



fortell

Fortell AI Hearing Aids
Instructions for use

Instructions for Use: Fortell AI Hearing Aids

Initial warnings

	WARNING: People younger than 18 should go to a doctor before using this. People younger than 18 years old need specialized care, and using this without a medical evaluation may worsen impairment or disability. A hearing aid user who is younger than 18 should have a recent medical evaluation from a doctor, preferably an ear-nose-throat doctor (an ENT). Before using this, a doctor should determine that the use of a hearing aid is appropriate.
	WARNING to Hearing Aid Dispensers: You should advise a prospective hearing aid user to consult promptly with a doctor, preferably an ear specialist such as an ENT, before dispensing a hearing aid if you determine through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions: • Visible deformity of the ear, either congenital or traumatic • Fluid, pus, or blood coming out of the ear within the previous 6 months • Pain or discomfort in the ear • History of excessive earwax or suspicion that something is in the ear canal • Dizziness, either recent or long-standing • Sudden, quickly worsening, or fluctuating hearing loss within the previous 6 months • Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears

	• Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz, and 2000 Hz
	WARNING to Hearing Aid Dispenser, Outputs over 132 dB SPL: You should exercise special care in selecting and fitting a hearing aid with a maximum output that exceeds 132 dB SPL because it may impair the remaining hearing of the hearing aid user.

	Caution: This is not hearing protection. You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.
	Caution: The sound output should not be uncomfortable or painful. You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your device.
	Caution: You may need medical help if a piece gets stuck in your ear. If any part of your hearing aid, like the dome, gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as possible. You should not try to use tweezers or cotton swabs because they can push the part farther into your ear, injuring your eardrum or ear canal, possibly seriously.

Note: What you can 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.
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Note: Tell FDA about any injuries, malfunctions, or other adverse events.

To report a problem involving your hearing aid, you should submit Information to FDA as soon as possible after the problem. FDA calls them “adverse events,” and they can include: skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, 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 FDA.

Note: Hearing loss in people younger than 18

- People younger than 18 should see a doctor first, preferably an ear-nose- throat doctor (an ENT), because they may have different needs than adults.
- The doctor will identify and treat medical conditions as appropriate.
- The doctor may refer the person to an audiologist for a separate test, a hearing aid evaluation.
- The hearing aid evaluation will help the audiologist select and fit the appropriate hearing aid.

A person younger than 18 years old with hearing loss should undergo medical evaluation by a doctor, preferably an ENT, before buying a hearing aid. The purpose of a medical evaluation is to identify and treat medical conditions that may affect hearing but that a hearing aid won't treat on its own.

Following the medical evaluation and if it is appropriate, the doctor will provide a written statement that the hearing loss has been medically evaluated and the person is a candidate for a hearing aid. The doctor may refer the person to an audiologist for a hearing aid evaluation, which is different from the medical evaluation and is intended to identify the appropriate hearing aid.

The audiologist will conduct a hearing aid evaluation to assess the person's ability to hear with and without a hearing aid. This will enable the audiologist to select and fit a hearing aid for the person's individual needs. An audiologist can also provide evaluation and rehabilitation since, for people younger than 18, hearing loss may cause problems in language development and educational and social growth. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of hearing loss in people younger than 18.

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Legal notice

Use of the Made for iPhone badge means that an accessory has been designed to connect specifically to iPhone 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. Please note that the use of this accessory with an Apple product may affect wireless performance.

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US Patents

Patent: www.fortell.com/patents

Document revision

FG-601-00001-00

Revision: A.1

2025-08-29

Introduction

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This guide explains how to use and care for your new hearing aids and charging case. Please read it carefully, including the **Warnings** section, to ensure safe use and to get the best performance from your devices.

	Warnings Text marked with a warning symbol must be read before using the device. It describes conditions, hazards, or unsafe practices that may result in serious personal injury or death.
	Cautions Text marked with a caution symbol should be read before using the device. It describes conditions, hazards, or unsafe practices that may result in minor injury or damage to the device.

A Fortell hearing care professional has adjusted your hearing aids to suit your individual needs. If you have further questions, please contact Fortell.

A Fortell hearing care professional (audiologist) is a qualified specialist trained to assess hearing, select and fit hearing instruments, and provide rehabilitation services for people with hearing loss. Their training and certification meet national or regional regulatory standards.

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About

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Model overview

This guide is for the Fortell AI Hearing Aids, model FR1.

The following receivers are available for the Fortell AI Hearing Aids:

- Sonion Steel Series XM
- Sonion Steel Series XP

The packaging box contains the following elements:

- Hearing aids (Left and Right), with domes and receivers attached
- Charging case
- Power brick
- USB-C charging cord
- Cleaning brush
- Cleaning cloth
- Wax guard kit
- Getting started guide

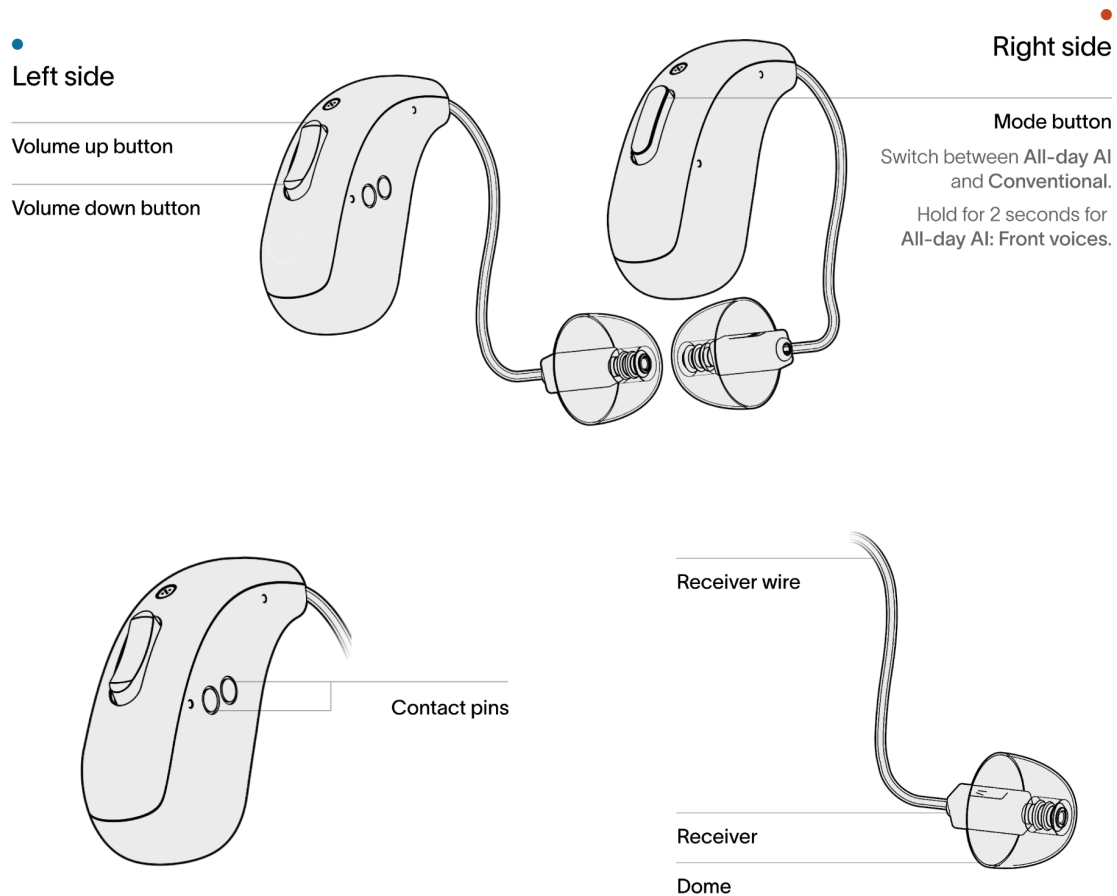
Intended use

Indications for use	The Fortell AI Hearing Aid is intended to amplify sound for individuals with hearing loss. It is intended for prescription use only.
Intended user of this IFU	Person with hearing loss using a hearing aid and their caregivers. Fortell hearing care professional responsible for adjusting the hearing aid.
Use environment	Indoor and outdoor.
Contraindications	Not suitable for infants below 36 months. Users of active implants must pay special attention when using the hearing aid. For more information read the Warnings section.
Clinical benefits	The hearing aid is designed to provide better speech understanding to help ease communication with the aim of improving quality of life.

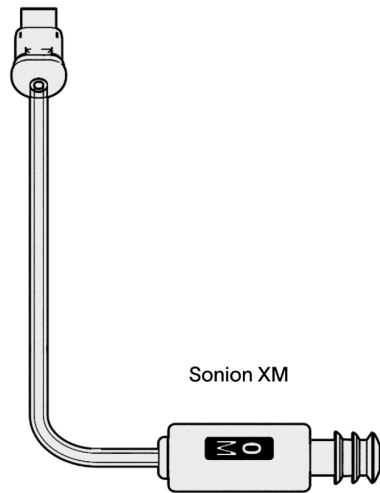
IMPORTANT NOTICE

Your hearing aid amplification is individually adjusted and optimized to your specific hearing needs during the fitting conducted by a Fortell hearing care professional.

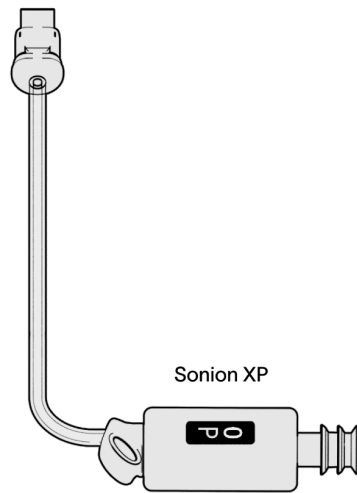
Your hearing aid, receiver and dome



The hearing aids use one of the following receivers:

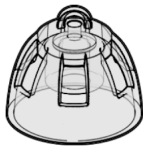


Sonion XM

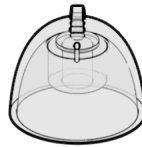


Sonion XP

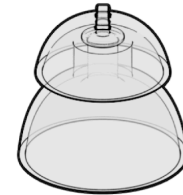
The receivers use one of the following domes:



Open dome

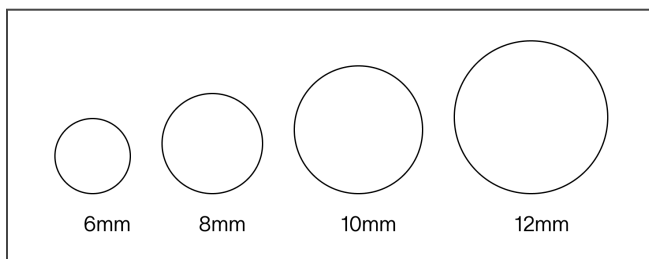


Closed dome

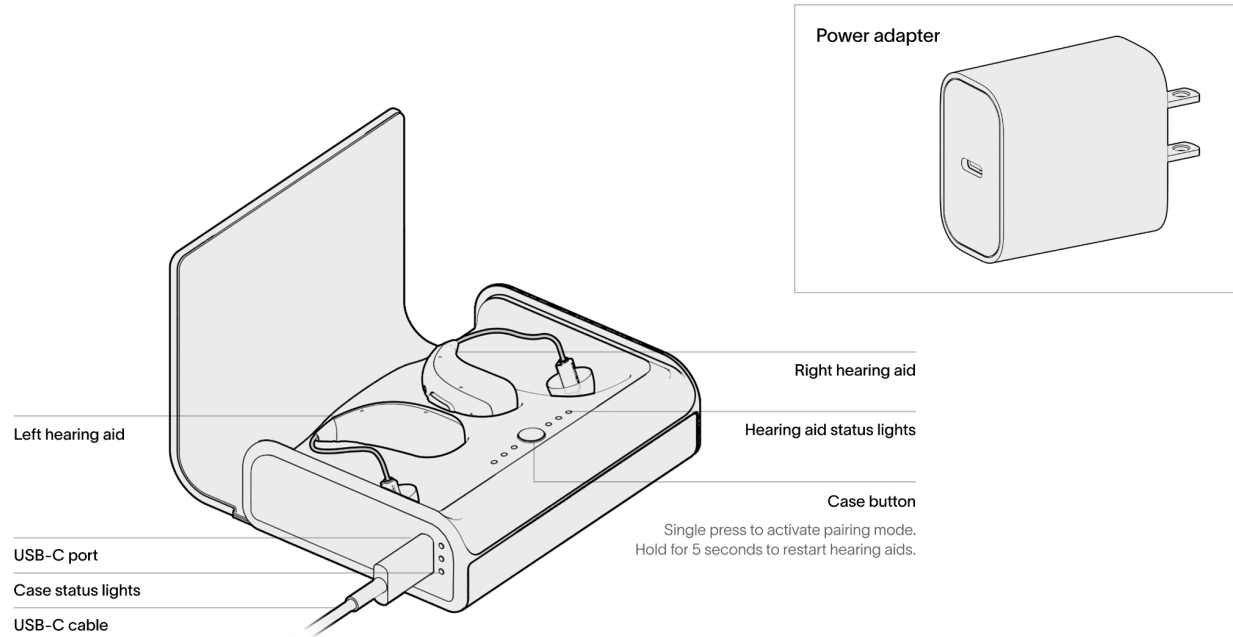


Power dome

Dome sizes



Your charging case



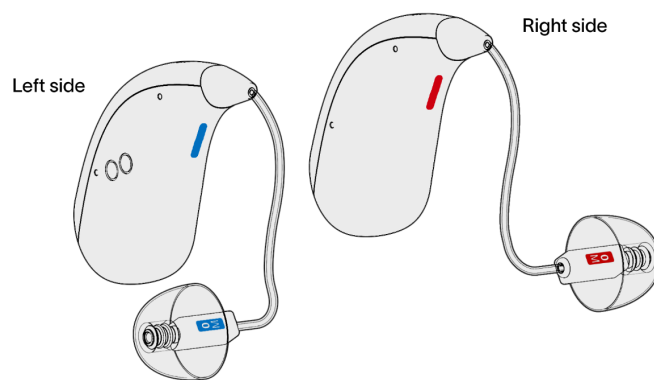
Getting started

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Left and right hearing aids

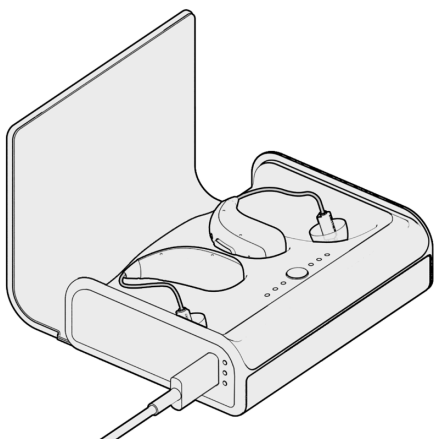
It is important to distinguish between the left and right hearing aids, as each may be programmed differently.

- Left hearing aid: marked with a blue indicator
- Right hearing aid: marked with a red indicator



Charging your hearing aids and charging case

Charging your charging case

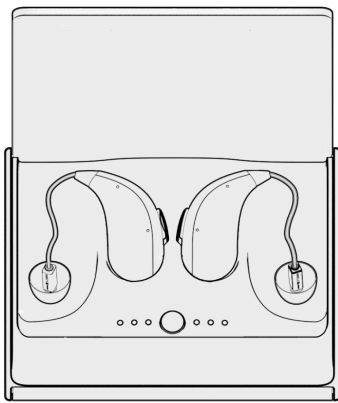


1. Connect the USB-C cable to the power brick.

2. Plug the other end of the USB-C cable into the USB-C port on the charging case.
3. Plug the power adapter into a wall outlet. The charging case will turn on automatically and begin charging its built-in power bank.

While connected to power, the charging status of the power bank is shown by the case status lights located on the side of the charging case near the USB-C port.

Charging your hearing aids



Place your hearing aids in the charging case

Place the hearing aids into the charging ports. Be sure to match each hearing aid with the correct color indicator on the charging case:

- Red = Right hearing aid
- Blue = Left hearing aid

Charging status

The status lights on the charging case turn on when the hearing aids are correctly placed in their charging ports.

If the status lights flash red, the hearing aids are not seated properly. Remove and reposition them until the status lights show white or orange, as described in the table below.

Charging status lights

Battery is dead	No lights	
Battery: 0–15%	1st light pulsing orange	
Battery: 15-33%	1st light pulsing white	
Battery: 33-66%	2nd light pulsing white	
Battery: 66-99%	3rd light pulsing white	
Battery: 100%	3 white lights	
Moisture detected on hearing aid	3 red lights	
Hearing aid is not placed correctly	3 flashing red lights	

*A pulsing white or orange light indicates that the battery is charging.

Charging time

Charging time may vary depending on the remaining battery level and may differ between the left and right hearing aids.

If a hearing aid battery is fully drained, the typical charging and usage times are:

Charge time (minutes)	Use time (hours)
15	2.4
30	4.8
60	9.7
180	16

Notes:

Actual battery life may vary depending on usage patterns, active features, degree of hearing loss, sound environment, and battery age.

When the hearing aid battery is fully charged, the charging process will stop automatically.

The charging case lid provides both protection and storage for your hearing aids. While charging, opening the lid will activate the status lights, which display the charging status of both the case and the hearing aids.

IMPORTANT NOTICE

Make sure your charging case is either plugged into power or has sufficient charge in its built-in battery when placing the hearing aids in the charging ports. If the charging case has no power, the hearing aids will stay on and continue using their own battery.

Charging case's built-in battery

Your charging case includes a built-in lithium-ion rechargeable battery that also functions as a power bank. When fully charged, it can recharge a pair of hearing aids up to three times while you are on the go.

Note

Power bank capacity may decrease as the battery ages.

When the charging case is plugged into a power source: both the hearing aids and the case's built-in battery are charged.

When the charging case is unplugged: the case switches to power bank mode, allowing you to charge your hearing aids without access to an outlet.

Your charging case's battery will fully charge in 8 hours*, with or without hearing aids in the charging case.

*Temperature conditions may affect the charging times.

Note

Keeping the lid closed while charging your hearing aids will reduce charge time.

When the charging case is connected to a power source, the charging case indicator status lights on the side of your charging case indicate the charging status of the power bank.

Power bank function

When the charging case is disconnected from power, the charging case status lights on your charging case indicate the charging case's power bank battery level when the lid is open. The status lights will turn off shortly after the lid is closed.

Battery status lights

Battery is dead	No lights	
Battery: 0–15%	1 orange light	
Battery: 15–33%	1 white light	
Battery: 33–66%	2 white lights	
Battery: 66–100%	3 white lights	

Long-term storage

Before storing the charging case for more than 14 days, make sure the built-in power bank battery is fully charged. This will help maintain battery health and ensure it can be recharged when needed.

Note

To protect the rechargeable battery, fully recharge the charging case at least once every 3 weeks. Failure to do so may reduce battery performance and could require battery replacement.

Turn hearing aids on/off

Your hearing aids can be switched on or off using the charging case:

- **When placed in the charging case:** the hearing aids turn off*. While charging, the case status lights indicate the hearing aid battery level.
- **When removed from the charging case:** the hearing aids turn on.

For details on the charging and battery lights, see the **Charging Status Lights** and **Battery Status Lights** sections.

*If the charging case is disconnected from power or its battery is depleted while charging, the hearing aids may turn on. Once the case is reconnected to power, the hearing aids will turn off again.

Daily use

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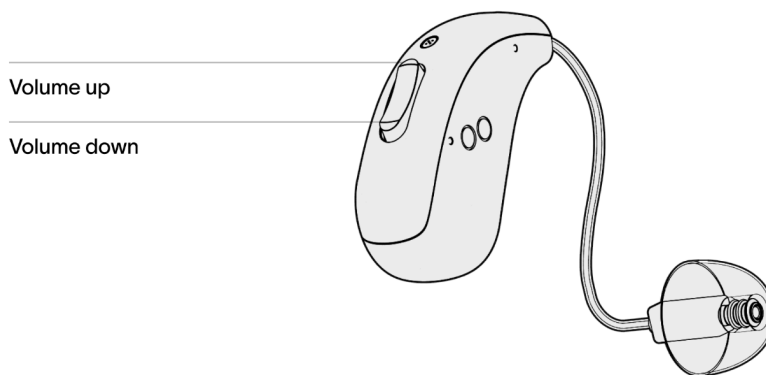
Putting on hearing aid

1. Place the hearing aid behind your ear. Always use the receiver with a dome attached, and only use parts designed for your Fortell AI Hearing Aid.
2. Hold the bend of the receiver wire between your thumb and index finger, with the dome pointing toward the opening of your ear canal.
3. Gently insert the dome into your ear canal until the receiver wire rests close to your head. If your receiver includes a sports lock, position it so it follows the natural contour of your ear.

Adjust volume

The left hearing aid has two buttons for volume control: **Volume Up** and **Volume Down**.

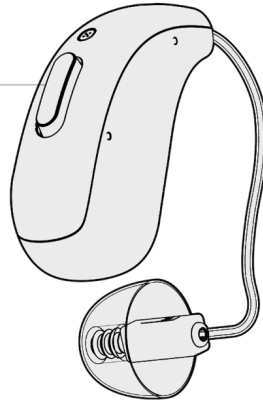
Press either button once to increase or decrease the volume in small steps. Each adjustment is confirmed with an audio signal.



Change mode

Your Fortell AI Hearing Aids include multiple listening modes, which are programmed by a Fortell hearing care professional. You can switch between modes using the **Mode button** on the right hearing aid.

Mode button



All-day AI

This amplifies people's voices and reduces all other noises.

- When **All voices** is selected, your hearing aids will not remove voices behind you.
- When **Front voices** is selected, your hearing aids will remove voices behind you.

Conventional

This amplifies voices and ambient noises like a conventional hearing aid.

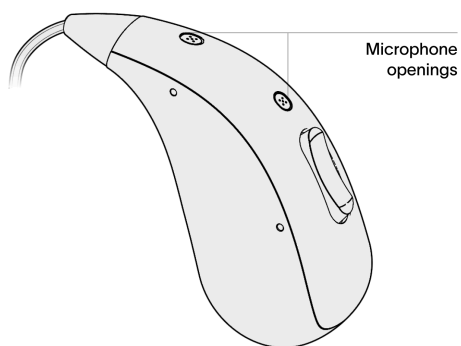
Live music

This is designed for more natural sounding music at a concert or live performance.

Cleaning

Your Fortell AI Hearing Aids come with a cleaning brush and cloth for removing earwax. If you need replacement parts, contact Fortell.

- **Handle with care:** Always hold the hearing aid over a soft surface to prevent damage if dropped.
- **Cleaning with brush:** Use the cleaning brush to gently remove debris from the openings and surrounding surfaces. Do not insert the brush forcefully into the microphone openings, as this may cause damage.
- **Cleaning charge pads:** Keep the charging pads clean for optimal performance. Wipe them carefully using the provided cleaning cloth.



IMPORTANT NOTICE

Use the cleaning cloth provided in the original packaging to clean your hearing aids. Never wash or immerse the devices in water or any other liquids.

Replacing domes

You may need to replace the domes if they start to discolor or feel brittle, or if they look dirty. A Fortell hearing care professional can provide extra domes.

1. Grip the wire firmly and pull the dome off.
2. Insert the receiver exactly into the middle of the new dome to get a secure fit.
3. Push the new dome on, making sure it has a firm fit so it does not fall off.

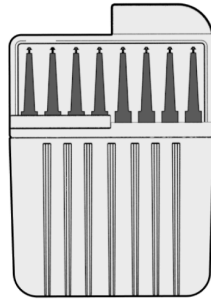
IMPORTANT NOTICE

If the dome is missing from the receiver after removing the hearing aid, it may still be in your ear canal. If this occurs, contact Fortell for assistance.

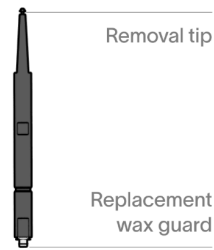
Wax guard

Each receiver has a white wax guard at the tip, beneath the dome. The wax guard prevents earwax and debris from entering and damaging the receiver.

Replace the wax guard if it becomes clogged or if the hearing aid sound quality is reduced. You may also contact Fortell for assistance.



Wax guard kit



Wax guard pick

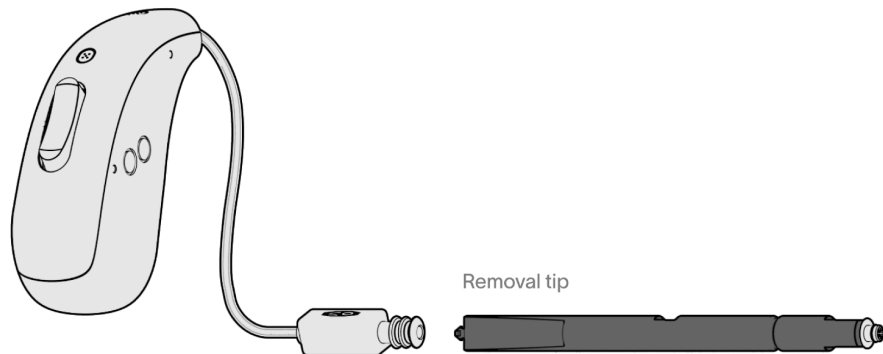
Replacing wax guards

Your Fortell AI Hearing Aids include a wax guard kit containing multiple picks. Each pick has two ends:

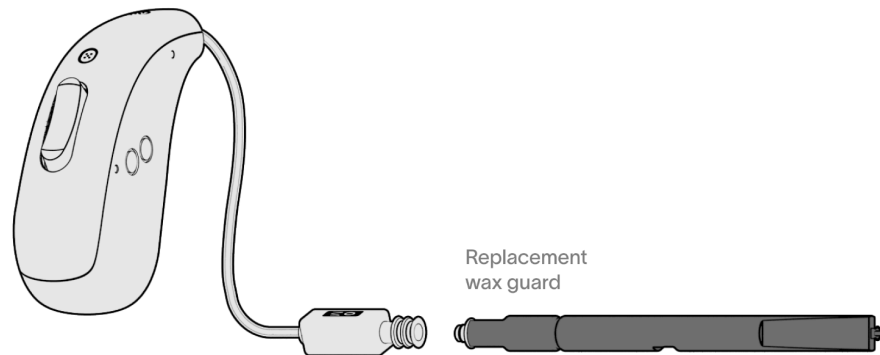
- One empty end for removing the old wax guard
- One end with a white replacement wax guard

Before starting, remove the dome from the receiver (see **Replacing Domes** section). Then follow these steps:

1. Remove a pick from the wax guard kit.
2. Insert the empty end of the pick into the wax guard on the receiver and pull it out.



3. Flip the pick and insert the end with the new white wax guard into the receiver. This installs the replacement wax guard.



4. Reattach the dome, as described in the **Replacing Domes** section.

IMPORTANT NOTICE

Always use the same type of wax guard originally supplied with your Fortell AI Hearing Aids. If you are unsure about selecting or replacing wax guards, contact Fortell for guidance.

Store your hearing aids

When not in use, keep your hearing aids in the charging case.

To maximize the life of the rechargeable batteries, avoid exposing the hearing aids and charging case to excessive heat. For example, do not leave them in direct sunlight, near windows, or inside a car—even if they are stored in the charging case.

If you plan to store your hearing aids for more than 14 days, place them securely in the charging case and keep the case plugged into a power outlet. This helps protect the rechargeable batteries and reduces the risk of damage.

Note

To protect the rechargeable battery, fully charge your hearing aids at least once every three weeks. If a stored hearing aid is not recharged within this period, the battery may become damaged or unable to hold a charge.

Caring for your charging case

Always ensure the charging case is dry and clean before use. Keep the charging ports free of dust by wiping them with the provided cleaning cloth. **Do not** use water or cleaning fluids on the charging ports.

Store the charging case in a dry location (for example, in a bedroom) and at a temperature between 14°F and 113°F (-10°C and +45°C).

IMPORTANT NOTICE

Ensure you remove the USB-C cable when you transport the charging case.

IMPORTANT NOTICE

Always ensure the charging case is dry and clean before use. Keep the charging ports free of dust by wiping them with the provided cleaning cloth. Do not use other objects (e.g., cotton swabs), and never use water or cleaning fluids to clean the charging ports.

Battery performance

Fully charge your hearing aids before first use, and recharge them every night to ensure they are ready for a full day of use.

Battery performance may vary depending on individual usage and hearing aid settings. Activities such as streaming audio from a mobile phone can reduce battery life.

If your hearing aids do not last a full day on a full charge, contact Fortell for assistance.

Low battery indication

When the hearing aid battery is low, you will hear three descending tones. After this notification, the hearing aid will continue to function for approximately two hours before the battery is depleted.

To extend battery life during this time, stop any media streaming.

Use your hearing aids with mobile devices

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Device compatibility

iPhone®

Your hearing aids are Made for iPhone hearing aids and allow for direct streaming from your iPhone.*

* A compatible iPhone® is required for hearing aid use. See fortell.com/compatibility for the list of compatible devices and operating system requirements.

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.

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Pairing and compatibility

To use your hearing aids with your mobile device, your hearing aids must pair to your mobile device using Bluetooth®.

1. Make sure that your mobile device's Bluetooth is turned on. On your iPhone, you can turn Bluetooth on by navigating to **Settings > Bluetooth**. Navigate to **Settings > Accessibility > Hearing Devices** and make sure no other hearing device is already paired to your iPhone. If you do see a connected hearing device, you can tap on it and press **Forget this device**.

2. With the hearing aids in the carrying case, press the case button once to put them into pairing mode. The hearing aid status lights should pulse blue, and the hearing aids will appear on your iPhone's list of hearing devices.
3. Select your hearing aids and pair them to complete the process.

Streaming phone calls and other media

When your hearing aids are paired to your iPhone, you can use them as wireless headphones to stream phone calls, music, and other media.

To automatically use your hearing aids as wireless headphones, navigate to **Settings > Accessibility > Hearing Devices > Audio Routing** and set **Call Audio** and **Media Audio** to **Automatic**. Your hearing aids will automatically stop streaming when they are placed in the case.

Using Voice Isolation to improve quality of phone calls

When you use your hearing aids during a phone call, they will act as a microphone to pick up your voice. To reduce the amount of ambient noise that your hearing aids pick up, you can turn on Voice Isolation by following the instructions at <https://support.apple.com/en-us/101993>.

Note

Be sure to keep your iPhone close to your hearing aids when you are streaming phone calls or other media to maintain a strong connection. For best performance, keep your iPhone in front of you within a few feet of your hearing aids.

The Fortell app

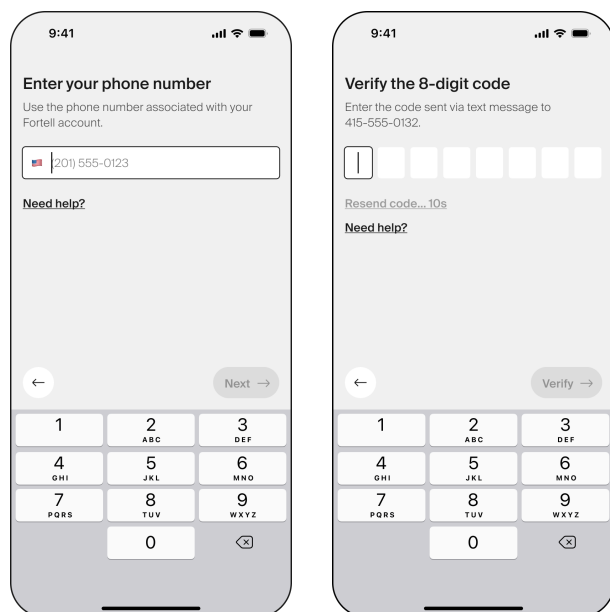
The Fortell app enables you to control and monitor your hearing aids. It gives you wireless access to your hearing aids through an iPhone for control of functionality, and that allows your hearing aids to be updated remotely. Ensure you only download the Fortell app from the official Apple App Store. The Fortell app will automatically connect to your paired hearing aids. If your hearing aids are not properly paired to your iPhone, the Fortell app will be unable to control them.

Ensure that you always update the app to the newest compatible version. Also, ensure that you update your device to the latest version of iOS. In case of any additional questions regarding the use of the app, contact Fortell. Be aware that some settings are dependent on the fitting done by the Fortell hearing care professional.



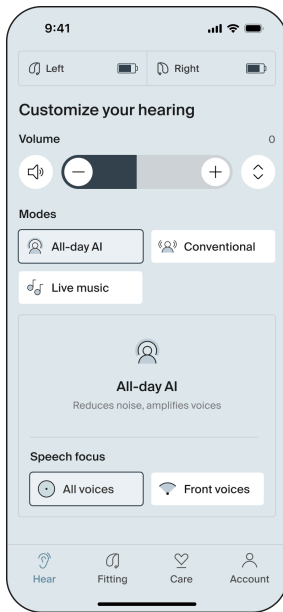
Logging in

To use the Fortell app, you need to log in using your phone number associated with your Fortell audiology account. This account is created at your first audiology appointment with Fortell. Within 30 seconds after entering your phone number, you will receive a text message containing a security code. Use the security code to finish log in. If you do not receive a security code, or you cannot remember which phone number you used to set up your account at your first audiology appointment, please reach out to Fortell for assistance.



Seeing connection status

When the Fortell app is opened, it will initially display the **Hear tab**, which allows you to see and adjust the status of your hearing aids. The **Hear tab** will notify you if you have not properly paired your hearing aids to your iPhone. Sometimes only one hearing aid is connected, and the other will indicate that it is not properly paired to your iPhone.



Checking battery

With your hearing aids paired to your iPhone, you can use the Fortell app to check the battery levels of each hearing aid. From the navigation bar at the bottom of the app, press **Hear** to navigate to the main view. At the top of the **Hear tab**, you'll see both the left and right hearing aids. If a hearing aid is properly connected to the app, there will be a battery icon that indicates how full the battery is. You can tap the battery to see a more precise battery level.

Adjusting volume

From the **Hear tab** you can also adjust the volume of one or both hearing aids. By default, only one volume control is visible, which controls both hearing aids at once. You can use the **+** and **-** buttons to increase or decrease the volume of both hearing aids. By default, your hearing aids will be at the level set by your Fortell audiologist.

To adjust hearing aids separately, use the split button to access left and right volume controls.

To mute and unmute your hearing aids, you can use the mute button next to the volume control. You can do this for both hearing aids at once, or for just one hearing aid at a time using the split button.

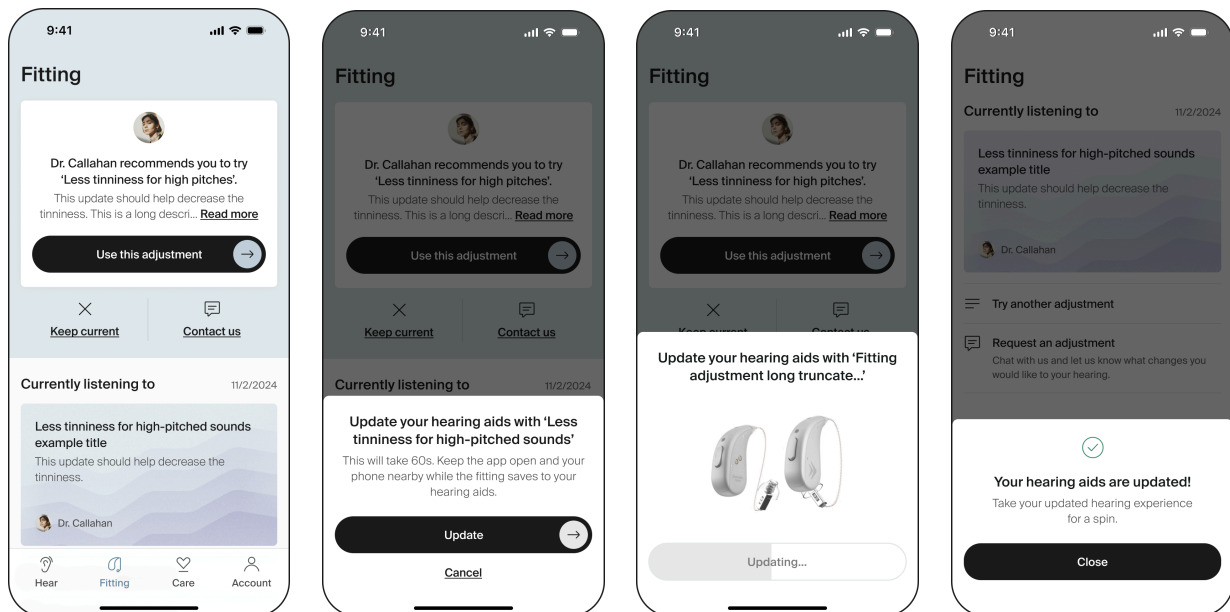
When you are streaming a phone call or other media, another volume control will appear for streaming volume. You can use this to adjust the volume streamed from your phone. While you are streaming, you can also adjust the environment volume using the normal volume controls.

Changing modes

Your Fortell AI Hearing Aids have a few built in modes that you can access from the Fortell app. You can access these modes by tapping them on the **Hear tab**.

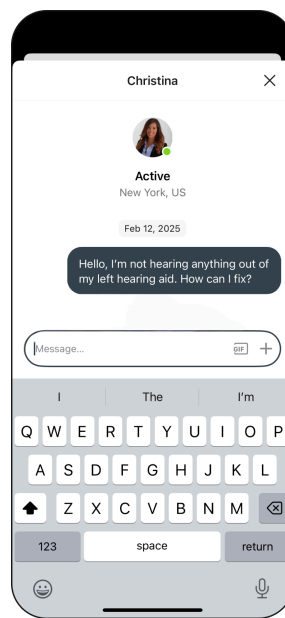
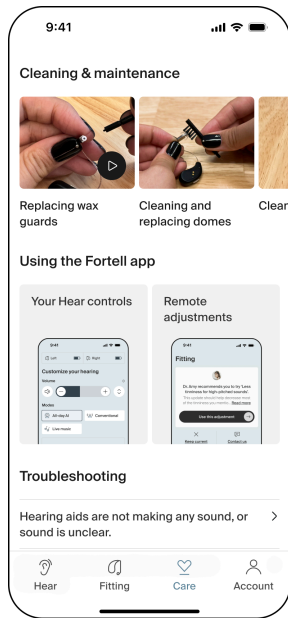
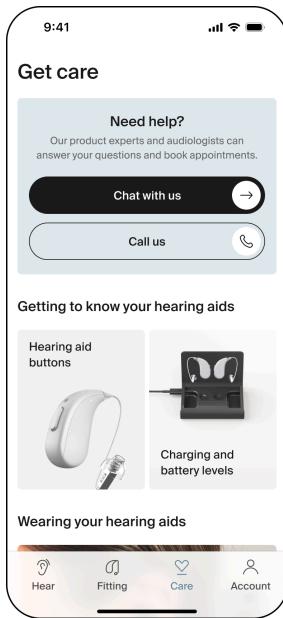
Remote fittings

Your audiologist can adjust your hearing aids through the Fortell app. When you receive a notification, tap it, or go to the **Fitting tab** in the app to view the update. Make sure your hearing aids are close by, then tap **Use this adjustment** and **Update**.



Getting help

Tap the **Care tab** in the Fortell app to call or message a Fortell audiologist or product specialist. You can also access tutorial videos and walkthroughs to answer common questions about your Fortell AI Hearing Aids.



IMPORTANT NOTICE

The hearing aid is still using battery power when muted.

General warnings

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For your safety and to ensure proper use, carefully review the following warnings before using your hearing aids and charging case. If your devices show unexpected behavior or you experience a serious incident, contact your hearing care professional. They can assist with troubleshooting and, if needed, reporting to the manufacturer or national authorities.

Hearing aids do not restore normal hearing and cannot prevent or improve hearing loss caused by natural processes such as aging or illness.

Hearing aids are only one part of hearing rehabilitation and may need to be supplemented with auditory training or instruction in lipreading.

To receive the full benefit, wear your hearing aids regularly.

Only charge your hearing aids with the designated charger. Using other chargers may damage the hearing aids or batteries.

This hearing aid contains a non-removable rechargeable lithium-ion battery. Always charge as directed and review the safety and handling information for rechargeable hearing aids.

Charging ports

Do not place anything other than rechargeable hearing aids in the charging ports. Other items may short circuit the charger and result in burns.

Usage of hearing aids

Hearing aids should only be used as directed by your hearing care professional. Misuse can result in sudden and permanent hearing loss. Never allow others to wear your hearing aids. Unauthorized use could cause permanent damage to their hearing.

Choking hazards of swallowing small parts

Keep all small parts (for example, hearing aids, earpieces, domes, etc.) out of reach and sight of children and others who might swallow these items. Seek emergency medical treatment immediately if someone is choking on small parts or batteries are swallowed.

If a hearing aid or small part is swallowed, see a doctor immediately and contact the National Poison Center at 1-800-222-1222 or National Battery Ingestion Hotline at 1-800-498-8666.

Strangulation hazards of cables

Keep all small cables out of reach of children and others who might become entangled with these items.

Keep away from environments with risk of explosions

Your hearing aids and charging case are safe to use under normal usage conditions. The hearing aids and charging case have not been tested for compliance with international standards concerning explosive environments.

Do not use the hearing aids or charging case in environments with danger of explosions such as mines, oil fields, oxygen rich environments or areas where flammable anesthetics are handled.

Do not attempt to open your hearing aids as it may damage the battery.

Never attempt to replace the battery. If battery replacement is needed, return your device to the supplier. The warranty is void if there are signs of tampering.

Never attempt to replace rechargeable batteries.

Never attempt to replace your charging case's rechargeable batteries

Do not attempt to access your charging case's battery as it may damage the battery.

Never attempt to replace the battery. If battery replacement is needed, contact Fortell. The warranty is void if there are signs of tampering.

Beware of battery leakage

Do not touch your hearing aids or charging case if the battery appears to be leaking as the acids may cause skin irritation. If you have been in contact with battery acids, wipe it off using a wet cloth. If you experience skin irritation, consult your doctor. In the event of battery leakage contact Fortell for further instructions.

Connection to external equipment

The safety of recharging batteries using a USB-C connector is determined by the external signal source. Only use the originally supplied power brick when connecting the charging case to a power outlet.

Connecting the charging case to external equipment

You must use the USB-C wire and power brick supplied with your hearing aids. Do not attempt to connect your charging case using any other connector wire.

Beware of your surroundings

Do not use your charging case while driving or in other situations that require your full attention.

Beware of sudden dysfunction

Your hearing aids may stop working without notice. For example, if they run out of battery or if the receiver is blocked. Keep this in mind especially in situations where you depend on warning sounds (for example when in traffic).

Use with active medical implants

Your hearing aids have been thoroughly tested and developed for human health according to international standards for human exposure (Specific Absorption Ratio – SAR), induced electromagnetic power and voltages into the human body.

The exposure values are well below international accepted safety limits for SAR, induced electromagnetic power and voltages into the human body defined in the standards for human health and coexistence with active medical implants, such as pacemakers and heart defibrillators.

If you have an active brain implant, contact the manufacturer of your implanted device for information about the use with a hearing aid.

Your hearing aids and charging case contain magnets and should be kept at least 15 centimeters (6 inches) away from any implanted medical device. Follow the guidelines from the manufacturer of your implanted medical device regarding their use with magnets.

Use with cochlear implants

If you are using a cochlear implant (CI) on one ear and a hearing aid on the other ear, make sure to always keep your CI at least 1 centimeter (0.4 inches) away from your hearing aid. The magnetic field from the CI may permanently damage the speaker unit in your hearing aid. Never place the devices close together on a table (for example, when cleaning).

Do not carry the CI and the hearing aid together in the same box.

Detached dome in ear canal

Ensure that the dome is still connected to the receiver when removing the hearing aid from your ear. If the dome is not on the receiver, the dome may still be in the ear canal. Contact Fortell.

Remove hearing aids and charging case before certain medical procedures

Remove your hearing aids and charging case before medical procedures such as X-ray examinations, CT/MR/PET scans, electrotherapy, surgery, etc. Your hearing aids and charging case may be damaged if exposed to strong magnetic or electromagnetic fields.

Keep away from extreme heat

Never expose your hearing aids or charging case to extreme heat. For example, do not leave your hearing aids or charging case inside a parked car in the sun.

Never use an external heating device to dry your hearing aids or charging case. For example, do not dry your hearing aids or charging case using a hair dryer or in an oven such as a microwave.

Keep away from chemicals

Remove your hearing aids and keep your charging case at a safe distance before applying products that contain certain chemicals that can damage your hearing aids. For example, cosmetics, hairspray, perfume, aftershave lotion, suntan lotion and insect repellent. Allow the products time to dry before putting on your hearing aids.

Potential side effects

You may produce more earwax when using hearing aids. In rare cases, the non- allergenic materials in the product may cause skin irritation or other side effects. If you experience any such side effects, consult your doctor.

Transporting charger on aircraft

Consult the airline for details about bringing your charging case onto an aircraft.

Charge charging case every 3 weeks

Ensure you charge the charging case every 3 weeks to prevent potential battery damage during storage.

Use of third-party accessories

Only use accessories, cables or transducers supplied by Fortell. Non-original accessories may result in reduced electromagnetic compatibility (EMC) of your hearing aids.

Do not modify hearing aids

Do not make any modifications to your hearing aids not expressly approved by Fortell. This will void the warranty.

More info

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Environmental considerations

Your hearing aid is designed to be worn in daily life situations and has undergone testing such as resistance to sweat, hand cream, hair gel, and lotion.

The charging case is dust resistant and protected against ingress of water, which means it is designed to be used in all daily life situations. The charging case has been tested to an IP64 rating.

Before charging the hearing aid or the charging case, make sure to wipe off any moisture with the cleaning cloth. Should your hearing aid or charging case come into contact with water and stop working, please reach out to Fortell.

IMPORTANT NOTICE

Do not wear your hearing aid while showering or participating in water activities. Do not immerse your hearing aid or charging case in water or other liquids.

Operating conditions for hearing aids and charging case

Operating conditions	Temperature: 32°F to 113°F (0°C to 45°C) Humidity: 15% to 90% relative humidity, non-condensing
Charging conditions	Temperature: 32°F to 113°F (0°C to +45°C) Humidity: 15% to 90% relative humidity, non-condensing
Transportation and storage conditions	Temperature and humidity shall not exceed the below limits for extended periods during transportation and storage: Transportation: Temperature: 14°F to 122°F (-10°C to +50°C) Humidity: 5% to 90% relative humidity, non-condensing Storage: Temperature: 14°F to 113°F (-10°C to +45°C) Humidity: 0% to 90% relative humidity, non-condensing

Note

If hearing aids or charging case have been stored below 32°F, they may take up to 1 hour to function as intended at 20°F.

Technical information

The hearing aid contains a radio transceiver using Bluetooth Low Energy technology operating at ISM band 2.4 GHz.

Use in fields with electromagnetic interference

Your hearing aids have been thoroughly tested for interference according to the most stringent international standards, including IEC 60601-1-2 and its amendments, IEC 60118-13 and ANSI C63.19. Electromagnetic interference may occur in the vicinity of equipment that can affect the performance of your hearing aids such as mobile phones, Wi-Fi routers or other equipment with the displayed symbol. If your hearing aids are affected by interference, move away from the source.

Due to the limited space available on the hearing aid, relevant approval markings can be found in this booklet.

These hearing aids use wireless transmission. Check first before using in areas where electronics or wireless devices are restricted.

RF information

FCC ID (Left RIC): 2BRSV-FR1RICLA

FCC ID (Right RIC): 2BRSV-FR1RICRA

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.

Changes or modifications to the device can void the user's authority to operate the equipment

This device complies with FCC RF exposure limits set forth for an uncontrolled environment and has been tested for portable use.

Use of other accessories not verified by the manufacturer may not ensure compliance with FCC RF exposure guidelines.

Should your hearing aid require service or replacement, contact Fortell for assistance. Many repair needs can be handled on-site at a Fortell clinic, and they will arrange for service if required.

Description of symbols accompanying the product

Symbols	Description
	Warning Indicates a potentially hazardous situation which, if not avoided, could result in serious injury or death.
	Caution Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury, or alerts against unsafe practices.
	FCC Indicates that the product complies with applicable electromagnetic interference and radio frequency regulations in the United States.
	Manufacturer The device is produced by the manufacturer whose name and address are stated next to the symbol.
	Date of Manufacturing Indicates the date on which the product was manufactured.
	Electronic Waste (WEEE) Recycle hearing aids, accessories or batteries according to local regulations. Hearing aid users can also return electronic waste to their hearing care professional for disposal.
	Bluetooth logo Registered trademark of Bluetooth SIG, Inc, where any use of such requires a license.
	Made for iPhone badge Indicates that the device is compatible with iPhone.
	Keep Dry Indicates a medical device that needs to be protected from moisture.
	Catalog Number Indicates the manufacturer's catalog number so that the medical device can be identified.
	Serial Number Indicates the manufacturer's serial number so that a specific medical device can be identified.

	Medical Device This device is a medical device.
	UDI Device Identifier Indicates a carrier that contains unique device identifier information.
	UL Classified (US and Canada) Indicates the product has been evaluated by UL for specific properties and conditions of use.
	Double Insulated Electrical Application Indicates that the product has double insulation and does not require a safety connection to electrical ground
	Indoor Use Only Indicates that the product is intended for use in indoor environments only
	Power Supply Efficiency Level VI Indicates that the external power supply meets U.S. Department of Energy Level VI energy efficiency requirements.
Rx only	Prescription Use Only Caution: Federal law restricts this device to sale by or on the order of a hearing care professional.
IP64	IP Rating Grade of the resistance of an enclosure against the intrusion of dust or liquids, with the first digit indicating resistance to dust and the second to liquids.. An IP rating IP64 indicates that the charging case is dust tight and protected against water jets.

Warranty

Your device is covered by a warranty issued by Fortell. This warranty covers manufacturing and material defects in the device itself, but not in accessories. Problems arising from improper/incorrect handling or care, excessive use, accidents, repairs made by an unauthorized party, exposure to corrosive conditions, physical changes in your ear, damage due to foreign objects entering the device, or incorrect adjustments are NOT covered by the warranty and may void it. The above warranty does not affect any legal rights that you might have under applicable national legislation governing the sale of consumer goods in the USA.

If you need service

Take your device to a Fortell hearing care professional, who may be able to sort out minor problems and adjustments immediately.

Expected service life

The expected service life of the hearing aids, charging case, and power adapter is 3 years. If your hearing aid stops performing as expected, contact Fortell for help with troubleshooting, servicing, or returning the device for disposal. Do not dispose of hearing aids or charging case with household waste.

Domes should be replaced if they start to discolor, feel brittle, or look dirty. The expected service life is 1-2 months, but may vary by individual or dome type.

Receivers should be replaced if they display signs of physical damage like fraying wires or bent connections. The expected service life is 12 months, but may vary based on the user, environmental conditions, and maintenance.

Contact Fortell if you need any replacement domes or receivers.

Your hearing aid controls

● Left Hearing Aid	
Increase volume	Single press – Volume Up
Decrease volume	Single press – Volume Down
Reset left hearing aid	Press & hold Volume Down – 15s

● Right Hearing Aid	
Turn on/off All-day AI: All voices	Single press – Mode button
Turn on/off All-day AI: Front voices	Press & hold – Mode button – 2s
Reset right hearing aid	Press & hold – Mode button – 15s

Your charging case controls

Case button		
Put hearing aids in pairing mode	Single press to see 3 pulsing blue lights	
Reset both hearing aids	Press and hold – 5s until alternating white lights	
Reset case	Press and hold – 15s until no lights	

LED indicators - Status Lights

Battery is dead	No lights	
Battery: 0–15%	1 orange light	
Battery: 15-33%	1 white light	
Battery: 33-66%	2 white lights	
Battery: 66-100%	3 white lights	
Moisture detected on hearing aid	3 red lights	
Hearing aid is not placed correctly	3 flashing red lights	

*A pulsing white or orange light indicates that the battery is charging.

Troubleshooting

Hearing aids are not making any sound, or the sound is cutting in and out.
1. Check hearing aid battery level in the Fortell app or by placing them in the case to make sure the battery has charge. 2. Clean the hearing aid domes with the brush. 3. Reset hearing aids by pressing the volume down button and mode button for 15 seconds, or place them in the case and press the case button for 5 seconds. 4. Replace wax guards using the wax guard kit.
Hearing aids are making a squealing noise.
1. Make sure the domes are properly inserted in your ear canals.

2. Use the volume down button on the left hearing aid or the Fortell app to reduce the volume levels of your hearing aids. 3. Contact Fortell for support in the event that earwax has accumulated in your ear canal.
Hearing aids are making a squealing noise inside the charging case.
1. Make sure the charging case is either charging or has charge by opening the lid and checking the charging case status lights on the side of the charging case next to the USB-C. If no lights are on, plug the charging case into an outlet using the USB-C charging cord and power brick included in the original packaging.
Hearing aids do not charge when placed in the charging case
1. Make sure that the hearing aids are properly placed in the charging case, and that the hearing aid status lights are on. 2. If you see flashing red lights, the hearing aids are not properly placed in the charging case. Remove them and try placing them again, being sure to put the hearing aids in the correct sides of the charging case. 3. If you see solid red lights, the hearing aids may have moisture on them. Dry the case and the hearing aids with the cleaning cloth provided in the original packaging.
Hearing aids do not turn ON after being removed from the charging case
1. Reset hearing aids by pressing the volume down button and mode button for 15 seconds, or place them in the case and press the case button for 5 seconds.
App is no longer connected to hearing aids.
1. Ensure your iPhone has Bluetooth turned on. 2. Restart your iPhone. 3. Reset hearing aids by pressing the volume down button and mode button for 15 seconds, or place them in the case and press the case button for 5 seconds.

Summary of relevant studies

Clinical evaluations conducted by or on behalf of the manufacturer provide evidence supporting the intended use and clinical benefits described in this IFU, as well as demonstrating regulatory

compliance. Clinical data are collected, assessed, and analyzed to confirm hearing aid performance, including:

- Providing sufficient audibility and hearing loss compensation based on best-practice prescriptive fitting methods
- Demonstrating improved speech understanding
- Measuring user outcomes through validated questionnaires and surveys

Non-clinical evidence supporting the overall performance of the hearing aids includes:

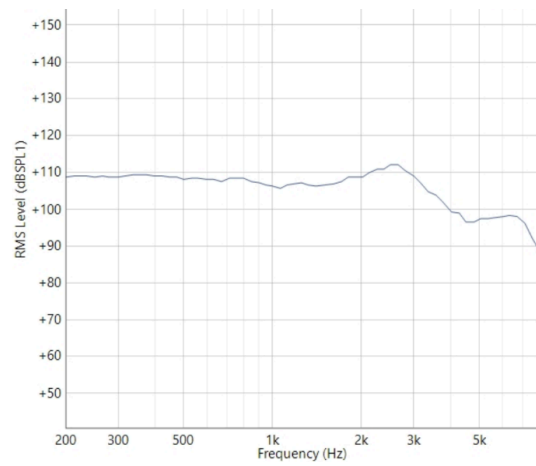
- Software verification
- Electroacoustic verification
- Electrical and mechanical safety evaluations
- Electromagnetic compatibility (EMC) testing
- Documentation of radio properties and performance

For more details, see the **Technical Information** section.

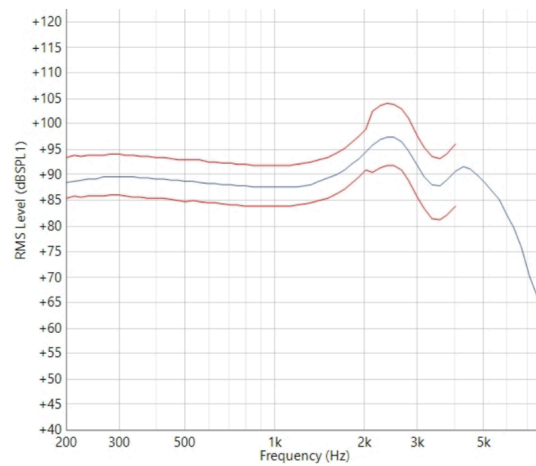
Technical Data

0 dB SPL ref. 20 μ Pa		Fortell AI Hearing Aids
OSPL90	Peak	112 dB SPL
	HF Average	109 dB SPL
Full-on Gain	Peak	55 dB
	HF Average	51 dB
Reference Test Gain		32 dB
Frequency Range		0.2-6.2 kHz
Telecoil output	HF Average SPLITS (left/right ear)	NA
Total Harmonic Distortion	500 Hz	1%
	800 Hz	1%
	1600 Hz	1%
Equivalent Input Noise Level	(omni/dir)	29 dB SPL/38 dB SPL
Attack Time @1kHz		13 ms
Release Time @1kHz		470 ms

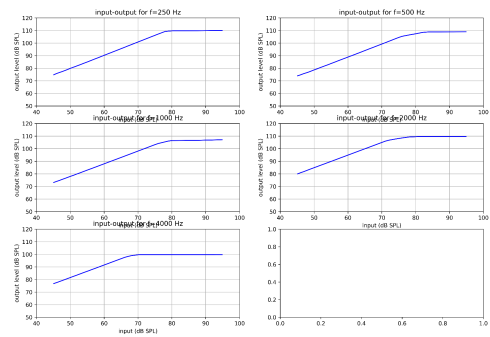
OSPL90 - Output Sound Pressure Level



Frequency Response



Input-Output



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