

Your SoundGear Hearing Aid App User Manual



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 **My SoundGear app**, and then follow the prompts to create your account, if desired and connect your hearing aids.

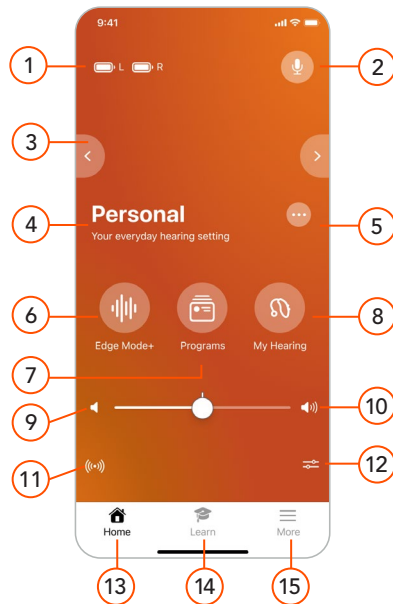
Connecting your hearing aids with your Android device

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 **My SoundGear 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. Learn: *Personalized tips, videos, and more*
15. More: *Account, Help Center, TeleHear*



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.

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 ANSI C63.19- 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.

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.
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 Eden Prairie, MN 55344 USA
www.starkey.com



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

UK Authorised Person:
 Starkey UK
 William F. Austin House
 Pepper Rd, Hazel Grove
 Stockport SK7 5BX, UK
www.starkey.co.uk



QUNIQUE GmbH
 Bahnhofweg 17
 5610 Wohlen
 Switzerland

Manufacturer according to Health Canada
 Starkey Labs Canada Co.
 2476 Argenta Road, Suite 301
 Mississauga, ON L5N 6M1
www.starkeycanada.ca

IFU applicable to the following:

My SoundGear Mobile App:

- SoundGear Amp Wireless Hearing Aids

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

Notes

Notes



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.

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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.

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Patent: www.starkey.com/patents