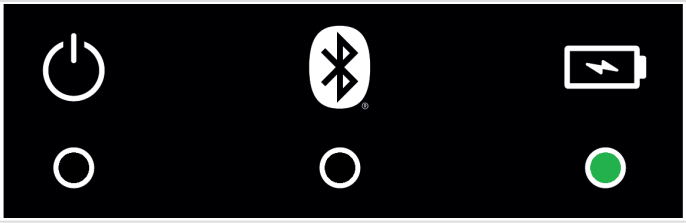
5.3.1.1 INDICATORS

Power Mode	Bluetooth Mode	Charging Mode
		
Indicates whether: • hearOAE Device is On or Off • Power Saving is On or Off • hearOAE Device requires charging	Indicates whether: • Bluetooth is ready to pair • Bluetooth is connected	Indicates whether: • the battery is charging • the battery is fully charged

5.3.1.2 HEAROAE DEVICE STATES

The hearOAE Device states are a combination of the above indicators. Typical hearOAE Device states are provided:

Status ID	Indicators	Status
1	hearOAE Device off	
2	hearOAE Device on Power saving on Bluetooth not paired	
3	hearOAE Device on Power saving on Bluetooth ready to start pairing process	

4	hearOAE Device on Power saving on Bluetooth connected	
5	hearOAE Device on Power saving off Bluetooth connected	
6	hearOAE Device on Probe disconnected (white flicker) Bluetooth connected	
7	hearOAE Device on Battery low Bluetooth connected	
8	hearOAE Device off hearOAE Device charging Battery not full	
9	hearOAE Device off hearOAE Device charging Battery 100% full	

5.3.2 PAIRING BLUETOOTH FOR FIRST TIME USE

1. Turn the hearOAE Device on
    a. Refer to Status ID 2
    b. Power Mode indicator turns Yellow
    c. Other indicators off
2. Open the hearOAE app via mHealth and ensure Bluetooth is enabled. A pop-up message will appear displaying the following text: “Please enable device Bluetooth” if Bluetooth is not enabled.
    a. Refer to Status ID 3
    b. Power Mode indicator - Yellow
    c. Bluetooth Mode indicator turns Orange
    d. Notification will appear on the Smart Device asking to pair with the hearOAE Device

3. Accept the notification in the hearOAE app
    a. Refer to Status ID 4
    b. Power Mode indicator - Yellow
    c. Bluetooth Mode indicator turns Blue

If the above steps are executed correctly a Bluetooth connection is successfully established between the hearOAE Device and hearOAE application. The devices should seamlessly connect when the hearOAE Device and Application are active.

5.3.3 CHARGING THE HEAROAE HARDWARE

The hearOAE has two components that require charging, namely the hearOAE Device and the smart device. The hearOAE Device is powered by a rechargeable lithium-ion battery, and the smart device is typically powered by a rechargeable lithium-polymer battery. The charge adapter provided can be used to charge both of these components. Before using hearOAE for the first time, both these components should ideally be fully charged. To charge the hearOAE Device or smart device, connect the USB charge adapter to the mains outlet and connect the USB-C cable to the hearOAE Device.

See the figure above for the location of the USB C port on the hearOAE Device, located on the bottom panel.

Please note:

- Tests cannot be performed if the battery level of the hearOAE Device or the smart device is below 10% or while the hearOAE Device's battery is charging.
- The capacity of the batteries will decrease with time and usage. The battery is not user replaceable and must be returned to hearX for repair.
- To extend the battery life do not deplete the battery. Charge when 5-10 % of the battery remains.

Only use standard USB power supplies that provide +5V, preferably the power supply supplied with the hearOAE kit.

5.3.3.1 HEAROAE DEVICE BATTERY USAGE

A fully charged Device battery can perform around 200 tests. The battery status is indicated on both the hearOAE Device and on the smart device. On the smart device a battery icon with a percentage is shown next to the device status in the upper-left corner of the hearOAE app screen. The battery icon status on the hearOAE Devices are as follows:

(i) Green or Yellow Power mode indicates a sufficient battery level - **Status IDs 4 & 5**

(ii) Red Power mode light indicates a low battery level - **Status ID 7**

6. PERFORM A HEARING TEST

When operating hearOAE, please observe the following general precautions:

1. Use this device only as described in this manual.
2. Do not drop, and avoid other undue impacts to this device, specifically the probe. Do not use hearOAE if it is suspected that the device has been damaged.
3. When operating with hearOAE on a patient, it should be handled carefully with high attention. The patient should be calm during testing and the the Device and Probe should be kept steady and free of any movement or contact with other surfaces to avoid noise interference to ensure optimal accuracy.
4. Be sure to use only stimulation intensities applicable to the patient, this is ensured by either selecting the Adult or Child option in the test protocols.
5. It is recommended to conduct a Probe Check after periods of disuse in a 24 hour period prior to use so as to ensure that the hearOAE Probe and Device are functioning correctly.
6. Clean the probe coupler regularly to ensure wax or other debris stuck in the probe coupler does not affect the measurement. Please refer to the cleaning instructions in this document.
7. Use only the prescribed ear tips - Sanibel ADI series.
8. Keep the box of ear tips outside the reach of the patient, especially children.
9. Never clean the transducer (hearOAE Probe) housing with water or insert non-specified instruments into the transducers. Please refer to the cleaning instructions in this document.

6.1 ENVIRONMENT

6.2.1 USER ENVIRONMENT

hearOAE should be used in a suitable environment with low ambient noise. The environment must be free from distractions and the patient/guardian (parent) of a minor or child/infant must be able to understand the the instructions.

It is recommended that hearOAE be operated within an ambient temperature range of 15˚C to 35˚C, relative humidity between 30% and 90% (non-condensing), and static pressure within the range 98 kPa to 104 kPa.

6.2.2 STORAGE ENVIRONMENT

Use and store the instrument in a safe and dry place, indoors only. The device does not require a warm-up period if stored at room temperature.

Transport and store the hearOAE at a temperature between 5˚C to 40˚C.

6.2 PREPARING A PATIENT FOR TESTING

It is preferred that the patient's ear canals are examined prior to testing. Debris (e.g. excessive ear wax) in the ear canals may interfere with the test and give inaccurate results. Patients with debris, foreign bodies, acute or chronic middle ear infections , or active leaking in the ear canals need to be referred to a qualified professional for removal of the blockage prior to testing.

Ensure that all necessary disposables (probe coupler, ear tips etc.) are at hand and prepared for use.

The patient needs to be in such a position that will allow easy access to the ear canal. The patient should remain as still and quiet as possible while the test is being performed.

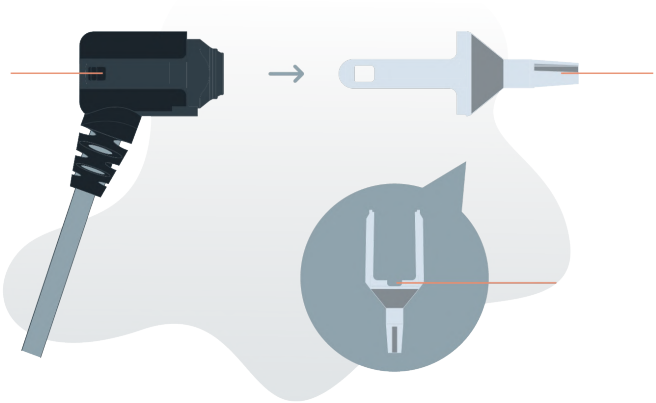
6.3 CONNECT PROBE

Insert the hearOAE Probe connector to the hearOAE Device connector found on the top panel. The key on the probe connector needs to align with the red dot displayed on the hearOAE Device connector. The user is required to place their fingers on part B of the probe connector and push the connector into place.

To remove the probe connector, the user needs to place their fingers on part A of the connector (retractable part) and pull it towards part B while pulling the connector away from the hearOAE Device.

6.4 HEAROAE PROBE COUPLER ATTACHMENT

Use the probe couplers provided with the hearOAE kit. The probe coupler needs to be placed onto the hearOAE Probe. The coupler arms need to align with the hearOAE Probe, and the notch on the probe coupler needs to align with the key on the hearOAE Probe (bottom side of Probe). The probe coupler should then be pushed onto the hearOAE Probe and the arms need to click into place to ensure a tight fit. To remove the probe coupler, the user should place his/her fingers over the probe coupler arms and gently pull the arms outwards and towards the probe coupler tip.



The probe couplers are reusable, but need to be disinfected using alcohol swabs and/or a disinfectant solution. It can also be cleaned using the cleaning floss provided by hearX, aiding to push any debris through the channels. It should only be cleaned once detached from the probe.

6.5 EAR TIP SELECTION & ATTACHMENT

When using hearOAE, use only the prescribe ear tips - Sanibel ADI series as intially provided with the hearOAE kit, and place them on the probe coupler. The ear tips are not reusable, as contaminated ear tips can lead to the spread of infection between patients.

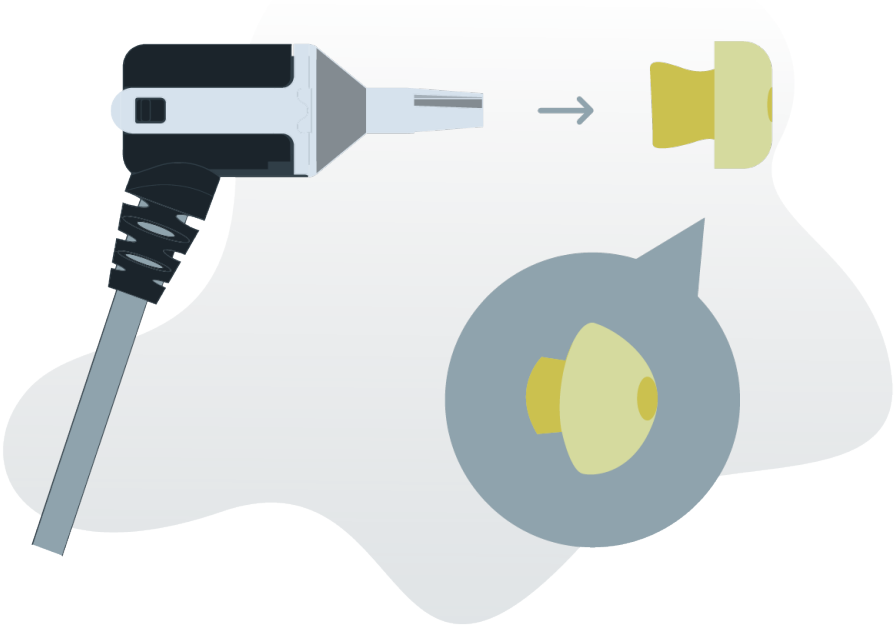
The appropriate tip selection is essential to ensure accurate OAE results. When selecting an ear tip, first inspect the ear to be tested to assess ear canal size ensuring it is clear and free from debris. Otoscopic examination prior to ear tip insertion is recommended. The ear tip choice will depend on the:

(i) Size and shape of the ear and ear canal, and

(ii) Personal preference of the user based on prior experience and/or knowledge.

After selecting an ear tip, it should be pushed onto the probe coupler until the the tip of the ear tip is flush with the tip of the probe coupler. Be sure that the ear tip is positioned properly on the hearOAE Probe and that there are no gaps between the ear tip and the probe coupler.

The following illustration displays the sequence of how the hearOAE Probe needs to be set up. The probe coupler is placed onto the hearOAE Probe and clicked in place. Thereafter, the ear tip can be placed on the probe coupler. Please ensure a tight fit between the ear tip and the probe coupler.



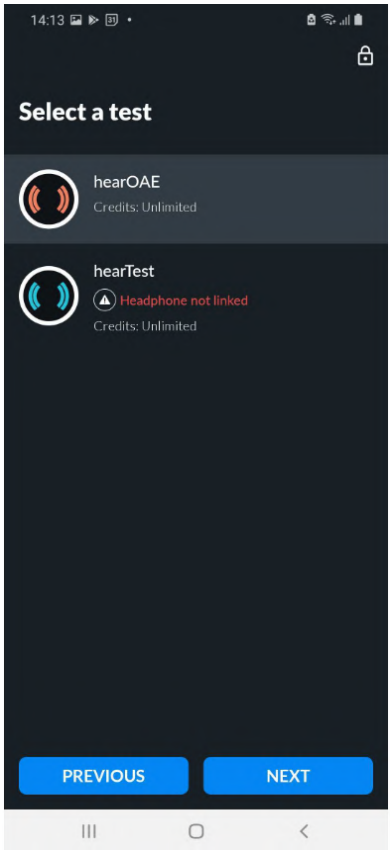
The hearOAE Probe with the probe coupler and the ear tip needs to be pressed firmly into the ear canal to create a seal. The seal in the ear canal is required for the duration of the test.

Notes:

- The ear tip needs to look slightly larger than the ear canal and should fit snugly, forming a complete seal with the ear canal wall.
- For adults, you may need to pull the tip of the ear (pinna) backward and upwards to straighten the ear canal.
- For the paediatric patients, you may need to pull the tip of the ear (pinna) backwards and downwards to straighten the ear canal.
- Do not insert the probe without an ear tip into a ear canal
- Do not insert the ear tip further than the first bend of the ear canal.
- Ensure you are not pressing the ear tip against the side of the ear canal.

6.6 ACCESSING HEAROAE IN MHEALTH STUDIO APPLICATION

For the setup of the mHealth Studio Application, refer to the Quick Start Guide supplied in the hearOAE carry case. The hearOAE app forms part of the mHealth Studio suite of products. To open the hearOAE app, the user needs to select the software from the mHealth Studio application list.

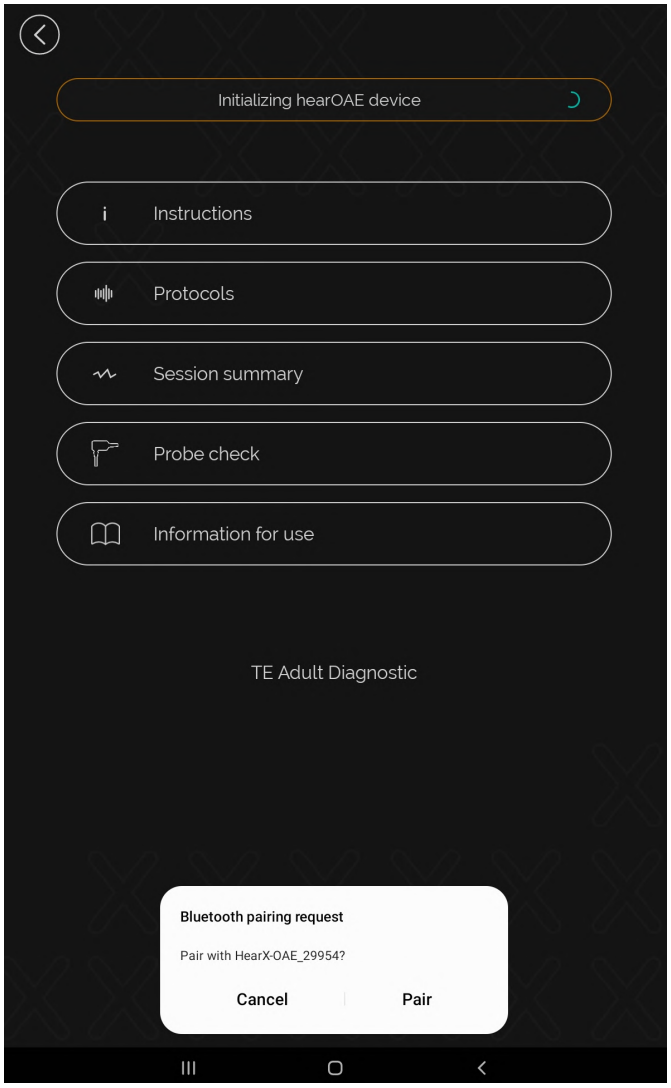


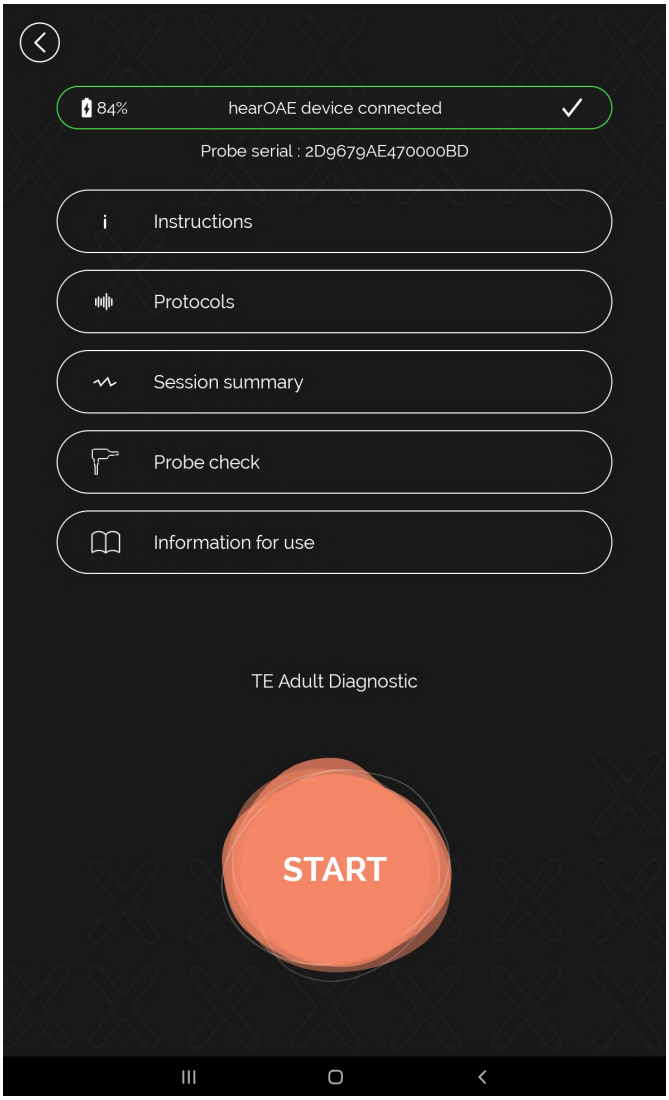
In the mHealth Studio Application, hearOAE is divided into two sets, namely hearOAE and hearOAE Screening, as these are the two types of OAE licenses that hearOAE user is able to select from..

Once the hearOAE app opens, the home page directs the users to the relevant features as depicted below.

Home Screen (Bluetooth Enabled):

Home Screen (hearOAE Device Connected):





6.7 HEAROAE HOME SCREEN

The Home Screen serves as the starting point for navigating the hearOAE App. Throughout the design, the logo colours are used to differentiate between TEOAE and DPOAE. Orange is used for TEOAE and yellow for DPOAE and these colours are used in all screens displaying information relevant to either a TEOAE or DPOAE test.

From the Home Screen, the user has access to information about the device at the top of the screen, and additional buttons at the top to navigate to other screens to execute various actions. All items on the Home Screen are listed below.

1. Instructions - this feature provides the user with guidelines on achieving a sufficient probe fit and setting up the hardware.
2. Protocols - this feature provides the user with the ability to: select a protocol, add a new TEOAE/ DPOAE protocol, and edit or delete a protocol.
3. Session Summary - this feature provides the user with a summary view of the tests that have been performed for a session (specific user).
4. Probe Check - This feature enables the evaluation of the probe. Users are provided with step-by-step instructions to carry out the probe check.
5. Instructions for Use - this feature provides the user with the instructions for use document.

6.7.1 HOME SCREEN CHECKS

The device status performs seven checks before the user is able to start a TEOAE or DPOAE test. Each of these checks are explained in detail below:

1. Bluetooth connectivity
2. hearOAE Device connection
3. Battery level
4. Battery charging
5. Probe connected
6. Probe calibration status
7. Probe
8. Check status

Only once all the checks have been done and passed, the user can start testing. While these checks are being performed, the circular TEOAE or DPOAE button is disabled. While performing the checks, the top bar provides information on the progress of each of the checks being performed. In some cases, these checks are completed quickly, and unless any issues or faults are detected, the user will not see all progress for each of the checks. If any of the checks fail, pop-ups are displayed to provide information to the user to take corrective action to ensure the hearOAE is ready for testing.

With each pop-up message displayed, the user has the option to execute the suggested action or to dismiss the message - some messages also display an "*OK*" button. If multiple checks have failed, a pop-up is displayed before the user returns to the start screen to ensure all messages are viewed by the user and to get the device in the correct state to begin testing.

Check 1: Bluetooth connectivity

This includes the following two sub-checks, in the order mentioned:

- Is the smart device's Bluetooth enabled?
- Is a Bluetooth connection established between the hearOAE Device and the smart device?

The hearOAE Device needs to be connected to the device for a test to start.

Check 2: The device is checking if the battery level of the hearOAE Device is at an acceptable level for testing

The hearOAE Device battery level is displayed on the smart device's interface and is communicated to the device via Bluetooth. The text displayed is grouped into two categories:

1. Battery level >=10% - the battery level is sufficient for testing. On the hearOAE Device, the Power mode indicator is displayed in green.
2. Battery level < 10% - the battery level is too "low" for testing. On the hearOAE Device, the Power mode indicator is displayed in red.

CHECK 3: DEVICE IS CHARGING

Tests cannot be performed while the hearOAE Device is being charged.

Check 4: The device is checking if the probe is connected

The hearOAE Probe must be connected to the hearOAE Device for a test to start.

CHECK 5: CHECKING THE CALIBRATION STATUS

If the hearOAE app detects that the hearOAE Probe is used for the first time, the calibration information of the hearOAE Probe is downloaded. This requires the Android smart device to be connected to the internet. If the calibration of the probe has expired the user will also be warned. The recommended calibration period of the hearOAE probe is annually.

CHECK 6: CHECKING THE PROBE HEALTH STATUS

The hearOAE Probe health is determined by the daily Probe Check. The results are stored locally on the device. If a different probe unique identifier is detected, the user has to redo the Probe Check before starting the screening session. If consecutive Probe Checks fail, the user is asked if he/ she cleaned the probe coupler. If the user cleaned the probe coupler, the user will be instructed to replace the current hearOAE Probe with a new probe.

Only once all the checks have been performed and passed, the device status is displayed as "OAE device ready" with a tick-mark next to it. From here the TEOAE or DPOAE test button is enabled and can be selected to start testing.

Check 7: Checking the hearOAE Device connection status

Once charged and hearOAE Device is powered on, there will be a yellow light on the hearOAE Device indicating that it is powered on and a blue light indicating once connected to the smart device via Bluetooth. The yellow light will change to a green light to indicate full connection. The application will display a status message on the home page saying that the hearOAE device is ready. During the test process the hearOAE application monitors the connection status in the background and if disconnected the test stops and a message is provided "Connection lost".

6.8 PROBE CHECK

A button called "*Probe Check*" is included on the Home Screen. A Probe Check is enforced in three instances:

- On first time use if a new probe is detected
- Once a day on entering the application.
- If it is detected that the probe requires maintenance, based on a previous Probe Check.

Probe Check is a useful function to determine whether device performance has changed, specifically the probe. This is done by comparing the *Baseline* (set as 75 dB SPL) and subsequent values namely *Current* - see figure for Probe Check passed below. dB SPL values are provided in a table at 440, 1000, 2000, 3000 and 4000 Hz as soon as a check is completed. If a problem is identified, an error message is shown (together with the dB SPL measurements) which can help the user troubleshoot the potential probe issue.

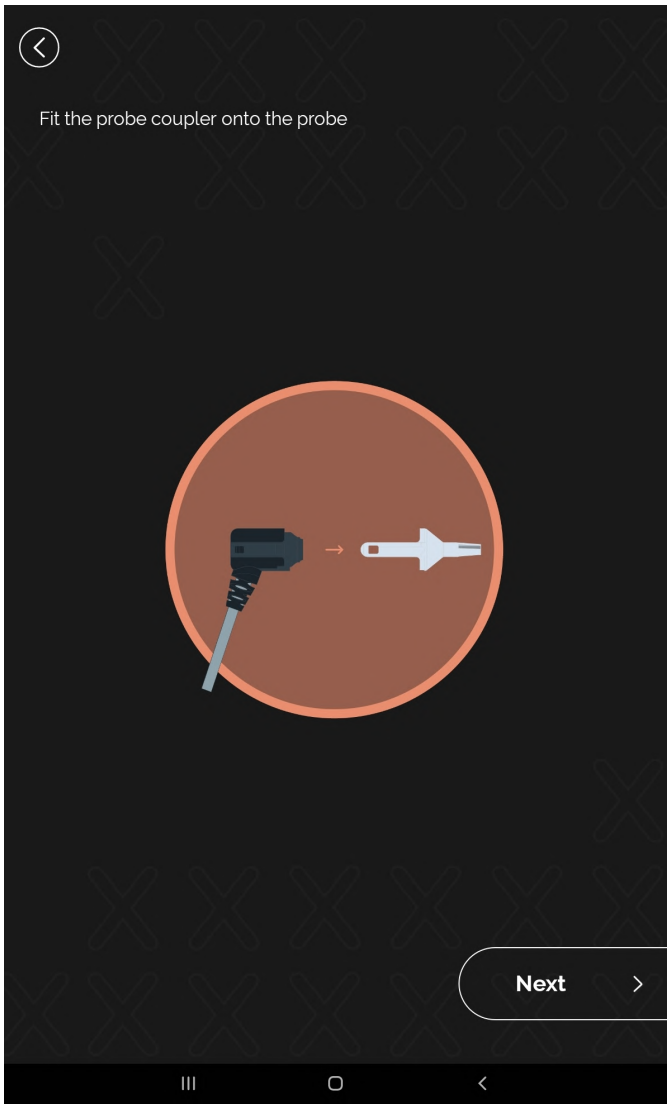
Steps to complete a *Probe Check*

1. Connect the coupler to the probe and ensure the arms are clicked in placed (see Section 6.4). Don't add an ear tip.
2. Place the hearOAE Probe into the cavity, which is the opening on the bottom side of the hearOAE hearOAE Device (select the Next button to continue to the next screen).
3. A start button is displayed. The screen automatically moves to the next screen once the button is selected.
4. The result of the Probe Check is displayed as a green tick or a red cross, representing a pass or fail of the Probe Check. Irrespective of whether the probe check passes or fails, the dB SPL values are shown in a table.

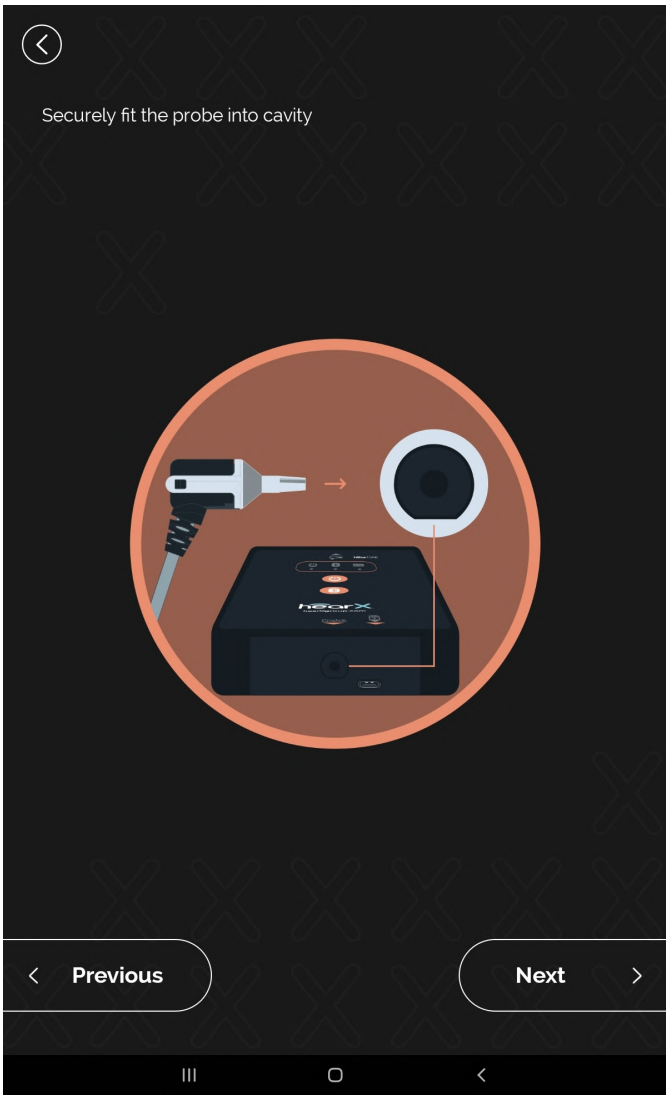
- If the Probe Check passed: a green tick is displayed. From here, the user returns to the Home screen.
- If the Probe Check failed: a red cross is displayed. This indicates that the probe might be at risk, and it will be required to redo the Probe Check. An error message is displayed similar to failing a Probe fit - please see section 6.10.2.

The above diagram displays the cavity on the bottom panel of the hearOAE Device in which the hearOAE Probe should fit.

First Probe Check Instruction Screen:



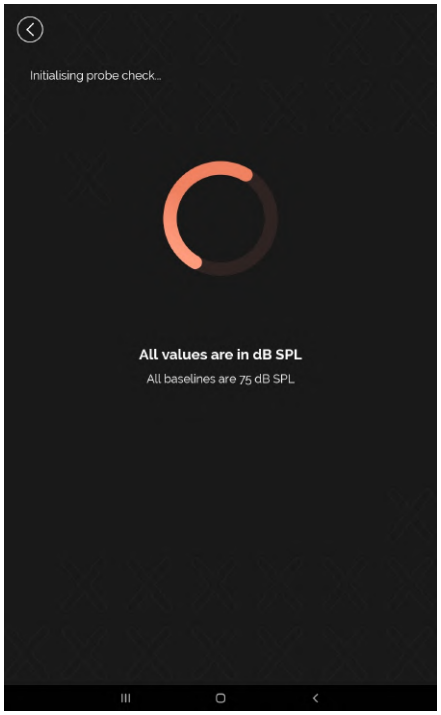
Second Probe Check Instruction Screen:



Probe Check Executing Screen:

Probe Check Passed Screen:

Probe Check Failed Screen:



6.9 TEST PROTOCOL

6.9.1 SELECTING A TEST PROTOCOL

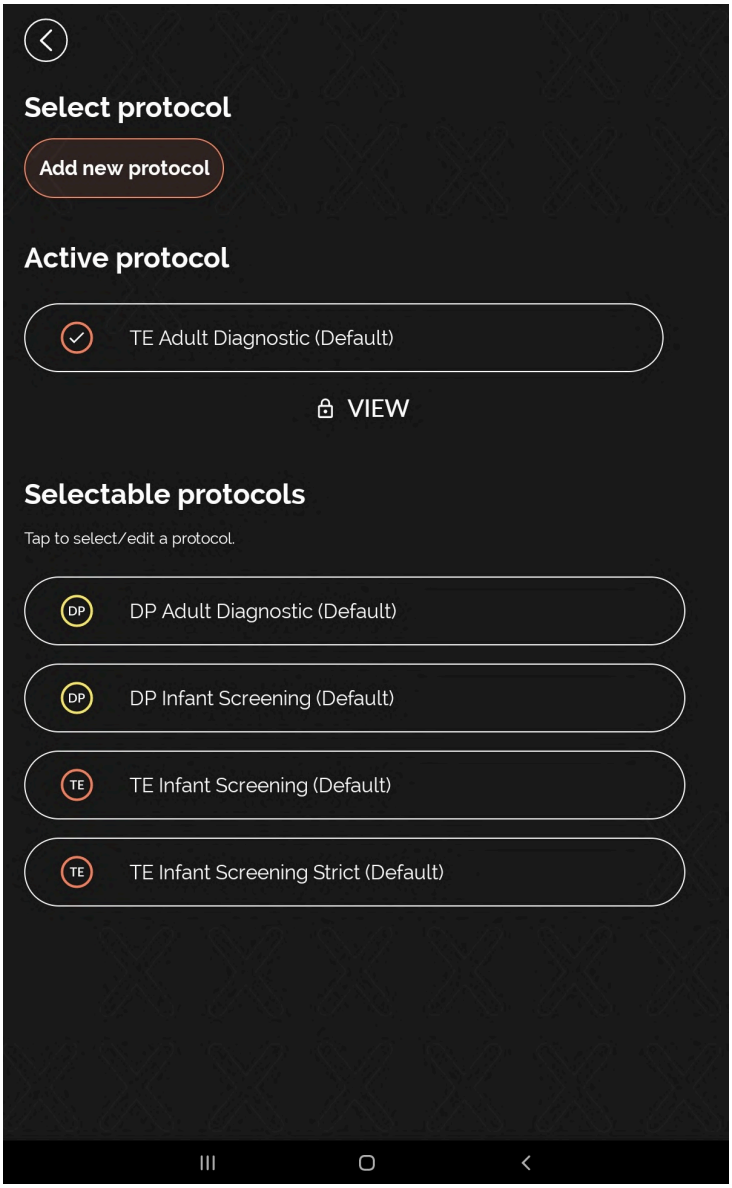
The protocol screen allows the user to select a protocol. A first-time user will have a default protocol for TEOAE and DPOAE listed. If a custom protocol has been added, the user should be able to activate the custom protocol by tapping on the custom protocol's name. The user should then be able to edit the protocol.

The software allows the user to create a customized protocol. This is done by selecting the "*Add new protocol"* button underneath the Select Protocol heading. This will redirect the user to the *Add Protocol* screen. Customized protocols that were previously set-up are listed under a unique name, as specified by the user. TEOAE and DPOAE protocols are listed on the same screen and an icon displaying either TEOAE or DPOAE is displayed next to the protocol name that allows the user to differentiate the test type between the listed protocols. The back button returns the user to the Home screen without saving any changes.

The protocol selection screen has a section labeled "Active protocol". "Selectable protocols" are listed below and can be selected to move to the "Active protocol" list, by clicking the the ACTIVATE text. When a protocol is selected, the protocol moves to the "Active protocol" list.

Protocols can be edited by clicking on the EDIT text. A protocol can also be locked when the lock icon is open, and can't be edited when the lock icon is closed unless a code is entered.

The "*ACTIVATE"* and "*EDIT""* buttons can be found by selecting the protocol name. The buttons will then be displayed underneath the selected protocol. An active protocol will only display the "*EDIT"* or "*VIEW"* button. All default protocols have only the "*VIEW"* button as they are uneditable.



6.9.2 ADDING A NEW TE TEST PROTOCOL

By selecting the "*Add new protocol"* button, the user can create a customized protocol for a TEOAE or DPOAE test. The protocol needs to be assigned a unique name, as entered by the user. This is a compulsory field and the user cannot save (by selecting "*Save"*) without entering a name in the field provided. The user can customize protocols in the "adjustment" tab, based on the following fields:

1. General
    a. Adult/Child selector: This is to indicate if the protocol is relevant to which age group when doing OAE tests. The choice effects the initial level of the stimuli that is presented during a pre-test. For an adult, the starting level is at 75 dB SPL, and for child it is at 60 dB SPL.
    b. Screening/Diagnostic selector: This is to indicate if the protocol used for the test is to perform a diagnostic or screening test. For a diagnostic test, the pass/refer result will be hidden from the result screen as well as from the detailed result screen for each test accessed via the result summary view.
2. Frequencies
    a. Diagnostic: 5 Frequencies are available - 1000, 1500, 2000, 3000, 4000 Hz.

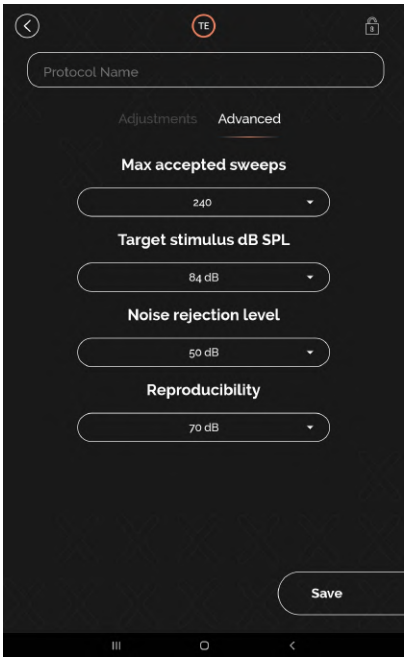
   b. Screening: 5 Frequencies are available - 1000, 1500, 2000, 3000, 4000 Hz. The user however has the option to test a minimum of 4 frequencies.
3. Pass/Refer criteria
   a. SNR Criterion: Four options are available to choose from - 3dB, 4dB, 6dB and 9dB. The user can select only one SNR Level. If the SNR criteria is met at a certain frequency, the frequency is deemed valid. For Diagnostic the SNR criterion serves only as a visual aid.
   b. Number of Frequencies: This is only applicable to Screening. It represents the number of valid frequencies required for a Pass. The available options are given as a dropdown criterion with the following options:
      i. If 4 frequencies are selected: the choice of 2, 3 or 4 valid frequencies is available for a Pass
      ii. If 5 frequencies are selected: the choice of 3, 4 or 5 valid frequencies is available for a Pass
4. From here, the remainder of the customizable criteria are listed under a separate tab, "Advanced".
   a. Max accepted sweeps - The maximum number of sweep pairs to be accepted according to noise rejection level. The test will wait until the sweep count is reached. In the case of a Screening test, if the maximum amount of sweeps is reached the result will, in all certainty, be a Refer.
   b. Target stimulus (dB) - The target dB per SPL value that the stimulus will be calibrated towards in the ear.
   c. Reproducibility - Indicates the correlation between the A and B waveform. Only available to set for Screening.
   d. Noise rejection level (dB SPL) - Threshold noise level for an individual sweep, classifying the sweep as accepted or rejected.

When adding a new protocol, the customizable fields are not empty, and contain the default values provided in the default TEOAE protocols. The user can customize the protocol by selecting and deselecting the default protocol, the customized protocol is only saved if the user selects *SAVE.* The user can also create their own TEOAE protocols.

TEOAE Screening Protocol:

TEOAE Screening Protocol Adjustments Screen:

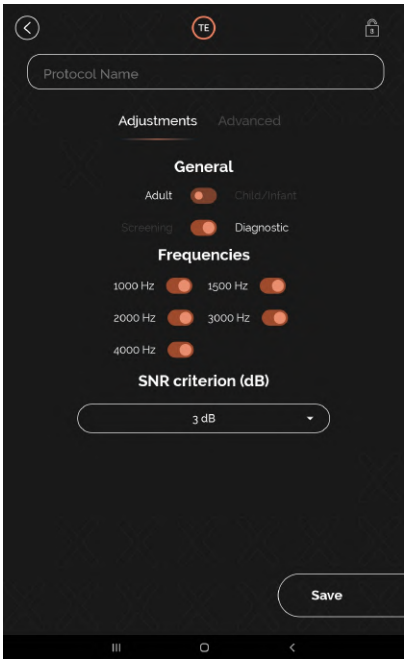
TEOAE Screening Protocol Advanced Screen:

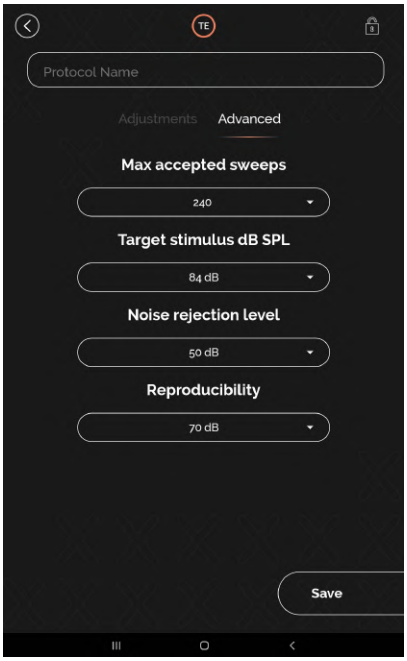


TEOAE Diagnostic Protocol:

TEOAE Diagnostic Protocol Adjustments Screen:

TEOAE Diagnostic Protocol Advanced Screen:





6.9.3 ADDING A NEW DP TEST PROTOCOL

By selecting the "*Add new protocol"* button, the user can create a customized protocol for a TEOAE or DPOAE test. Similarly to the TE process, the protocol is assigned a unique name, as entered by the user. This is a compulsory field and the user cannot save (by selecting "*Save"*) without entering a name in the field provided. The user can customize a protocol on the "Adjustments" tab, based on the following fields:

1. General
    a. Adult/Child selector: To indicate that the protocol is relevant to a specific age group when conducting OAE tests. The choice affects the initial level of the stimuli that is presented during a pre-test. For an adult, the starting level is at 75 dB SPL and for a child it is at 60 dB SPL.
    b. Screening/Diagnostic selector: This is to indicate if the protocol used for the test is to perform a diagnostic or screening test. For a diagnostic test, the pass/refer result will be hidden from the result screen as well as from the detailed result screen for each test accessed via the result summary view.
    c. In test probe fit: This is to indicate if the probe fit should be checked between DP frequency pairs while a test is running.
2. Frequencies: All frequencies are located at f2. The display for the frequencies to be specified for a DPOAE test will depend on the screening or diagnostic selector:
    a. Screening: A maximum of 6 frequencies can be tested for - 1000, 1500, 2000, 3000, 4000, 5000, 6000 Hz. The user however has the option to test a minimum of 3 frequencies.
    b. Diagnostic - the list of frequencies will be replaced by providing 3 indicators for determining the testing frequencies.
        i. Points per octave - specifying the number of points per octave to be included in the frequency list. 1 = Octave bands, 2 = Half-octave bands, 3= Third-octave bands. This parameter also dictates the start and end frequencies that will be selectable in the list to the user.
        ii. Start - the lowest frequency which will be tested.
        iii. End - the highest frequency which will be tested.
            1. The available list is provided in the table below:

1 Octave		1/2 Octave		1/3 Octave	
Start (Hz)	End (Hz)	Start (Hz)	End (Hz)	Start (Hz)	End (Hz)

1000, 2000	4000, 8000	700, 1000, 1400, 2000	5500, 8000	800, 1000, 1200, 1500, 2000	5000, 6000, 8000

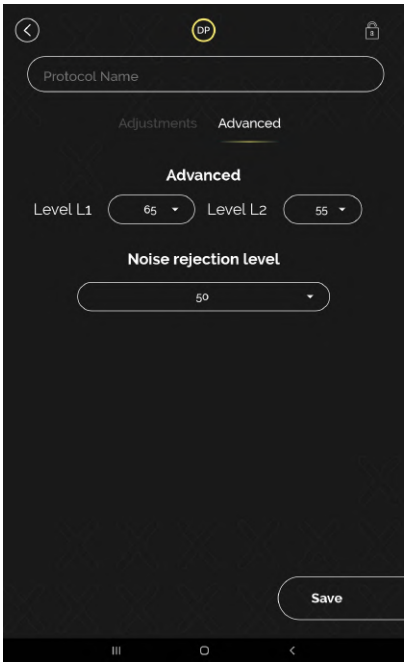
3. Pass/Refer criteria
    a. SNR criterion: Four options are available to choose from - 3dB, 4dB, 6dB and 9dB. The user can select only one SNR Level. If the SNR criteria is met at a certain frequency, the frequency is deemed valid. For Diagnostic the SNR criterion serves only as a visual aid.
    b. Number of frequencies: Only applicable to Screening. It represents the number of valid frequencies required for a Pass. The available options are given as a dropdown criterion with the following options:
        i. If 3 frequencies are selected: the choice of 2 or 3 valid frequencies is available for a Pass
        ii. If 4 frequencies are selected: the choice of 2, 3 or 4 valid frequencies is available for a Pass
        iii. If 5 frequencies are selected: the choice of 3, 4 or 5 valid frequencies is available for a Pass
        iv. If 6 frequencies are selected: the choice of 4, 5 or 6 valid frequencies is available for a Pass
        v. If 7 frequencies are selected: the choice of 5, 6 or 7 valid frequencies is available for a Pass
4. From here, the remainder of the customizable criteria are listed under a separate tab, "Advanced".
    a. Level L1/L2 - The target dB SPL value that the stimulus pairs will be calibrated towards in the ear.
    b. Averaging time (seconds) - The number of accepted buffer counts (in time) a frequency pair will be presented, the options are between 2 and 10 seconds. This option is only available for Diagnostic.
    c. Noise rejection level (dB SPL) - Threshold noise for an individual sweep, classifying the sweep as accepted or rejected.

When adding a new protocol, the customizable fields are not empty, and contain the default values provided in the default DPOAE protocols. The user can customize the protocol by selecting and deselecting the default protocol, the customized protocol is only saved if the user selects *DONE*. The user can also create their own DPOAE protocols.

DPOAE Screening Protocol:

DPOAE Screening Protocol Adjustments Screen:

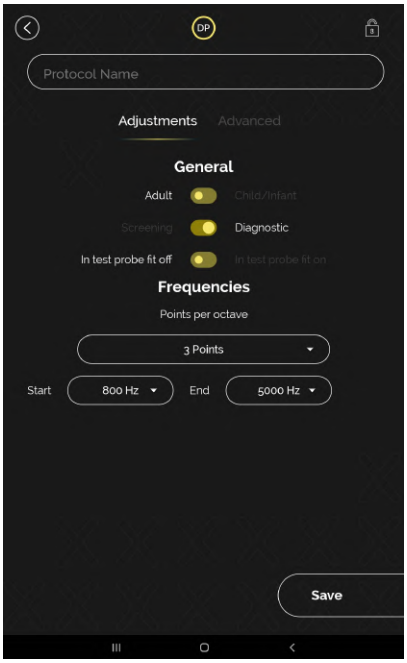
DPOAE Screening Protocol Advanced Screen:

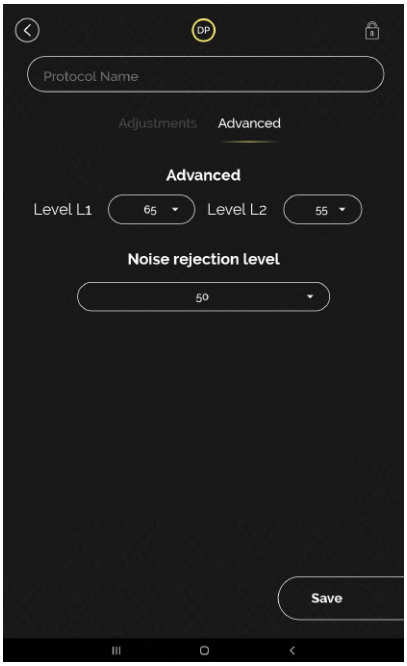


DPOAE Diagnostic Protocol:

DPOAE Diagnostic Protocol Adjustments Screen:

DPOAE Diagnostic Protocol Advanced Screen:





6.9.4 EDIT OR DELETE A TEST PROTOCOL

The default protocols cannot be edited or deleted. However, the customized protocols offer this functionality.

If the EDIT button is selected - the "Adding a protocol screen" opens for the user to edit parameters as required. From here the user can make any changes to the parameters.

When editing a protocol, the protocol may be deleted by selecting the trash icon (in the right top corner, next to the lock icon) - the user will be asked to confirm their decision to delete the protocol.

6.9.5 DEFAULT TEST PROTOCOLS

The **TEOAE Diagnostic** default protocol as well as the adjustable limits are presented below:

PARAMETER	DEFAULT	USER ADJUSTABLE LIMITS FOR SETTING OF PROTOCOL
Frequencies (kHz)	1, 1.5, 2, 3, 4	1, 1.5, 2, 3, 4
Sweeps	240	80-300
Target stimulus (dB SPL)	84	70-90
Noise rejection level (dB SPL)	50	40-60

The **TEOAE Screening** default protocol as well as the adjustable limits are presented below:

PARAMETER	DEFAULT	USER ADJUSTABLE LIMITS FOR SETTING OF PROTOCOL
Frequencies (kHz)	1.5, 2, 3, 4	1, 1.5, 2, 3, 4
Pass criteria - Number of valid frequencies	3/4	2,3,4/4 OR 3,4,5/5
Pass criteria - SNR level (dB SPL)	3	3, 4, 6, 9

Sweeps	240	80-300
Target stimulus (dB peSPL)	82	60-86
Reproducibility (%)	70%	60, 65, 70, 75, 80, 85, 90
Noise rejection level (dB SPL)	50	40-60

The **DPOAE Diagnostic** default protocol as well as the adjustable limits are presented below:

PARAMETER	DEFAULT	USER ADJUSTABLE LIMITS FOR SETTING OF PROTOCOL
Points per octave	3 Points	1, 2, 3
Start and end (Hz)	1000 and 6000	Refer to Table at *6.9.3 Adding a New DP Test Protocol*
Level (L1 and L2 dB SPL)	L1 = 75 L2 = 70	L1 adjustable from 30 to 75 L2 adjustable from 30 to 70
Noise rejection level (dB SPL)	50	40 to 60
Averaging time (seconds)	4	2, 4, 6, 8

The **DPOAE Screening** default protocol as well as the adjustable limits are presented below:

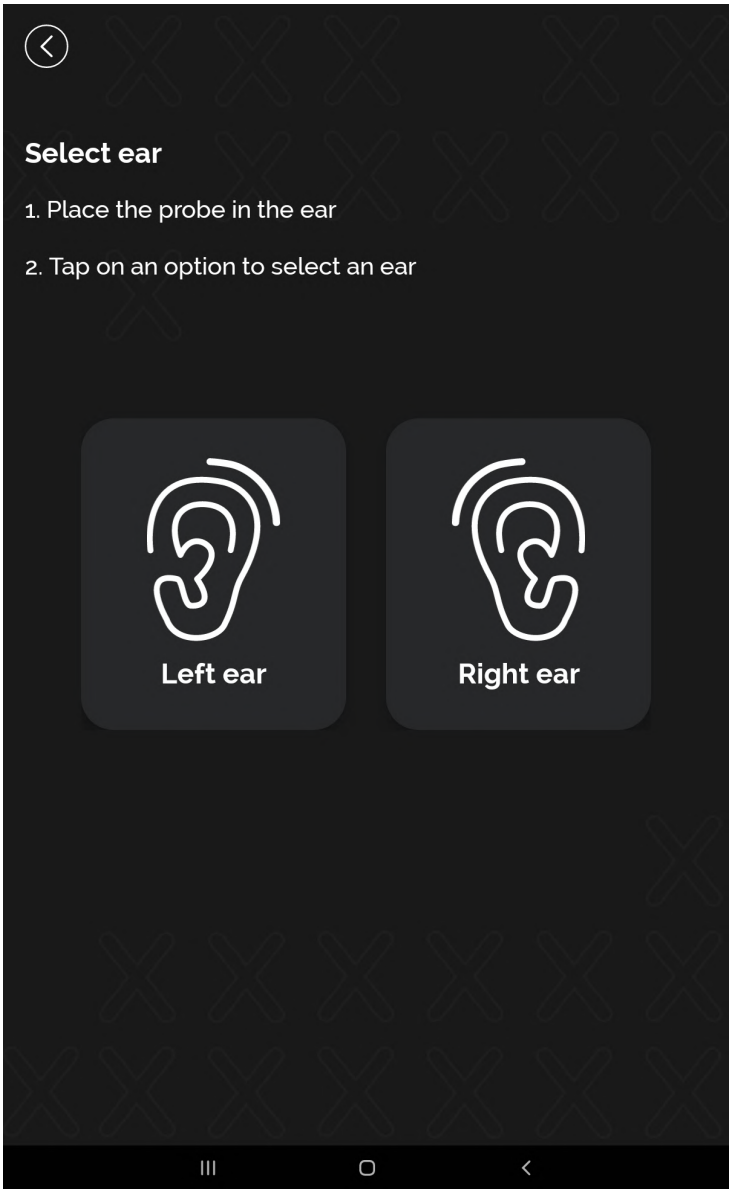
PARAMETER	DEFAULT	USER ADJUSTABLE LIMITS FOR SETTING OF PROTOCOL
Frequencies (kHz)	1.5, 2, 3, 4, 5	1, 1.5, 2, 3, 4, 5, 6
Pass criteria - Number of valid frequencies	4/5	3,4/4 OR 3, 4,5/5 OR 4,5,6/6 OR 5,6,7/7
Pass Criteria - SNR level (dB SPL)	6	3, 6, 9, 12
Level (L1/L2)	65/55	65/55 OR 75/70
Noise rejection level (dB SPL)	50	40-60

6.10 PRE-TEST

To start a DPOAE/TEOAE test, the user needs to select the "*START*" button on the Home Screen. The name of the activated DP/TE protocol is displayed above the "*START*" button on the Home Screen. The default protocol will be activated for TEOAE, unless changed by the user in the protocols menu on the Home Screen.

6.10.1 SELECT AN EAR

The screen prompts the required messages to start with a test. The user needs to select the ear in which the hearOAE Probe is inserted. The instrument will store the test result for the ear that was selected.



6.10.2 PRE-TEST

During the pre-test, three specific checks are done: 1. Probe fit, 2. Symmetry, 3. In-ear calibration. This is referred to as the Pre-Test process. Note, for Probe Check (*section 6.8 Probe Check*) - the same Probe fit and Symmetry procedure is completed as explained here.

1. Probe fit determines whether the probe is properly inserted into the ear with focus on the seal. If the seal is not adequate the user is informed by an error message. Appropriate adjustment of the hearOAE Probe position and ear tip size selection need to be made until the probe fit is successful.
2. Symmetry verifies whether the output of the two driver channels are similar. If one channel is softer than the other, the probe might be pressing against the ear canal wall.
3. In-ear calibration is performed once the Probe fit and Symmetry processes are successful. This feature is only for TE tests.

The following error messages may be displayed resulting from failure to meet the **Probe fit** and **Symmetry** measurement criteria.

- Inadequate seal: “Check probe seal”.
- Microphone reading low or channel(s) blocked: “Refit probe. Alternatively clean coupler channels”.

- Excessive environmental or patient noise: “Too Noisy - Testing environment not ideal”.

Once the error message is displayed, the user has the options to:

- *“Restart”*, or if
- *Options* is selected:
  - *“Continue Anyway”* which starts the chosen OAE test, or
  - *“Quit”* and go to the Home Screen.

If the pre-test fails the user is advised to remove the hearOAE Probe from the ear, visually inspect the channels of the Probe coupler to identify any objects or blockages, clean the Probe using the recommended steps in the user manual (section *11.2 Probe Cleaning*), and replace the Probe into the ear. If the error pop-up reappears multiple times even after cleaning the hearOAE Probe, the user needs to perform a Probe Check.

If the in-ear calibration passes, the app displays “Probe fit Complete” with a green check mark.

6.11 TEST

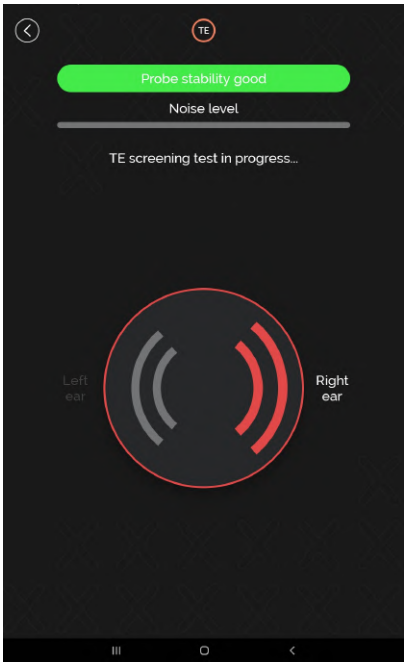
Once the user has completed the pre-test, the test starts automatically, and the user interface transitions to the in-testing screen for the relevant test.

6.11.1 TESTING

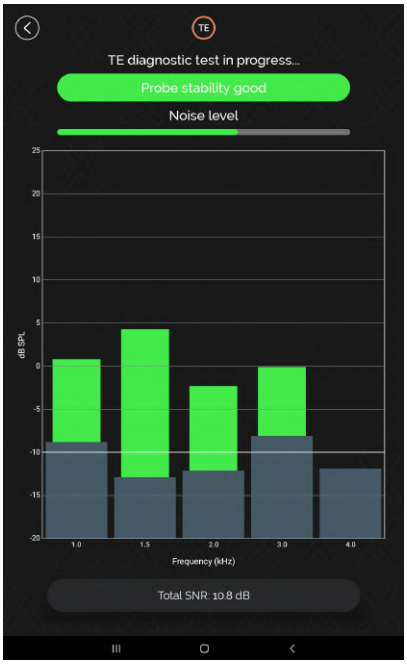
Depending on the test type chosen, one of four visuals are displayed to the user consisting of the information below:

1. Noise level
2. Stability
3. Test progress
4. Ear being tested
5. The probe fit - only applicable to a DPOAE test
6. Frequency being tested - only applicable to a DPOAE test

TEOAE Screening

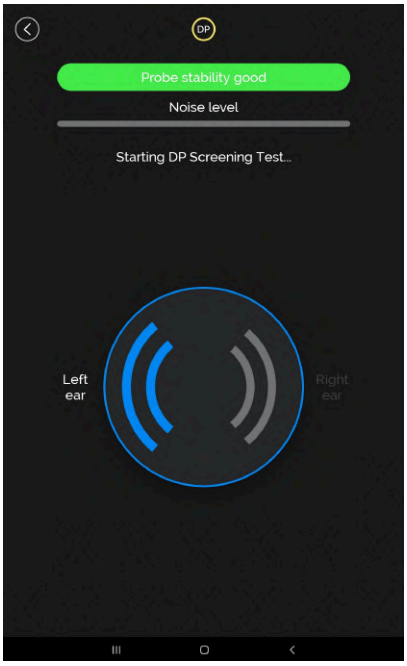


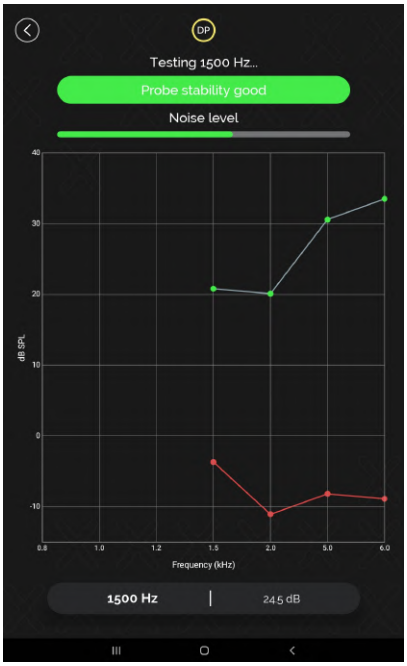
TEOAE Diagnostic



DPOAE Screening

DPOAE Diagnostic





The noise level

The device displays the noise captured within the ear, however, the external environmental noise contributes to the noise within the test subject's ear. As the noise level changes, the colour of the meter at the top of the screen also changes. When the noise level is acceptable, a green line is displayed. As the noise level increases, the line color changes to orange. When the noise meets the maximum allowable noise level, it enters the red range. In the event that the noise exceeds the maximum noise level for a certain period of time, the following pop-ups are displayed for TEOAE and DPOAE.

1. TEOAE: The test will not pause due to excessive noise levels. The user can manually stop the test by pressing the back button.
2. DPOAE: The test is paused and the user is asked to either:
    a. Retest the current frequency by selecting "*Retest Frequency*".
    b. Restart the test from the beginning by selecting "*Restart Test*".
    c. "*Stop*", which takes the user back to the Home Screen.

The acceptable noise level is a user-definable parameter, with a minimum of 40 dB and a maximum of 60 dB SPL.

Progress of test

For screening tests:

- This is displayed by a pulsing hearX half circle icon. The movement mimics a sound wave being produced. The purpose of this visual is to indicate to the user that the test is in progress.

For diagnostic tests:

- This is displayed by a TEOAE gram or a DPOAE gram (depending on the test being performed) that is updated in real-time. The purpose of this visual is to indicate to the user what the actual SNR values are.

Probe fit

The probe fit indicator (at the top right corner of the screen) changes from green to red to show the quality of the probe fit. Once the seal enters the red range, the test is stopped, and the user is informed to reposition his/her probe.

Ear indicator

The ear being tested is displayed on the progress visual. The ear displayed is chosen based on the ear selected prior to the test.

Frequency being tested - only applicable to DPOAE tests.

The frequency displayed to the user is the frequency presented and this changes multiple times during the test, depending on the number of frequencies selected by the user. The test progress visual does not fill for each frequency, but shows the progress of the overall testing time. If the pass criteria is met before the last frequency is tested, the progress visual will fill up completely before transitioning to the results screen.

6.11.2 TEST INTERRUPTIONS

The test can be interrupted by one of four methods:

1. User selects the Home button:
   The back button is disabled during the test. The home button is not disabled, therefore if the user selects the Home button, the test stops. On re-entering the App, the user receives a message that reads: "The test has stopped. Please restart the test.".
   - If it was the first test performed in the session, the user is redirected to mHealth.
   - If it was not the first test performed in the session, the user is redirected to the summary screen.
2. User pulls down the status bar:
   If the user pulls down the status bar of the Android device during the test, the test is not stopped. However, if the user selects an App or notification on the status bar that causes him to leave the hearOAE app, the test is stopped. On re-entering the App, the user receives a message that reads: "The test has stopped. Please restart the test.".
   - If it was the first test performed in the session, the user is redirected to mHealth.
   - If it was not the first test performed in the session, the user is redirected to the summary screen.
3. Probe disconnects during test:
   If the hearOAE Probe disconnects during the test, the test is stopped. On re-entering the App, the user receives a message that reads: "The test has stopped. Please restart the test.".
   - If it was the first test performed in the session, the user is redirected to mHealth.
   - If it was not the first test performed in the session, the user is redirected to the summary screen.
4. Bluetooth disconnects during test:
   If the Bluetooth disconnects during the test, the test is stopped. On re-entering the App, the user receives a message that reads "The test has stopped. Please restart the test.".
   - If it was the first test performed in the session, the user is redirected to mHealth.
   - If it was not the first test performed in the session, the user is redirected to the summary screen.
5. hearOAE application is minimised during test:
   If the user minimised the application during the test, the test is stopped. On re-entering the App, the user receives a message that reads "The test has stopped. Please restart the test.".
   - If it was the first test performed in the session, the user is redirected to mHealth.
   - If it was not the first test performed in the session, the user is redirected to the summary screen.

6.12 TEST RESULTS

6.12.1 TEST RESULTS

In the case that either a screening or diagnostic test was performed, the screen automatically transitions to the "DP/TE Gram" screen for Diagnostic or "Summary" screen for Screening.

The "DP/TE Gram" screen displays the Overall OAE and Overall Noise metrics:

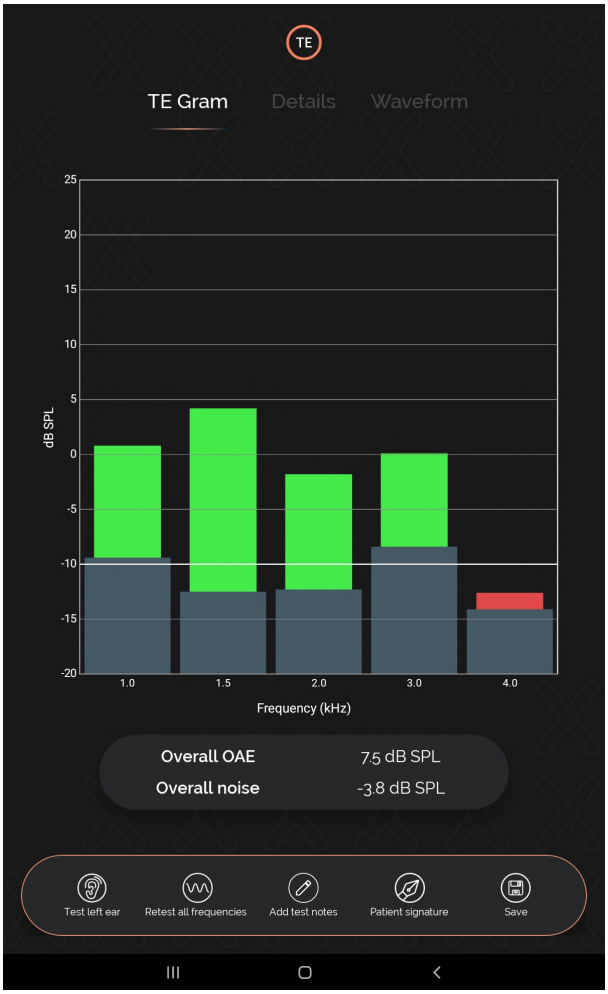
- Overall OAE: The logarithmic average of the OAE amplitudes across all tested frequencies where a valid response is detected. This is calculated to represent the average strength of the OAE signal over the tested frequency range, accounting for the logarithmic nature of decibel measurements.
- Overall Noise: The logarithmic average of the noise levels across all tested frequencies. This is calculated provide a single noise value that reflects the average noise level over the frequency range, accounting for logarithmic decibel scaling.

The user can selection to transition to the "Details" screen and "Waveform" screen (for TE only) whilst in the results view.

6.12.1.1 TEOAE Diagnostic and Screening Options

The screen displays the following options:

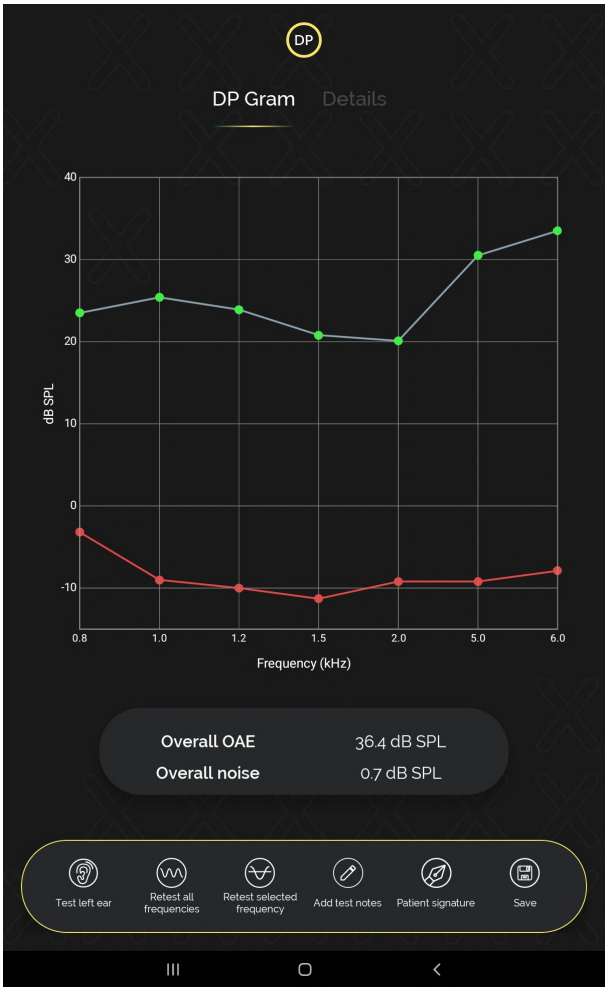
- *"Save"* button which directs the user to the Session Summary screen.
- *"Retest all frequencies"* - if the user selects this button, the entire TEOAE test will restart (using the same protocol as previously selected).
- *"Test left/right ear"* - the test conducted is saved and the user navigates to the Probe fit screen where a Probe fit is immediately started. Dependent on what ear was tested first (for example right), the message displays "Test left ear".
- *"Notes"* - the user is provided with a text box where notes can be made which forms part of the conducted test result.
- *"Patient signature"* - the user is provided with a space for an electronic signature where a patient may sign for the test results. **Note:** This is not a compulsory field.



6.12.1.2 DPOAE Diagnostic and Screening Options

- *"Save"* button which directs the user to the Session Summary screen.
- *"Retest all frequencies"* - if the user selects this button, the entire TEOAE test will restart (using the same protocol as previously selected).
- *"Retest selected frequency"* - the user has the option to retest a specific frequency. For screening, if the test result was "Refer", the outcome of the retest on that specific frequency may alter the result to "Pass".
    - A frequency is selected by tapping on the DP gram. The card below the gram will update to show the user which frequency is currently selected as well as the results associated with that frequency.

- *"Test left/right ear"* - the test conducted is saved and the user navigates to the Probe fit screen where a Probe fit is immediately started. Dependent on what ear was tested first (for example right), the message displays "Test left ear".
- *"Notes"* - the user is provided with a text box where notes can be made which forms part of the conducted test result.
- *Patient signature"* - the user is provided with a space for an electronic signature where a patient may sign for the test results. **Note:** This is not a compulsory field.



6.12.2 DETAILED TEST RESULTS

6.12.2.1 TEOAE DETAILED RESULTS

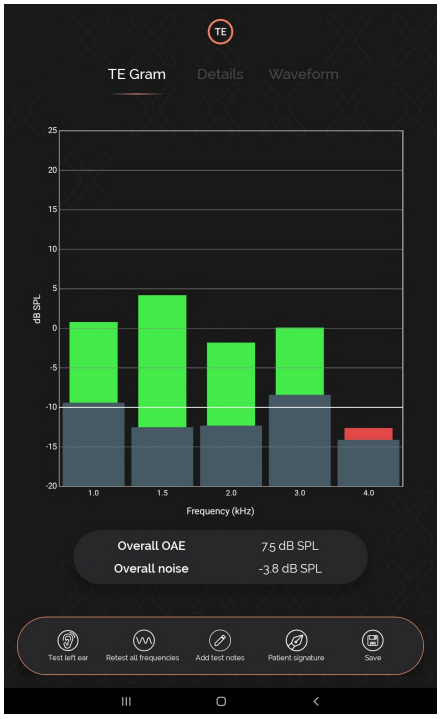
The TEOAE results are grouped into three separate tabs, namely "TE GRAM", "DETAILS" and "WAVEFORMS". The Ear indicator at the top of the screen displays the results of the current ear, and if there is a test on the other ear, the results are displayed.

1. The first tab is referred to as TE GRAM and displays the SNR bar graph.
   - The x-axis displays the frequencies in kHz (as selected by the user) and the y-axis is the level measured in dB SPL.
   - The line at -10 dB SPL, indicates the minimum level of the signal. This is set as one of the pass criteria.
   - Based on the pass criteria as per the protocol parameters set by the user, each bar is red or green in colour, which indicates if the user has or has not met that parameter per frequency.
   - In the case that a screening test has been performed, the test result is displayed above the bar graph as a pass/refer. If a diagnostic test is performed, the pass/refer is hidden.

- Below the graph, the following is displayed:
- Overall OAE (in dB SPL)
- Overall Noise (in dB SPL)

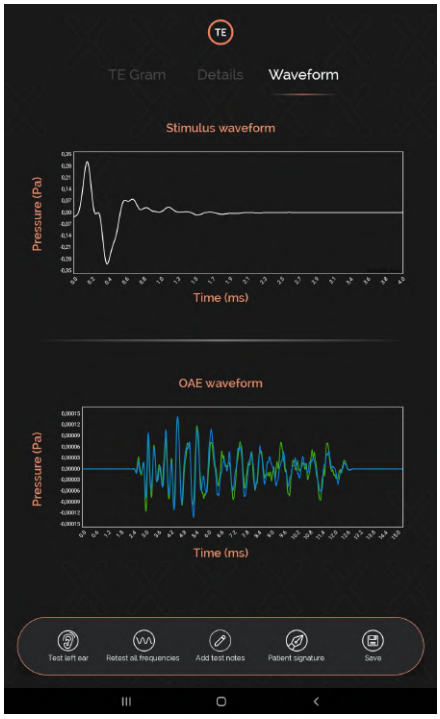
2. The second tab is referred to as DETAILS and displays:
   - A table with the following per band:
   (i) Signal,
   (ii) Noise,
   (iii) SNR and
   (iv) Reproducibility
   - Below the table, the following is displayed:
   (i) Sweeps (Acc/Rej),
   (ii) Overall OAE (in dB SPL),
   (iii) Overall Noise (in dB SPL),
   (iv) Overall Reproducibility (%),
   (v) Artifacts (%),
   (vi) Stability (%),
   (vii) Test duration (in seconds)
3. The last tab is referred to as WAVEFORMS and displays:
   - Stimulus waveform
   - OAE waveform

TE GRAM



DETAILS

WAVEFORMS



6.12.2.2 DPOAE DETAILED RESULTS

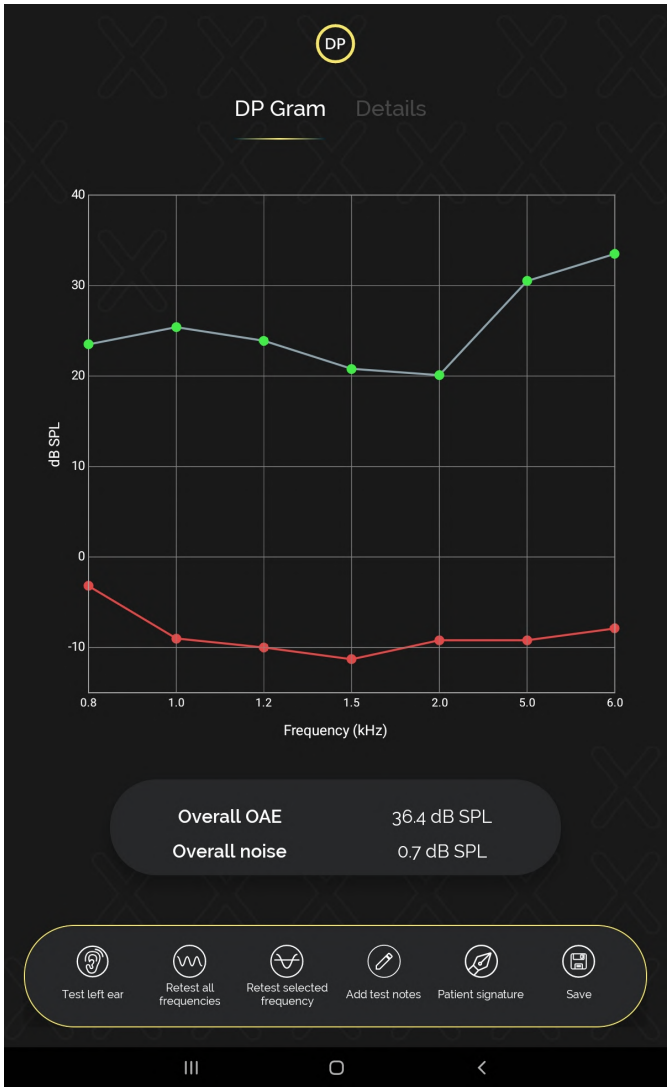
The DPOAE results are grouped into two separate tabs, namely “DP GRAM” and “DETAILS”. The Ear indicator at the top of the screen displays the results of the current ear, and if there is a test on the other ear, the results are displayed.

1. The first tab is referred to as the DP GRAM and displays the DP Gram.
   - The x-axis displays the frequencies in kHz (as selected by the user) and the y-axis is the level measured in dB SPL.

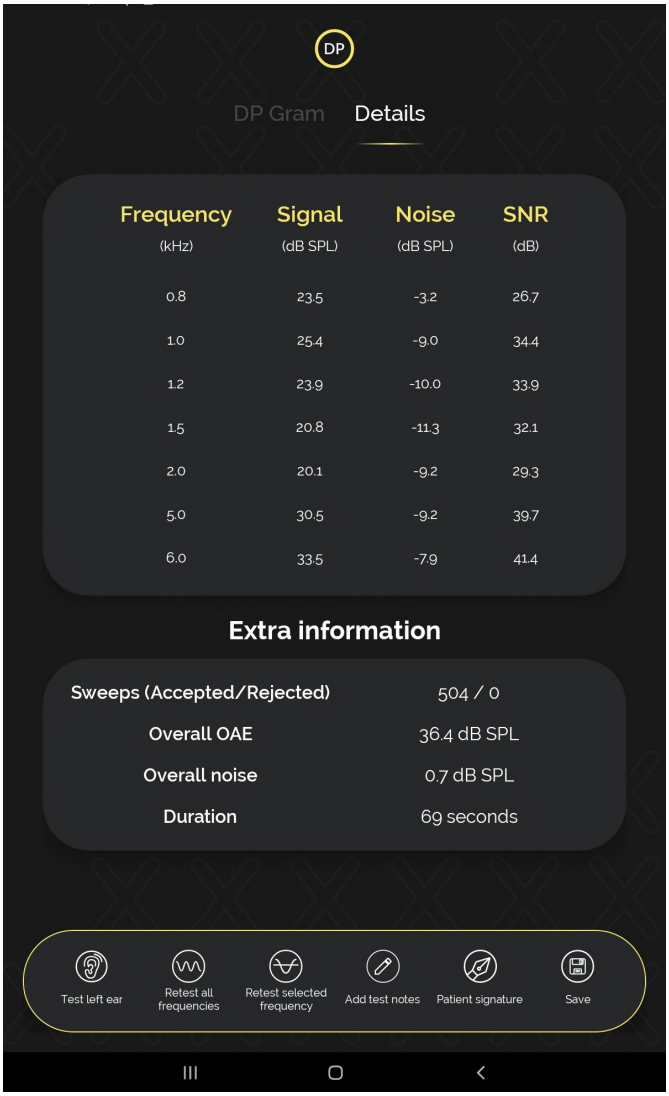
- The SNR figures can be viewed upon selecting a dot in the line graph.
- Based on the pass criteria, each dot on the DP Gram is either red or green in colour, indicating whether the frequency pair has met the the selected criteria as by the user.
- In the case that a screening test has been performed the test result is displayed above the DP gram as a pass/refer. If a diagnostic test is performed, the pass/refer is hidden.
- Below the graph, the following is displayed:
- Overall OAE (in dB SPL)
- Overall Noise (in dB SPL)

2. The second tab is referred to as DETAILS and displays:
- A table with the following per frequency pair:
(i) Signal,
(ii) Noise and
(iii) SNR
- Below the table, the following is displayed:
(i) Sweeps (Acc/Rej),
(ii) Overall OAE (in dB SPL),
(iii) Overall Noise (in dB SPL) and
(iv) Test Duration (in seconds)

DP GRAM



DETAILS



6.12.3 SESSION SUMMARY

Session Summary provides a summary of the current session. A session consists of multiple tests for a single patient. The tests include testing multiple ears and conducting different test types (TEOAE and DPOAE).
The test data is separated into two tabs or sections, namely TEOAE (indicated using TE) and DPOAE (indicated using DP).

The user can navigate between the two tabs by:

- Clicking on the text of the tab
- Swiping from right to left to access the DPOAE tab and left to right to swipe back to the TEOAE tab

For the certain test type (DPOAE/TEOAE), the left ear data is displayed first (and the right ear in the section below).

For each test, an overall test result is provided for the specific ear. The format is given as i.e. Screening | Time Stamp | Pass/ Refer OR Diagnostic | SNR 16.4 dB SPL | Time Stamp. The most recent result will be at the top of the list.

The user can access the detailed results for each test conducted, by clicking on the eye icon. By selecting the "*New test*" button, the user is redirected to the Home Screen. By selecting the "*Done*" button, the user is redirected to the mHealth start screen.

7. LIMITATIONS OF USE

The instrument must not be used when it is likely that the validity of the test results may be compromised. Do not conduct a test on a patient who may have an ear infection with active drainage from the ear, as this may cause damage to the equipment or harm other patients. For the purpose of hygiene, never reuse ear tips. Adult patients must be able to follow verbal instructions and cooperate to undergo the OAE test(s). When testing infants or children, they must be placed in position that will allow for easy access to the ear canal. The patient should be able to remain still and quiet while the test is being performed. The instrument should not be used in a domestic or home environment.

8. HEAROAE COMPATIBLE DEVICES

hearOAE has been designed for use with a Samsung smart device with a minimum OS of Android 10. The hearOAE Device and the hearOAE Probe are required for testing.

9. TEST SPECIFICATIONS

9.1. TEOAE TEST SPECIFICATIONS

Parameter	Description
Stimulus	83 µs alternating broadband square wave
Sample rate	48 kHz
Stimulus pattern	Non-Linear: Each sweep presents 4 stimuli, 3 smaller stimuli in one polarity and 1 larger stimulus in the opposite polarity. The pattern can be described as: X X X Y where Y = -3X
Response buffer averaging	The responses from each stimulus in a sweep are summed and averaged. Averaging this stimulus pattern removes artefacts leaving only the OAE signal which is non linear. These sub averages are alternately added to two separate averages. These separate averages are referred to as waveforms A and B.
Signal and noise calculation	Measures the average signal and noise levels between waveforms A and B.
Stimulus repetition rate	One stimulus every 21.3ms, approximately 47 stims per second.

Response window	3 - 20 ms
Response frequency bands	Half octave, centers at 1000, 1414, 2000, 2828 and 4000 Hz

9.2 DPOAE TEST SPECIFICATIONS

Parameter	Description
Stimulus	Pure tones with a frequency ratio of 1.22
Sample rate	48 kHz
FFT and bin size	4096 and 11.72 Hz
DP noise calculation	Noise is calculated as the mean plus two standard deviations. The noise bandwidth considered is 230 Hz around the center of the OAE.
DP signal reported	The distortion product is measured at 2f1-f2, and reported at the nominal frequency f2.

10. HEAROAE FEATURES

FEATURE	AUDIOLOGICAL FUNCTION	WHEN IS THIS USEFUL?	TECHNICAL CONSIDERATIONS
Noise monitoring	Noise monitoring	During the testing to monitor the reliability of the test results	The noise rejection level is set as part of the protocol used for conducting a test. The default value is 50 dB SPL.
Stability	Provides an indication of the stability of the stimulus while the test is conducted.	During the test to monitor whether the probe placement is changing.	-
Overall OAE	Represents the average strength of the otoacoustic emissions across tested frequencies, indicating outer hair cell function.	Useful for determining if the cochlea is producing emissions strong enough to indicate normal function, particularly in newborn hearing screening and ototoxicity monitoring.	Calculated using a logarithmic average of OAE amplitudes across valid frequencies; higher values indicate a stronger response.
Overall Noise	Represents the average background noise level during the test, which may come from the environment, patient movement, or physiological sources.	Helps identify whether excessive noise is affecting test reliability, ensuring accurate differentiation between actual emissions and noise artifacts.	Calculated using a logarithmic average of noise levels across frequencies; excessive noise can mask emissions, leading to false negative results.
Protocol name	The protocol settings can be adapted to suit your test situation. It is important to name your protocol accordingly.	This function is important to determine when to use the appropriate protocol for a specific test setting, e.g. infant versus adult testing, or screening vs diagnostic.	-

FEATURE	AUDIOLOGICAL FUNCTION	WHEN IS THIS USEFUL?	TECHNICAL CONSIDERATIONS
Diagnostic: selection of frequencies	With respect to DPOAE, this function allows you to select the frequencies you wish to test. Specifically the frequency bandwidth as well as the points per selected octave.	The outcome is that the user may focus on a certain frequency range, and can also decide to view a small or larger amount of frequency points in that bandwidth.	-
Screening: selection of frequencies	This function allows you to select the frequencies you wish to test and unselect the frequencies you wish to skip.	Providing the flexibility of testing different frequencies is useful specifically when testing infants. This in combination with the next point, provides the audiologist with the opportunity to optimize the screening protocol.	-
Screening: protocol specific pass criteria	This function allows you to set the pass criteria, based on your testing subject and environment.	See above.	-
Protocol specific parameters	This function allows you to set the parameters, based on your testing subject and environment.	The TEOAE parameters include: (i) test type (screening or diagnostic), (ii) child or adult testing, (iii) frequencies to be presented, (iv) maximum accepted sweeps, (v) target stimulus, (vi) reproducibility and, (vii) the noise rejection level. The DPOAE parameters include: (i) test type (screening or diagnostic), (ii) child or adult testing, (iii) frequencies to be presented for screening tests and a starting and ending frequency with an octave band (1, 2, or 3) for diagnostic tests, (iv) level (L1/L2), (v) averaging time, (vi) SNR value (for diagnostic tests), (vii) the noise rejection level and, (viii) in test probe fit.	-
Edit or Delete a protocol	This function allows you to edit or delete custom protocols.	-	-
Retest	A retest can be performed on the entire TEOAE or DPOAE test or part of the test can be reperformed based on the specified number of sweeps (TEOAE) or frequencies selected by the user.	If the user wants to be able to quickly redo the test or retest selected frequencies.	-
Test other ear	The other ear can be tested, using the same protocol.	If the user wants to test the other ear, using the same protocol.	-

FEATURE	AUDIOLOGICAL FUNCTION	WHEN IS THIS USEFUL?	TECHNICAL CONSIDERATIONS
View results for both ear	The other ear's results can be viewed.	If the user wants to view the other ear's results to make an informed comparison.	-

11. INSTRUMENT MAINTENANCE AND CLEANING

11.1 MAINTENANCE

This instrument requires regular maintenance including routine cleaning. The probe may require replacement when a Probe Check has failed multiple times, as this indicates a defective probe. However, prior to this the probe coupler should be either cleaned or replaced as troubleshooting steps.

A defective product should not be used. Make sure all connections to external accessories are snug and secured properly. Parts that may be broken or missing, or are visibly worn, distorted or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from hearX SA.

Equipment is not user repairable. Repairs must be performed by a qualified service representative only. Contact *support@hearxgroup.com* for assistance. Annual calibration is recommended and regular replacement of probe parts should be done to ensure optimal test results.

hearX SA is only considered to be responsible for the effects on safety, reliability and performance of the equipment if:

1. Regular calibration, assembly operations, extensions, readjustments, modifications, or repairs are carried out by authorized persons.
2. The electrical installation of the relevant room complies with the appropriate requirements, and
3. The equipment is used by authorized personnel in accordance with the documentation supplied by hearX SA.

11.2 INSTRUMENT CLEANING

The following is the suggested method to clean the hearOAE Device and its components.

hearOAE Probe: It should be noted that the hearOAE Probe is a precision assembly, and, as such, care should be taken throughout its handling and cleaning. External parts of the probe can be cleaned to remove visible particle contamination. Do not attempt to insert any object into probe. The probe coupler can be detached from the probe head and debris can be cleaned out with the provided cleaning floss.

Device surfaces: After each patient examination, ensure that there has been no contamination to the parts touching the patient. General precautions must be observed in order to avoid cross-contamination of disease from one patient to another. Water and, alcohol wipes if required, should be used for frequent cleaning.

- Before cleaning, always switch off and disconnect from the power supply .
- Use a soft cloth lightly dampened with cleaning solution to clean all exposed surfaces.
- Dry the surfaces with a tissue immediately afterwards.
- Do not immerse the hearOAE Device or Probe in fluids, or attempt to sterilize the instrument or any of its accessories.
- Do not use any hard or pointed objects, other than the cleaning floss provided for the probe coupler, to clean any part of the instrument or accessory.
- Do not let parts that have been in contact with fluids dry before using a cleaning solution.
- Never clean the transducer housing with water or insert non-specified instruments into the transducer channels.
- Ear tips are single patient use.
- Cleaning floss are single patient use.
- Ensure that alcohol does not come into contact with any silicone tubes or rubber parts.

- Long-term exposure to any disinfecting agents has the potential to alter the material properties of the plastic housing and labelling of the device. Always follow the safety and disposal guidelines given by the manufacturer of cleaning and disinfectant chemicals.

Recommended cleaning and disinfection solutions:

- Warm water with mild, nonabrasive cleaning solution (soap)
- 70% isopropyl alcohol only on hard cover surfaces
- Alcohol swab (provided)

11.2.1 CHANGING OF EAR TIPS

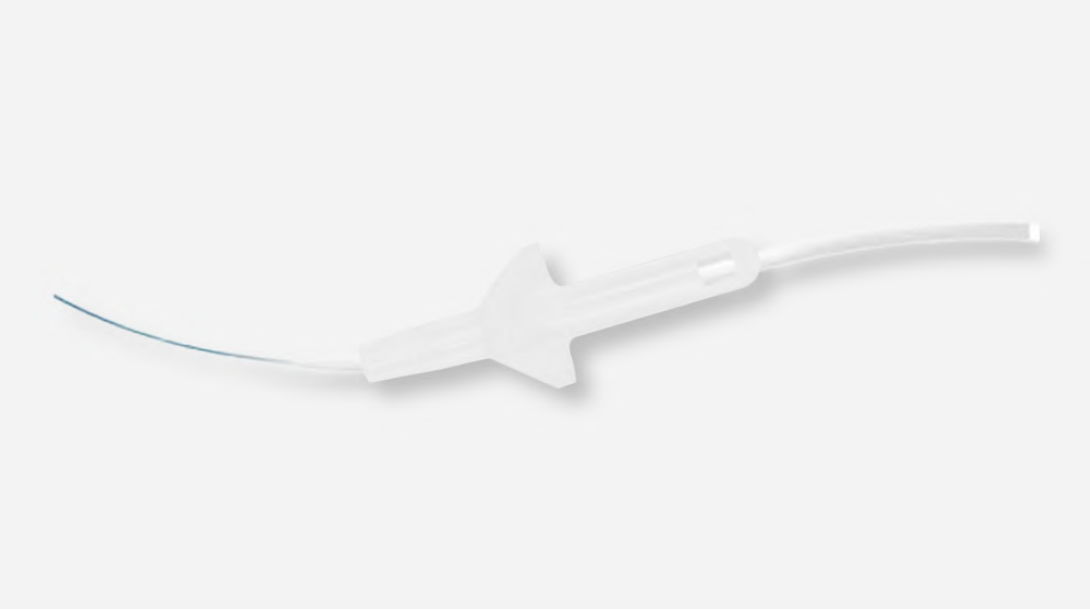
Use a new ear tip for each new patient. Ear tips are for single patient use only.

11.2.2 CLEANING AND REPLACING PROBE COUPLERS

The probe coupler, which does not make direct contact with the patient, should be cleaned if there is any sign of contamination or if the test will not progress past the "Probe Check" phase. It is advised to use a new probe coupler when the Probe Check fails consistently. Disinfection of the probe coupler between patients is not required if there are no signs of contamination.

Please note that the cleaning floss used in the cleaning of the probe coupler is a single use consumable and should be disposed of after use (the same floss can be used to clean all three coupler channels).

In order to achieve correct measurements it is important to ensure that the hearOAE Probe system is kept clean at all times. Therefore, please follow the illustrated instructions on how to clean the probe coupler.



1. Remove the ear tip from the probe coupler.
2. Unclip the probe coupler by taking the coupler arms and gently pulling them outwards and towards the probe coupler tip.
3. Thread the cleaning floss through each of the three probe coupler channels.
4. Pull the cleaning floss completely through the probe coupler channels to remove the debris collected in the channels.
5. Use a soft cloth lightly dampened with cleaning solution, or an alcohol swab to clean ONLY the probe coupler surfaces.
6. Dispose of used probe couplers (if necessary), as well as ear tips and used cleaning floss immediately to avoid confusing used components and new components.

11.3 WARRANTY

hearX SA warrants that this product is free from defects in material and workmanship and, when properly used, will perform in accordance with applicable specifications. If this instrument requires service or does not meet these criteria within one year of original shipment, the purchaser should communicate directly with hearX SA. Repair or replacement will be carried out at hearX SA's expense, subject to the terms of this warranty. The product requiring service should be returned promptly, properly packed, and postage prepaid. Loss or damage in the return shipment to hearX SA shall be at the purchaser's risk.

Changes to the product not approved by hearX SA shall void this warranty. In no event shall hearX SA be liable for any incidental, indirect, or consequential damages in connection with the purchase or use of any hearX product.

This warranty shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product.

This warranty is in lieu of all other warranties, expressed or implied, and of all other obligations or liabilities of hearX SA. hearX SA does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of hearX SA any other liability in connection with the sale of hearX products.

12 TECHNICAL SPECIFICATIONS

12.1 CLASSIFICATION AND STANDARDS

hearOAE is classified as a Class IIa medical device according to Rule 10 of Annex VIII of Regulation (EU) 2017/745 and Class II device according to Code of Federal Regulations (FDA) Title 21 (21CFR874.1050).

STANDARD	DESCRIPTION
IEC 60645-6	Electroacoustics – Audiometric equipment – Part 6: Instruments for the measurement of otoacoustic emissions
EN 60645-1	Electroacoustics - Audiometric equipment - Part 1: Equipment for pure-tone and speech audiometry
IEC 60645-3	Electroacoustics - Audiometric equipment - Part 3: Test signals of short duration
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
EN 62304	Medical device software - Software life-cycle processes
ISO 10993-1	Biological Evaluation of Medical Devices

12.2 PACKAGING SPECIFICATIONS

Dimensions	350 x 270 x 120 mm
Net Weight (Contents: Smart device, Probe, hearOAE Device and charger)	< 1 Kg
Shipping Weight (Quantity=1)	1 Kg
Power Source	Internally Powered
Case Protection	ISTA 3A-2018
Degree of Protection (electric shock)	Type B applied part

Warm-up Time	None
Usage Environment	Professional Healthcare Environment
Operating Environmental Conditions • Temperature • Humidity • Ambient Pressure	 15 ˚C to 35 ˚C 30% to 90% RH (Non-Condensing) 98 kPa to 104 kPa
Transport and Storage Conditions • Temperature • Humidity • Ambient Pressure	 5 ˚C to 40˚C 10% to 90% RH (Non-Condensing) 50 kPa to 110 kPa

12.3 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 gram
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	Wi-Fi: The smart device supports high-speed wireless internet connectivity through the Wi-Fi protocol, enabling access to online resources, cloud services, and remote communication. Bluetooth Low Energy (BLE): The Bluetooth technology allows wireless pairing with a variety of peripherals, such as compatible medical devices, for interaction and data exchange. Long Term Evolution (LTE): The smart device offers optional LTE connectivity for access to cellular networks, enabling data connectivity and communication in areas with mobile coverage.

12.4 PROBE SPECIFICATIONS

Type of OAE	Distortion Product Otoacoustic Emissions (DPOAE) Transient Evoked Otoacoustic Emissions (TEOAE)
Stimulus Frequency Range	DPOAE: 700 to 8000 Hz TEOAE: 400 to 5000 Hz

Stimulus Level Range	DPOAE: 30 to 75 dB SPL TEOAE: 60 to 86 dB SPL
Cable length	1.2 meter
Weight	30 gram
Interfaces	8-pin circular push-pull: 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.

12.5 HEAROAE DEVICE SPECIFICATIONS

Battery Capacity	4.2 V 2200 mAh Li-ion
Expected Battery Lifetime	2 years of regular use
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 gram
Protection Against Ingress (IP)	IP30
Interfaces	USB-C Port: The hearOAE Device features a USB-C port for charging. Note that the port is exclusively intended for charging purposes and does not support data transfer or other functionalities. 8-pin circular push-pull: The hearOAE 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.
Wireless Communication Protocols	Bluetooth Low Energy (BLE): The Bluetooth technology allows wireless pairing with the smart device for interaction and data exchange.

12.6 EMC

Electromagnetic Compatibility (EMC)		
Electrical medical equipment requires special precautions regarding EMC and requires to be put into service according to the guidance provided below.		
Guidance and manufacturer's declaration – electromagnetic emissions		
The hearOAE instrument is intended for use in the electromagnetic environment specified below. The customer or user of the hearOAE instrument should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**

RF emissions CISPR 11	Group 1	The hearOAE Device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.	
RF emissions CISPR 11	Class B	The hearOAE is suitable for use in all establishments.	
Harmonic emissions IEC 61000-3-2	N/A		
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A		
Guidance and manufacturer's declaration – electromagnetic immunity			
The hearOAE instrument is intended for use in the electromagnetic environment specified below. The user of the hearOAE instrument should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	Not applicable, see note		
Surge IEC 61000-4-5	Not applicable, see note		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable, see note		
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	
NOTE: Power supply or data line (input/output part ports) tests are not applicable. If the presence of a USB connection is detected (either for data transfer or charging operations) the hearOAE instrument will not execute a test.			
Guidance and manufacturer's declaration – electromagnetic immunity			
The hearOAE instrument is intended for use in the electromagnetic environment specified below. The customer or user of the hearOAE instrument should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz, and 6 Vrms in ISM and amateur radio bands between 150 kHz to 80 MHz. 3 V/m 80 MHz to 2.7 GHz, including wireless communications equipment at other discrete frequencies [a].	6 Vrms 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the hearOAE device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 0.60 √P d = 0.35 √P 80 MHz to 800 MHz d = 0.70 √P 800 MHz tot 2.5 GHz where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [b], should be less than the compliance level in each frequency range [c]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Notes:

1. At 80 MHz and 800 MHz, the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects and people.

1. Tests conducted according to Table 9 of IEC 60601-1-2 2014.
2. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the hearOAE instrument is used exceeds the applicable RF compliance level above, the hearOAE instrument should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the hearOAE instrument.
3. Over the range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

Recommended separation distances between portable and mobile RF communications equipment and the hearOAE instrument

The hearOAE instrument is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the hearOAE instrument can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the hearOAE device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz **d = 0.60 √P**	**80 MHz to 800 MHz** **d = 0.35 √P**	**800 MHz to 2.7 GHz** **d = 0.70 √P**
0.01	0.06	0.04	0.07
0.1	0.19	0.11	0.22
1	0.6	0.35	0.7
10	1.9	1.1	2.2
100	6	3.5	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.

NOTES:

1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection from structures, objects, and people.

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13. TROUBLESHOOTING

- It is recommended to set up the instrument in an environment with internet access prior to testing in the field to ensure all controls are up to date and in place.
- Ensure the hearOAE Probe is properly connected to the hearOAE Device.
- It is recommended that the smart device and hearOAE Device be fully charged before commencing with testing.
- Ensure the hearOAE Probe is still in calibration before conducting a test.
- Ensure tests are conducted within acceptable noise levels.
- Ensure that the probe is inserted in the correct ear and that a tight fit is obtained.
- Results will not upload to the cloud without an internet connection.
- Ensure that you have the latest version of the software application installed on the smart device prior to testing.
- Please note that certain functionalities of the instrument are dependent on cloud services and an active internet connection. These include actions such as signing in to mHealth, syncing data, and generating or downloading reports. In the event that you encounter a "Service unavailable, try again later" notification and you have confirmed that the instrument has access to the internet, we advise you to follow these instructions: kindly reach out to hearX support via email or the provided contact number. Our support team will promptly assist you in resolving the issue. Your prompt communication ensures that any cloud or connection dependencies are appropriately addressed, allowing you to seamlessly continue utilising the instrument's features for accurate and efficient outcomes.

14. INCIDENT RESPONSE PLAN

In the event of detecting or suspecting a cybersecurity event, promptly follow these instructions to initiate the incident response plan:

1. Contact Support: Immediately reach out to our support team via email at *support@hearxgroup.com* or through the company's official support number [ZA: +27 12 030 0268 | US: +1 415 212 5500 | UK: +44 1246 385500]. This step ensures that our technical experts are informed of the situation and can guide you through the appropriate actions to mitigate the potential risks.
2. Provide Details: When communicating with support, provide as much detail as possible regarding the incident. Describe any unusual activities, error messages, or behaviors you have observed. This information is crucial for our team to assess the situation accurately and take swift action.
3. Follow Expert Guidance: Our technical experts will provide you with step-by-step instructions tailored to the specific incident. Follow their guidance carefully to minimize the impact and prevent any further escalation of the event.
4. Preserve Evidence: If applicable and safe to do so, preserve any evidence related to the incident. This could include screenshots, logs, or any other relevant information. Such evidence may assist in the investigation and subsequent actions.
5. Implement Temporary Measures: If advised by our support team, you may need to implement temporary measures to isolate or mitigate the incident's effects. These measures are intended to prevent the incident from spreading further and causing additional harm.
6. Cooperate with Investigation: In some cases, further investigation may be required. Please cooperate fully with our cybersecurity team during this process. Your input and assistance are invaluable in understanding the scope and nature of the event.
7. Stay Informed: Our support team will provide regular updates and guidance throughout the incident response process. Stay connected and informed as we work together to address the situation effectively.

By following this incident response plan and promptly contacting our support team, you contribute to safeguarding the security and integrity of our systems and data. Your swift action ensures that potential risks are mitigated, and appropriate measures are taken to maintain the confidentiality, availability, and reliability of our services.