

#### NoviOne RIC Wireless OTC Hearing Aids

WARNING: If you are younger than 18, do not use this. You should go to a doctor, preferably an ear-nosethroat doctor (an ENT), because your condition needs specialized care. Over-the-counter hearing aids are only for users who are age 18 or older.

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

#### WARNING: When to See a Doctor

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

- Your ear has a birth defect or an unusual shape. Your ear was injured or deformed in an accident
- $\cdot$  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)
- $\cdot$  Your hearing changed suddenly in the past months
- · Your hearing changes: it gets worse then gets better again
- $\cdot$  You have worse hearing in one ear
- $\cdot$  You hear ringing or buzzing in only one ear

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

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

#### Caution: This is not hearing protection.

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

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

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

# Caution: You might need medical help if a piece gets stuck in your ear.

If any part of your hearing aid, like the eartip, gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as you can. You should not try to use tweezers or cotton swabs because they can push the part further into your ear, injuring your eardrum or ear canal, possibly seriously.

#### 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.

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

To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. FDA calls them "adverse events," and they might include: 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.

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# 1 Getting Started

Congratulations on purchasing your new NoviOne RIC Wireless OTC hearing aids! In this User Manual is a brief introduction to the product and an explanation on how your hearing aids work. Delivered in these little hearing aids are state-of-the-art digital signal processing features based on the latest advances in hearing science. This product has been finely tuned by us to create an elite listening experience.

#### Download the App

Download on the

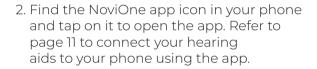
App Store

You can use the NoviOne mobile app to choose situational programs, adjust hearing aid volume, and adjust sound quality settings.

GET IT ON

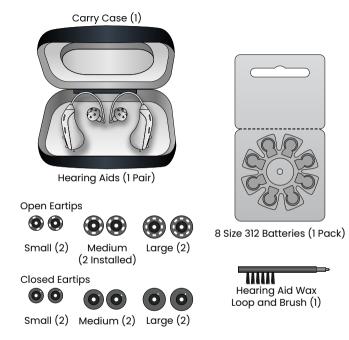
Google Play

 Download and install the NoviOne app from the App Store<sup>®</sup> or on Google Play<sup>™</sup>.





#### What's in the Box



#### Connecting Your Hearing Aids to Your Phone and the App

- When connecting your hearing aids to your phone for the first time, your phone will display pop-up messages requesting location permission for the app and a Bluetooth<sup>®</sup> wireless technology pairing for each hearing aid; you must accept all the requests.
- 2. If you experience any problems, power your hearing aids off and on and toggle the Bluetooth off and on through your phone to try reconnecting again.
- 3. After your hearing aids are paired to your phone, the app will automatically connect with your hearing aids when they are powered on and within range of your phone. The app will disconnect from your hearing aids if they are out of range or the app is closed.

#### Wireless Connectivity

Your hearing aids use Bluetooth Low Energy<sup>®</sup> (BLE) technology to communicate with a paired smart device (e.g. your smart phone) and also to communicate between the left and right hearing aids.

#### Streaming for iOS

Your hearing aids have Bluetooth Low Energy and Made-for-iPhone® audio streaming built right in. This allows you to adjust your hearing aids with your smartphone and hear your phone audio directly in both of your hearing aids.

Apple<sup>®</sup> iOS users can receive and play audio. This may be a phone call or video call, music, television or movie audio, audio books, podcasts, and more. You will need to hold your phone near your mouth during a phone call so the person can hear you clearly on the other end.

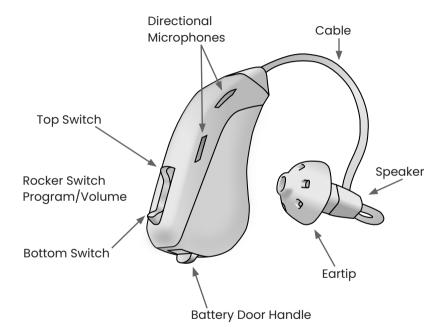
#### Clearing Saved Bonds in Your Hearing Aids

Sometimes to resolve Bluetooth connection issues or to connect your hearing aids to a different Bluetooth device, it may help to remove the Bluetooth pairing bonds between your hearing aids and phone.

- 1. Turn **ON** your hearing aids (refer to page 15) and insert them in your ears (refer to page 18).
- 2. Press and hold down the bottom switch on the rocker switches for about 10 seconds until you hear the voice alert "Delete bonds", then release the switch.

Note: After clearing your hearing aid bonds you will need to pair your hearing aids to a phone or tablet again. Refer to page 11.

#### **Hearing Aid Parts**



#### **Battery Door Positions**

The battery door has three positions: **ON** (fully closed), **OFF** (partially open), and **OPEN**.



The **ON** position is when the battery door is fully closed. When the battery door is in the fully closed position with a functioning battery installed, your hearing aid will power on and be ready to use.

The OFF position of the battery door is located between fully closed and fully open. It is used to turn your hearing aid OFF without allowing the battery to fall out of your hearing aid. When your hearing aid is not in use, open the battery door to the OFF position. This will avoid draining the battery and extend the battery life. This is especially important to do before you go to sleep at night. It is acceptable to completely open the battery door as well.

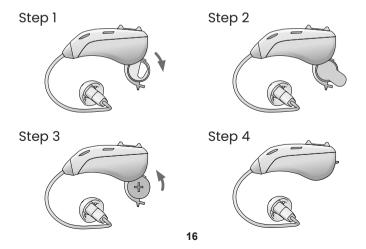
The **OPEN** position is when the battery door is fully open. When the battery door is fully open, the battery is accessible for removal and replacement.

#### Installing the Battery

Before using your hearing aids, a size 312 battery must be installed. The package usually has a brown color indicator.

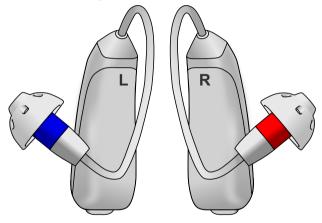
- 1. Using the battery door handle, open the battery door to the **OPEN** position.
- 2. Place the 312 battery, with tab side up, into the battery door.
- 3. Remove the tab.
- 4. Fully close the battery door to turn your hearing aid on.

Note: When your hearing aid is not in use, pull the battery door open to the **OFF** position (refer to page 15). When battery is low, a voice indicator will sound.



# 2 Setting Up Your Hearing Aids

#### Left and Right Indicators



The left hearing aid is indicated by the letter "L" on the bottom of the case and by the color blue on the speaker.

The right hearing aid is indicated by the letter "R" on the bottom of the case and by the color red on the speaker.

#### Inserting Your Hearing Aids in Your Ears

- 1. Place your hearing aid behind your ear and hold it in place.
- 2. Using the other hand if needed, gently insert the eartip and speaker into ear canal until the cable rests flat against your head.

Caution: Do not insert the eartip past this point. Do not force the eartip further down into the ear canal than the depth allowed by the bend in the cable.

3. Ensure the eartip is seated all the way in your ear securely and your hearing aid is resting comfortably behind your ear.





## Physical Fit of Your Hearing Aids

For the best and most discrete fit, your hearing aids should fit properly on and in your ears.



CORRECT

INCORRECT

# Removing Your Hearing Aids from Your Ears

- 1. Grasp the cable with your thumb and finger.
- 2. Gently pull the cable outward to remove eartip and speaker from your ear canal.
- 3. Remove your hearing aid from behind your ear.

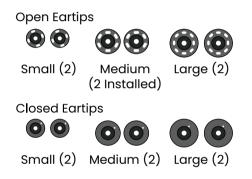




### Selecting Eartip Size

Your hearing aids come with the medium size open eartip pre-installed. In the box you will find size small, medium, and large eartips in both open and closed types (refer to page 21).

A properly fitting eartip should feel stable and comfortable in your ear. It should be snug but should not feel tight.



Try a larger eartip if...

- $\cdot$  The eartip backs out of your ear.
- $\cdot$  The eartip moves inside your ear canal.

Try a smaller eartip if...

- $\cdot$  The eartip causes discomfort in your ear.
- $\cdot$  The eartip feels tight inside your ear canal.

## Selecting Eartip Type

Select the correct eartip type. Your hearing aids come with size medium open eartips pre-installed.

Closed eartips give a slightly fuller sound. They allow for higher volume without feedback or whistling.

Open eartips can help keep your ears from feeling "plugged." However, they may cause feedback or whistling in some ear canals, especially if you turn up the volume.



Try the <mark>open</mark> eartip if...

- · Your ear feels "plugged."
- Sounds are loud.
- Voices are "boomy."

**Open Eartip** 



Try the closed eartip if...

- You are experiencing feedback or whistling. Try a larger closed tip if feedback or whistling continues (refer to page 20).
- · Sounds are "tinny."
- · Sounds are not loud enough.

#### Selecting Your Cable

Your hearing aids come pre-installed with the medium cable. The size medium cable fits most ears.



Your cable should lie flat against the side of your face with your hearing aid resting comfortably on your ear. Refer to pages 18 and 19 for correct placement of your hearing aids.

You may need a larger size cable if...

- Your hearing aid sits too far forward on your ear.
- The cable feels tight or pulls along the front of your ear.

You may need a smaller size cable if...

- Your hearing aid sits too far behind your ear.
- Your hearing aid is loose on your ear and moves when you shake your head or open and close your mouth.

Call customer service at (763) 285-6633 to request a different size (refer to page 46).

### Adjusting the Volume & Programs

To adjust the volume on your hearing aids you can use the rocker switch on your hearing aid or you can use the mobile app (refer to page 24). The volume and program control using the rocker switch is adjusted via ear-to-ear synchronization; adjusting the volume or program on one hearing aid will automatically adjust the other hearing aid. The volume using the mobile app can be adjusted one hearing aid at a time or synchronized. Synchronization performance will vary while connected to the mobile app.

#### Rocker Switch Volume Control

Quick press the top or bottom switch for less than 1 second, then release to adjust volume; the top switch will adjust volume up and the bottom switch will adjust volume down. A tone/indicator will sound when the volume changes. A voice indicator will play when the minimum/maximum volume has been reached. The volume on your hearing aids will power on to the last setting used.





#### Mobile App Volume Control

To adjust your hearing aid volume, drag the volume slider located at the bottom of the main screen of the NoviOne app. Refer to page 9 for app download instructions. Drag the slider to the right to increase volume and drag it to the left to decrease volume. The number value displayed on screen will show you your selected volume level.

To mute and unmute your hearing aids, select the speaker icon to the left of the volume slider





Select the down link button to collapse and adjust both ears together.

Note: hearing aid loudness level should be adjusted to a comfortable level ro avoid hearing damage.



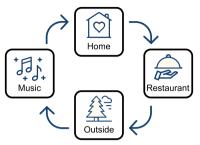


#### Mobile App Streaming Volume Control

You can adjust the streaming volume by using your phone volume controls.



#### Programs



Home: All-around listening.

Restaurant: Noisy situations. Sounds in front of you are amplified and sounds behind you are reduced.

Outside/Car: Listening outside, especially in wind, or in a car with road noise or windows down.

Music: Listening to music in a room, concert, auditorium, or theater. May provide benefit for television, lectures, or worship services.

#### Mobile App Program Control

To select programs with the mobile app, select your desired program tile from the four program tiles on the main screen. Selecting the program tile will set both hearing aids to your chosen program.

#### Rocker Switch Program Control

Programs are designed to provide additional benefit in certain listening situations, but you don't need to change programs to hear well. When you turn on your hearing aids, they always power up to the Home program. The Home program is designed to help in all listening situations, in particular in quieter environments such as watching TV or in small groups.

To select the next program, press and hold for more than 2 seconds on the top switch, then release. To select the previous program, press and hold the bottom switch for more than 2 seconds and release. A voice alert will play when the button has been pressed long enough. A voice indicator will play indicating the program that has been selected. Adjusting the program on one hearing aid will automatically change program on the other hearing aid.





#### Adjusting Sound Quality of Programs

The mobile app can be used to adjust the sound quality of your hearing aids for each acoustic environment (Program) independently. On the main screen of the NoviOne app, select the "Sound Options" button to open the sound options screen for the currently selected acoustic Program.





Whisper Boost

Noise Reduction

Whisper Boost Tile: The Whisper Boost enabled makes soft sounds louder. Whisper boost increases emphasis on soft sounds to help you hear even the quietest sounds around you. Try this option if you are struggling to hear low volume TV or movies, soft-spoken individuals, or speech from a distance. It is important to note that Whisper Boost may make environmental sounds like HVAC and fans louder.

Noise Reduction Tile: The Noise Reduction enabled helps further reduce constant background noises like HVAC, fans and machines/motors.



Brightness Slider: The Brightness Slider adjusts the amount of treble, or high-frequency emphasis, for the selected Program. Drag to the right on the brightness slider to increase the amount of treble; drag to the left on the brightness slider to decrease the amount of treble.

Fullness:

Fullness Slider: The Fullness Slider adjusts the amount of bass, or low-frequency emphasis, for the selected Program. Drag to the right on the fullness slider to increase the amount of bass; drag to the left on the fullness slider to decrease the amount of bass.

Reset to Defaults

Reset to Defaults Button: The Reset to Defaults Button will revert your hearing aids back to the manufacturer's default settings.

# 3 Care and Maintenance

Your hearing aids are designed to resist moisture and perspiration; however, maintenance and care are important to sustaining excellent performance and long life of your hearing aids. If your hearing aids are exposed to water, sweat, or excess dust, your hearing aids must be cleaned.

#### **Cleaning Your Hearing Aids**

Inspect your hearing aids for signs of dirt, earwax, and moisture. Clean the surface of your hearing aids with the brush provided in the package. Eartips should be cleaned daily using the brush included in your package. Use the loop end on the brush to clear any blockage present. Do not use water, soap, or any type of moist cleaning product on any part of your hearing aids.

Brush Here:

#### Component Replacement Recommendations

Expected service life of product and components is 2 years.

It is recommended that you replace your eartips every 3 months. If you notice your eartip is loose, damaged, torn or plugged with ear wax, replace the eartip immediately.

It is recommended that you replace the cables annually. If sound is distorted or intermittent, replace the cable immediately.

Please dispose of used batteries, hearing aids and hearing aid accessories properly following local regulations.

Refer to page 46 to order replacement components.

#### Wax Guard

The wax guard is the white basket in the speaker. It is an extra layer of protection for people with waxy ears.



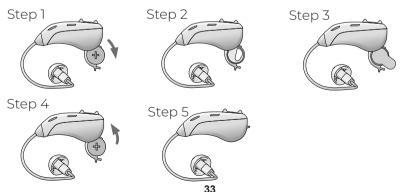
If you notice continual wax build up in the eartip, it is recommended to remove the eartip (refer to page 35) and inspect your wax guard. When inspecting the wax guard, look for any wax blockages. If blockage is present, replace your wax guard. Please refer to page 46 to contact us for any questions about your wax guards or to order replacement wax guards.

#### Replacing the Battery

Each hearing aid uses one 312 size zinc-air battery. The package usually has a brown color indicator. A low battery indicator will sound when the battery is low. Refer to page 46 to order replacements.

- 1. Using the battery door handle, open the battery door to the **OPEN** position (refer to page 15).
- 2. Remove the dead battery and dispose of it properly following local regulations.
- 3. Place a new 312 battery, with tab side up, into the battery door.
- 4. Remove the tab.
- 5. Fully close the battery door to turn your hearing aid **ON**.

Note: When your hearing aid is not in use, pull the battery door open to the **OFF** position (refer to page 15).

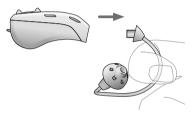


#### **Replacing the Cable**

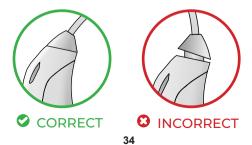
Your hearing aids arrive with medium length cables already installed. Refer to page 22 to select your cable size. If you need a new cable refer to page 46.

To remove a cable, hold onto your hearing aid with one hand and the cable with the other hand. Pull the cable straight out until it separates from your hearing aid. It may take some force to pull it off.





The cable is installed by holding it by the plastic connector end and pushing it into the hearing aid socket until it is fully seated in the orientation shown below. Ensure that the cable is fully inserted into the hearing aid socket.

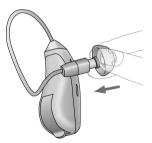


#### **Replacing an Eartip**

An eartip may be removed to be replaced or to change sizes. To remove the eartip, hold the cable in one hand and pinch the end or side of the eartip with the other hand. Pull the eartip straight out from the barb of the speaker. Refer to pages 20 and 21 for more information about eartips.

A new eartip is installed by holding onto the end of the eartip and pushing the eartip over the barb of the speaker. Ensure the eartip is completely seated over the barb of the speaker.





# **Inspecting the Eartips**

Double check that the eartip is completely seated by gently pulling on it. Ensure it is secure before putting the eartip into your ear canal.

Caution: The eartip could get lodged in your ear canal if the eartip is not installed correctly.





# Hearing Aid Storage

Your hearing aids should be stored in a dry place at room temperature with the battery door in the **OFF** or **OPEN** position when your hearing aids are not being used. Refer to page 48 for information on storage conditions for your hearing aids.

# Hearing Aid Troubleshooting

lssue	Possible Remedies			
Does not turn on, no sound	<ol> <li>Ensure battery door is completely closed.</li> <li>Replace battery (refer to page 33).</li> <li>Make sure to remove battery stickers and place in battery door correctly. Check battery orientation if its difficult to close the door.</li> </ol>			
	4. Inspect the eartip for earwax or other material clogging the opening. Use the brush and loop to clean out the blockage (refer to page 30).			
Own voice sounds loud, hollow or "in a barrel"	<ol> <li>Change eartip to the open style eartip (refer to page 21).</li> </ol>			
	2. Select sound options in mobile app and adjust the Fullness slider (refer to page 29).			

lssue	Possible Remedies	
Too much background	<ol> <li>Select Restaurant or Outside program (refer to pages 26 and 27).</li> </ol>	
noise	2. Turn down the volume (refer to pages 24 and 25).	
	3. Select Sound Options in mobile app and select Noise Reduction (refer to page 28).	
	4. Select Sound Options in mobile app and deselect Whisper Boost (refer to page 28).	
Feedback or Whistling	Note: Your hearing aids may whistle or chirp at times when first powered on, when changing settings or if objects get near your ears. Your hearing aids are designed to adapt to changes over time to stop the whistle. If it persists, try the following:	
	<ol> <li>Ensure hearing aid is properly inserted. Remove and re-insert hearing aid (refer to pages 18 and 19).</li> </ol>	
	2. Ensure proper style and size eartip is in use. Try larger size or closed style eartip (refer to pages 20 and 21).	
	3. Select Sound Options in mobile app and drag the Brightness slider to the left (refer to page 29).	
	4. Turn down the volume (refer to pages 23	
	and 24). <b>38</b>	

Issue	Possible Remedies			
Feedback or Whistling Continued	5. Select Sound Options in mobile app and deselect Whisper Boost (refer to page 28).			
Too loud	<ol> <li>Turn down the volume (refer to pages 23 and 24).</li> </ol>			
	2. Try an open style eartip (refer to page 21).			
	3. Select a different program (refer to pages 26 and 27).			
	4. Select Sound Options in mobile app and select Noise Reduction (refer to page 28).			
	5. Select Sound Options in mobile app and deselect Whisper Boost (refer to page 28).			
Does not fit and/or stay	<ol> <li>Check that your hearing aid is properly inserted (refer to pages 18 and 19).</li> </ol>			
in ear	<ol> <li>Check that you are inserting the correct hearing aid in the correct ear (refer to page 17).</li> </ol>			
	3. Try a different size eartip (refer to page 20).			
	4. Try a different size cable (refer to page 22).			
Visible Wax	1. Clean your hearing aid (refer to page 30).			
Build Up	2. Review component replacement recommendations (refer to page 31).			

lssue	Possible Remedies			
Unable to hear your phone call	For mobile phone streaming:			
	1. Turn up your phone volume.			
	2. Mute the hearing aid not being used with the phone.			
	For landline or mobile phone speaker:			
	<ol> <li>Ensure your phone is not pressed against your ear too hard; this can block the microphones on your hearing aids and cause sound to be muffled.</li> </ol>			
	2. Try holding your phone speaker slightly above and to the front or back of the hearing aid to align the speaker with the hearing aid microphones. This helps align the speaker to your hearing aid microphones.			

Issue	Possible Remedies			
Weak sound	<ol> <li>Inspect the eartip and speaker opening for earwax or debris. Replace wax guard if found.</li> </ol>			
	2. Turn up the volume (refer to pages 23 and 24).			
	3. Select Sound Options in mobile app and select Whisper Boost (refer to page 28).			
	4. Select sound options in mobile app and drag the Brightness slider to the right (refer to page 29).			
	5. Select sound options in mobile app and drag the Fullness slider to the right (refer to page 29).			

# Mobile App Troubleshooting

lssue	Possible Remedies
One or both hearing aids don't connect (aka "pair") to your mobile phone	<ol> <li>Ensure your batteries are fresh and inserted correctly with the battery stickers removed.</li> </ol>
	2. With the app open, open and close the battery doors to the ON position (refer to page 15) to put your hearing aids in "pairing mode". Open and close the battery door(s) again if one or both hearing aids did not pair to your phone within 3 minutes.
	3. Be sure to select "Allow" or "Allow for this app" on all permission requests for the app to Find nearby devices, Access device location, etc. Uninstall and reinstall the app if you didn't "Allow" twice or no longer get the permission requests and did not successfully pair to your mobile phone.
	4. Be sure to select "Pair" each time when prompted, once for the left hearing aid and again for the right hearing aid.
	5. Turn the Bluetooth feature on your phone Off and back On and repeat 2 through 4.

Issue	Possible Remedies
One or both hearing aids don't connect (aka "pair") to your	<ol> <li>"Forget" (iOS) or "Unpair" (Android™) any currently paired hearing aids in your phone in Settings -&gt; Accessibility -&gt; Hearing Devices (iOS) or Hearing enhancements -&gt; Hearing aid support -&gt; Bluetooth hearing aids (Android) and repeat 2 through 4.</li> </ol>
mobile phone continued	<ol> <li>Delete any "Saved Bonds" in your hearing aids (refer to page 13) and repeat 2 through 4.</li> </ol>
One or both hearing aids don't connect to the mobile app	<ol> <li>Ensure your batteries are fresh and inserted correctly with the battery stickers removed. Note: very weak batteries will disconnect your hearing aids from your phone so you can't use the app but you will still hear sounds being amplified.</li> </ol>
	<ol> <li>Ensure both of your hearing aids are "paired" to your phone. The app helps you do this the first time you open the app and power on your hearing aids. You can also check status and pair your hearing aids with the phone OS in Settings -&gt; Accessibility -&gt; Hearing Devices (iOS) oR Hearing enhancements -&gt; Hearing aid support -&gt; Bluetooth hearing aids (Android).</li> </ol>

Issue	Possible Remedies		
One or both hearing aids don't connect to the mobile app continued	3. Turn the Bluetooth feature on your phone off and back on.		
	4. Open and close the battery doors to power the hearing aids off and on and put the hearing aids in "advertising mode".		
	5. Close and reopen the app.		
	6. Select the "Connect" button next to the hearing aid icons in the app if present.		
Can't find the NoviOne	1. Open Google Play store or the App Store on your phone and type "NoviOne" in the search bar.		
арр	2. Open or install the app once found.		
NoviOne	1. Close and reopen the app.		
app doesn't work on phone	2. Restart your phone.		
	3. Uninstall and reinstall the app on your phone.		
	4. Ensure your phone is compatible with the app.		

## Service and Warranty

Your hearing aids come with a 1-year limited warranty against manufacturing defects. Accessories (i.e. cables, eartips, wax guards, etc.) and cleaning are not covered. The warranty does not cover hearing aids that are damaged, misused, abused or physically altered (including unauthorized repairs). This also includes removal or tampering with the serial number label. The warranty is also void if any other brand cable or eartip are used on these hearing aids. Please only use NoviOne RIC Wireless parts.

# Hearing Aid Repair

Contact Novidan (678 Mendelssohn Ave. N, Golden Valley, MN 55427) for information on how and where to obtain repair service or extra eartips and cables. Feel free to call us to order additional parts, accessories and batteries.

# Available Replacement Components

We offer:

- Batteries
- Wax Guard Kits
- Wax Loop and Brush
- · RIC Cable Small (left and right)
- · RIC Cable Medium (left and right)
- · RIC Cable Large (left and right)
- · Open Eartips (small, medium and large)
- · Close Eartips (small, medium and large)

Visit www.novidaninc.com under the accessories tab to order replacement components.

Contact us at: (763) 285-6633 sales@novidaninc.com



# **Operating Conditions**

Your hearing aids can be operated in temperatures not exceeding 122°F and humidity not exceeding 95% rH. Your hearing aids are classified as IP57. It is not recommended to immerse your hearing aids in water. They are designed to withstand daily life (mild rain, perspiration). They are not intended to withstand liquids with chemical content such as detergents, chlorinated water, soap, hair spray, makeup, cosmetics or saltwater.

Avoid excessive vibration, mechanical shock, strong electromagnetic fields, and dropping your device on hard surfaces. Avoid exposure to excessive heat, fire, humidity or water. These conditions may damage your device and void the warranty.

Do not share or resell hearing aids.

This product contains magnetic material. Consult your physician on whether this might affect your implantable medical device.

It is recommended to use the product with a secure network.

It is recommended to follow secure mobile device practices.

# Conditions Causing Adverse Effect

Avoid excessive vibration, mechanical shock, and dropping your hearing aids on hard surfaces. Avoid exposure to excessive heat, fire, humidity or water. These conditions may damage your hearing aids and void the warranty.

# **Storage Conditions**

When storing your hearing aids for an extended period of time, remove the batteries, close the battery door and place them in the case. Your hearing aids should be kept between -13°F and 158°F with humidity not exceeding 90%rH. Prior to use after long term storage, be sure to let your hearing aids acclimate for 1 hour to an ambient temperature of 68°F.

### Features

Category	NoviOne RIC Wireless OTC Hearing Aids
Fixed or Level-Dependent Frequency Equalization	Have fixed frequency equalization that is adjusted via user controls.
Level-Dependent Gain/Compression	Have multi-channel, wide dynamic range compression to make soft sounds louder without making loud sounds too loud.
Noise Reduction	Have multi-band active noise reduction to make continuous noises (like fans, motors, road noise, etc.) less loud.
Signal-to-Noise Ratio Enhancement	Have directional microphones to emphasize sounds from in front, making conversations in noisy places easier.
Feedback Control	Have an adaptive feedback canceller to reduce feedback (whistling).

Category	NoviOne RIC Wireless OTC Hearing Aids
Personalization	Are customized by the user for selectable acoustic environments (Programs) from the app or hearing aid rocker switch. User's hearing thresholds are not required to personalize the settings.
Coupling to the Ear	Have soft, user-selectable, open and closed eartips to adjust for fit and sound quality.
Wireless Connectivity	Use Bluetooth technology to connect and control the hearing aids from a paired smart device.

Features per ANSI/CTA-2051:2017.

# **Technical Data**

Specification	Value	Units
Maximum Acoustic Output	112	dBSPL
Full On Gain	40	dB
Total Harmonic Distortion + Noise	2.5	%
Self-generated Noise	26	dBA
Latency	5.5	ms
Frequency Response Bandwidth	100-7000	Hz
Estimated Battery Life	4-5	Days

All measurements per ANSI/CTA-2051:2017. Actual battery life varies with user's volume setting, hours of use and streaming per day, and battery quality.

# Wireless Information

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 equipment 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/TV technician for help.

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 complies with FCC non-ionizing radiation exposure limits set forth for the general population. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

FCC Model: Kamen Wireless FCC ID: 2AXQ3G1P1

Radio Technology: Bluetooth Low Energy (BLE) and proprietary technologies.

Radio Transceiver Frequency Range: 2.4 to 2.4835 GHz

Radio Receiver Bandwidth: 2 MHz

Modulation Type: 1 Mb/s and 2 Mb/s GFSK

Peak Effective Isotropic Radiated Power: 0 dBm

This equipment has been tested and found to comply with the limits per CISPR 11 class B.

#### Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The hearing aid is intended for use in the electromagnetic environment specified below. The user of the hearing aid should assure that it is used in such an environment.

Emissions Test	IEC60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	Group 1	The hearing aid is suitable for use in all establishments, including domestic establishment and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.

Emissions Test	IEC60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
RF emissions CISPR 11	Class B	Class B	The hearing aid uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

#### Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The hearing aid is intended for use in the electromagnetic environment specified below. The user of the hearing aid should assure that it is used in such an environment.

Immunity	IEC60601 Test	Compliance
Test	Level	Level
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 kV air
Radiated RF	10 V/m	10 V/m
EM Fields	80 MHz – 2.7 GHz	80 MHz – 2.7 GHz
IEC 61000-4-3	80% AM at 1 kHz	80% AM at 1 kHz

Immunity	IEC60601 Test	Compliance
Test	Level	Level
Proximity fields from RF wireless communications equipment IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	9 V/m; 710, 745, 780 MHz; Pulse modulation 18 Hz 9 V/m; 5240, 5500, 5785 MHz; Pulse modulation 217 Hz 27 V/m; 385 MHz; Pulse modulation 18Hz 28 V/m; 450 MHz FM +/- 5 kHz deviation; 1 kHz sine 28 V/m; 810, 870, 930 MHz; Pulse modulation 18 Hz 28 V/m; 1720, 1845, 1970, 2450 MHz; Pulse modulation 217 Hz

# 5 Safety, Regulatory and Legal Information

# Keep Out Reach of Children and Pets

Keep and store hearing aids, batteries, and accessories out of the reach of children and pets. These hearing aids is not intended to be used for children under the age of 18 years old. These small parts may be a choking hazard. Battery ingestion can cause serious harm.

# ▲ Warnings and Cautions

Consult a physician if any irritation, discomfort, accelerated accumulation of cerumen or other side effects result from using your hearing aids.

Hearing aids will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. In most cases, infrequent use of a hearing aid does not permit a user to attain full benefit from it. The use of a hearing aid is only part of hearing rehabilitation and may need to be supplemented by auditory training and instruction in lipreading.

These hearing aids should be not used as a sole safety measure where lack or inability to hear may result in serious injury or death. WARNING: Avoid use of this hearing aid adjacent to other equipment, other than as instructed in this user manual, because it could result in improper operation. If such use is necessary, observe the hearing aids and the other equipment to verify that they are operating normally.

**WARNING:** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this hearing aid could result in increased electromagnetic emissions or decreased electromagnetic immunity of this hearing aid and result in improper operation.

WARNING: Do not use accessories, detachable parts or materials not described in the user manual. If unauthorized components are used, it could result in the improper function of the device.

WARNING: Keep small parts and batteries out of children's reach. Small parts may be a choking hazard. Ingestion of batteries can cause bodily harm.

**CAUTION:** Check first before using the hearing aid systems in areas where electronics or wireless devices are restricted.

**CAUTION:** Do not use the device if the device or package is damaged.

**CAUTION:** It can be unsafe to interconnect the hearing aid with other equipment not described in the user manual.

**CAUTION:** The specific hearing aid shall only be used by the intended person and not by others.

**CAUTION:** Do not to use the hearing aid in explosive or oxygen-enriched atmospheres.

**CAUTION:** Only connect hearing aid to equipment that conforms to relevant international safety standards.

**CAUTION:** No modification of this equipment is allowed.

**CAUTION:** In the event of a battery leak, do not allow the liquid to make contact with skin or eyes; if contact is made, seek medical attention.

#### Intended Use

The NoviOne RIC Wireless OTC Hearing Aids are a wireless air conduction hearing aid intended for use and customization by individuals 18 years and older with perceived mild to moderate hearing impairment.

# Indications for Use

The NoviOne RIC Wireless OTC Hearing Aids are intended to amplify sound for individuals 18 years of age or older with perceived mild to moderate hearing impairment. It is customized by the user to meet the user's hearing preferences. No pre-programming or hearing test is necessary. The device is intended for over-the-counter sale and use without the assistance of a hearing care professional.

# Validation Data

In a user validation study, the majority of the participants reported that the technology contained in the NoviOne RIC hearing aids is easy to use, improved their ability to hear in noisy environments, sound quality is clear and it is comfortable to wear all day.

# Legal

The Bluetooth<sup>®</sup> word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Starkey Laboratories, Inc. is under license. Other trademarks and trade names are those of their respective owners.

Google Play and the Google Play logo are trademarks of Google LLC.

Apple and iPhone are registered trademarks of Apple Inc., registered in the U.S. and other countries. App Store is a service mark of Apple Inc.

NoviOne and NoviOne logo are trademarks of Novidan, Inc. NoviOne RIC Wireless is a trademark of Novidan, Inc.

Please read and retain all user instructions and safety information.

# Symbols and Descriptions



\land Warning

# Important Information from the FDA

#### Warning to Hearing Aid Dispensers

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines 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:

(i) Visible congenital or traumatic deformity of the ear.

(ii) History of active drainage from the ear within the previous 90 days.

(iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.

(iv) Acute or chronic dizziness.

(v) Unilateral hearing loss of sudden or recent onset within the previous 90 days.

(vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.

(vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.

(viii) Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).)

# Important Notice for Prospective Hearing Aid Users

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of 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 a 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.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

# Children with Hearing Loss

In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.



#### NoviOne RIC Wireless OTC Hearing Aids

**Contact us at:** (763) 285-6633

sales@novidaninc.com www.novidaninc.com

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