

Instructions For Use - Safety & Warranty



Instructions For Use - Safety & Warranty

Nuance Audio™ Hearing Aid

WARNING: If you are younger than 18, do not use this.

You should go to a doctor, preferably an ear-nose-throat doctor (an ENT), because your condition needs specialized care. Over-the-counter hearing aids are only for users who are age 18 or older.

This OTC hearing aid is for users who are 18 and older. People who are younger than 18 with hearing loss should see a doctor, preferably an ENT, because they may need medical testing and management. Hearing loss can affect speech and learning, so professional fitting and continuing care are also important.

WARNING: When to See a Doctor

If you have any of the problems listed below, please see a doctor, preferably an ear-nose-throat doctor (an ENT).

- Your ear has a birth defect or an unusual shape. Your ear was injured or deformed in an accident.
- You saw blood, pus, or fluid coming out of your ear in the past 6 months
- Your ear feels painful or uncomfortable
- You have a lot of ear wax, or you think something could be in your ear
- You get really dizzy or have a feeling of spinning or swaying (called vertigo)
- Your hearing changed suddenly in the past 6 months
- Your hearing changes: it gets worse then gets better again
- You have worse hearing in one ear
- You hear ringing or buzzing in only one ear

WARNING: This hearing aid should not cause pain when wearing it.

Remove this device if it causes pain or discomfort when you wear or place it. To try again, make sure to follow the instructions. If you feel pain or discomfort again, contact the manufacturer. If your pain or discomfort doesn't go away, contact your hearing healthcare professional. You can also report this to FDA as an adverse event according to the instructions that appear later.

Caution: This is not hearing protection.

You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.

Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your device.

Note: If you remain concerned, consult a professional.

If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.

Note: What you might expect when you start using a hearing aid

A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss. People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counseling can help them get more out of their devices. If you have hearing loss in both ears,

you might get more out of using hearing aids in both, especially in situations that make you tired from listening—for example, noisy environments. Nuance Audio™ Glasses provide hearing assistance to both ears.

Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your device.

Note: Tell FDA about injuries, malfunctions, or other adverse events.

To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. FDA calls them “adverse events”, and they might include: injury from the device (like cuts or scratches, or burns from an overheated battery), suddenly worsening hearing loss from using the device, etc. Instructions for reporting are available at <https://www.fda.gov/Safety/MedWatch>, or call 1- 800-FDA-1088. You can also download a form to mail to the FDA.

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 **WARNING** To reduce the risk of personal injury, discomfort, or property damage, please read and follow the health and safety information below before using the Nuance Audio™ SaMD OTC Hearing Aid ("Nuance Audio™ Hearing Aid").

1. Intended Use

The Nuance Audio™ OTC SaMD Hearing Aid is an over-the-counter (OTC) hearing aid intended to amplify sound for adult users (18yrs and older) with a perceived mild to moderate hearing impairment.

2. Indications For Use

The Nuance Audio™ OTC SaMD Hearing Aid Software is a software-only mobile medical application that is intended to be used with compatible wearable electronic products. The feature is intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. The software utilizes a preset fitting strategy and is adjusted by the user to meet their hearing needs without the assistance of a hearing healthcare professional. The device is intended for Over-the-Counter use.

3. Important Health and Safety Information

 **Read the Instructions.** Read the Instructions for Use for the correct functioning of the Nuance Audio™ Hearing Aid.

 It is very important to read and follow this Instructions for Use, the User Guide, and all the safety, warnings and regulatory information thoroughly and completely before using the Nuance Audio™ Hearing Aid. Follow safety instructions to avoid damage or injury. Follow also all instructions provided through the App.

Do NOT resell the Nuance Audio™ Glasses or share them with others. They are intended for use by a single user

This Nuance Audio™ Hearing Aid may help you hear better if you strain to follow conversations when others don't, especially in noisy places.

3.1. Intended Use Environment. The Nuance Audio™ Hearing Aid is intended to be used for listening to the sounds in a variety of environments (e.g., home, office, transit, social settings, outdoors, etc.), and it is suitable for home and healthcare environments. The device should not be used while bathing or swimming (i.e., hearing aids should not be submerged in water).

3.2. The Nuance Audio™ Hearing Aid may not be right for you if you: Consistently experience feedback (whistling) of the hearing aid when you turn up Volume to a level that is comfortable for you, even after you have followed the suggestions in these Instructions for Use to make sure your hearing aid fits properly. Feel the hearing aid is not providing enough amplification even at the highest Volume setting. You should see a hearing health care professional if you:

- Have a visible deformity of the ear.
- Have a current ear infection or a history of active discharge from one or both ears within the past 90 days.
- Have sudden or rapid progression of hearing loss within the past 90 days in one or both ears.
- Have acute or chronic dizziness, poor dexterity, poor vision, or significant dementia.
- Suspect that you have significant ear wax accumulation or a foreign object in the ear canal. Symptoms of significant ear wax accumulation can include itching in your ear, a feeling of fullness in your ear, and/or reduced hearing.
- Experience pain or discomfort in the ear.
- Have a noticeable difference in hearing between ears.

- Have sudden onset or rapid worsening of tinnitus (ringing in the ear) in one or both ears within the past 90 days.

It is good health practice for a person with a hearing loss to have a medical evaluation by a licensed physician, preferably a physician who specializes in ear, nose, and throat (ENT). Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists, or otorhinolaryngologists. The purpose of a medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated.

3.3. Warnings, Precautions, and Safety Considerations

 For safe and effective operation of the Nuance Audio™ Hearing Aid, please familiarize yourself with the following information. Please read and keep all safety and use instructions.

NOTE: The hearing aids are designed for personal use

3.3.1. Warnings

Over-the-counter hearing aids are only for users who are age 18 or older.

- Remove the Nuance Audio™ Hearing Aid if you encounter overly loud sounds or if they become uncomfortable.
- The Nuance Audio™ Glasses and the Charging Pad contain magnetic material and components that emit radio waves, which could affect the operation of medical devices such as but not limited to pacemakers or insulin pumps, or other implantable devices, consult your doctor or the medical device manufacturer before using the Nuance Audio™ Glasses and the Charging Pad.
- If you have an active or inactive implant device (e.g. defibrillator, pacemaker), follow the implant manufacturer's instructions regarding the use of mobile

devices. The Nuance Audio™ Glasses should be kept at least 6 inches from implantable pacemakers. In the event of malfunctions, stop using your Nuance Audio™ Glasses and contact your doctor or the implant manufacturer. If you have an active brain implant, ask your doctor or the implant manufacturer for a risk analysis.

-  The Nuance Audio™ Glasses are MR Unsafe and could present as a projectile hazard.
-  Check before using the Nuance Audio™ Glasses and the Charging Pad in areas where electronics or wireless devices are restricted. This may cause interference.
- **Warning:** Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- **Warning:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- **Warning** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- **Do NOT** resell the Nuance Audio™ Hearing Aid or share it with others. It is intended for use by a single user.

- Keep the Nuance Audio™ Glasses and the Charging Pad away from fire, heat sources and excessive heat (e.g., from storage in direct sunlight, near candles, or in a hot car) to avoid burns or damage to the Nuance Audio™ Hearing Aid and/or the Charging pad.
- ☔ Do NOT submerge in water or liquids, wear in the shower, or wear while participating in water sports (e.g., swimming, water-skiing, surfing, etc.). Prolonged exposure to water or liquids may damage the Nuance Audio™ Glasses. The Nuance Audio™ Glasses are not designed to resist extended exposure to water or other liquids. In case of water exposure, dry the Nuance Audio™ Glasses thoroughly.
- Nuance Audio™ Glasses level of protection against dust and water is IP54. IP5 rating offers protection against dust in quantities not sufficient to compromise the operation of the equipment and IPX4 rating offers protection against splashes of water.
- Do not submerge the Charging Pad in water and keep it away from liquids. Exposure to water or other liquids may damage the Charging Pad and lead to injury. It is not water resistant and is not designed to resist submersion or exposure to other liquids. In case of water exposure, dry the Charging Pad thoroughly.

When to see an Ear, Nose, and Throat doctor (ENT)

- If you have any of the problems listed below, please see a healthcare professional.
- Your ear has a birth defect or an unusual shape. Your ear was injured or deformed in an accident.
- You saw blood, pus or fluid coming out of your ear within the past 6 months.
- Your ear feels painful or uncomfortable

- You have a lot of earwax or you think something could be in your ear
- You get dizzy or have a feeling of spinning or swaying (called vertigo)
- Your hearing changed suddenly in the past 6 months
- Your hearing changes: it gets worse then gets better again
- You have worse hearing in one ear
- You hear ringing or buzzing in only one ear
- Avoid unauthorized modifications to the Nuance Audio™ Glasses and the Charging pad.
- Do not use the Nuance Audio™ Glasses and the Charging Pad in environments where there is a risk of explosion (e.g. in mines or industrial plants subject to such risk). Do not store or carry flammable liquids, gases, or explosive materials in the same compartment as your Nuance Audio™ Glasses, its parts, and/ or components.

3.3.2. Battery

- The Nuance Audio™ Glasses should not be exposed to temperatures below 14°F (-10°C) or above 113°F (+45°C) or when conditions are expected to exceed these temperatures. Using the Nuance Audio™ Glasses above 113°F could result in overheating, fire, or injury.
- If abused or misused, the lithium-ion battery may leak and may cause chemical burns.
- Keep battery away from excessive heat such as heaters, fires, and solar radiation as batteries may rupture and release corrosive materials.
- Store batteries in a dry, moisture-free environment at room temperature. Do not keep battery in a refrigerator, in excessively warm areas or in a dehumidifying device. Appropriate battery care reduces the risk of leakage which is harmful to

you and your hearing aids, and it saves battery life.

3.3.3. Precautions

- When the Nuance Audio™ Glasses can have the option of mounted prescription lenses, it is intended only for use by the prescribed user only. Use of Nuance Audio™ Glasses with prescription lenses by other users may provide inadequate vision correction or vision that is worse than normal.
- We recommend that you remove the Nuance Audio™ Glasses before sleeping. While not harmful, wearing your Nuance Audio™ Glasses while sleeping can be uncomfortable, disrupt sleep, and drain the battery.
- Exposure to loud sound may damage your hearing and could distract you. You can reduce risks by avoiding loud environments and using appropriate hearing protection devices.
- The sound output should not be uncomfortable or painful. You should turn down the volume or remove the Nuance Audio™ Hearing Aid if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your Nuance Audio™ Hearing Aid. See section 'Nuance Audio™ App Setup and Bluetooth® Pairing' for instructions.
- The Nuance Audio™ Glasses and the Charging Pad shouldn't overheat or cause thermal discomfort during normal use. If they do, stop using them immediately and contact support.
- •Check applicable aviation security restrictions on personal electronics before flying with the Nuance Audio™ Glasses and the Charging Pad. The Nuance
- Audio™ Glasses contains lithium-ion batteries and should not be placed in checked-in luggage.

- Use the Nuance Audio™ Glasses and the Charging pad in compliance with all the applicable local laws, rules and regulations. Use common sense and respect third parties' rights, privacy, and confidentiality.
- Interacting with the Nuance Audio™ Hearing Aid may distract you or increase the time it takes to react to hazards. Always pay attention to your surroundings, including signage and obstacles.
- Use caution when operating a vehicle while wearing the Nuance Audio™ Glasses and keep your focus on driving. Follow local laws and requirements applicable to mobile phone operation. If the Nuance Audio™ Glasses impairs your peripheral vision, do not wear while driving. Adjust all relevant settings of the Nuance Audio™ Glasses before driving and do not interact with it or any of the components when the vehicle is in motion.
- To safely terminate operation of Nuance Audio™ Hearing Aid, switch it off.
- This Nuance Audio™ Hearing Aid must not be used as eye safety or protection against mechanical impact. They are not to be used as protection against UV rays.
- The Nuance Audio™ Glasses are intended to be worn for extended periods. If you feel any discomfort (for example, headaches, nausea or other abnormalities, etc, take a break from using the electronic functionalities and the Nuance Audio™ Glasses. If discomfort persists, stop using the Nuance Audio™ Glasses and consult a healthcare professional.
- The Nuance Audio™ Glasses can be only be charged with a Nuance Audio™ Charging Pad. If the Nuance Audio™ Glasses are placed on generic wireless charge pads, it will not charge.
- Use only with original components and with the compatible USB-C cables and

wall plugs/adapters indicated below. Using non-approved components may permanently damage the Nuance Audio™ Glasses, void the Luxottica Limited Warranty, and increase the risk of injury or damage to other property.

- Use only with the authorized Nuance Audio™ App. Update the App and the Nuance Audio™ Hearing Aid firmware when prompted. Do not attempt to modify the software provided. Software is provided as-is and is subject to terms and conditions.
- Features, functionality, and content of the Nuance Audio™ Hearing Aid are subject to change or withdrawal at any time, may be protected by digital rights management technology, may be unavailable or restricted in some areas, may depend on wireless service plan or internet service provider, and may require subscriptions or fees. The Nuance Audio™ Hearing Aid may require software updates to be installed from time to time, including prior to first use. Detailed system requirements, software terms of license and terms of service are available at www.nuanceaudio.com.

Note: If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a healthcare professional.

3.4. Preventing damage and malfunctions to the Nuance Audio™ Glasses

- For safe operation do not submerge the Nuance Audio™ Glasses in liquid. Liquids entering the housing of the Nuance Audio™ Glasses will damage the electronics.
- Avoid exposure of the Nuance Audio™ Glasses and the Nuance Audio™ Charging pad to extreme temperatures and intense heat sources (hairdryer, heater, etc).
- Do not store the Nuance Audio™ Glasses and the Charging Pad in direct sunlight.
- Avoid exposure to water and salt water.

- Avoid exposure to sand and fine particulates.
- Do not use the Nuance Audio™ Glasses and the Charging Pad if there are visible sharp edges, cracks, or damage to the housing.

3.5. Recommended Use and Storage

- Operating conditions: 14°F (-10°C) to 113°F (+45°C); 101.3kPa to 61.9kPa; humidity between 20% and 60% under 95°F (+35°C) for 1000 hours; maximum altitude of 13,000 ft for 1 hour at 32°F (0°C) and 95°F (+35°C).
- Transport and Storage conditions: Hearing Aid shall remain functional after recovery from minimum -22°F (-30°C) or maximum +167°F (+75°C) storage temperatures; high humidity 90% and temperature (113°F/+45°C) for 288 hours; exposure to altitude of 40,000 ft (18,8kPa) for 12 hours at both 14°F (-10°C) and 113°F (+45°C).

3.6. Cybersecurity

EssilorLuxottica has assessed the Nuance Audio™ Hearing Aid and Nuance Audio™ Glasses from a Cybersecurity perspective, in accordance with FDA guidance. A full risk assessment of the device in regard to cybersecurity revealed no vulnerabilities impacting safety or efficacy with the product. Based on this assessment, the only action required by the user to ensure the product remains secure is to keep the product updated with the latest product updates. For information on how to keep your product up to date, please see "Updating the Nuance Audio™ Hearing Aid" in the mobile App. In the unlikely event that your Nuance Audio™ Hearing Aid have been compromised from a cybersecurity perspective, please reach out to us immediately at csirt@essilorluxottica.com for assistance. Proper operation of the Nuance Audio™ Hearing Aid requires a safe, private, and secure operating environment. To ensure

your security, we recommend following best practices for securing your home network and mobile device. For more information, refer to the US Federal Trade Commission's guidance on online security.

Visit: consumer.ftc.gov/topics/online-security

4. What's in the Box

A 1 Nuance Audio™ Glasses

B 1 Folded Case

C 1 Cleaning Cloth

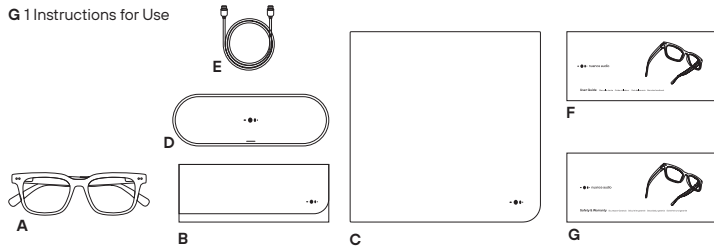
D 1 Nuance Audio™ Charging Pad

E 1 USB-C Charging Cable

The Box also includes:

F 1 User Guide

G 1 Instructions for Use

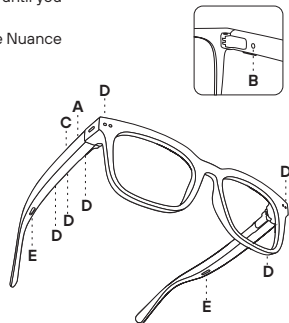


5. Opening the Box

- Ensure the components mentioned above are included in the package.
- Scan the QR Code printed on the inside lid of the box and download the Nuance Audio™ App.
- Extract the User Guide from the envelope inside the box's drawer and follow the instructions.

Do not use the Nuance Audio™ Hearing Aid until the App has instructed you to do so and until you have read the User Guide indications.

Figure: Figure: Schematic Diagram of the Nuance Audio™ Glasses



Nuance Audio™ Hearing Aid sizes:

Sizes	Panthos 48	Square 54	Square 56
Size model (caliper)	1,89 in. / 48 mm	2,13 in. / 54 mm	2,20 in. / 56 mm
Bridge	0,87 in. / 22 mm	0,71 in. / 18 mm	0,71 in. / 18 mm
Base lens	B4	B4	B4

6. The Nuance Audio™ Glasses

The Nuance Audio™ OTC SaMD Hearing Aid Software is a software-only mobile medical application that is intended to be used with Nuance Audio™ Glasses. The Nuance Audio™ Hearing Aid components are:

- Nuance Audio™ Charging Pad: Charges the rechargeable battery in the compatible wearable electronic Nuance Audio™ Glasses. The Charging Pad has a LED on top view, to give info to the user regarding the charging status of the Nuance Audio™ Glasses. Please refer to the User Guide or 'Charging the Battery' section for images and usage explanation of the Charging Pad.
- •USB-C Charging Cable: to be connected to the Nuance Audio™ Charging Pad.
- •Folded Case: intended to be used to carry the Nuance Audio™ Glasses when not in use, with the main functionality to be protective and easily carried by the user. The Folded Case does not contain any electronics.
- Cleaning Cloth: to be used for cleaning the lenses.

Nuance Audio™ App: The Nuance Audio™ Glasses are required to be used in conjunction with the Nuance Audio™ App, via Bluetooth® wireless connection

with a mobile phone. Use of the App requires a mobile phone with Android or an iPhone with iOS operating systems and internet access. The Nuance Audio™ App is to be considered mandatory and it can also serve as a remote control for the device.

7. Nuance Audio™ App Setup and Bluetooth® Pairing

The Nuance Audio™ Hearing Aid are a wireless Bluetooth® hearing aid intended to be used for wirelessly listening to the world around you. Download the Nuance



Audio™ App by scanning the QR Code located on the inside lid of the box or on the first page of the

User Guide, or by accessing the App via the Apple® App Store or Google Play® Store. Once installed, open the App to begin the setup process. All setup instructions will be in the App to guide you. Do not start using the Nuance Audio™ Hearing Aid until the App has instructed you to do so. Proceed with pairing the Nuance Audio™ Glasses and Bluetooth® set up using the Nuance Audio™ App. Android®, Google Play® and the Google Play® logo are registered trademarks of Google LLC. The Apple® wordmark, the Apple® logo, App store and iPhone® is a trademark of Apple Inc., registered in the U.S. and other countries. The trademark iPhone® is used with a license from Apple Inc. Apple Inc. is not responsible for the operation of this device or its compliance with safety and regulatory standards. The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by is under license. is a registered trademark of Essilor International SAS.

7.1. Review Required Labelling

The first time you log into the Nuance Audio™ App, the first screen to appear will contain information pertaining to over-the-counter hearing aid controls and

associated labelling. You must acknowledge that you have read and understand the information before you will be allowed to proceed. Refer to Fig. 3.

7.2. Onboarding the Nuance Audio™ App

 Onboarding is performed the first time you access the Nuance Audio™ App. The primary purpose of the onboarding section of the App is to systematically walk you through the setup and configuration of the Nuance Audio™ Hearing Aid.

7.2.1. Creation of the Nuance Audio™ App user account

User authentication is mandatory to use the Nuance Audio™ App, the first action is to complete the sign-in process starting from the authentication/sign-in page. **Fig. 1**
1. Authentication page The user is prompted to input an email address to be used as login ID and password, together with some personal information. **Fig. 2. Sign-in form** Email address is verified through a onetime code sent via email do the email address used in the account creation process. The user must type in the code to complete the sign-in. **Fig. 3. Onetime code input and verification** If the onetime verification code is not received, user may ask to send a new one directly from the page of fig 3 below.

7.2.2. First pairing Once the sign-in process is completed and the user executes the login to the app, all is ready for the first pairing procedure. The Nuance Audio™ Glasses must be set in pairing mode before starting the scanning from the mobile app tapping on the "Pair my Hearing Aid" button. **Fig. 4 Pair my Glasses** The mobile phone will ask permission to the user to use Bluetooth before starting the scanning of Nuance Audio™ Glasses. All the found devices are listed, the user must select the one she/he is interested to pair with. The last step is to accept the Bluetooth pairing pop-up displayed by the operating system of the mobile phone. **Fig. 5 Pairing**

pages A successful pairing is represented by the page here below. **Fig. 6 Pairing completed with success**

7.2.3. Nuance Audio™ Hearing Aid tutorial

The tutorial on how to use the Nuance Audio™ Hearing Aid is displayed right after the first pairing. If skipped, the same tutorial is always available in the Support session of the mobile app.

7.2.4. Calibration

Personal calibration is the procedure required to personalize the Nuance Audio™ Hearing Aid performance to the user. It is a three steps process lasting no more than few minutes: **Step 1:** Measurement of the noise level of the room where the calibration is performed. **Step 2:** Feedback calibration. **Step 3:** User's voice calibration. The calibration procedure can be repeated any time from the mobile app Settings menu.

7.2.5. App calibration

Once the Personal calibration is completed the user may access the mobile app tutorial that is also available for later access in the Support page of the mobile app.

7.3. Application main page

The application main page is displayed in the app when the Nuance Audio™ Hearing Aid is turned on and correctly paired with the mobile phone.

- Set the level of the hearing of the background noise (lowered, standard, heightened)
- Set the volume of the speakers, 5 levels available;
- Check the battery charge level.
- Measure the environmental noise

- Select the preferred Preset configuration (A, B, C, D)
- Select the audio mode between Frontal or All Around

7.3.1. Battery level

A battery level indicator is displayed in the top left angle of the home page. When the indicator turns red is time to charge the Nuance Audio™ Glasses.

7.3.2. Noise tracking

Noise tracking measures the ambient room noise using the microphone of the mobile phone, user must give permission to the Nuance Audio™ App to use the microphone.

7.3.3. Background noise

From the background noise command in the main page the user can select the level of background noise filtering from Lowered, Standard or Heightened

7.3.4. Volume

Volume setting, 5 levels, is also available in the home page controls. Tapping on the plus or minus icons the user can adjust volume.

7.3.5. Presets

Four different predefined presets are also available for the user to choose the one that enhances the listening experience best for the user. Each preset addresses different amplification needs at different frequencies.

7.3.6. Audio Mode

The audio mode selector allows the user to choose their desired listening focus based on their environment. Frontal mode enhances sound coming from the front, making it easier to focus on conversations with someone directly in front. All-around mode amplifies sounds and speech from all directions.

7.4. Menu

7.4.1. Nuance Audio™Hearing Aid selection and add new Hearing Aid

This menu item gives the user the possibility to switch between all the Nuance Audio™ Hearing Aid associated with the user profile and paired with the mobile phone. Up to a maximum of 4 Hearing Aid can be associated to a single profile. It is also possible to add new Hearing Aid to the profile initiating a new pairing process.

7.4.2. My account

Personal Information

The personal information section contains profile information such as full name, email, phone number, date of birth, and gender.

Password

In the password section it's possible to change the password by entering the current password and the new one. Password accepted format is:

- 8 chars
- 1 upper case
- 1 lower case
- 1 number
- 1 special char

Preferences

Language

The application language is automatically set to the same language of the mobile phone if supported, otherwise default is English. User can select a new language from this configuration page.

Push notifications

User can enable push notifications from this section and can also flag which

categories they are interested in. Available notifications categories are: FW upgrades or suggestions on how to better configure the Nuance Audio™ Hearing Aid.

Newsletter

In the newsletter section, the user can choose whether to enable commercial emails and/or whether to enable tracing of activities and configurations applied to the Nuance Audio™ Hearing Aid.

Legal documents

All documents regarding privacy and data processing can be found in the legal documents section.

Delete account

User can decide to permanently delete the account and all the associated data. After this operation the user will no longer be able to log into the Nuance Audio™ mobile application.

Log-out

Clicking the log out button disconnects the account from the application.

7.4.3. Settings

Preset Volume

User can select one of the three available volume profiles to enable when volume is changed using the physical button on the frame. Low profile enables volume levels 1, 2 and 3. Default profile enables volume levels 2, 3 and 4. High profile enables volume levels 3, 4 and 5.

My own voice

User can select how much he/she wants to hear back the own voice. Possible choices are: No, Some, Yes.

Personal calibration

From this Settings' menu item, the user can execute a new Personal calibration operation or switch back to the default one which is the same for all the Nuance Audio™ Hearing Aid users.

My Glasses

This section of the Settings menu includes all the Glasses configuration activities the user can execute.

My Glasses: Edit name

User can customize the Nuance Audio™ Glasses name by overwriting the default name

My Glasses: Configuration and FW upgrade

This section contains information on the FW version of the Nuance Audio™ Hearing Aid and prompt the user if a new FW version is available.

FW upgrade can be executed only if the charging level of the battery is above 30%. During the FW upgrade operation, it is mandatory to keep the mobile phone nearby to the Nuance Audio™ Glasses. At the end of the upgrade the app will wait for the Nuance Audio™ Glasses to reboot with the new firmware.

My Glasses: Detailed information

This section of the My Glasses page contains all the detailed information on the Glasses such as the Serial Number and the Model.

My Glasses: Forget these Glasses

This function removes the link between the user account profile and the paired Glasses. Hearing Aid configuration is not erased because of the Forget operation. This operation is mandatory if the very same pair of Glasses needs to be paired and

associated with a different user's phone. No undo is available with this operation, but user is prompted for a confirmation. Mobile phone Bluetooth association with the Nuance Audio™ Glasses must be also deleted from the mobile phone Bluetooth setting page.

My Glasses: Factory reset

Returns the Nuance Audio™ Hearing Aid to the factory configuration. All data stored in the Hearing Aid and the association with the user account is cleared.

No undo is available with this operation, but user is prompted for a confirmation. Mobile phone Bluetooth association with the Nuance Audio™ Glasses must be also deleted from the mobile phone Bluetooth setting page.

About

This page contains all the information on the application such as the app version number and other product codes. For App label please check App details page.

7.5. Dashboards

The dashboard page shows information on the device usage: how many hours it has been used and in which Audio Mode. Dashboards collect data for the last 30 days.

7.6. Support

The Support section of the mobile app includes:

- Access to the Nuance Audio™ Hearing Aid tutorial
- Access to the mobile app tutorial
- Link to the FAQ pages of the www.nuanceaudio.com website

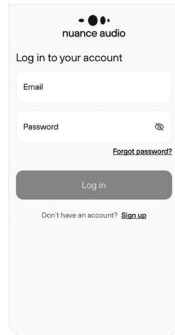
A screenshot of the 'Log in to your account' page. At the top is the 'nuance audio' logo. Below it is the title 'Log in to your account'. There are two input fields: 'Email' and 'Password'. A link 'Forgot password?' is next to the password field. A 'Log in' button is at the bottom. Below the button is a link 'Don't have an account? Sign up'.

Fig. 1.
Authentication
page

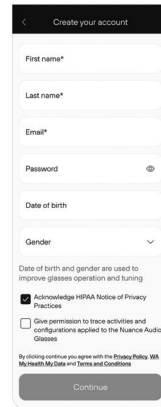
A screenshot of the 'Create your account' page. At the top is a back arrow and the title 'Create your account'. There are several input fields: 'First name*', 'Last name*', 'Email*', 'Password', and 'Date of birth'. There is a 'Gender' dropdown menu. Below these fields is a note: 'Date of birth and gender are used to improve glasses operation and tuning'. There are two checkboxes: 'Acknowledge HIPAA Notice of Privacy Practices' (checked) and 'Give permission to trace activities and configurations applied to the Nuance Audio Glasses' (unchecked). At the bottom is a 'Continue' button.

Fig. 2. Sign-in form

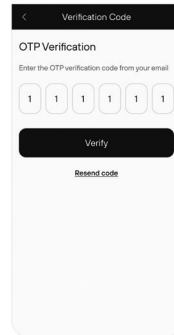
A screenshot of the 'Verification Code' page. At the top is a back arrow and the title 'Verification Code'. Below it is the title 'OTP Verification' and a note 'Enter the OTP verification code from your email'. There are six input fields, each containing the digit '1'. Below these fields is a 'Verify' button. At the bottom is a link 'Resend code'.

Fig. 3. Onetime
code input and
verification

- Link to the Troubleshooting pages on the www.nuanceaudio.com website
- Link to the Educational resources on the www.nuanceaudio.com website
- Link to the Contact is section on the www.nuanceaudio.com website

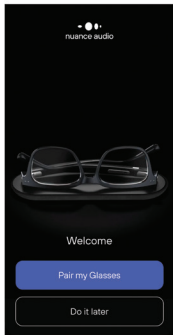


Fig. 4 Pair my Hearing Aid

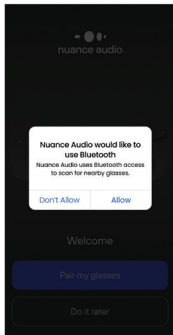


Fig. 5 Pairing pages

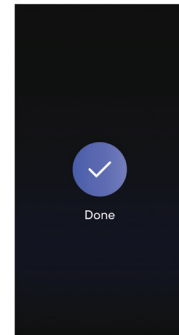
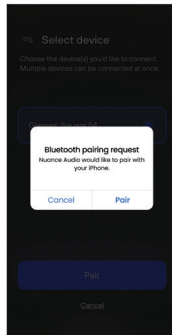
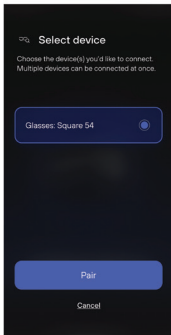


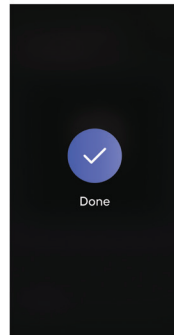
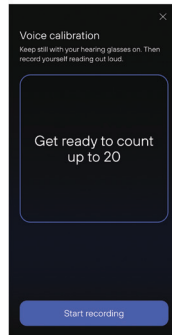
Fig. 6 Pairing completed with success



Fig. 7 Nuance Audio™ Hearing Aid tutorial. Start page and a sample of one of the tutorial's steps.



Fig. 8 Calibration



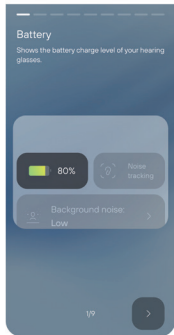


Fig. 9 Mobile app tutorial

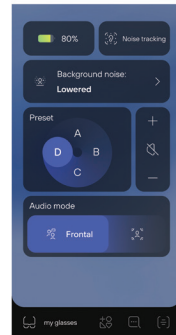


Fig. 10 Home page The following configuration options are directly available from the home page.



Fig. 11 Noise tracking

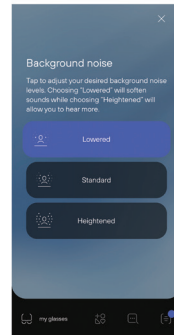


Fig. 12 Background noise configuration

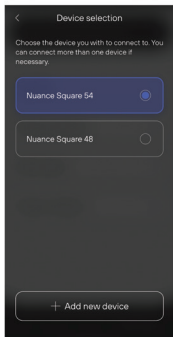


Fig. 13 Hearing Aid selection

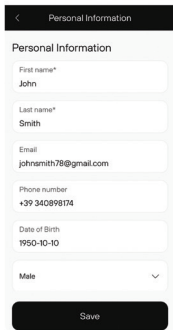


Fig. 14 Personal information

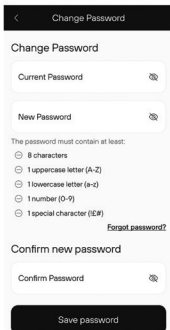


Fig. 15 Change password

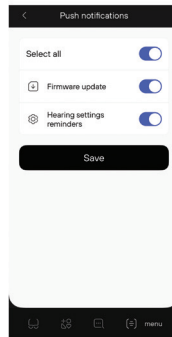


Fig. 16 Push Notifications

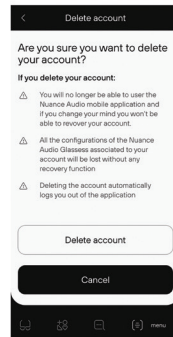


Fig. 17 Delete account, warning page

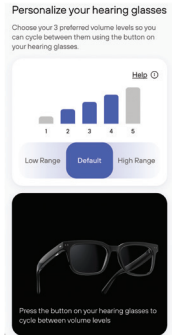


Fig. 18 Preset volume

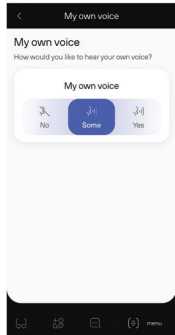


Fig. 19 Own voice

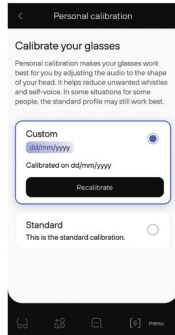


Fig. 20 Personal calibration

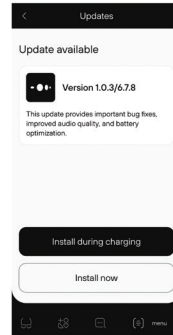
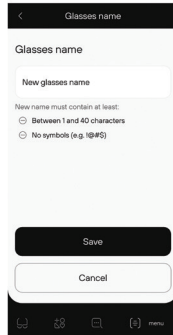
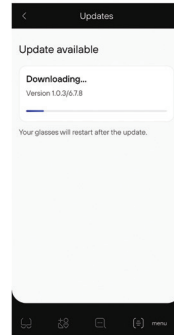


Fig. 21 Firmware update steps



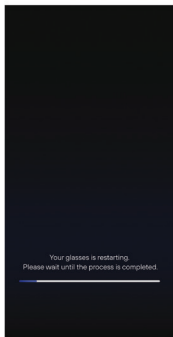


Fig. 22 Waiting for reboot and successful execution

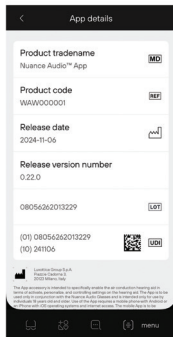
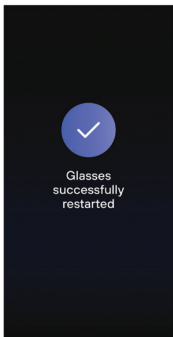


Fig. 23 Detailed information

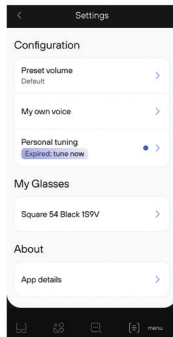


Fig. 24 About

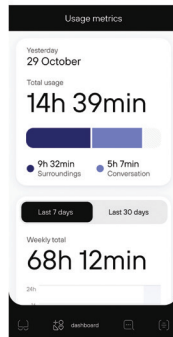


Fig. 25 Dashboards

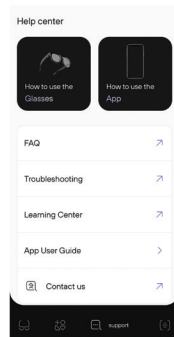


Fig. 26 Support page

8. Nuance Audio™ Care and Maintenance

8.1. Battery Information

The Nuance Audio™ Glasses contains a lithium-ion battery that is not user-replaceable. Do not attempt to remove or replace the battery. The battery may present a fire or chemical burn hazard if misused. Do not disassemble, crush, or puncture the Nuance Audio™ Hearing Aid. Do not leave or store the Nuance Audio™ Hearing Aid under direct sunlight or expose to excessive heat or incinerate. Dispose of the battery in line with instructions and local requirements. Nuance Audio™ Hearing Aid have 500 x battery cycles (about one and a half years of use) before their battery life naturally start to gradually degrade, despite until 1000 battery cycles the charge will still top up at about 80% of its maximum capacity. Once fully charged, the battery lasts at least 7 hours of continuous use under average conditions (moderate surrounding noise and standard amplification settings). This performance can be extended if the Hearing Aid is turned off when amplification is not needed, or when the surrounding environment requires less amplification and/or noise reduction.

Here are some tips to maximize your Hearing Aid' battery life & lifespan:

- Always make sure your Hearing Aid are using the latest firmware version;
- Charge the battery at room temperature instead of a lower or higher temperature;
- Charge your battery only when necessary;
- Make sure to charge it fully before unplugging it.

8.2. Charging the battery

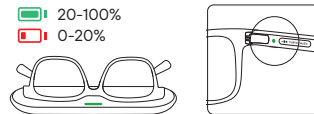
IMPORTANT! If battery is not fully recharged every 6 months from last use this could lead to permanent damage to the battery, which could render the Nuance Audio™ Hearing Aid inoperable. When the Nuance Audio™ App displays a battery level of

20% or less, or when the low battery alert sounds in your ear, the Nuance Audio™ Hearing Aid should be charged. For charging, place the Charging Pad flat on a flat surface to ensure it does not shake and place the Nuance Audio™ Hearing Aid flat on the Charging Pad. Ensure that the Nuance Audio™ Hearing Aid is aligned with the magnetic components on the Charging Pad. If the alignment is not accurate, you can try adjusting the position's angle of the Nuance Audio™ Hearing Aid. During the charging process, do not move or vibrate the Nuance Audio™ Hearing Aid significantly to avoid affecting the charging effect.

8.3. The Charging Pad works thanks to a USB-C Charging Cable.

Use only the provided Charging Pad to charge the Nuance Audio™ Hearing Aid. Use the supplied USB-C Charging Cable or other USB-C type cable, with a USB wall plug/adaptor (not included). It is prohibited to connect the Charging Pad to a wall plug/adaptor that is not certified for the market in which the Charging Pad is marketed. It is recommended to use a wall plug/adaptor which complies with IEC 60601-1 or IEC 62368-1 standards. The wall plug/adaptor must have a minimum output level of DC5V/1A.

Figure 33: Charging the Nuance Audio™ Glasses



- The Charging Pad may become warm to the touch while charging. If the Charging Pad becomes hot to touch discontinue use.
- If the Charging Pad cannot charge properly or experiences any malfunctions, please stop using it immediately.
- Do not clean the Nuance Audio™ Hearing Aid and the Charging Pad while you are charging it.
- Periodically inspect the Nuance Audio™ Hearing Aid, the Charging Pad and the Charging Cable for damage or signs of wear. Do not use if any part is damaged, cracked, or if any internal component is exposed.
- Do not try to repair the Nuance Audio™ Hearing Aid or its components, or replace parts yourself, instead contact support at www.nuanceaudio.com.

8.4. Caring for the Nuance Audio™ Glasses

Important Note: We do not recommend using alcohol wipes when caring for your Nuance Audio™ Hearing Aid.

8.5. General Maintenance

- Handle with care & avoid damage. Follow the steps under the General Information section below to help maintain quality and performances of your Nuance Audio™ Hearing Aid.
- Inspect the Nuance Audio™ Hearing Aid regularly for particulate build up and follow cleaning procedures.
- Only wipe the Nuance Audio™ Glasses with a soft cloth. Don't use any other cleaning tool (such as a hearing aid brush, tooth stick, or air pressure) to clean the Nuance Audio™ Glasses. Do not use dirty or abrasive cloths which could alter the lenses' features. Moisture can damage the Nuance Audio™ Glasses or

cause it to fail. To clean the lenses, use a lens spray, available in stores. Make sure to spray on a cloth and not directly on the lenses.

- To clean the Nuance Audio™ Glasses, wipe with a dry, clean cloth. Avoid all types of sprays, solvents, chemicals, or cleaning solutions containing alcohol or ammonia.

8.6. General Information

- The Nuance Audio™ Glasses and Charging Pad have a service life of at least 3 years.
- The Nuance Audio™ Glasses and the Charging Pad are sensitive electronic equipment and should be handled with care. Do not heat or bend the Nuance Audio™ Glasses and the Charging Pad, including for fitting, as they may become damaged and even catch fire.
- Take care when folding the temples (earpieces or arms) in or out.
- Do not drop, strike, or shake the Nuance Audio™ Glasses and the Charging Pad excessively.
- Do not use the Nuance Audio™ Glasses or the Charging Pad if it is damaged.
- Do not attempt to open, disassemble, or tamper with the Nuance Audio™ Glasses or the Charging Pad.
- Protect your Nuance Audio™ Glasses against moisture (e.g. showers, rain), and take your Nuance Audio™ Glasses off before using hairspray or similar cosmetic product.
- It is recommended carrying out daily care and preventative maintenance as the Nuance Audio™ Glasses are exposed to moisture and dust through ordinary use, even when handled with care.
- Keep the Nuance Audio™ Glasses dry. Never wear the Nuance Audio™ Glasses in the shower, bath, pool, or while swimming. Protect the Nuance Audio™ Glasses

from prolonged exposure to rain. If the Nuance Audio™ Glasses become excessively wet, thoroughly dry it, store it in a container with desiccants or in a drying case. This can help if you live in a humid climate or sweat often.

- Should your Nuance Audio™ Glasses still not function correctly despite regular care, contact us at www.nuancehearing.com.
- Do not try under any circumstances to repair your Nuance Audio™ Glasses by yourself.
- The serial number of the Nuance Audio™ Glasses may be found marked on the inner part of the left temple.

General Maintenance for the Charging Pad:

- Do not soak in water or stay in a humid environment for a long time.
- Do not be exposed to the sun.
- Do not place it around high-power electrical fields audio, do not be in a strong magnetic environment, do not place it on a metal surface for charging.
- To clean the Charging Pad, use a dampened cloth and mild soap avoiding all types of sprays, solvents, chemicals, or cleaning solutions containing alcohol or ammonia.
- Do not use dirty or abrasive cloths which could damage the Charging Pad.
- Keep the Charging pad dry. If the Charging pad becomes excessively wet, there is a risk of damaging the charging function, thoroughly dry it, store them in a container with desiccants or in a drying case.

9. Privacy To view the Company Privacy policy visit the section "Governance" on www.essilorluxottica.com and click on Compliance/Data Privacy.

11. Troubleshooting

11.1. Common Solutions for the App

THE APP DOES NOT RESPOND TO COMMANDS. WHAT SHOULD I DO?

If the mobile app is functioning properly in some sections, such as accessing menus, but you are unable to interact with the Nuance Audio Hearing Aid from the Home Page, the easiest solution is to close and reopen the app. This will re-establish the synchronization with the Nuance Audio Hearing Aid.

If the issue persists, follow these steps: **STEP 1:** Restart your phone and ensure Bluetooth is enabled. Restarting your mobile phone can help clear any temporary issues. Also, make sure that Bluetooth is turned on. **STEP 2:** Check the compatibility of your phone's operating system. If the problem continues, check if your mobile phone's operating system version is listed as supported. **STEP 3:** Turn off your Nuance Audio Hearing Aid. Power off the Hearing Aid by pressing and holding the button on the frame for about 1 second. **STEP 4:** Turn on your Nuance Audio Hearing Aid. Turn the Hearing Aid back on by pressing and holding the button on the frame for about 2 seconds, then check if the app is now working properly. If you need further assistance, feel free to reach out. **STEP 5:** Uninstall and reinstall the app. Sometimes, uninstalling and reinstalling the app can resolve software-related issues.

I RECEIVED A CONNECTIVITY ERROR IN THE APP. WHAT SHOULD I DO?

To perform eyewear pairing, user registration and authentication, and firmware upgrades, a stable network connection (either SIM or Wi-Fi) is required. If there is no connection or if an error occurs, these functionalities will be blocked.

STEP 1: Check Your Network Connection. If you encounter an error, please verify that your Wi-Fi or mobile data connectivity is correctly configured and functioning.

STEP 2: Retry Commands. Sometimes, connectivity errors can occur due to communication issues between the mobile app and the Nuance Audio Hearing Aid. In such cases, simply retry the commands that failed. If you need further assistance, feel free to reach out.

I HAVE ISSUES DOWNLOADING THE APP. WHAT SHOULD I DO?

If you are experiencing issues while trying to download the Nuance Audio app, please follow these troubleshooting steps: **STEP 1:** Check Your Wi-Fi or Mobile Data Connection. Ensure that your internet connection is stable. **STEP 2:** Verify Available Storage Space. Check that there is sufficient storage space on your mobile phone. **STEP 3:** Update Your Operating System. Ensure that your mobile phone is running the latest operating system version. **STEP 4:** Close and Reopen the App Store. If you are trying to download the Nuance Audio app, close and reopen the store.

11.2. Other Troubleshooting Tips

MY HEARING AID ARE NOT CHARGING. WHAT SHOULD I DO?

If your Hearing Aid isn't charging, please ensure the following:

STEP 1: Check the Charging Position. Make sure that the charging area of the Charge pad is facing up and that the eyewear is placed properly on the charging pad. **STEP 2:** Verify Connections. Ensure that the charging pad is correctly connected to the charging cable, and that the charging cable is properly connected to the transformer. **STEP 3:** Inspect the Transformer. Check that the transformer is in good condition and not damaged. **STEP 4:** Adjust Hearing Aid Position. If all the above conditions are met and the Hearing Aid still isn't charging, try gently adjusting the position of the Hearing Aid while it is lying on the pad.

By following these steps, you should be able to resolve the charging issue with your

Nuance Audio Hearing Aid. If you need further assistance, feel free to reach out.

THE BATTERY IN MY HEARING AID DRAINS VERY QUICKLY. WHAT SHOULD I DO?

To ensure optimal battery performance, it is advisable to turn off the audio when it is not needed. If your Hearing Aid is relatively new and its battery life is less than 6 hours, follow these steps: **STEP 1:** Reset the Hearing Aid. Begin by resetting your Hearing Aid.

STEP 2: Fully Discharge and Recharge. Next, drain the battery until the Hearing Aid shut down completely. After that, wait for about 30 minutes or more. Then, place the Hearing Aid back on the charging pad and allow it to charge fully. It is recommended to keep them on the pad for at least 4 hours to ensure a complete charge.

If you need further assistance, feel free to reach out.

HOW CAN I FORCE RESTART MY HEARING AID?

To force restart your Hearing Aid, please follow these steps:

STEP 1: Initiate the Restart. While the Hearing Aid is powered on, press and hold the button located on the right temple for approximately 10 seconds, until the red light on the right side of the Hearing Aid turns on. **STEP 2:** Release the Button. After the red light activates, release the button. **STEP 3:** Complete the Restart. Press the button again for about 2 seconds until you see a solid light (not just a short flash) on the LED located on the frame. Please note that performing a force restart will not reset the device to factory settings. If you need further assistance, feel free to reach out.

I HEAR MY OWN VOICE VERY LOUDLY. WHAT SHOULD I DO?

Experiencing your voice as amplified is completely normal with any hearing solution. This occurs because you are now receiving amplification of all sounds around you, including your own voice. It typically takes about 30-40 minutes of continuous

use in a noisy environment to start feeling more comfortable with this sensation, while full acclimatization usually occurs within just a few days. To help you adjust, consider trying the following tips: **STEP 1:** Adjust the "Own Voice" Configuration. Ensure that the "Own Voice" setting is configured to "No." This adjustment can help reduce the amplification of your voice. **STEP 2:** Perform the personal calibration guided process. If you haven't performed the personal calibration guided process yet, or if you need to re-perform the personal calibration guided process, doing so can enhance your overall experience. **STEP 3:** Explore Different Presets. Different sound presets may provide a more comfortable auditory experience. Feel free to experiment with these settings. Remember, it's entirely normal to feel a bit odd about your amplified voice at first. With a little patience and these adjustments, you'll likely find a more enjoyable auditory experience in no time. If you have any further questions or need assistance, don't hesitate to reach out.

THE AMPLIFICATION OF SPECIFIC SOUNDS IS ANNOYING (METALLIC, UNNATURAL). WHAT SHOULD I DO?

The Nuance Audio Hearing Aid opens up a world of sound that may have previously been inaccessible to you. It's important to understand that your brain will need some time to adjust to these new auditory experiences. Since most hearing losses occur in the high-frequency range, the initial amplification of these sounds may come across as tinny, robotic, or unnatural. Discomfort during this adjustment period is common, and it typically lasts a few days. To ease the transition, consider starting with lower volume levels and gradually increasing them as you become more comfortable. Here are some additional tips to help you acclimatize to your Hearing Aid:

a. Experiment with Different Presets. Different presets can provide a more comfortable sound experience. b. Adjust the Background Noise Setting. Try lowering the background noise setting from "Standard" to "Lowered." c. Perform the personal calibration guided process. If you haven't performed the personal calibration guided process yet or need to re-perform the personal calibration guided process, this step can significantly enhance your experience. By following these tips, you can make the acclimatization process smoother and more enjoyable. Remember, it's perfectly normal to feel some discomfort at first, but with time and patience, you'll likely find a comfortable auditory experience that enhances your daily life. If you have any further questions or need assistance, don't hesitate to reach out.

I HEAR SOUNDS IN FRONT OF ME BUT SOUNDS FROM BEHIND DO NOT SEEM AMPLIFIED. WHY? WHAT SHOULD I DO?

If you're hearing sounds in front of you but sounds from behind aren't amplified, here's what you can do: Adjust the Audio Mode. The most common reason for limited amplification from behind is the Audio Mode setting. To change this, navigate to the App home page and switch the Audio Mode from "Frontal" to "All-around." This adjustment allows your Hearing Aid to pick up and amplify sounds from all directions. Increase the Background Noise Setting. Try increasing the background noise setting (example: from "Lowered" to "Standard"). Increase the Volume. Sometimes, simply raising the volume can enhance your audio experience. Experiment with Different Presets. Trying out different sound presets may help you find a configuration that works better for you. If you have any further questions or need assistance, don't hesitate to reach out.

11. Warranty

11.1. LUXOTTICA, LIMITED WARRANTY

This Warranty is provided by Luxottica Group S.p.A., Piazzale Cadorna 3, 20123 Milano, Italy. This Warranty covers defects and malfunctions in the new Luxottica product(s) it accompanies (the "Product"). The Warranty continues for one (1) year from the date of purchase of the Product (the "Limited Warranty Period"). However, if you purchase the Product from within the EU or EFTA, the Limited Warranty Period shall be two (2) years.

FOR THE US ONLY, ANY IMPLIED WARRANTIES THAT CANNOT BE DISCLAIMED ARE EXPRESSLY LIMITED TO THE DURATION OF THE LIMITED WARRANTY PERIOD AS SET OUT IN THIS LIMITED CONSUMER WARRANTY (THE "WARRANTY").

Some countries, states, provinces, and territories (including the EU, EFTA and UK) do not allow the exclusion or limitation of incidental or consequential damages, the exclusion or limitation of certain damages or types of loss or allow limitations on how long an implied warranty or condition may last, so the limitations or exclusions described in this Warranty may not apply to you.

For products purchased in California:

The Nuance Audio™ hearing aid is warranted to be specifically fit for the particular needs of you, the buyer. If the hearing aid is not initially fit for

your particular needs, it may be returned to the seller within 45 days of the initial date of delivery to you. If you return the hearing aid, the seller will either adjust or replace the hearing aid or promptly refund the total amount paid. This warranty does not affect the protections and remedies you have under other laws.

We warrant that the Product will, under normal and intended use, function in accordance with the technical specifications or accompanying product documentation (the "Warranted Functionality") during the Limited Warranty Period. For the avoidance of doubt, any software or services that are required to achieve the Warranted Functionality may be updated, modified, or limited, so long as it continues to maintain (or exceed) the Warranted Functionality. This Warranty is not available to products that were purchased from any source other than Luxottica or an authorized dealer. This Warranty is valid only with proof of purchase that clearly shows the purchase date. If you send us a Product without valid proof of purchase, then we reserve the right to return the Product to you at your cost, subject to prepayment, or, if such costs are not prepaid, we will keep the Product for thirty (30) days for your pick-up. This Warranty is limited and not applicable to any lens scratches. The installation or replacement of any lenses* should be conducted by Luxottica or a Luxottica authorized dealer. Any damage caused by the unauthorized

installation, replacement or alteration of the lenses is not covered by this Warranty. If your Product is defective or malfunctioning, we will either repair or replace that Product, or update software or services, so that the Product performs substantially in accordance with the Warranted Functionality. In some cases, we may instead refund the purchase price paid for the Product. Your remedy under this Warranty will be the repair, replacement or refund of the Product unless it is impossible or disproportionate for us to do so.

This Warranty gives you specific legal rights, and you may also have other rights under consumer protection laws or regulations in the jurisdiction of purchase or, if different, in your country of residence. Such rights vary from state to state and country to country. The benefits conferred by this Warranty are in addition to and do not affect any rights and remedies conveyed by such consumer protection laws and regulations (including, without limitation, national laws implementing Directive 1999/44/EC and Directive 2019/771). You are entitled to remedies free of charge in the event that your goods do not conform with the requirements set out under the laws in your jurisdiction. The other remedies available to you according to the laws in your jurisdiction are not affected by this Warranty. For full information on your rights according to the laws in your jurisdiction, please see below and/or contact your local consumer rights organization/citizens advice bureau.

This Warranty applies only to those countries to which Luxottica ships and supports. Please visit us at www.nuanceaudio.com for information about the countries Luxottica supports and to get helpful service and contact information. The scope of technical support offered by Luxottica consists of helping to diagnose and resolve problems with defects in the Product. Please note that when contacting Luxottica via telephone,

long distance charges may apply, depending on your calling area.

For French consumers

This Warranty applies without prejudice to the legal warranty of conformity and the warranty against hidden defects. The consumer has a period of two (2) years from the date of delivery of the goods to obtain the implementation of the legal warranty in the event of any lack of conformity. During this period, the consumer is only required to establish the existence of the lack of conformity and not the date on which it became apparent. Where the contract for the sale of goods provides for the supply of digital content or a digital service on a continuous basis for a period of time of over two (2) years, the legal warranty shall apply to that digital content or digital service throughout this period. During this period, the consumer is only required to establish the existence of the lack of conformity affecting the digital content or service and not the date on which it became apparent. The legal warranty entails an obligation on the seller's part, where applicable, to provide any updates necessary to maintain the goods in conformity. The legal warranty shall give the consumer the right to repair or replace the goods within thirty (30) days of his or her request, free of charge and without any major inconvenience to him or her. If the goods are repaired under the legal warranty, the consumer shall benefit from a six (6) -month extension of the initial warranty. If the consumer asks for the good to be repaired, but the seller requires it to be replaced, the legal warranty of conformity shall be renewed for a period of two (2) years from the date on which the good is replaced. The consumer may obtain a reduction in the price of the goods while keeping the goods or a full refund by terminating the contract and in exchange of the goods, if:

- 1° The professional refuses to repair or replace the goods;
- 2° The goods are repaired

or replaced after a downtime period of thirty days; 3° The repair or replacement of the goods causes major inconvenience to the consumer, in particular where the consumer definitively bears the cost of taking back or removing the non conforming goods, or if he or she bears the cost of installing the repaired or replaced goods; 4° The lack of conformity of the goods persists after the seller's unsuccessful attempt to bring them into conformity. The consumer is also entitled to a reduction in the price of the goods or to termination of the contract where the lack of conformity is so significant that it justifies the reduction in price or termination of the contract being immediate. The consumer is then not required to request repair or replacement of the goods beforehand. The consumer shall not be entitled to terminate the sale if the lack of conformity is minor. Any period of immobilization of the goods for the purpose of repair or replacement shall suspend the warranty that was running until the goods are delivered in good condition. The rights mentioned above result from the application of Articles L. 217-1 to L. 217-32 **of the French Consumer Code.**

The professional who hinders the implementation of the legal warranty of conformity in bad faith shall be liable to a civil fine of up to 300,000 euros, which may be increased by 10% of the average annual turnover (Article L. 241-5 of the French Consumer Code). The consumer also benefits from the legal warranty for hidden defects under Articles 1641 to 1649 of the French Civil Code, for a period of two (2) years from the discovery of the defect. This warranty entitles the consumer to a reduction in price if the goods are kept or to a full refund in return for the return of the goods. The limitation of liability clause will not apply to French consumers in case of breach of any of its obligation by Luxottica.

For Italian consumers

This Warranty is a conventional warranty offered by Luxottica Group S.p.A. according to Article 135-quinquies of the Legislative Decree of 6 September 2005, no. 206 ("Consumer Code"). Regardless of the Warranty offered by Luxottica Group S.p.A., the consumer has the statutory rights set forth by Article 128-135-septies of the Consumer Code for two (2) years as from delivery of the Product. Therefore, this Warranty does not affect consumers' statutory rights concerning the legal warranty of conformity. For additional information about your statutory rights under Article 128-135-septies of the Consumer Code, please visit www.nuanceaudio.com.

11.2. REGISTRATION

Product registration is not required as a condition to coverage under this Warranty, but some Luxottica products require periodic connection to an online account to ensure full functionality.

11.3. HOW TO MAKE A WARRANTY CLAIM

If you have a problem with your Product, please visit us at www.nuanceaudio.com to get helpful service and contact information, and to obtain warranty service. Unless specifically stated elsewhere in this Warranty and except as provided by applicable state law, to make a warranty claim, you need to return your Product to Luxottica or to the authorized dealer from which the product was purchased, together with your proof of purchase.

If your warranty claim is deemed to be valid, and we find a defect or malfunction covered by this Warranty, we will replace or repair the Product so it provides the functionality warranted. Subject to your rights under any local laws, if we determine that a Product should be replaced, the replacement may be a new, refurbished, or a re-manufactured Product. The Limited Warranty Period is extended by a duration

equal to the time during which we had the Product in our possession for performance of the Warranty, as described above. Save for your rights and remedies available under your local laws, the provision of a repaired or replacement product does not restart or otherwise extend the Limited Warranty Period. Should it be found that none of the listed means are reasonable to correct a defect or malfunction, then we may refund to you the price you paid to purchase the Product. We may not return the original Product to you. If your warranty claim is not deemed to be valid, then we reserve the right to return the Product to you at your cost, subject to prepayment, or, if such costs are not prepaid, we will keep the Product for thirty (30) days for your pick-up before it is disposed of. Except to the extent that the law requires otherwise, any expenses incurred by you in returning the Product for warranty assessment will be borne by Luxottica using a pre-paid returns label which will be provided to you to enable you to return your Product for warranty assessment free of charge, or other methods listed at www.nuanceaudio.com. If the returned Product is deemed (at Luxottica's discretion) to be eligible for a valid warranty claim, then Luxottica will automatically incur the costs of any further freight charges required to return the repaired or replacement product to you. If the warranty claim is deemed to be invalid and we do not find a defect or malfunction covered by this Warranty, we will contact you to see if you want us to conduct repairs at your cost and, in any event, you will be charged for the outbound freight to return your Product based on Luxottica's standard shipping rates.

11.4. LIMITATIONS AND EXCLUSIONS

THIS WARRANTY DOES NOT COVER, AND LUXOTTICA IS NOT RESPONSIBLE FOR: DELIVERY OR INSTALLATION, OR LABOR CHARGES FOR SETUP OF THE PRODUCT

AND/OR ADJUSTMENT OF CUSTOMER CONTROLS ON THE PRODUCT. DAMAGES CAUSED BY MISUSE, ABUSE, ACCIDENTS, FIRE, THEFT, DISAPPEARANCE, MISPLACEMENT, FLUCTUATIONS AND POWER SURGES, CONNECTIONS TO IMPROPER VOLTAGE OR INCORRECT ELECTRICAL LINE VOLTAGE, VIRUSES, MALWARE, RECKLESS, WILLFUL, OR INTENTIONAL CONDUCT OR NEGLIGENCE. DAMAGES CAUSED BY SERVICING THE PRODUCT WHICH HAS NOT BEEN PRE- AUTHORISED BY LUXOTTICA. DAMAGES CAUSED BY USAGE THAT IS NOT IN ACCORDANCE WITH THE PRODUCT INSTRUCTIONS/DOCUMENTATION. DAMAGES CAUSED BY FAILURE TO FOLLOW THE PRODUCT INSTRUCTIONS/ DOCUMENTATION OR FAILURE TO PERFORM CLEANING OR PREVENTIVE MAINTENANCE. DAMAGES CAUSED BY THE COMBINATION OF THE PRODUCT WITH OTHER NON-LUXOTTICA BRANDED PRODUCTS, ACCESSORIES, PARTS OR COMPONENTS OR USE OF PRODUCTS, EQUIPMENT, SYSTEMS, UTILITIES, SERVICES, SOFTWARE, PARTS SUPPLIES, ACCESSORIES, APPLICATIONS, INSTALLATIONS, REPAIRS, EXTERNAL WIRING OR CONNECTORS NOT SUPPLIED OR AUTHORISED BY LUXOTTICA THAT DAMAGE THE PRODUCT. SIGNAL ISSUES, RECEPTION PROBLEMS AND DISTORTION RELATED TO NOISE, ECHO, INTERFERENCE OR OTHER SIGNAL TRANSMISSION AND DELIVERY PROBLEMS. ANY EQUIPMENT OR COMPONENTS THAT WERE NOT INCLUDED IN, OR WITH YOUR PRODUCT AS ORIGINALLY SOLD. NORMAL WEAR AND TEAR, INCLUDING LENS SCRATCHES. DAMAGE CAUSED AS A RESULT OF IMPROPER TRANSPORTATION OR PACKING/PACKAGING WHEN RETURNING THE PRODUCT TO LUXOTTICA OR A COLLECTION DEALER. DAMAGES CAUSED BY MODIFICATION OR ADAPTATION THAT MAY BE REQUIRED TO ENABLE A PRODUCT TO OPERATE IN ANY COUNTRY

OTHER THAN THE COUNTRY FOR WHICH IT WAS DESIGNED, MANUFACTURED, APPROVED AND/OR AUTHORISED, OR REPAIR OF THE PRODUCT WHICH RESULTS IN DAMAGE AS A RESULT OF THESE MODIFICATIONS. DAMAGE TO PRODUCTS WHERE THE ANTI-COUNTERFEITING CODE (OR EQUIVALENT) HAS BEEN REMOVED, ERASED, DEFACED, ALTERED OR MADE ILLEGIBLE.

This Warranty does not include any specific guarantees that the Product will be error-free, or regarding uptime or continued availability of data security features of software or online accounts, that any software, firmware or online sites will function uninterrupted or error-free. Except in the US and to the extent prohibited by any applicable law in any other country, this Warranty is void if a Product is returned with removed, damaged or tampered labels or any alterations (including the unauthorized removal of any component or external cover).

11.5. IMPLIED WARRANTIES

EXCEPT IN THE EU, EFTA AND UK AND EXCEPT TO THE EXTENT PROHIBITED BY ANY APPLICABLE LAW IN ANY OTHER COUNTRY, ANY IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT IS DISCLAIMED.

IF YOU ARE A CONSUMER SUBJECT TO THE QUEBEC CONSUMER PROTECTION ACT, THE WARRANTY DISCLAIMER CONTAINED IN THIS SECTION DOES NOT LIMIT YOUR RIGHTS AND REMEDIES UNDER SUCH ACT, INCLUDING THE RIGHT TO MAKE A CLAIM UNDER ANY OF THE STATUTORY WARRANTIES PROVIDED UNDER SECTIONS 34 TO 54 OF SUCH ACT.

11.6. LIMITATION OF LIABILITY

EXCEPT TO THE EXTENT PROHIBITED BY ANY APPLICABLE LAW, LUXOTTICA

SHALL NOT, UNDER THIS WARRANTY, BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES FOR BREACH OF ANY EXPRESS OR IMPLIED WARRANTY. EXCEPT TO THE EXTENT PROHIBITED BY LAW, LUXOTTICA'S MAXIMUM LIABILITY FOR ANY CLAIM ARISING OUT OF OR RELATED TO THIS WARRANTY IS LIMITED TO THE PURCHASE PRICE PAID BY YOU FOR THE PRODUCT PLUS ANY INTEREST ALLOWED BY LAW REGARDLESS OF THE FORM OF CLAIM. TO THE EXTENT PERMITTED BY LAW, LUXOTTICA IS NOT LIABLE FOR EVENTS BEYOND ITS CONTROL, SUCH AS ACTS OF GOD, VIRUSES, PROPERTY DAMAGE, LOSS OF USE, INTERRUPTION OF BUSINESS, LOST PROFITS, LOST DATA OR OTHER CONSEQUENTIAL, PUNITIVE OR SPECIAL DAMAGES, HOWSOEVER CAUSED, FOR BREACH OF THIS WARRANTY, CONTRACT OR TORT (INCLUDING NEGLIGENCE). This Warranty does not affect your legal rights under any applicable state and national law governing the sale of consumer goods.

*Lenses can be mounted only by Luxottica or a Luxottica authorized dealer in order to ensure the proper fitting and functionality of the Product.

11.7. Returns and Exchanges

If you bought Nuance Audio Glasses from an EssilorLuxottica banner, you may return them within 30 days from the date of purchase, or any longer period expressly provided by applicable law or the specific EssilorLuxottica banner. Nuance Audio Glasses purchased through non-EssilorLuxottica retailers must be returned to those retailers in accordance with their return policies. For further information on EssilorLuxottica returns, please visit <http://nuanceaudio.com/en-us/c/terms-and-conditions>.

12. Hearing Aid Technical Specifications

KEY FEATURES	Inputs
Processing Channels	16
WDRC	Yes
Feedback Management	Yes
Battery	Rechargeable, Li-ion
Programs	4 selectable 'presets'
iOS App	Yes
Android App	Yes
Volume Control	Yes via on device button or app
Microphone Pattern	Focused and Omni options
Self-Setup & Personalization	Yes via app
Low Battery Alarm	Yes via LED & App
App Compatibility	Android 12 and above, iOS 16.6.1 and above
Hands-free Calling	No
WIRELESS CONNECTIVITY	
Bluetooth® Compatible	Yes, BT LE
Bluetooth® Phone Call Compatible	1. 1. No
Operation frequency	MHz 2402-2480

Max radiated power	Free space max EIRP is -3.22 dBm
Modulation	GFSK
Channel spacing	2MHz
Channel bandwidth	2. 2MHz
Number of channels	40
WIRELESS CHARGING	Yes
Transmitting frequency	MHz 13,56
Receiving frequency	MHz 13,56
Max/Effective radiated power	W 1.8
Modulation type transmitting	modified Miller %100 ASK
Modulation type receiving	16/Load Modulation subcarrier fc 848kbit/s) OOK Manchester)
FITTING AND PROGRAMMING	Not intended to be a fitted device or programmed
Nuance Audio™ App	Yes, for set up
TECHNICAL SPECIFICATIONS	
Microphones	microphones 6

TRANSPORT AND STORAGE CONDITIONS	
Temperature	3. From -22°F (-30°C) to +167°F (+75°C)
Humidity	From 20% to high humidity 90% and temperature (113°F/+45°C) for 288 hours
Altitude & atmospheric pressure	Altitude of 40,000 ft (18,8kPa) for 12 hours (at both 14°F (-10°C) and 113°F (+45°C)
Time to warm from minimum storage temperature until it is ready for intended use	Approximately 15 minutes
Time to cool from the maximum storage temperature until it is ready for intended use	Approximately 10 minutes
OPERATING CONDITIONS	
Temperature	(From 14°F (-10°C) to 113°F (+45°C)
Humidity	From 20% to humidity 60% under 95°F(35°C) for 1000 hours
Altitude & atmospheric pressure	Altitude of 13.000 ft for 1 hour at 32°F (0°C) and 95°F (+35°C); 101.3kPa to 61.9kPa

Electroacoustic Characteristics (ANSI S3.22:2014 & CTA-2051:2017)	
OTC Hearing Aids	
Frequency Band	Standard Band Device
Frequency Response Bandwidth	200Hz - 5000 Hz
Equivalent Input Noise	31,2 dB
Total Harmonic Distortion	<1%
Maximum OSPL90	110,5 dB
HFA OSPL90	100,1 dB
Maximum Full-On-Gain	20,3 dB
HFA Full-On-Gain	9,8 dB
Input Distortion at 80 dB SPL	1 %
Latency	8,8 ms

Data for all parameters measured per ANSI S3.22:2014 / CTA-2051:2017 can be found at <https://www.nuanceaudio.com/en-us/c/technical-reports.html>

Guidance and manufactures declaration for electromagnetic emissions			
Emission standard		Type	Compliance to standard
CISPR 11		Radiated RF emissions	Yes, Group 1, Class B
Guidance for application Environment			
Nuance Audio™ Hearing Aid is suitable for use in both professional as well as domestic environments. The device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.			
Guidance and manufactures declaration for electromagnetic immunity			
Emission standard	Type	Compliance level	Specific guidance for application environment
EN/IEC61000-4-2	Electrostatic discharge (ESD)	± 4kV, ± 8kV contact ±2kV, ±4kV, ±8kV, ± 15kV air	Suitable for use on wood, concrete , or ceramic floor materials. Keep relative humidity below 30% when used on floors of syntitic materials e.g. carpets.
EN/IEC61000-4-8	Power frequency magnetic field	30 A/m 50/60 Hz	Suitable for in proximity to equipment mains connected to public low-voltage network supplying domestic environment. Portable and mobile radio devices, including their wires, should not be used closer to the unit than the recommended safe distance or 30 cm. The level for Power frequency magnetic fields corosponds to the levels typical for professional or domestic Environment.

EN/IEC61000-4-3	RF electromagnetic fields. Proximity fields from RF wireless communication equipment. Test freq. MHz 385 450 710, 745, 780 810, 870, 030 1720, 1845, 1970 2450 5240, 5500, 5785	80 MHz to 2.7 GHz, 80% AM at 1 kHz, 10 V/m		Portable and mobile radio devices, including their wires, should not be used closer to the unit than the recommended safe distance or 30 cm.
		V/m		
		27		
		28		
		9		
		28		
		28		
		28		
		9		
EN/IEC61000-4-39	IMMUNITY to proximity magnetic fields 30 kHz 134.2 kHz 13,56 MHz	Test frequency	A/m	The device is tested to function in close proximity to powerful magnetic fields, e.g. from RFID equipment. The test levels ensure a safe distance of 15 cm.
		8		
		65		
		7.5		

Features per ANSI/CTA 2051-2017

Feature Category	The Hearing Aids
Fixed or Level Dependent Frequency Equalization	Tone Control Available ANSI/CTA-2051-2017 clause 4.10
Level Dependent Gain/Compression	Multiband Wide Dynamic Range Compression ANSI/CTA2017-2051- clause 4.11
Feedback Control	Available with the Nuance Audio Hearing Aid ANSI/CTA2017-2051- clause 4.14
SNR Enhancement	Available with the Nuance Audio Hearing Aid ANSI/CTA2017-2051- clause 4.13

13. Nuance Audio™ Glasses, Charging Pad, Charging Cable and Battery disposal.

The Nuance Audio™ Glasses, Nuance Audio™ Charging Pad, and the USB-C Charging Cable should not be discarded as household waste and should be delivered to an appropriate collection facility for recycling. The Nuance Audio™ Glasses should be disposed according to local regulations and guidelines for product with lithium-ion batteries. Dispose of batteries in an environmentally friendly way in accordance with Federal and State requirements. For more info on proper disposal, please visit www.nuanceaudio.com.

14. Regulatory Compliance Information

Applicable to the Nuance Audio™ Hearing Aid and to the Charging Pad

14.1. FCC compliance statement

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio technician for help.

Note: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC Radiation Exposure Statement. This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Keep the Product away from the womb of pregnant women.

Keep the Product away from the lower abdomen of adolescents.

Use the Product in good reception conditions to reduce the amount of electromagnetic radiation received.

Country	Type Approval	Regulatory Mark/Logo
Global	The Nuance Audio Glasses comply with the following domestic and international regulations for medical devices: IEC 60601-1:2005 Ed3+C1, C2, A1, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-1-2 4th Edition, FCC 47 Part 15.247 Classification: Type B Applied Part, IEC 60601-2-66, this Nuance Audio Glasses have no essential performance. The testing performed above has been in accordance with IEC 60601-1-2:2014 (4th Ed). The values identified during this evaluation were found to be within acceptable specified ranges.	

15. Symbols and Descriptions



Federal Communications Commission (U.S.)



WEEE Directive (Directive 2012/19/EU)



Bluetooth®



Review operating instructions prior to use



Warning



Serial Number



Medical Device



MR Unsafe



Single patient, multiple use



Date of manufacture



Manufacturer



Model Number



Type B applied part



Magnetic field warning. Possible interference with cardiac pacemakers, implanted defibrillators (ICD's) and other implants



Contains small parts which may be choking hazard. Not suitable for children under the age of 3



Operating Instructions



Made in China



Patient Information Website



Keep Dry



Temperature Limit



Do NOT use if package is damaged



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1. Nuance Audio™ Hearing Aid FCC ID: 2AYOA-4004
2. Nuance Audio™ Charging Pad FCC ID: 2AYOA-4005



Luxottica Group S.p.A.
Piazzale Cadorna 3,
20123 Milan, Italy



Made in China
Fabriqué en Chine



www.nuanceaudio.com



Raccolta carta
Papel y cartón

