FOR USA ONLY

Nuance Audio™ Hearing Aid Software

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.

The Nuance Audio™ Hearing Aid Software is for use by adults who have perceived mild to moderate hearing loss.

How do you know if you have a perceived mild to moderate hearing loss?

- You have trouble hearing speech in noisy places
- You find it hard to follow speech in groups
- You have trouble hearing on the phone
- Listening makes you tired
- You need to turn up the volume on the TV or radio, and other people complain that is it too loud

Some people with hearing loss may need help from a hearing healthcare professional even after using the Nuance Audio™ Hearing Aid Software. How do you know if you need to see a hearing healthcare professional?

- You can't hear speech even if the room is quiet
- You don't hear loud sounds well, for example, you don't hear loud music, power tools, engines, or other very noisy things
- If this hearing aid does not help you enough, ask for help from a hearing healthcare professional
- If your hearing loss makes it hard to hear loud noises, this hearing aid may not be your best choice without help from a professional

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

Note: The Nuance Audio™ Hearing Aid Software and firmware (FW) are compatible with the Nuance Audio™ Glasses (smart glasses) delivering the same amplification to each ear. This means that if you have worse hearing in one ear you will choose a preset audiogram profile setting and volume setting that will meet your hearing needs for the worse ear. IT IS RECOMMENDED THAT YOU SEE A DOCTOR, PREFERABLY AN EAR-NOSE-THROAT DOCTOR IF YOU HAVE WORSE HEARING IN ONE EAR BEFORE USING AN OTC HEARING AID.

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 constantly need to turn the volume down, you may need to further adjust your Nuance Audio™ Glasses preset or volume settings.

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.
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.
PLEASE REFER TO SECTION 3.3 OF THIS DOCUMENT FOR A MORE COMPLETE LIST OF WARNINGS AND PRECAUTIONS.
Note: Tell the FDA about injuries, malfunctions, or other adverse events associated with your use of the device.
To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. The FDA calls them "adverse events", and they might include: skin irritation in your ear, 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.

Table of contents

1.	**INTENDED USE**	**8**
2.	**INDICATIONS FOR USE**	**8**
3.	**IMPORTANT HEALTH AND SAFETY INFORMATION**	**8**
3.1.	Intended Use Environment	9
3.2.	The Nuance Audio™ Hearing Aid may not be right for you	9
3.3.	Warnings, Precautions, and Safety Considerations	9
3.3.1.	Warnings	9
3.3.2.	Battery	10
3.3.3.	Precautions	10
3.4.	Preventing damage and malfunctions to the Nuance Audio™ Hearing Aid	10
3.5.	Recommended Use and Storage	11
3.6.	Cybersecurity	11
4.	**WHAT'S IN THE BOX**	**11**
5.	**OPENING THE BOX**	**12**
6.	**THE NUANCE AUDIO™ HEARING AID**	**12**

7.	**NUANCE AUDIO™ APP SETUP AND BLUETOOTH® PAIRING**	**12**
7.1.	Review Required Labelling	13
7.2.	Onboarding the Nuance Audio™ Hearing Aid	13
7.2.1.	Creation of the Nuance Audio™ App user account	13
7.2.2.	First pairing	13
7.2.3.	Nuance Audio™ Hearing Aid tutorial	13
7.2.4.	Personal Calibration	13
7.2.5.	App tutorial	13
7.3.	Application main page	13
7.3.1.	Battery level	14
7.3.2.	Noise tracking	14
7.3.3.	Background noise	14
7.3.4.	Volume	14
7.3.5.	Presets	14
7.3.6.	Audio Mode	14
7.4.	Menu	15
7.4.1.	Nuance Audio™ Hearing Aid selection and add new Hearing	15
7.4.2.	My account	15
7.4.3	Settings	15
7.5	Support	16
8.	**NUANCE AUDIO™ CARE AND MAINTENANCE**	**23**
8.1.	Battery Information	23
8.2.	Charging the battery	23
8.3.	The Charging Pad works thanks to a USB-C Charging Cable	23
8.4.	Caring for the Nuance Audio™ Hearing Aid	24
8.5.	Hearing Aids General Maintenance	24
8.6.	General Information	24
9.	**PRIVACY**	**25**
10.	**TROUBLESHOOTING**	**25**
10.1.	Common Solutions for the App	25

10.2.	Other Troubleshooting Tips	25
11.	**HEARING AID TECHNICAL SPECIFICATIONS**	**26**
12.	**NUANCE AUDIO™ HEARING AID, CHARGING PAD, CHARGING CABLE AND BATTERY DISPOSAL**	**30**
13.	**REGULATORY COMPLIANCE INFORMATION**	**30**
13.1.	FCC compliance statement	30
14.	**SYMBOLS AND DESCRIPTIONS**	**31**

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™ Hearing Aid.

1. INTENDED USE

The Nuance Audio™ Hearing Aid is a software-only mobile medical application that is intended to be used with a compatible wearable electronic computing platform. The Nuance Audio™ Hearing Aid Software is intended to amplify sounds for individuals 18 years of age or older with perceived mild to moderate hearing loss. The Nuance Audio™ Hearing Aid Software also allows for user customization to suit their perceived hearing needs through utilizing 4 pre-set fitting options based on typical hearing loss profiles of a mild to moderate hearing loss (Urbanski et al, 2021). The presets are selected subjectively by the user to meet their hearing needs without the assistance of a hearing healthcare professional. The Nuance Audio™ Hearing Aid Software device is intended for over-the-counter (OTC) use.

2. INDICATIONS FOR USE

The Nuance Audio™ 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 loss. 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 (OTC) use.

NOTE: Nuance Audio™ Glasses in these instructions refers to the HW platform together with the hearing aid functionality enabled software.

3. IMPORTANT HEALTH AND SAFETY INFORMATION

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™ Glasses. 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™ Glasses 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™ Glasses is intended to be used for listening to the sounds in a variety of environments (e.g., home, office, transit, social settings, outdoors, etc.). 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™ Glasses may not be right for you if you: Consistently experience feedback (whistling) of the hearing aid when you turn up the 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.

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

3.3. Warnings, Precautions, and Safety Considerations

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

NOTE: The Nuance Audio™ Glasses 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™ Glasses 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™ Glassses 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.
- **Do NOT** resell the Nuance Audio™ Glasses 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™ Glasses 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). 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™ Glassses 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 (+45°C) 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 has mounted prescription lenses, it is intended only for use by the prescribed user. 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™ Glasse 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™ Glasses. 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.
- 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.
- This Nuance Audio™ Glasses must not be used as safedy or protection against mechanical impact.
- The Nuance Audio™ Glasses can be only be charged with a Nuance Audio™ Charging Pad. If the Nuance Audio™ Hearing Aid are placed on generic wireless charge pads, it will not charge.

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

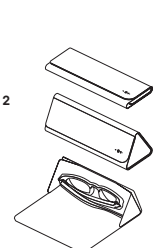
- Operating conditions: 14°F (-10°C) to 113°F (+45°C); 101.3kPa to 61.9kPa; humidity between 20% and 60% under 95°F (+35°C) for 1000 hours; maximum altitude of 13.000 ft for 1 hour at 32°F (0°C) and 95°F (+35°C).
- Transport and Storage conditions: Hearing Aid shall remain functional after recovery from 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 Software 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

1 - 1 each Nuance Audio™ hearing Glasses
2 - 1 each Audio Folder Case
3 - 1 each Cleaning Cloth
4 - 1 each Nuance Audio™ Charging Pad
5 - 1 each USB-C Charging Cable



The Box also includes:

6 - 1 each Instructions for Use
7 - 1 each User Guide



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.

The Nuance Audio™ GLASSES

A - Multifunction button
B - LED
C - Tap area
D - Microphones
E - Speakers

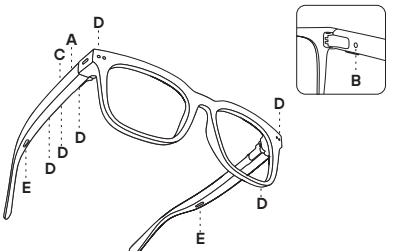


Fig. 0 Schematic Diagram of the Nuance Audio™ Glasses

Nuance Audio™ Glasses 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™ HEARING AID

The Nuance Audio™ Hearing Aid is considered an air conduction hearing aid software within a smart glasses frame. Nuance Audio™ Glasses in these instructions refers to the HW platform together with the HA functionality enabled SW. The Nuance Audio™ Glasses components are:

- Nuance Audio™ Glasses: Smart glasses compatible with Nuance Audio™ Hearing Aid Software.
- Nuance Audio™ Charging Pad: intended to enable the air conduction hearing aid functionality in terms of charging the hearing aid. 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 during the day, 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. The App requires an iPhone with iOS operating systems (iOS 16.6.1+) or a smartphone with an Android (Android 12 or above) operating system. It is possible to use the Nuance Audio™ Hearing Aid main functions without the App, using the button and the tap area on the Nuance Audio™.

7. Nuance Audio™ APP setup and Bluetooth® pairing

Download on the App Store GET IT ON Google Play

The The Nuance Audio™ Glasses 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. Follow the Nuance Audio™ App registration and set up instructions prior to using the Nuance Audio™ Glasses. 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**. Overall, clinical data showed that people with mild to moderate hearing impairment perceived a hearing benefit when using the Nuance Audio™ Hearing Aid Software in conjunction with the Nuance Audio™ Glasses.

7.2. Onboarding the Nuance Audio™ Glasses

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™ Glasses.

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 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 paring is represented by the page here below**.**

Fig. 6 Pairing completed with success

7.2.3. Nuance Audio™ App and Nuance Audio™ Glasses 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. **Fig. 7A, 7B**

7.2.4. Personal Calibration

Personal calibration is the procedure that considers the user's head shape to minimize acoustic feedback. The device incorporates a feedback control algorithm to reduce the likelihood of the user experiencing acoustic feedback. Please follow the Nuance Audio™ App instructions to perform the required steps to complete personal calibration It is best to be in a quiet environment to set up the device and perform the personal calibration set up steps. The user will hear a short burst of sound and should remain quiet during the initial personal calibration sound measurement, then the user will be asked to speak per the prompts in the Nuance Audio™ App personal calibration procedure to finalize the measurements. The personalization calibrating procedure can be repeated at any time from the mobile app Settings menu. Once you have completed the onboarding and set up, then you can begin using the Nuance Audio™ Glasses.

The Nuance Audio™ Glasses will start with a default setting of preset C, Sloping Moderate Hearing Loss profile, and volume setting 3. You can fine tune your device using the main App screen choices (see section 9.3). Select a hearing preset (A, B. C, and D) that is best suited to meet your listening needs.

7.2.5. App tutorial

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. **Fig. 9**

7.3. Application main page

The application main page, also called home page, is displayed in the app when the Nuance Audio™

Glasses are turned on and correctly paired with the Nuance Audio™ App in your mobile phone. **Fig. 10A**
The following configuration options are directly available from the Home page.

- Select the preferred Preset configuration (A, B, C, D)
- Background noise adjustment
- Volume Control
- Battery charge level.
- Environmental noise measurement
- Audio Mode (Frontal or All Around)

Preset Fitting Settings:

Note: Default setting is Preset C and Volume 3

- **Preset A:** Flat mild hearing loss. Slightly amplifies sounds across low to high pitches
- **Preset B:** Sloping mild hearing loss. Amplification in the higher pitches
- **Preset C:** Sloping moderate hearing loss. Amplification in the higher pitches with increased volume
- **Preset D:** Flat moderate hearing loss. Slightly amplifies sounds across low to high pitches with increased volume

NOTE: You cannot choose a different preset for each ear. The preset chosen will be the same amplification provided to both ears. Therefore, if you have worse hearing in one ear, then please choose a profile that serves your needs for the worse ear and use the volume adjustment to adjust to meet your hearing needs.

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 it is time to charge the Nuance Audio™ Hearing Aid. Tapping on the component the Hearing Aid name and FW version is displayed.

7.3.2. Noise tracking

Noise tracking measures (**Fig. 11**) the environmental noise using the microphone of the mobile phone. The user must give permission to the Nuance Audio™ app to use the microphone before executing this measure. To access the noise tracking measurement, touch the Noise tracking icon on the top right of the main App screen. The background noise tracking is for informational purposes only.

NOTE: If the Noise tracking shows that you are in a "Very High" noise environment, it is recommended that the user turn off the Nuance Audio™ Glasses.

- 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™ Glasses 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™ App preset selection settings.

7.3.3. Background noise

From the background noise command in the main page the user can select how much background noise to hear while using the hearing aid. Options are: Low, Medium and High. **Fig. 12**
Tapping one of the Background noise settings allows you to adjust your desired background noise level. Choosing "Low" will soften sounds to the maximum noise reduction setting, "Medium" will allow the user to hear more sounds amplified in the environment, and "High" will allow a more transparent amplification setting with minimal noise reduction with all sounds amplified.

7.3.4. Volume

Volume setting, 5 loudness levels, are available on the main Nuance Audio™ App menu. Tapping on the plus or minus icons allows the user to adjust volume loudness. Volume 1 is the lowest level and softest loudness setting. Volume 5 is the highest level and highest loudness setting. Volume 3 is the default loudness setting.

7.3.5. Presets

Four different predefined presets are also available to the user for customization to their individual hearing needs. It is recommended to choose the one that better fits the listening situation where the Nuance Audio™ Glasses will be used.

7.3.6. Audio Mode

The audio mode selector gives to the user the additional option to configure the Nuance Audio™ Glasses 'hearing mode' by selecting frontal beamforming or all-around mode.

- Frontal mode: Provides directional microphone beamforming to provide amplification to sounds coming from the front of the user and minimizes any amplified sounds from the side or behind the

user for improved hearing in noisy environments.

- All-around mode: Provides 360-degree amplification of all sounds from the back, side and front of the user for awareness and improved hearing in quiet environments or when hearing all-around is important for awareness of sounds.

7.4. Menu

7.4.1. Nuance Audio™ Glasses selection and add a new device

This menu item gives the user the opportunity to switch between multiple Nuance Audio™ Glasses that are associated with the user profile and paired with the mobile phone. This feature allows up to 4 hearing aids that can be associated to a single profile. This is done by adding a new device (maximum of 4) to the user profile by initiating a new pairing process. **Fig. 13**

7.4.2. Personal Information

The personal information section contains profile information such as full name, email, phone number, date of birth, and gender. **Fig. 14**

Password

In the password section (**Fig. 15**) allows the user to change their password by entering the current password and then replacing it with a new one. Password accepted format is:

- 8 characters
- 1 upper case
- 1 lower case
- 1 number
- 1 special character

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 notification from this session and can also flag their categories of interest. Available 'Notifications' categories are firmware (FW) upgrades or suggestions on how to better configure the Nuance Audio™ Glasses. **Fig. 16**

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

In the legal documents section, all the documents regarding privacy and data processing can be found.

Delete account

User can decide to permanently delete the account and all the associated data. If engaging this operation, the user can no longer log-in to any to the Nuance Audio™ App. **Fig. 17**

Log-out

Clicking the log out button disconnects the account from the Nuance Audio™ App.

7.4.3. Settings

Multifunction Button Volume Profile

The multifunction button volume profile setting allows the user to select manually a volume profile when not using the Nuance Audio™ App wireless volume control. The preset volume profile adjustments, once chosen, are accessed via the multifunction button located on the bottom front of the right temple (Image Section 6, Multifunction Button "A"). The User preselects a multifunction button volume profile via the Nuance Audio™ App prior to using the on-device multifunction button from one of three (3) volume profile settings, as follows: (**Fig. 18**)

Multifunction Button Volume Profiles:

Note: Volume 1 is the softest and Volume 5 is the loudest volume level

- Low Range: enables volume levels 1, 2 and 3
- Default: enables volume levels 2, 3 and 4
- High Range: enables volume levels 3, 4 and 5.

My own voice

User can select how to perceive and monitor own voice. Settings are: No, Some, Yes (**Fig. 19**)

Personal calibration

From this Settings menu item, the user can select from the user's most recent Personal Calibration measurement or select the standard default setting (**Fig. 20A**)

My Hearing Aid

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

My Hearing Aid: Edit name

Provides the user the ability to customize the Nuance Audio™ Glasses name overwriting the default name. **Fig. 20B**

My Hearing Aid: Configuration and Firmware (FW) upgrade

This section contains information on the FW version of the Nuance Audio™ Hearing Aid Software and prompts 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%. **Fig. 21**

At the end of the upgrade the app will wait for the Nuance Audio™ Glasses to reboot with the new firmware. **Fig. 22**

My Hearing Aid: Detailed information

This section of the My Hearing Aid page contains all the detailed information on the Nuance Audio™ Glasses such as the serial number, model, color, etc. **Fig. 23**

My Hearing Aid: Forget these Hearing Aid

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 Hearing Aid: Factory reset

This returns the Nuance Audio™ Glasses and Nuance Audio™ App to the factory configuration. All data stored in the hearing aid and in association with the user account is cleared.

Note: The factory reset is permanent, there is no ability to undo this operation. The user is prompted for a confirmation prior to factory reset completion.

About

This page contains all the information on the application such as the App version number and other product codes. For App label, pleas check App details page. **Fig. 24**

Clinical and non-clinical performance testing

Overall, clinical data showed that people with mild to moderate hearing impairment perceived a hearing benefit when using the Nuance Audio™ Hearing Aid Software in conjunction with the Nuance Audio™ Glasses. The Nuance Audio™ Hearing Aid Software passed all relevant non-clinical performance testing and biological endpoints with the representative, compatible computing platform hardware (smart glasses). Software verification and validation, bench performance testing against established consensus standards for electrical safety, EMC and battery safety were conducted with the representative, compatible hardware (smart glasses) to verify the amplified acoustic signal output by the hardware platform.

Please visit www.nuanceaudio.com for more information.

7.5. Support

The Support section of the mobile app includes: **Fig. 25**

- 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
- 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

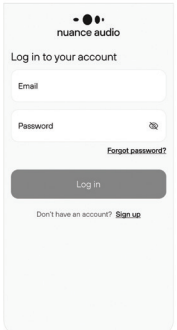


Fig. 1. Authentication page

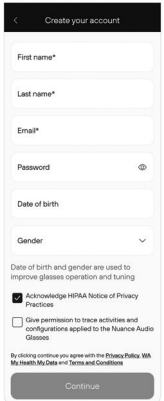


Fig. 2. Sign-in form

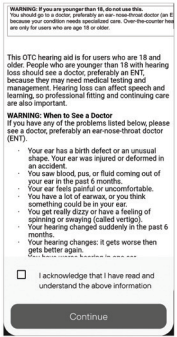


Fig. 3. Review Required Labelling

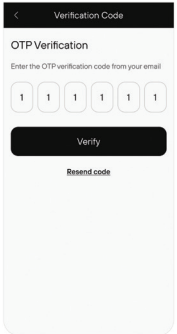


Fig. 4. Onetime code input and verification

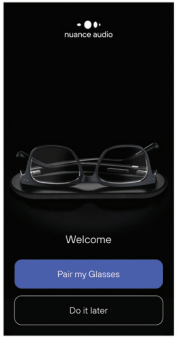


Fig.5A Pair my Hearing Aid

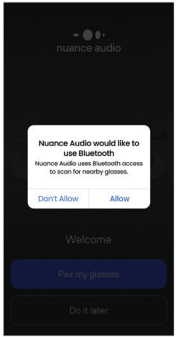


Fig. 5B



Fig. 5C

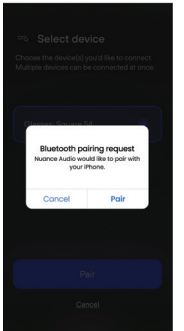


Fig. 5D

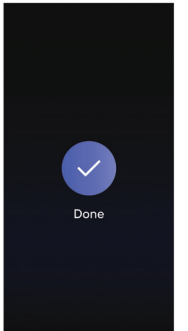


Fig. 6 Pairing completed with success

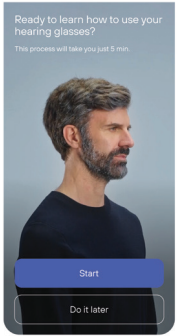


Fig. 7A Nuance Audio™ Hearing Aid tutorial.
Start page and a sample of one of the tutorial's steps.



Fig. 7B



Fig. 8A Calibration

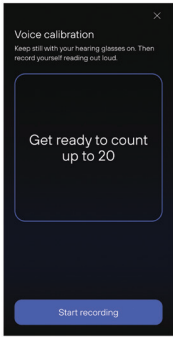


Fig. 8B

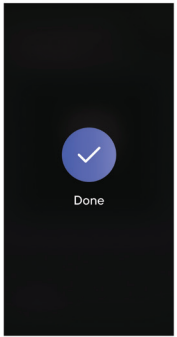


Fig. 8C

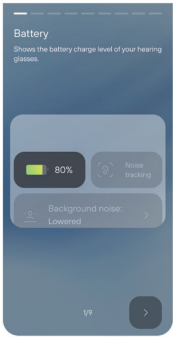


Fig. 9A Mobile app tutorial

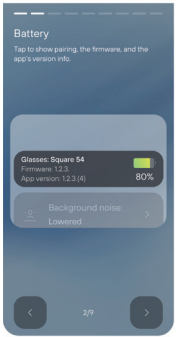


Fig. 9B

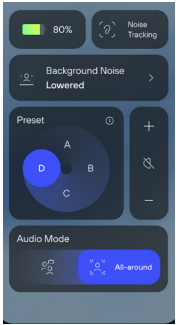


Fig. 10A Home page
The following configuration options are directly available from the home page

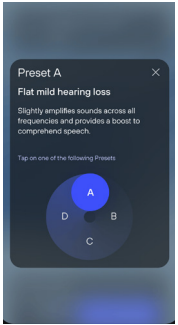


Fig. 10B

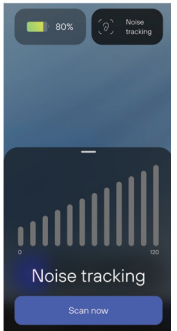


Fig. 11 Noise tracking

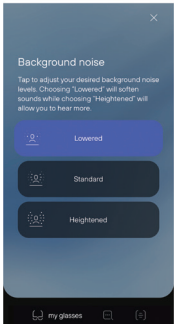


Fig. 12 Background noise configuration

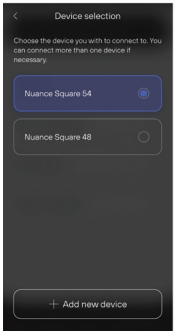


Fig. 13 Hearing Aid selection

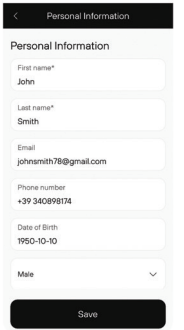


Fig. 14 Personal information

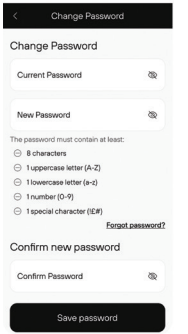


Fig. 15 Change password

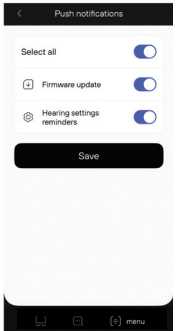


Fig. 16 Push Notifications

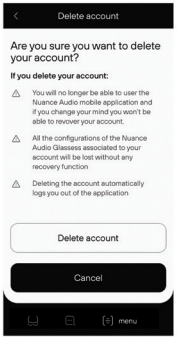


Fig. 17 Delete account, warning page

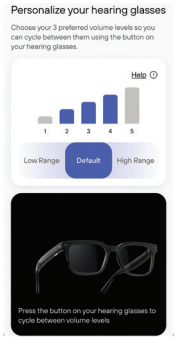


Fig. 18 Preset volume

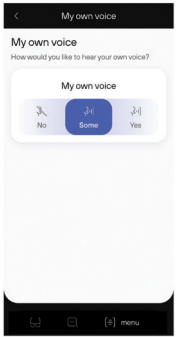


Fig. 19 Own voice

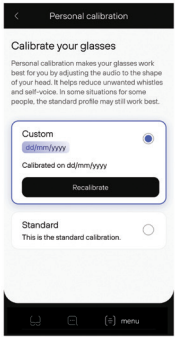


Fig. 20A Personal calibration

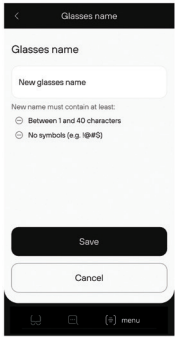


Fig. 20B

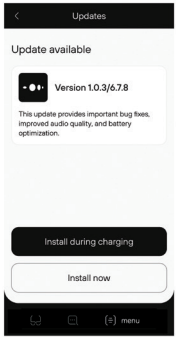


Fig. 21A Firmware update steps

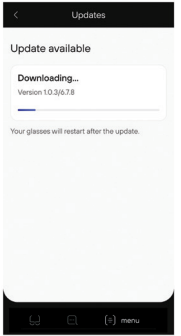


Fig. 21B

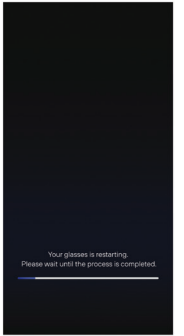


Fig. 22A Waiting for reboot and successful execution

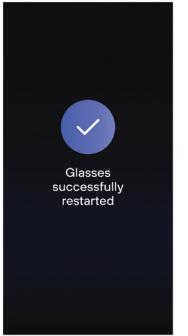


Fig. 22B

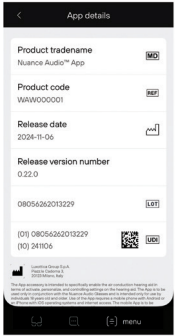


Fig. 23 Detailed information

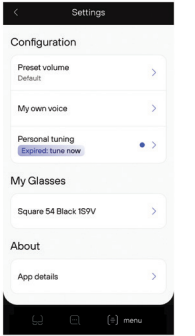


Fig. 24 About

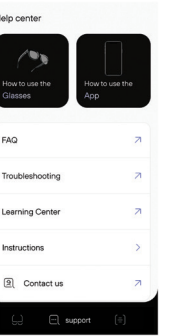


Fig. 25 Support page

8. Nuance Audio™ Care and Maintenance

8.1 Battery information

The Nuance Audio™ Glasses contain 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™ Glasses. Do not leave or store the Nuance Audio™ Glasses under direct sunlight or expose to excessive heat or incinerate. Dispose of the Nuance Audio™ Glasses in line with instructions and local waste requirements.

The battery contained in the Nuance Audio™ Glasses is expected to perform as follows, provided the Nuance Audio™ Glasses are always used under Normal Use Conditions (see below) (the "Expected Battery Performance"):

- at original capacity, and once fully charged, the battery is expected to provide at least 8 hours of continuous use under average conditions (being where there is moderate surrounding noise and the standard amplification settings are being used).
- Assuming that you do, approximately, 1 full charge per day, following 500 full charging cycles (corresponding to approximately 16 months of use) the battery is expected to perform at or above 85% of its original capacity, meaning the battery will allow for at least 6 hours and 48 minutes of continuous use under average conditions.

"Normal Use Conditions" means:

- Operating the product in line with this user manual, in particular Section 3 (Warnings, Precautions and Safety Considerations), which includes operating the product within the recommended temperature range.
- Not exposing the product to extreme heat, cold or humidity, as indicated in Section 12 (Nuance Audio™ Glasses technical specifications key features).
- Using the product only for its intended use, as described in Section 1 (Intended Use).
- Using only the provided or certified charging accessories as indicated in Section 8.3 (The Charging Pad works thanks to a USB-C charging cable).
- Ensuring the battery is charged and discharged in accordance with the guidelines provided at Section 8.2 below.
- Always making sure that Nuance Audio™ Glasses is using the latest firmware version.
- Charging the battery at room temperature instead of a lower or higher temperature.
- Charging the battery only when necessary.
- Making sure to charge the battery fully before unplugging it.

Luxottica does not guarantee the above battery performance beyond the term of the Limited Warranty Period. Please refer to the "Warranty" section.

Battery performance may 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.

8.2. Charging the battery

IMPORTANT! If the Nuance Audio™ Glasses battery is not recharged for a prolonged period (6 months from last use) then this could lead to permanent damage to the battery, which may render the Nuance Audio™ Glasses 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™ Glasses should be charged. For charging, place the Charging Pad flat on a non-metal table or desktop to ensure it will not shake and move. Place the Nuance Audio™ Glasses (as shown below) on the Charging Pad. Ensure that the Nuance Audio™ Glasses are aligned with the magnetic components on the Charging Pad. If the alignment is not accurate, you can try adjusting the positioning of the Nuance Audio™ Glasses. During the charging process, do not move or disturb the Nuance Audio™ Glasses to avoid interfering the charging operation.

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

Use only the provided Charging Pad to charge the Nuance Audio™ Glasses. Use only the supplied USB-C Charging Cable with USB-C wall adapter with a minimum output level of DC5V/1A (sold separately). (Fig. 26)

- The Charging Pad may become warm to the touch while charging.
- If the Charging Pad becomes hot to touch,



Fig. 26 Charging the Nuance Audio™ Glasses

immediately remove the Nuance Audio™ Glasses and disconnect the USB-C charging cable from adapter and discontinue use. Contact customer support at www.nuanceaudio.com

- If the Charging Pad cannot charge properly or experiences any malfunctions, please stop using it immediately.
- Do not clean the Nuance Audio™ Glasses and the Charging Pad while charging.
- Periodically inspect the Nuance Audio™ Glasses, 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™ Glasses 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 or liquid cleaning agents when caring for your Nuance Audio™ Hearing Aid.

8.5. Hearing Aids 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™ Glasses.
- Inspect the Nuance Audio™ Glasses 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, toothpick, or pressurized air) to clean the Nuance Audio™ Glasses. Do not use dirty or abrasive cloths which could negatively affect the lenses' surfaces. Moisture can damage the Nuance Audio™ Glasses and device failure. To clean the lenses, make sure to only spray lens cleaner on a clean, non-abrasive lens cloth. Do not spray lens cleaner directly on the lenses.
- To clean the Nuance Audio™ Glasses, wipe with a dry, clean cloth.

8.6. General Information

- The Nuance Audio™ Glasses and Charging Pad service life is about 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 may void the warranty.
- 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.
- 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 and remove your Nuance Audio™ Glasses when using hairspray.
- It is recommended carrying out cleaning visible debris or moisture daily if exposed to moisture and dust.
- 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 wet, thoroughly dry. Should your Nuance Audio™ Glasses not function correctly despite regular care, contact for customer support at www.nuanceaudio.com.
- Do not try under any circumstances to repair your Nuance Audio™ Glasses by yourself as this will void your warranty.
- The serial number of the Nuance Audio™ Glasses may be found marked on the inner part of the left temple or in the Nuance Audio™ App.

Only for the Charging Pad:

- Do 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.
- Should your Nuance Audio™ Charging Pad not function correctly despite regular care, contact for customer support at www.nuanceaudio.com.

9. PRIVACY

In developing Nuance Audio Glasses, EssilorLuxottica followed the principle of privacy by design. A full description of how Nuance Audio Glasses and the mobile app linked process personal data can be found in the Privacy Notice within the App. To learn more about EssilorLuxottica Governance on personal data, you can visit the section "Governance" on www.essilorluxottica.com and click on "Compliance/Data Privacy".

10. TROUBLESHOOTING

10.1. Common Solutions for the App

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

Close the Nuance Audio™ App and reopen it again. This will refresh the connection with the Nuance Audio™ Glasses and should resolve the issue.

If the issue is still present:

- Uninstall the app and install it again
- Restart your mobile phone and control that Bluetooth is enabled
- If the issue is present, please check if the OS version of your mobile phone is listed as a supported version
- Turn off and on again your Nuance Audio™ Glasses pressing and holding the multifunction button on the frame for about 2 secs
- Press and hold for 2 secs to turn on the Nuance Audio™ Glasses and test again if the mobile app functions properly.

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

You must have network connectivity (Cellular or Wi-Fi). In case you get this error please check if your Wi-Fi or mobile data connectivity are correctly configured and working. Sometimes connectivity errors are generated because of an error in the communication between the mobile app and the Nuance Audio™ Glasses. Close the Nuance Audio™ App and reopen it again. This will refresh the connection with the Nuance Audio™ Glasses and should resolve the issue.

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

- Check your Wi-Fi or mobile data connection
- Check available storage space on your mobile phone
- Check for latest iOS or Android software upgrades available for your mobile device.
- Close and re-open the app store where you are attempting to download the Nuance Audio™ App and retry
- If none of these steps solve the issue, then shutdown and restart your mobile phone

10.2. Other Troubleshooting Tips

MY NUANCE Audio™ GLASSES ARE NOT CHARGING. WHAT SHOULD I DO?

If your device isn't charging, make sure that:

- The charging area is facing up and the Nuance Audio™ Glasses are placed on Charing Pad properly
- The Charging Pad is connected correctly to the provided USB-C charging cable, and that the charging cable is connected properly to a USB-C power source with a minimum output level of DC5V/1A (sold separately).
- The power source is in proper condition and not damaged
- If all 3 conditions above are met, try to gently adjust the position of the hearing aid lying on the charging pad

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

If your glasses are new and their battery lasts less than 6 hours, to maximize battery life, it is recommended to turn off the hearing aid function when it is not being used. See section 10.2 for battery charging instructions. contact for customer support at www.nuanceaudio.com.

HOW CAN I FORCE RESTART MY NUANCE AUDIO™ GLASSES?

In order to force restart on the Nuance Audio™ Glasses, follow these steps (Fig. 7):

- While the Nuance Audio™ Glasses are on, press Multifunction Button on bottom of right temple of glasses for about 10 seconds until the red light turns on
- Release the multifunction button
- Press Multifunction button until you see a solid red LED light (not just the short flash) that lasts 2 seconds
- Force restarting will not reset the device to factory settings

AMPLIFIED SOUNDS ARE METALLIC AND UNNATURAL. WHAT SHOULD I DO?

Here are some tips for improving sound quality:

- Try changing the volume loudness level
- Select a different presets profile (A, B, C or D) to provide a more comfortable listening setting.
- Try to select a different the Background noise setting (see section 9.3.3)
- Repeat Personal Calibration process (see section 9.2.4)

WHAT DO I DO IF I DON'T FIND BENEFIT AFTER USING DEVICE?

If you have a problem with your Product, please visit us at www.nuanceaudio.com to get support. You may return the product to the retailer that you purchased it from based on that retailers return policy.

WHAT DO I DO IF I RETURN THE DEVICE AND HAVE PURCHASED THE OPTIONAL PRESCRIPTION VISION LENSES?

If you have a problem with your Product, please visit us at www.nuanceaudio.com to get support. If you have purchased the device and chose to purchase the optional prescription vision lenses, you must return to the retailer where you purchased the optional prescription vision lenses based on their prescription lenses warranty, return and/or replacement policies.

IS THE NUANCE AUDIO™ HEARING AID SUITABLE FOR ME IF I ONLY HAVE HEARING LOSS IN ONE EAR OR I PERCEIVE WORSE HEARING IN ONE EAR VERSUS THE OTHER EAR?

The Nuance Audio™ Hearing Aid Software is compatible with the Nuance Audio™ Glasses, and delivers the same amplification to each ear. Once you have chosen a preset based on your listening preference (A, B, C or D), you may also adjust the volume setting to meet your hearing needs.

NOTE: IT IS RECOMMENDED THAT YOU SEE A DOCTOR, PREFERABLY AN EAR-NOSE-THROAT DOCTOR IF YOU HAVE PERCEIVED WORSE HEARING IN ONE EAR BEFORE USING AN OTC HEARING AID.

11. HEARING AID TECHNICAL SPECIFICATIONS

KEY FEATURES	
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 & Personalisation	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

KEY FEATURES	
WIRELESS CONNECTIVITY	
Bluetooth® Compatible	Yes, BTLE
Bluetooth® pt Phone Call Compatible	No
Operation frequency	MHz 2402-2480
Max radiated power	Free space max EIRP is -3.22 dBm
Modulation	GFSK
Channel spacing	2MHz
Channel bandwidth	2MHz
Number of channels	40

WIRELESS CHARGING	Yes
Transmitting frequency	13,56 MHz
Receiving frequency	13,56 MHz
Max Radiated Power	69,72 dBuV/m at 3m"
Modulation type transmitting	ASK 100% modified Miller
Modulation type receiving	Load Modulation subcarrier fc/848 (16kbit/s) OOK Manchester
FITTING AND PROGRAMMING	Not intended to be a fitted device or programmed
Nuance Audio™ App	Yes, for set up

KEY FEATURES	
TECHNICAL SPECIFICATIONS	
Microphones	6 Microphones

TRANSPORT AND STORAGE CONDITIONS	
Temperature	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)

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 Response Bandwidth	200Hz - 5000 Hz
Equivalent Input Noise	31,2 dB
Total Harmonic Distortion	<1%
Maximum OSPL90	110,5 dB
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

Guidance and manufactures declaration for electromagnetic emissions

Emission standard	Type	Compliance to standard
CISPR 11	Radiated and conducted 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.

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/CTA-2051-2017 clause 4.11
Feedback Control	Available with the Nuance Audio™ Hearing Aid ANSI/ CTA-2051-2017 clause 4.14
SNR Enhancement	Available with the Nuance Audio™ Hearing Aid ANSI/ CTA-2051-2017 clause 4.13

Guidance and manufactures declaration for electromagnetic immunity

<table>
<tr><th>Emission standard</th><th>Type</th><th>Compliance level</th><th>Specific guidance for application environment</th></tr>
<tr><td>EN/IEC61000-4-2</td><td>Electrostatic discharge (ESD)</td><td>± 4kV, ± 8kV contact
±2kV, ±4kV, ±8kV, ± 15kV air</td><td>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.</td></tr>
<tr><td>EN/IEC61000-4-8</td><td>Power frequency magnetic field</td><td>30 A/m
50/60 Hz</td><td>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 corresponds to the levels typical for professional or domestic Environment.</td></tr>
<tr><td>EN/IEC61000- 4- 3</td><td>RF electromagnetic fields.

Proximity fields from RF wireless communication equipment.</td><td>80 MHz to 2.7 GHz,
80% AM at 1 kHz, 10 V/m
<table><tr><th>Test freq. MHz</th><th>V/m</th></tr><tr><td>385</td><td>27</td></tr><tr><td>450</td><td>28</td></tr><tr><td>710, 745, 780</td><td>9</td></tr><tr><td>810, 870, 930</td><td>28</td></tr><tr><td>1720, 1845, 1970</td><td>28</td></tr><tr><td>2450</td><td>28</td></tr><tr><td>5240, 5500, 5785</td><td>9</td></tr></table></td><td>Portable and mobile radio devices, including their wires, should not be used closer to the unit than the recommended safe distance or 30 cm.</td></tr>
<tr><td>EN/IEC61000- 4- 39</td><td>IMMUNITY to proximity magnetic</td><td><table><tr><th>Test frequency</th><th>A/m</th></tr><tr><td>30 kHz</td><td>8</td></tr><tr><td>134.2 kHz</td><td>65</td></tr><tr><td>13,56 MHz</td><td>7.5</td></tr></table></td><td>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.</td></tr>
</table>

12. 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. Please contact customer support if you have questions at www.nuanceaudio.com 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.

13. Regulatory Compliance Information

13.1. 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.

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.	

14. SYMBOLS AND DESCRIPTIONS

	Federal Communications Commission (U.S.)
	Bluetooth®
	Review operating instructions prior to use
	Warning
	Serial Number
	Medical Device
	MR Unsafe
	Single patient, multiple use
	Date of manufacture / Manufacturer
	Manufacturer
	Type B applied part

	Operating Instructions
	Made in China
	Patient Information Website
	Keep Dry
	Temperature Limit
	Atmospheric pressure limitation
	Humidity limitation
	Model Number
	Do NOT use if package is damaged
IP54	IP54 rating
	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

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Nuance Audio™ is a registered trademark of Essilor International SAS.

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

Common Name: Air Conduction Hearing Aid Software

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

Made in China
Fabriqué en Chine

www.nuanceaudio.com

This information and other labeling, including the user instructional brochure, are available on the internet at: nuanceaudio.com/support/manual-guide.
You may also call 844-844-0919 or write to customerservice@nuanceaudio.com or to Customer service, 4000 Luxottica Place, Mason, OH 45040 to request a paper copy of this information and other labeling.

For the latest and up-to-date Instructions For Use - Safety and Warranty, please refer to the Instructions in the Support section of the Nuance Audio™ App and to the following website page:
nuanceaudio.com/support/manual-guide

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

EN These Instructions For Use, Safety & Warranty is applicable to 0AW5001, 0AW5002, 0AW5004 Nuance Audio™ Glasses models.
Product availability, regulatory requirements, and warranty terms may vary by Country.

IT Queste Istruzioni per l'uso, Sicurezza e Garanzia valgono per i modelli 0AW5001, 0AW5002, 0AW5004 dei Nuance Audio™ Glasses.
La disponibilità dei prodotti, i requisiti normativi e i termini di garanzia possono variare a seconda del Paese.

FR Ces instructions d'utilisation, de sécurité et de garantie s'appliquent aux modèles Nuance Audio™ Glasses 0AW5001, 0AW5002 et 0AW5004.
La disponibilité des produits, les exigences réglementaires et les conditions de garantie peuvent varier selon le pays.

ES Estas instrucciones de uso, seguridad y garantía son aplicables a los modelos Nuance Audio™ Glasses 0AW5001, 0AW5002, 0AW5004.
La disponibilidad de los productos, los requisitos normativos y las condiciones de garantía pueden variar según el país**.**

DE Diese Gebrauchsanweisungen, Sicherheits- und Garantiebestimmungen gelten für die Nuance Audio Glasses - Modelle 0AW5001, 0AW5002, 0AW5004.
Die Produktverfügbarkeit, die regulatorischen Anforderungen und die Garantiebedingungen können je nach Land variieren.





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