

# ORKA

Orka One User Guide

**Welcome**

Thank you for choosing Orka One hearing aids to be your listening buddy and accompany you in your daily life. Please kindly read the user guide to ensure that you understand the device functionality in detail and get the best out of your hearing aids.

For more information on features and benefits, please contact your hearing care professional, or visit our official website:

**<https://www.hiorka.com/>** for US users or

**<https://www.hiorka.ca/>** for CA users.

We wish you many years of listening pleasure.

# Contents

<b>List of Accessories</b> .....	<b>10</b>	<b>Caring for Your Device</b> .....	<b>36</b>
<b>Your Hearing Aids</b> .....	<b>12</b>	Care and maintenance	
Instrument type		Exchanging the accessories	
Intended use		<b>Troubleshooting</b> .....	<b>43</b>
Components and names		<b>Taking Your First Orka Step</b> .....	<b>47</b>
<b>Using the Hearing Aids</b> .....	<b>16</b>	<b>Contraindications &amp; Safety Information</b> .....	<b>55</b>
Left and right hearing aid markings		<b>Appendix</b> .....	<b>59</b>
Putting on the hearing aids		Product specifications	
Removing the hearing aids		Performance parameters	
Turning on/off		Power supply specifications	
Charging the hearing aids		Compliance information	
Sound indications		Wireless radio transmission	
Charging the charging case		Operating, transport, and storage conditions	
Reset button		Possible side effects	
<b>App &amp; Bluetooth</b> .....	<b>28</b>	Privacy policy	
Downloading the Orka Health app		Information of symbols	
Signing into the app		Classification description	
Pairing to a Bluetooth enabled device		Regulations	
Phone calls		Important notices	
Navigating the app		Service and warranty	
		Disposals	

**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 ear wax 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 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 farther into your ear, injuring your eardrum or ear canal, possibly seriously.

**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.

**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.

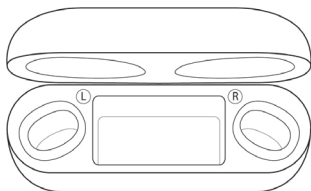
A person who is younger than 18 years old with hearing loss should have a medical evaluation by a doctor, preferably an ENT, before buying a hearing aid. The purpose of a medical evaluation is to identify and treat medical conditions that may affect hearing but that a hearing aid won't treat on its own.

Following the medical evaluation and if 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.

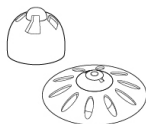


The audiologist will conduct a hearing aid evaluation to assess the person's ability to hear with and without a hearing aid. This will enable the audiologist to select and fit a hearing aid for the person's individual needs. An audiologist can also provide evaluation and rehabilitation since, for people 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.

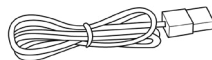
# List of Accessories



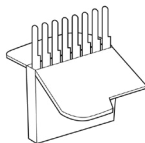
Charging case (1)



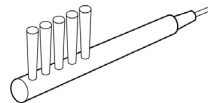
Domes (2 types\*):  
sizes 1, 2\*, and 3



Charging cable (1m\*1)

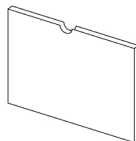


Wax guard (8)

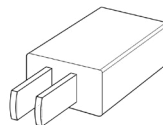


Brush (1)

\*2 types: closed and open domes;  
size 2 closed domes are attached to  
the hearing aids.



User guide (1)



USB-A power adapter (1)



Always keep small swallowable parts (hearing aids, domes, and other removable parts) out of reach of children.

# **Your Hearing Aids**

## **Instrument type**

Your hearing aid is a RIC (Receiver-in-Canal) model. The receiver is placed within the ear canal and connected to the instrument via a receiver tube. Each hearing aid has a built-in lithium-ion battery which is rechargeable and non-removable.

## **Intended use**

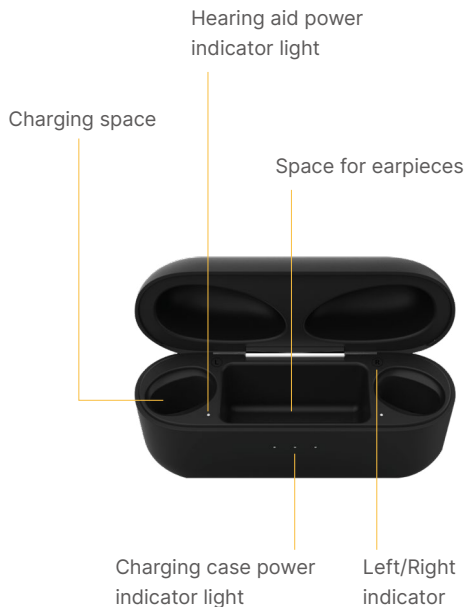
Help people with air conduction hearing impairment compensate for hearing loss.

# Components and names

## Hearing aid



## Charging case

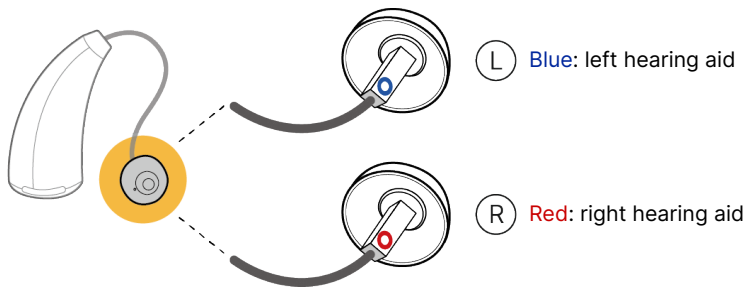


# Using the Hearing Aids

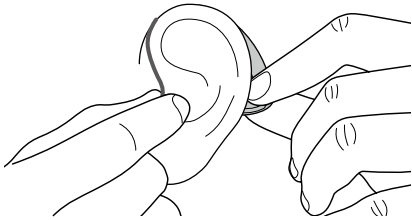


## Left and right hearing aid markings

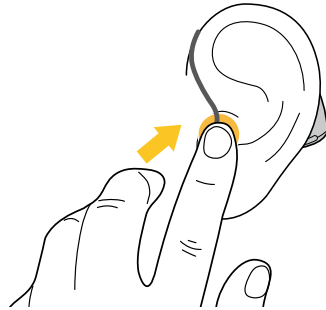
There is a red or blue marking on the receiver. The colors indicate if it's a left or a right hearing aid:



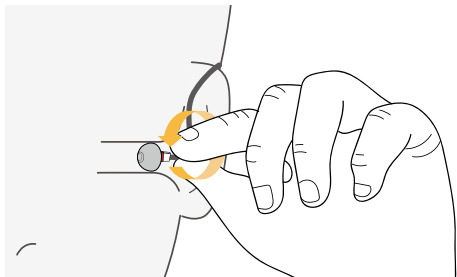
# Putting on the hearing aids



Place the hearing aid behind your ear.



- Hold the receiver tube at the bend closer to the earpiece.
- Insert the earpiece into your ear canal.

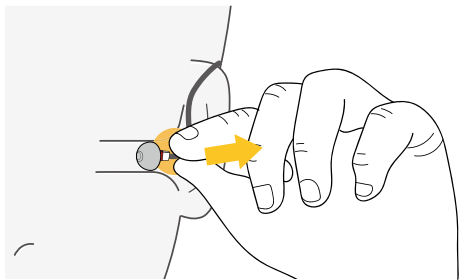


Twist it slightly until it sits well.

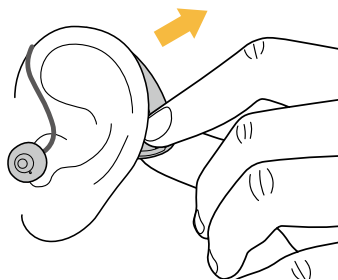


Insert the earpiece carefully and not too deep into the ear. It is recommended to always clean the ear canal before putting on the hearing aids.

## Removing the hearing aids



- Hold the receiver tube.
- Take the earpiece carefully out of the ear canal.

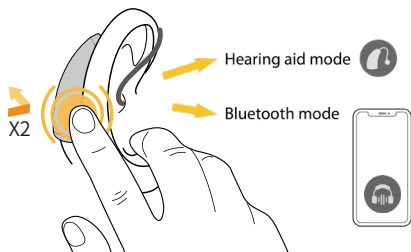


Remove the hearing aid from behind the ear.



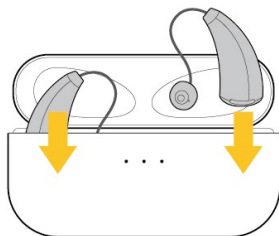
In some extremely rare cases, the earpiece could remain in your ear canal when removing the hearing aid. If this happens, have the earpiece removed by a medical professional.

## Turning on/off



**Turning on:** Take the hearing aids out of the charging case, the hearing aids will turn on, and the hearing aid mode will be selected automatically.

**Switching mode:** Double tap on the back to switch between hearing aid and Bluetooth mode.

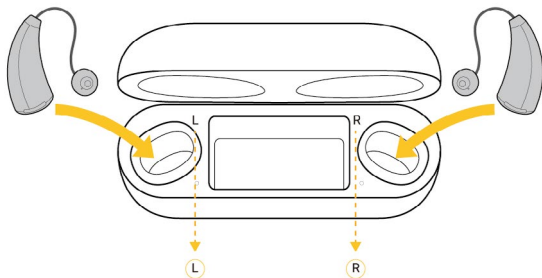


**Turning off:** Place the hearing aids in the charging case, close the charging case, and the hearing aids will be automatically turned off.

## Charging the hearing aids



- You will hear three tones with voice notification "low battery" when the battery is low. This means that the hearing aids need to be charged as soon as possible.
- Each hearing aid has a built-in lithium-ion battery which is rechargeable and non-removable.
- Do not hold the RIC tubes to remove the hearing aids from the charging case. This can damage the tubes.



**Please refer to the following instructions to charge your hearing aids:**

- The two LED lights near the left and right charging spaces display the power of the two hearing aids respectively. Insert the left and right hearing aids into the corresponding left and right charging spaces. The hearing aid power indicator will light up for a few seconds.
- Close the charging case when charging your hearing aids. It takes about 1.5 hours to fully charge the hearing aids.

- Open the charging case, the hearing aid power indicator lights will light up for a few seconds, and the color of the indicator lights will show the charging status of the hearing aids:

Hearing aid power indicator light	Charging state
Orange	Charging
Green	Fully charged

## Sound indications

Voice reminders are presented in ***bold italic*** format.

Status Indicators	Sound
Start-up	Beginning music
Bluetooth Connected	2 tones followed by <b><i>Bluetooth connected</i></b>
Bluetooth Disconnected	2 tones followed by <b><i>Bluetooth disconnected</i></b>
Double Tap without Bluetooth connected	2 tones followed by <b><i>Bluetooth disconnected</i></b>
Enhanced mode	4 taps
Automatic mode	2 tones



Warning Indicators	Sound
Low battery	3 tones followed by <b>low battery</b>
Power off	3 tones with <b>low battery</b> followed by 4 tones
Device locked	2 tones

## Charging the charging case

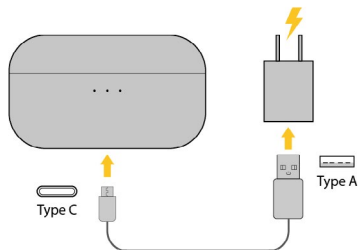
Three continuous LED lights on the outside of the charging case display the power of the charging case. When you open the charging case, the charging case power indicator light will light up for a few seconds; when the charging case is closed, the indicator light will go out. When the charging case battery is low, the left indicator light will flash.

Charging case power indicator light	Charging state
1 or 2 LED lighted up	Charging
3 LED lighted up	Fully charged



The hearing aids must be dry before charging. See the chapter "Safety Information."

## Connecting to the power supply



- Plug the USB-A end of the charging cable into the power adapter.
- Plug the USB-C end of the charging cable into the USB-C connection on the charging case.
- Plug the power adapter into a power outlet.
- The charging case power indicator light will light up throughout the charging process.
- The number of indicator lights that are on indicates the battery level. When all 3 lights are on, the device is fully charged.

## **Reset button**

The button behind the charging case is the reset button. It is used to restore the hearing aid to factory settings. Do not use the reset button unless there is a special reason. Even then, please ensure that you use it under the guidance of a hearing care professional.

# App & Bluetooth

# Downloading the Orka Health app

## To download the Orka Health app from App Store



- Open the App Store on your iPhone.
- Enter Orka Health in the search bar and select the app.
- Tap **Get** to download the app for free.
- Tap **Install**.
- Enter your Apple ID password when prompted to complete the installation.



## To download the Orka Health app from Google Play

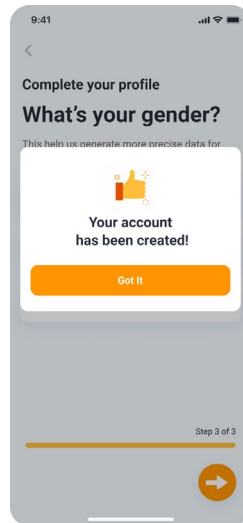
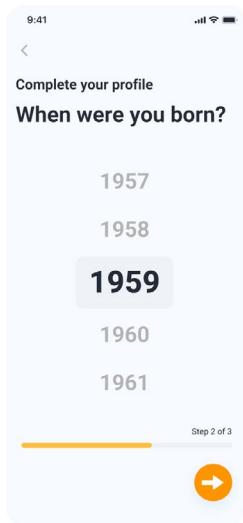
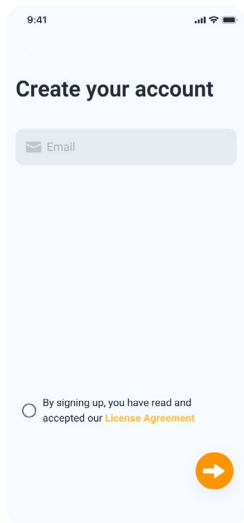


- Open the Google Play Store on your Android device.
- Enter Orka Health in the search bar and select the app.
- Tap **Install** to download the app for free.
- Tap **Accept**, and follow the on-screen instructions to complete the download.



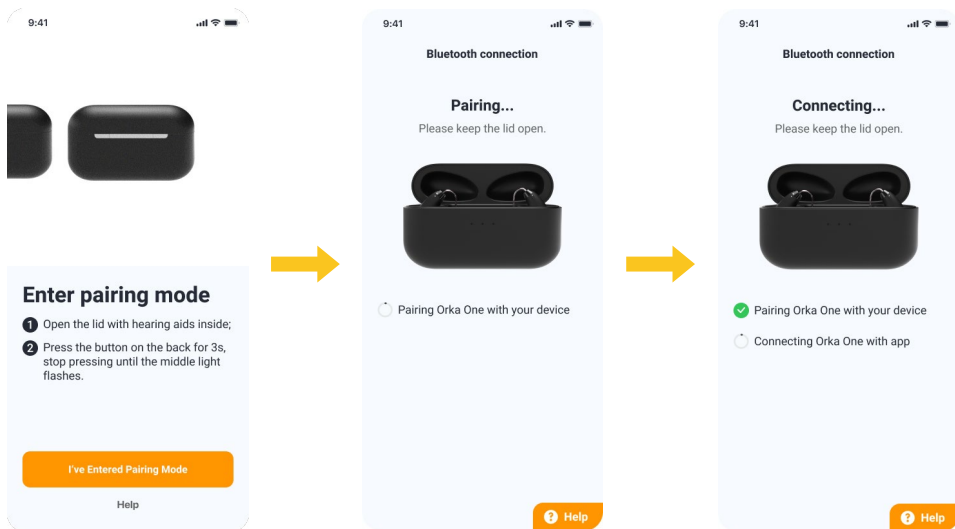
## Signing into the app

- Open Orka Health App. If you have an existing account, sign in and you will be directed to connect your device with Orka One. Otherwise, follow the steps below to sign up.
- You must create an account and log in to use certain features. To create your Orka One new account, tap **Create Account**.
- Enter your email address to begin the sign-up process. Once you are done, tap the **Next** button and open your Mail app to verify your email address.
- Once you have verified your email address, we will need your basic info to ensure that you have the best experience when using our product and services. Select birth year and click **Next** button.
- Proceed to select gender and click **Next** button to complete the account registration process.
- After creating your account, you will be directed to connect your device with Orka One. You are now ready to experience the full functionalities of the Orka Health App.



# Pairing to a new Bluetooth enabled device

Please follow the instructions in the app to complete the Bluetooth connection.



If you encounter any issues, please contact us via [support@hiorka.com](mailto:support@hiorka.com).



# Phone calls

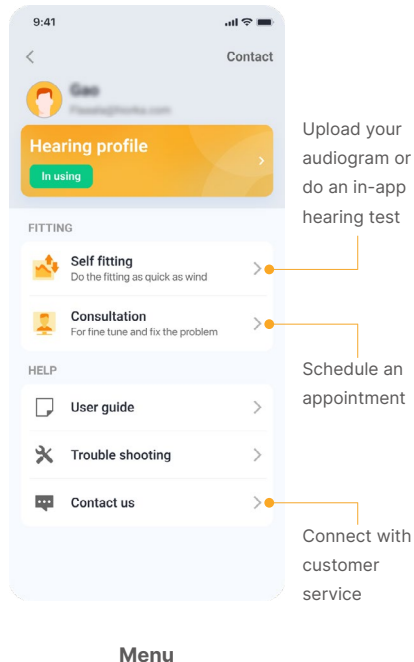
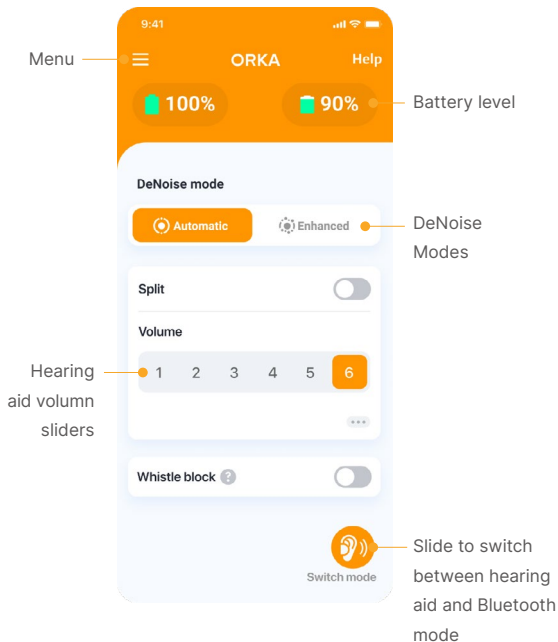
When pairing and connecting the hearing aids to your phone, whether in hearing aid mode or Bluetooth mode, you can answer calls from Bluetooth devices through your hearing aids.

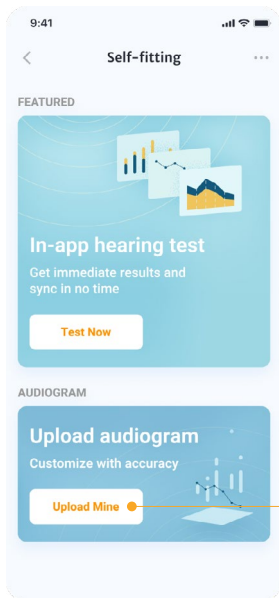
- Accept the call by tapping either of the hearing aids twice or directly via your phone.
- You can end the call directly on your phone.



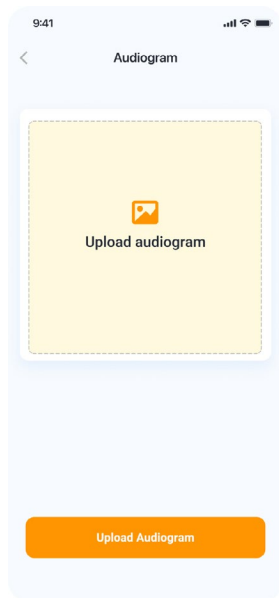
It is recommended that you use your hearing aids to answer phone calls through Bluetooth connection. If you receive a call directly through your phone, please lower the phone volume and keep a distance from the hearing aids to prevent the excessive volume from damaging your hearing.

# Navigating the app





**Self-fitting**



**Audiogram Upload**

# Caring for Your Device

# Care and maintenance

Routinely caring for your hearing aids and charging case contributes to enhancing your using experience and outstanding device performance. Please refer to the following specifications when cleaning, drying, and storing your Orka One hearing aids. For further information regarding product safety, see the chapter "Safety Information".

## Cleaning

- Wipe the hearing aids daily with a soft and dry tissue. Clean the hearing aid body with the brush. Make sure the microphone is not missed.
- Check the receiver and earpiece for earwax or moisture. Clean the earpiece right after removal with a soft and dry tissue. This prevents earwax from becoming dry and hard.
- Consult your hearing care professional about recommended cleaning products, unique care sets, or more information on maintaining your hearing aids in good condition.



- Before using hair spray or applying cosmetics, please remove the hearing aids first.
- Never use soap or household detergent to clean the hearing aids.
- Never use any kind of liquid to clean your hearing aids.
- Never apply excessive pressure while cleaning.

## Drying

Use conventional products to dry your hearing instruments. Consult your hearing care professional about recommended drying products and specific instructions on drying your hearing aids using the recommended tools.



- After exposing the hearing aids to dust or sweat, clean and dry them immediately.
- Remove the hearing aids when bathing or swimming, and never immerse the hearing aids in water.
- Always make sure that the hearing aids and charging case are completely dry before charging.
- Always make sure that the charging case is disconnected from power before cleaning.

## Storage

Turn off your hearing aids by placing them in the charging case and closing the case.

You can get more information on the storage conditions in the section “Operating, transport and storage conditions.”



When not in use for a long time, place the hearing aid in the charging case and keep the case fully charged at least once every 6 months.

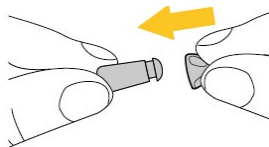
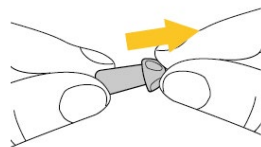
# Exchanging the accessories

Check out more tutorials at:

<https://www.hiorka.ca/HowToVideo> for CA customers, or  
<https://www.hiorka.com/HowToVideo> for US customers.

## Exchanging domes

- Hold the receiver with one hand and the dome with the other.
- Gently pull off the dome to remove.
- Clean the receiver with a soft cloth.
  
- Hold the receiver with one hand and the dome with the other.
- Slide the dome over the receiver outlet.
- The receiver and the dome should fit perfectly together.

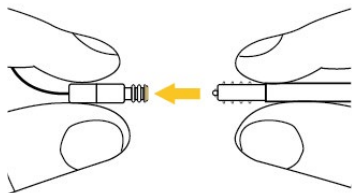


Domes may accelerate the accumulation of ear wax.

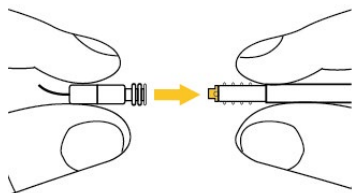
Please only use accessories provided or suggested by Orka service team.

## Exchanging the earwax guard

Each of your hearing aids is equipped with a wax guard to protect the receiver from earwax damage. Please check the wax guard regularly and exchange it if being dirty or if sound quality deteriorates. The wax guard should be replaced each month.

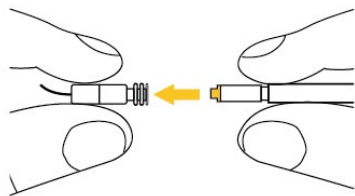


- Remove the dome.
- Insert the replacement tool's removal hook into the old wax guard.

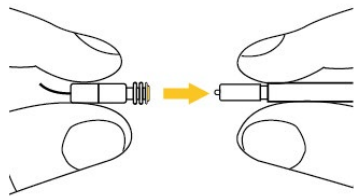


Carefully pull and remove the earwax guard straight out of the speaker.





Insert the new wax guard on the other side of the tool into the top of the receiver.



Press down the wax guard firmly, take out the replacement tool, and the wax guard is successfully replaced.

## How to seek replacements

For more information about accessories, please visit our website:

**<https://www.hiorca.ca/Product/Accessories/Showcase>** for CA customers,  
or **<https://www.hiorca.com/Product/Accessories/Showcase>** for US customers.

# Troubleshooting

For more information, please visit the website:

<https://www.hiorka.ca/TroubleShooting> for CA customers, or

<https://www.hiorka.com/TroubleShooting> for US customers.

<b>Problem</b>	<b>Solution(s)</b>
Hearing aids no sound	<ol style="list-style-type: none"><li>1. Check the remaining power of the hearing aid</li><li>2. Check the volume control in the app</li><li>3. Check the microphone hole, domes, wax guards, and ear canal are free of earwax</li><li>4. Make sure that your hearing aids are in "hearing aid" mode</li><li>5. Restart your hearing aids</li><li>6. Do the hearing test again</li></ol>
Hearing aids whistle	<ol style="list-style-type: none"><li>1. Place the earpiece correctly in your ear canal</li><li>2. Choose a suitable dome (try different types and sizes)</li><li>3. Check the volume control in the app</li><li>4. Check the microphone hole, domes, wax guards, and ear canal are free of earwax</li><li>5. Keep your ear canal clean and free from earwax</li></ol>

<b>Problem</b>	<b>Solution(s)</b>
Hearing aids too loud	<ol style="list-style-type: none"> <li>1. Check the volume control in the app</li> <li>2. Do the hearing test again</li> </ol>
Hearing aids not loud enough or distorted	<ol style="list-style-type: none"> <li>1. Check the volume control in the app</li> <li>2. Choose a suitable dome (try different types and sizes)</li> <li>3. Place the earpiece correctly in your ear canal</li> <li>4. Check the microphone hole, domes, wax guards, and ear canal are free of earwax</li> <li>5. Keep your ear canal clean and free from earwax</li> <li>6. Do the hearing test again</li> </ol>
Hearing aids can't be charged	<p>It takes 1.5 hours to fully charge the hearing aids and 5 minutes to use it for half an hour. Please let us know if it takes more than 2 hours to fully charge the hearing aids.</p> <p>The hearing aid case can fully charge the hearing aids three times.</p> <p>(If there is just one aid that cannot be charged) Put the aid in the slot for another aid in the charging case to check whether it can be charged.</p>
Charging case can't be charged	<p>The charging case takes about 2 hours to be fully charged. Please let us know if it takes more than 3 hours to fully charge the hearing aids.</p>

<b>Problem</b>	<b>Solution(s)</b>
Double tap does not work	<ol style="list-style-type: none"><li>1. Please make sure hearing aids have been charged</li><li>2. Restart your hearing aids</li><li>3. Re-pair the Bluetooth</li></ol>
Can't connect with paired devices	<ol style="list-style-type: none"><li>1. Restart your hearing aids</li><li>2. Reconnect the device Bluetooth</li><li>3. Re-pair the Bluetooth</li><li>4. Reset your hearing aids</li></ol>
Firmware upgrades not successful	<ol style="list-style-type: none"><li>1. Check if cellular data/WiFi is turned on</li><li>2. Restart the hearing aids</li><li>3. Restart the Orka Health app</li></ol>

# Taking Your First Orka Step

## The beginning of a new hearing journey

Yes! It's finally happening! That's the first thought that pops up in every user's mind when they get their hands on the brand new AI DeNoise hearing aids. Well, outstanding hearing aids may completely change your world. Everything automatically sounds better. Once the hearing sensation improves, the environment around you sounds vibrant, fun, and lively.

All these feelings can be overwhelming. Hearing so many sounds clearly after a while may be too much to comprehend.

But it's okay. Even though it might take a while to adapt to your new set of hearing aids fully, you'll finally get the hang of it. After you fully adjust to your hearing aids, you'll never go a day without your hearing buddies!



## What to expect in the first few weeks

The first days are always the hardest. As you get started with your Orka One hearing aids, you'll notice some changes in the sounds received in your ears. That's why we thought it would be best to let you know what to expect.

Before using hearing aids, you may be hearing muffles or not able to distinctively pick up sounds, depending on the severity of your hearing loss. First, there are a lot of adjustments your brain and ears need to get accustomed to.

If you were not using hearing aids before, this means your ears weren't used to continually holding a device. Therefore, at first, it might be uncomfortable. We recommend a remote fitting appointment with a hearing care professional at Orka via the Orka app or through our official website at **[www.hiorka.ca](http://www.hiorka.ca)** for CA customers, or **[www.hiorka.com](http://www.hiorka.com)** for US customers.

The brain also has to start processing sound sensations and auditory stimuli. Remember, this is something that your brain has to learn doing once again, especially if it's been a while since you heard a range of sound.

## Why is it so loud?

It's okay...it will get loud. Your hearing aids are bound to pick up sounds which you may have never heard before distinctively. Let's say, even though the sound of crunching crisps is not a new thing, it may sound louder. That's why we always advise our users to keep the volume low when wearing your hearing aids for the first time.

As mentioned earlier, your brain will take some time before it gets adjusted to the new high-fidelity sounds. The adjustments won't happen overnight. It might take days or weeks, but eventually, you'll be well adjusted. Just be patient and trust the process.

For the first two to four weeks, you'll be hearing a lot of unfamiliar sounds. Your voice may sound a little different. This is known as the occlusion effect.

During the familiarization phase, you can start by using your hearing aids indoors, for instance, watching TV, listening to the music as you learn how to increase or reduce the hearing aids volume to suit your needs. You may also opt to wear the hearing aids only for a while. As time goes by, start increasing the length of time you use your hearing aids. Before you know it, you'll be comfortable and regularly using hearing aids.

Therefore, before you fully get accustomed to your new life, kindly keep the volume low. Remember, the sound coming in should sound clear, not loud.

## Learning your device inside out

When your Orka hearing aids arrive, there will be the actual device and accessories. Accessories include the charging case, charging cable, wax guard, power adapter, etc. Everything in the package serves unique purposes. This is where the concept of learning your hearing aid comes into play.

You have to learn how to correctly insert and remove the hearing aids, maintain and clean it to keep the device in excellent condition for long. There are several dos and don'ts. Therefore, please make sure to read the user guide thoroughly before using the device. We understand that a product manual is often dull, detailed, and the excitement of trying on your new device may thin your reading patience even further. But, kindly find the time, before using the device, to familiarize yourself with the user guide.

You can also seek an audiologist to help guide you on using and adjusting your hearing aid settings. Remember, if you have any inquiries or need clarification on your hearing aids, always seek professional help from the Orka support team or an audiologist near you.

## Conversations are about to get better

Say goodbye to the hassle of holding and maintaining conversations in noisy places. Once you start adjusting to the new sounds from your environments and getting accustomed to the Orka hearing aids, your ability to understand speech will significantly improve.

The best part is, your speech understanding will only get better over time. Since the device amplifies human voices in real-life, you'll be able to understand your friends and family even outside!

Understanding conversations better doesn't happen immediately, you just need to get adapted to your hearing aids step by step. It is essential to be very patient and continuously practice using your hearing aids. If your family and friends encouraged you to get hearing aids or are supportive, ask them to help you. Tell them to hold more conversations around you and talk slowly. Be honest and open with them. If they are talking too loud or too fast, let them know.

## The final step

After learning how to clean, maintain, and get fully adjusted to using your hearing aids in the house where it's less noisy, try wearing it in places with many background noises like restaurants. Use the settings to filter out the background noises to see if you can hold a conversation with the person right in front of you without getting distractions.

We call this the final step because once you successfully pass this stage, you're able to use your hearing aids anywhere, anytime conveniently. And we believe it is the ultimate end goal!

## Main takeaways

Remember:

- It takes training, patience, and time to adjust to your hearing aids fully.
- Carefully and thoroughly read the user guide before using your hearing aids.
- Keep the volume low when using the hearing aids for the first time.
- Cleaning and properly maintaining your hearing aids will make them last longer.
- Practice often with your family, friends, or the people around you.
- When training your hearing, start using hearing aids for a short time and increase the time length as you progress.
- The world will be loud for the first couple of hours.

If you experience any problems adjusting to your hearing aids, get in touch with our audiologists or Orka support team, and we will gladly help you out.

# **Contraindications & Safety Information**

## Contraindications

- Patients with acute otitis externa, tympanitis, chronic suppurative otitis media (in the period of runny infection), and acute suppurative otitis media.
- Patients who are allergic to the material of this product.

## Safety Information

⚠ To avoid possible personal injury or property damage caused by electric shock, high temperature, fire, radiation, explosion, mechanical hazards, and improper use, please read and observe the following items before using this product:

- These hearing aids are customized according to a personal audiogram and can only be used by the person who owns it. If they are lent to another person, he/she may be at risk of getting hearing damage.
- This product and accessories should be placed indoor in a dry and ventilated place. Do not store your hearing aids in a humid or dusty environment for a long time.
- Do not cover the whole charging case while charging, for example, with a cloth, etc.
- Keep the product out of reach of children, individuals with cognitive impairment, and pets. The hearing aids are small devices with tiny parts. If any part of the device is accidentally swallowed by anybody, please consult a physician or a hospital immediately as the hearing aids can be choking hazards!
- Do not use the hearing aids and charging accessories in explosive areas (mines or industrial areas with danger of explosions, oxygen-rich environments or areas where flammable anesthetics are handled) or places where electronic equipment is prohibited.



- The hearing aids and charging case both contain lithium-ion batteries that can be taken onto airplanes as carry-on luggage but cannot be placed in the checked-in baggage.
- Please use a clean and dry soft cloth to wipe the product.
- If there are any uncomfortable symptoms such as inflammation, skin allergies, and accelerated earwax accumulation behind your ears, please consult your hearing care professional or professional physician.
- In very rare cases, the dome can remain in your ear canal when removing the hearing tube from the ear. If it happens, it is strongly recommended to see a physician for safe removal. To avoid pushing the dome towards the eardrum, never re-insert the speaker into the ear canal.
- Keep the wireless hearing aids at least 15 cm (6 inches) away from the active implant. If you experience any interferences, do not use the wireless hearing aids and contact the active implant manufacturer. Please note that interferences can also be caused by power lines, electrostatic discharge, and airport metal detectors, etc.
- When going for special medical activities, including X-ray, CT scan, MRI/NMRI scan, etc, please remove the hearing aids in advance and place it outside the medical room. Electromagnetic radiation may affect the normal function of the hearing aids.
- They should be shipped per all the rules and regulations on the safe shipment of lithium-ion batteries.
- Carefully and thoroughly read the user guide before using your hearing aids.
- Keep the volume low when using the hearing aids for the first time.
- The hearing aids have to be dry before charging. If not, the charging reliability cannot be guaranteed.

- Do not immerse the product in water. Remove your hearing aids before showering, swimming, or using a hairdryer.
- Do not wear your hearing aids when applying perfume, spray, gels, lotion, or cream.
- Never wash the microphone inlet. Doing so could cause the hearing aids to lose its special acoustic features.
- Protect your hearing aids and charging accessories from heat. Never use a microwave or other heating devices to dry your hearing aids or charging accessories due to the risk of fire or explosion.
- Do not place the charging accessories close to an induction cooking surface. Conductive structures inside the charging accessories could absorb inductive energy resulting in thermal destruction.
- Mind not to drop your hearing aids and your charging case! Falling onto a hard surface can damage your hearing aids or charging case.
- Store your hearing aids in the charger if you are not using it for an extended period.
- Only use the approved power adapter and charging cable described in this user guide for charging your hearing aids. Otherwise, the devices may be damaged.
- The USB-C port of the charging case is to be used for the described purpose only.
- Your hearing aids and charging case both contain lithium-ion batteries with a Watt-hour rating < 3Wh, which have been tested according to IEC62133 and UL1642.

# Appendix

## Product specifications

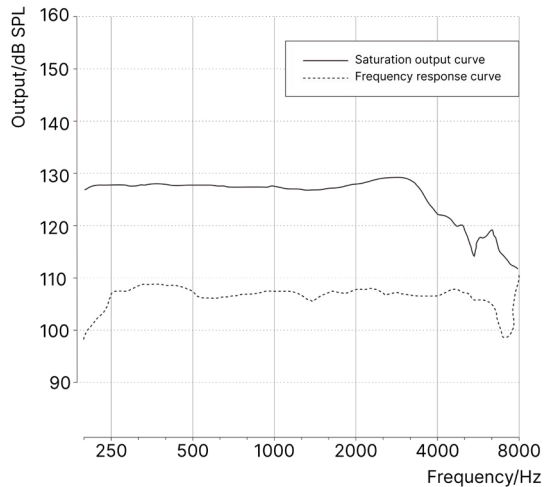
Product model	Orka One
Bluetooth	Bluetooth 5.0
Battery specification	Lithium-ion rechargeable battery
Size	Hearing aid: 30*30*9.6mm Charging case: 95*30*56mm
Weight	Hearing aid: 4.60g Charging case: 75.50g
Charging time	Hearing aid: 1.5h Charging case: 2h
Standby time	Hearing aid mode: 11h Bluetooth mode: 10h
Radio Frequency (RF) range	2.4GHz - 2.48GHz

# Performance parameters

Product model

Orka One

Saturation output curve  
Frequency response curve



Output saturation  
(90 dB SPL input)

Max: 130dB@2800Hz  
HFA: 128dB

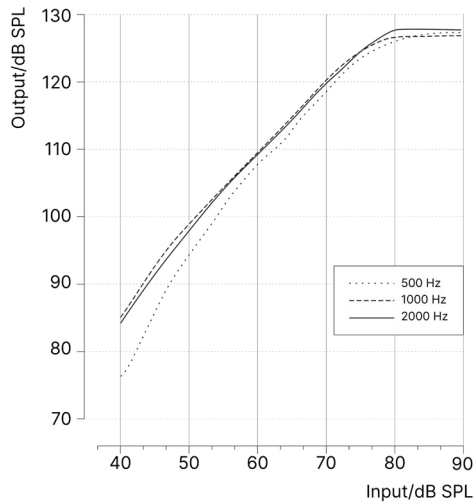
---

Full-on gain	HFA: 48dB
Reference test gain	48dB
Frequency range	<200-8000Hz
Total harmonic distortion	2%: 500Hz 70dB 1%: 800Hz 70dB 1%: 1600Hz 65dB
Equivalent input noise (Noise reduction disabled)	18dB
Latency	11ms

---

---

Input-output curve



---

Attack time

150ms

Release time

300ms

---

## Power supply specifications

---

**Power adapter input voltage** 100-240V 50/60Hz 0.2A

---

**Power adapter output voltage** 5V/1A

---

**Charging case input voltage** 5V/1A

---

**USB cable specifications** USB 2.0 Type-C 3A, Length 1m

---



# Compliance information

## Declaration of conformity

Orka hereby declares that this Orka One product meets the requirements of the Medical Devices Directive 93/42/EEC as well as the Radio and Telecommunications Terminal Equipment Directive 1999/5/EC. The full text of the Declaration of Conformity can be obtained from the manufacturer.

Certification information for hearing instruments with wireless functionality:

Product model: Orka One

FCC ID: 2AXYS-HR01

## Notice 1

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.
- 2) This device must accept any interferences received, including interference that may cause undesired operation.

## Notice 2

Changes or modifications made to this device that are not directly approved by Orka may void the FCC authorization to operate this device.

## Notice 3

This equipment has been tested and found to comply with a Class B digital device's limits, and pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interferences in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used per the instructions, may cause harmful interferences to radio communications. However, there is no guarantee that interferences will not occur in a particular installation. If this equipment does cause harmful interferences to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct interferences using one or all 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.

# Wireless radio transmission

The following tables summarize the technical details of the wireless technology:

## Wireless functions and operating characteristics

<b>Antenna type</b>	Monopole antenna
<b>Operation frequency</b>	2.4GHz-2.48GHz
<b>Modulation</b>	GFSK, Pi/4 DPSK, GMSK
<b>Radiated power</b>	<1mW

## Wireless functions and operating characteristics - Bluetooth

<b>Range</b>	≤10m
<b>Bluetooth mode</b>	5.0 Dual-Mode
<b>Profiles supported</b>	HFP(Hands-free profile), A2DP

## Wireless security measures

Secure wireless signals are assured through the device system design that includes:

- Individual MAC wireless for each unit is checked during each transmission.
- A built-in pairing table that specifies valid and legitimate pairing among units.
- A proprietary Orka communication protocol that checks the package numbers during each transmission.
- A Cyclic Redundancy Check (CRC) to check data validity and correct errors.

## Operating, transport, and storage conditions

Operating conditions	Discharging	Charging
Temperature	-10-50°C	0-40°C
Relative humidity	5-93%	5-93%



- Risk of injury, fire, or explosion during shipment. Shipping hearing instruments needs to abide by local regulations.
- Please use this product within the specified temperature range. If the temperature is too high or too low, it may cause equipment failure. When the temperature is lower than 5°C, battery performance is limited.

During extended period of transport and storage, please observe the following conditions:

	<b>Storage</b>	<b>Transport</b>
<b>Temperature (recommended)</b>	10-25°C	-20-60°C
<b>Temperature (maximum range)</b>	10-40°C	-20-60°C
<b>Relative humidity (recommended)</b>	20-80%	5-90%
<b>Relative humidity (maximum range)</b>	10-80%	5-90%

## Possible side effects

Minor itchiness, redness, irritation, and accelerated accumulation of cerumen (ear wax) may occur as your ear becomes accustomed to having an object in it. If this or anything related may arise, please contact Orka. Identification of any known physiological side effects associated with the use of the prescription hearing aid that may **warrant consultation with a physician, referring to an ear-nose throat doctor when preferable**, including if applicable, skin irritation and **accelerated accumulation of cerumen (ear wax)**.

# Privacy policy












The Orka Privacy Policy is available at:

US: <https://www.hiorka.com/legal/PrivacyPolicy>

CA: <https://www.hiorka.ca/legal/PrivacyPolicy>

**REF** EL-HR01

## Information of symbols

	General warning sign		This symbol confers that the electromagnetic interference from the device is under limits approved by the US Federal Communications Commission.
	Type B applied part		
	Keep dry		Power supply with double isolation
	Catalogue number		"Not for general waste". When a product is to be discarded, it must be sent to a designated collection point for recycling and recovery to prevent from harming the environment or human health due to the hazardous substances contained.
	Manufacturer		Date of manufacture
	Fragile, handle with care		Consult instructions for use or consult electronic instructions for use



## Classification description

- The type of protection against electric shock classification: TYPE II, INTERNAL ELECTRICAL POWER SOURCE.
- The degree of protection against electric shock classification: TYPE B APPLIED PARTS.
- Mode of operation classification: CONTINUOUS OPERATION.
- The equipment is not of the AP or APG type.

# Regulations

No.	Classification	Regulation
1	Electrical safety	IEC 60601-1: 2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2	Electromagnetic compatibility	IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
		IEC 60118-13:2019 Electroacoustics - Hearing aids - Part 13: Requirements and methods of measurement for electromagnetic immunity to mobile digital wireless devices
3	Hearing aids characteristics	ANSI/ASA S3.22-2014 Specification Of Hearing Aid Characteristics
4	Wireless communication	FCC

## 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.

<b>Emission Test</b>	<b>EC 60601 Test Level</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment Guidance</b>
<b>RF emissions CISPR 11</b>	Group 1	Group 1	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.
<b>RF emissions CISPR 11</b>	Class B	Class B	The hearing aid is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

## 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.

<b>Immunity Test</b>	<b>Standard</b>	<b>IEC 60601 Test Level</b>	<b>Compliance Level</b>
<b>Electrostatic discharge (ESD)</b>	IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 kV air
<b>Radiated RF EM Fields</b>	IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz
<b>Proximity fields from RF wireless communications equipent</b>	IEC 61000-4-3	9 V/m; 710, 745, 780 MHz; Pulse modulation 217 Hz 9 V/m; 5240, 5500, 5785 MHz; Pulse modulation 217 Hz 27 V/m; 385 MHz; Pulse modulation 18 Hz 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	9 V/m; 710, 745, 780 MHz; Pulse modulation 217 Hz 9 V/m; 5240, 5500, 5785 MHz; Pulse modulation 217 Hz 27 V/m; 385 MHz; Pulse modulation 18 Hz 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

# Important notices

## 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).)

### **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.

### **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.

### **Additional notices**

A hearing aid 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 habilitation and may need to be supplemented by auditory training and instruction in lipreading.

## Service and warranty

Orka One offers a 2-year limited warranty and a 45-day free trial period valid from the date you receive the product. This limited warranty covers manufacturing and material defects in the hearing aids and charging case, but does not cover accessories including tubes, domes, and external receivers respectively. The warranty does not affect any legal rights that you might have under applicable national legislation governing sale of consumer goods. Users are not covered by the warranty if one of the following occurs:

- The device exceeds the warranty period.
- Without valid proof of purchase.
- Damage from improper handling or care.
- Damage due to unauthorized disassembly or repair.
- The device is soaked in water, broken, or the circuit board is burned.



## Disposals

Hearing aids and accessories do not degrade on their own in nature, and any indiscriminate disposal can pollute the environment. Used earplugs, hearing aids, and accessories should be disposed of in accordance with national regulations for the disposal of waste products after they have been disposed of or decided not to be used.

**Manufactured by:**

Evoco Labs Co., Ltd.,  
Room 315-01, Building 1 No. 58, Xiangke  
Road China (Shanghai) Pilot Free Trade  
Zone Shanghai China, Shanghai, China  
Postcode: 201210

**After-sales service provided by:**

Evoco Labs Co., Ltd.,  
Room 315-01, Building 1 No. 58, Xiangke  
Road China (Shanghai) Pilot Free Trade  
Zone Shanghai China  
Postcode: 201210

**Period of use:**

3 years

Information in this brochure is subject to  
change without notice.

©2020 Evoco Labs Co., Ltd.,  
All rights reserved. Rev A 11/20

**[www.hiorka.com](http://www.hiorka.com)**  
**[www.hiorka.ca](http://www.hiorka.ca)**