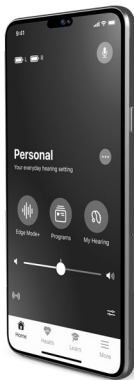


# Your Hearing Aid App User Manual



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Get full control over your hearing aids to help you hear better and live better.

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## Compatibility

For best performance, we recommend using the most current software version available for your device.

### Apple

iPhone, iPad, iPod

- The app runs on all versions of iOS & iPadOS 16 or later.

### Android

- The app runs on all versions of Android 8 or later.

## Connecting your hearing aids with your Apple device

1. On your device, ensure **Bluetooth** is **ON**.
2. Select **Settings > Accessibility > Hearing Devices**.
3. Turn your hearing aids **OFF** and then **ON** to activate pairing mode.
4. Under **MFI HEARING DEVICES** you should see your hearing aids (e.g. "Jane's hearing aids"). Tap this.
5. Tap **Pair** for each hearing aid (**RIGHT and LEFT**). Pairing is complete.
6. Open the **hearing aid app**, and then follow the prompts to create your account, if desired and connect your hearing aids.

## Connecting your hearing aids with your Android device

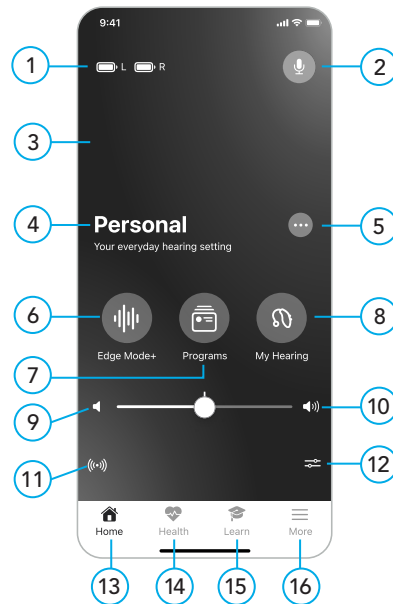
1. Tap the **Settings icon** on your device.
2. On your device, ensure **Bluetooth** is **ON**.
3. Turn your hearing aids **OFF** and then **ON** to activate pairing mode.
4. Open the **hearing aid app**, and then follow the prompts to create your account, if desired and connect your hearing aids.
5. When you see your hearing aids listed on the screen, select the box(es) next to each hearing aid (**RIGHT and LEFT**).
6. Tap **CONNECT**. Pairing is complete.

## Home overview

Find the key features that enhance your hearing aid use on the **Home screen**.

1. Left & right battery indicators
2. Smart Assistant\*
3. Change program
4. Program in use
5. Program options
6. Edge Mode+: *Instant sound adjustments\**
7. Programs
8. My Hearing: *Self Check, Find My Hearing Aids, additional sound settings*
9. Mute
10. Volume slider
11. Accessories: *View streaming options for available wireless accessories.*
12. Split volume control
13. Home
14. Health: *Monitor hearing and physical activity\**
15. Learn: *Personalized tips, videos, and more*
16. More: *Account, About & privacy, TeleHear*

\*Feature may vary by hearing aid model



## Tinnitus

**Tinnitus** is a “ringing” or other continuous sound in your ear that only you can hear. Your app may help relieve tinnitus using technology that plays comforting sounds through your hearing aids. These can help mask tinnitus “sounds.”

### To use the Tinnitus screen programmed by your hearing care professional):

1. On the **Home** screen, tap the **My Hearing** button.
2. The **My Hearing** menu appears. Tap Tinnitus.



3. Customize the **volume** or **speed** of the tinnitus relief sounds to suit your personal needs.

### To control the volume of the comfort sounds:

1. Ensure the **Volume** tab is open. (This tab should be open by default.)
2. Move the **right** (right hearing aid) and **left** (left hearing aid) **sliders** to adjust the **volume** of the comfort sounds:
  - For **LESS** volume, move sliders **LEFT**.

- For **MORE** volume, move sliders **RIGHT**.

### To control the speed of the comfort sounds:

1. Tap the **Speed** tab.
2. Move the **right** (right hearing aid) and **left** (left hearing aid) **sliders** to adjust the speed and variation of the comfort sounds:
  - For **LESS** speed/variation, move sliders **LEFT**.
  - For **MORE** speed/variation, move sliders **RIGHT**.

## Fall Alert overview

**Fall Alert\*** helps keep you safe when you fall by notifying friends, family or others. These are your Fall Alert contacts.

### How Fall Alert works

Your hearing aids detect when you fall. When this happens, you'll be alerted by a message through your hearing aids.

#### Next:

After a brief countdown, this app sends an alert text message to your Fall Alert contacts. This contains details on your fall and a map of your location.

You'll also hear an **"alert sent" indicator** and receive a **confirmation message** that your alert was sent.

Your Fall Alert contact will receive an alert text message from this app, notifying them of your fall. After they receive it, you'll hear an **"alert received" indicator** through your hearing aids.

### Canceling a Fall Alert

Cancel an **alert text message** to your contact by pushing **any button** on your hearing aids. Or tap **Cancel, I'm okay** on the **timer screen** before the countdown ends. When canceled, you'll hear an **"alert canceled" indicator** through your hearing aids.

*\*Feature may vary by hearing aid model.*

## Invite a contact

Set up Fall Alerts by inviting a contact who can be notified by an alert text message if you fall.

### To set up Fall Alert:

1. On the **Home screen**, tap the **Health button**.
2. The **Health screen** appears. Tap **Wellness > Fall Alerts**.
3. Learn about Fall Alert on the first 2 **welcome screens**.
4. On the **third screen**, fill in your **contact's details**.
5. Tap **Send** to invite them to be your Fall Alert contact.
6. The **Invite Sent screen** confirms the invite message was texted to your contact. (It also allows you to add another Fall Alert contact.)

## About & privacy

Your **About & privacy screen** lets you view info about this app, user guidelines and agreements. These include:

### About

This gives you info about the purpose of your app and the app manufacturer, Starkey Laboratories, Inc.

### Privacy Policy

This describes your right to privacy in terms of the personal details or data you enter into this app. This policy is in accordance with privacy and protection laws.

### EULA (End User License Agreement)

This is an agreement with the manufacturer on the ways you can use the app.

### Consents

This lets you review and edit your permissions to share specific types of data. For example, certain consents are needed if you use your app to interact with third parties like your hearing care professional or a caregiver.

## Safety Information

**⚠ 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.

### IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS:

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 diseases of the ear) before purchasing a prescription hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of the medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

In some geographies, you must have a medical evaluation before purchasing a prescription hearing aid. Some States allow an adult to waive the medical evaluation.

A hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. Use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lip reading. In most cases infrequent use of a hearing aid does not permit a user to attain full benefit from it.

Some hearing instrument users have reported a buzzing sound in their hearing instrument when they are using mobile phones, indicating that the mobile phone and hearing instrument may not be compatible. It is well-known that mobile phones are potential sources of noise for hearing aids. Your Starkey Hearing Aids have been tested for compliance to two standards that define hearing aid immunity to digital wireless devices and meet the requirements of ANSIC63.19-2019 as well as the criteria for user compatibility as defined by IEC 60118-13:2019.

**⚠ CAUTION:** If set to the maximum output level and worn for periods of time exceeding the recommendations below, the patient's exposure to sound energy has the potential to exceed noise exposure limits. This instrument is intended for use for a maximum of sixteen (16) hours a day when set at the maximum output level.

### TINNITUS THERAPY CONCEPTS AND BENEFITS

Multiflex Tinnitus Technology can be used as a part of a tinnitus treatment program.

Multiflex Tinnitus Technology plays a white noise through the hearing aid.

Multiflex Tinnitus Technology is programmed according to your hearing loss and preference, and your hearing professional can adjust the settings of Multiflex Tinnitus Technology to meet your needs.

Multiflex Tinnitus Technology may provide temporary relief of your tinnitus.

**⚠ WARNING** Auto Alert may not detect 100 percent of falls

**⚠ WARNING** Decreasing the Auto Alert Sensitivity may prevent some falls from being detected by your Fall Alert system. For example, Auto Alert may not detect a fall if:

- The Sensitivity setting is not appropriate for the user.
- The fall is very slow, or you slide down gradually.
- You get up and begin walking immediately after a fall.

As a reminder, you can initiate a Manual Alert if Auto Alert does not detect a fall. Manual Alert must be configured by your hearing professional before it can be used.

**⚠ WARNING** Auto Alert may initiate false alerts. To prevent false-alert text messages from being sent to your contact(s), you may cancel the alert from either your smartphone or by pressing the user control on either hearing aid.

**⚠ WARNING** To reduce Fall Alert communication failures:

- Your hearing aid(s) need to be powered on, paired and connected with your smartphone using Bluetooth® connectivity.
- The mobile device must be powered on, with the Thrive app open (in the foreground or background).
- The mobile device must have a connection to the internet (via a cellular network or WiFi).

### Adverse Event Reporting

Any serious incident that has occurred in relation to your Starkey device should be reported to your local Starkey representative and the Competent Authority of the Member State in which you are established. A serious incident is defined as any malfunction, deterioration in

the characteristics and/or performance of the device, or inadequacy in the device Operations Manual/ labeling which could lead to the death or serious deterioration in the state of health of the user, OR could do so upon recurrence.

### Intended Use

The Hearing Aid Mobile Application is a software medical device intended to allow a user to remotely control volume, memory selection, Mute/Unmute, Media Streaming Start/Stop, and the tinnitus masking feature of Starkey 2.4 GHz wireless hearing aids. It also provides a mobile phone interface for these hearing aids and allows the user to use their iOS or Android device as an audio streaming device.

### Indications for Use

The Hearing Aid Mobile Application is an optional program indicated for patients using Starkey 2.4 GHz wireless hearing aids and who wish to use an iOS or Android device to serve as a remote control, cell phone interface or media streamer.

### Intended User and User Environment

Lay persons in a home environment.

### Clinical Benefit

The Hearing Aid Mobile App itself does not provide a direct clinical benefit. An indirect clinical benefit is provided by enabling the hearing aids to achieve their intended purpose.

## Regulatory information

For service or repair, please contact your hearing care professional first. If necessary, you can send your hearing aids to:



**Manufacturer according to FDA and EU Medical Device Regulation 2017/745**  
**Starkey Laboratories, Inc.**  
 6700 Washington Ave. South  
 Eden Prairie, MN 55344 USA  
[www.starkey.com](http://www.starkey.com)

EC	REP
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**Starkey Laboratories (Germany) GmbH**  
 Weg beim Jäger 218-222  
 22335 Hamburg  
 Germany

CH	REP
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**QUNIQUE GmbH**  
 Bahnhofweg 17  
 5610 Wohlen  
 Switzerland

**UK Authorised Person:**  
 Starkey UK  
 William F. Austin House  
 Pepper Rd, Hazel Grove  
 Stockport SK7 5BX, UK  
[www.starkey.co.uk](http://www.starkey.co.uk)

**Manufacturer according to Health Canada**  
 Starkey Labs Canada Co.  
 2476 Argenta Road, Suite 301  
 Mississauga, ON L5N 6M1  
[www.starkeycanada.ca](http://www.starkeycanada.ca)

## IFU applicable to the following:

### My Starkey Mobile App:

- Starkey Wireless Hearing Aids - Genesis AI, Edge AI

### My Audibel Mobile App:

- Audibel Wireless Hearing Aids - Intrigue AI, Vitality AI

### Hear Circle Mobile App:

- NuEar Wireless Hearing Aids - NE NXG AI, Edge AI
- MicroTech Wireless Hearing Aids- MT NGX AI, Edge AI

## Security Notice

Patient data is private and protection of it is important, therefore please refer to the following:

- Make sure smartphones are kept up to date with the latest operating system security updates.
  - Make sure your installed app version is up to date.
  - Only use Starkey apps from official stores with your hearing aids.
  - Make sure you use strong passwords and keep credentials confidential.
  - Make sure installed apps only have permissions they need.
  - Avoid Bluetooth pairing in public areas to avoid unwanted third-party interference.
  - Do not use a jail broken phone to ensure data is kept safe at all times.
  - Protect your smartphone backups from data loss and theft.
  - Remove all data from smartphone if it will longer be used by your or will be disposed of.
- Please note that this is not an exhaustive list.

Symbol	Symbol Meaning	Applicable Standard	Symbol Number
	Manufacturer	BS EN ISO 15223-1:2021	5.1.1
	Authorized representative in the European Community	BS EN ISO 15223-1:2021	5.1.2
	Importer	BS EN ISO 15223-1:2021	5.1.8
	Country of Manufacture	BS EN ISO 15223-1:2021	5.1.3
	Date of Manufacture	BS EN ISO 15223-1:2021	5.1.3
	Catalogue Number	BS EN ISO 15223-1:2021	5.1.6
	Serial Number	BS EN ISO 15223-1:2021	5.1.7
	Medical Device	BS EN ISO 15223-1:2021	5.7.7
	Keep Dry	BS EN ISO 15223-1:2021	5.3.4
	Temperature Limit	BS EN ISO 15223-1:2021	5.3.7
	Humidity Limitation	BS EN ISO 15223-1:2021	5.3.8
	Caution	BS EN ISO 15223-1:2021	5.4.4
	General warning sign	EC 60601-1, Reference no. Table D.2, Safety sign 2	ISO 7010-W001
	Refer to instruction manual/booklet	EC 60601-1, Reference no. Table D.2, Safety sign 10	ISO 7010-M002
	Collect Separately	DIRECTIVE 201 2/19/EU (WEEE)	Annex IX
	Class II equipment	IEC 60417 Reference no. Table D.1	Symbol 9 (IEC 60417- 5172)
	Regulatory Compliance Mark (RCM)	AS/NZS 4417.1:2012	N/A
	UKCA Mark	SI 2002 No 618, as amended (UK MDR 2002)	N/A
	Giteki Mark	Japanese Radio Law	N/A
	Direct current	IEC 60601-1 Reference no. Table D.1	IEC 60417-5031
	Recycling Symbol	European Parliament and Council Directive 94/62/EC	Annex I-VII
	Recycling Symbol for electrical equipment and portable batteries	European Parliament and Council Directive 94/62/EC	Annex I-VII
	NOM Certification symbol	IEC 60601-1 (IEC 60529) Table D.3	Code 2
	Degree of protection	IEC 60601-1 (IEC 60529) Table D.3	Code 2
	Korea KCC Mark		
	Translation	BS EN ISO 15223-1:2021	5.7.8
	Consult instructions for use or consult electronic instructions for use		
	Authorized Representative in Switzerland, Medical Devices Ordinance (MedDO)		

\*For wireless products only



Specific hearing aid performance data and wireless information can be found at <https://eifu.starkey.com/eifu/> in the data sheets.



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For information on how we protect user data, please visit [www.starkey.com/privacy-and-terms](http://www.starkey.com/privacy-and-terms).

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Use of the Made for Apple badge means that an accessory has been designed to connect specifically to the Apple product(s) identified in the badge, and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards. Apple, the Apple logo, and App Store are trademarks of Apple Inc., registered in the U.S. and other countries. iOS is a trademark or registered trademark of Cisco in the U.S. and other countries and is used under license.

TeleHear, Hear Share and Edge Mode are trademarks of Starkey Laboratories, Inc.

All trade names and trademarks are properties of their respective owners.

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Patent: [www.starkey.com/patents](http://www.starkey.com/patents)