

# Tech Book

We refer to the safety regulations and technical information related to Orka Two here.

**ORKA TWO**



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# 1. Safety and health information

## Intended use

The Orka Two™ hearing aids are designed for people who have perceived mild to moderately severe hearing loss. They are wireless air-conduction hearing aids that can be customized to fit the user's needs.

## Indication for use

The Orka Two™ hearing aids are meant to increase the volume of sound for people who have perceived mild to moderately severe hearing loss. The user can adjust the device according to their individual hearing needs without any pre-programming or hearing test. These hearing aids are designed for direct-to-consumer sale and usage, without the involvement of a hearing care professional.

## Hearing health care information

**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 dome gets stuck in your ear.**

If any part of your hearing aid, like the dome, gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as 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. Indicative lab results under default settings.

**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.

## Important safety instructions

- If you have acute otitis externa, tympanitis, chronic suppurative otitis media (in the phase of purulent infection), or acute suppurative otitis media, please avoid using the product.
- When you first start using the product, you may experience minor itchiness, redness, or irritation as your ear gets used to having an object in it. If you experience any discomfort or related issues, please contact Orka for assistance.
- Use only the attachments/components that are specified by the manufacturer. There are no internal parts of the product that users can repair.
- The battery that comes with the product may cause a chemical burn if it is mishandled.
- Dispose of electronic waste according to local regulations.
- **Do NOT** modify the product without authorization.
- Use the hearing aids only with the supplied domes attached.



- The product contains magnetic material, so if you have an implantable medical device, consult your physician to determine if it may be affected by this product.
- **Do not use the hearing aids if any part of the device is damaged.** Contact Orka immediately if you experience any unusual situations.
- If you have any active implants, keep the hearing aids away from them.
- Unauthorized alterations to the hearing aids should not be made. The Orka Two devices contain rechargeable batteries that cannot be replaced.
- **Only** use accessories provided by Orka.

## **WARNINGS**

- **Keep the device and its components out of reach of children**, as they contain small parts that may pose a choking hazard.
- **Do NOT use** the hearing aids in explosive or oxygen-enriched atmospheres, as this may cause a fire or explosion.
- **Check before using the hearing aids** in areas where electronics or wireless devices are restricted, as this may cause interference.
- **The hearing aids are intended for use by a single user**, and reselling or sharing them with others is not recommended. This may lead to infection.
- **Keep the product away from fire** and excessive heat (e.g., from storage in direct sunlight, near candles, or in a hot car) to avoid burns or damage to product.
- **Do NOT submerge in water**, wear in the shower, or wear while participating in water sports, e.g., swimming, waterskiing, surfing, etc. Prolonged exposure to water may damage the hearing aids.

## CAUTIONS

- **Be aware** that some sounds may sound different when using the hearing aids, so keep this in mind when you need to be aware of your surroundings. You should adjust to this over time.
- **When adjusting the volume, turn it up gradually** until you reach a comfortable listening level.
- **Do NOT use the hearing aids or their components if any part of them is damaged**, if they emit loud unusual noise, if you experience a warming sensation, or if you experience a loss of audio. If any of these happen, remove the hearing aids immediately, power them off, and contact the Orka Team for assistance.
- The product contains non-removable rechargeable lithium batteries that can be carried as checked baggage.
- Follow the power supply specifications (refer to page 14) when charging the hearing aids. Charging should only occur when the hearing aids are placed in the charging case, otherwise the product may be damaged.
- **If the battery leaks, do not allow the liquid to come in contact with the skin or eyes**, and seek medical advice if contact is made.
- For protection, the product will turn off when placed in an electrostatic discharge environment and will resume operation when placed in the charging case and switched back on.

## Contraindications

- Patients with acute otitis externa, tympanitis, chronic suppurative otitis media (during the period of infection with discharge), and acute suppurative otitis media should not use the product.
- Patients who are allergic to the material of the product should not use it.

## 2. Product specifications

### Dimensions and weight

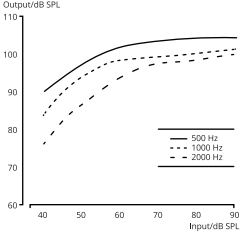
Dimensions	Hearing aid (without receiver wire)	13.6mm*9mm*28.9mm
	Charging case	82mm*56mm*31.5mm
Weight	Hearing aid (Single)	3.4g
	Charging case	75g

### Compatibility

Device compatibility	iOS 14 and later, Android 8 and later
Bluetooth	4.2/5.0/5.1/5.2/5.3

## Performance parameters

Measurements per ANSI S3.22:2003 where denoted with * Measurements per ANSI/CTA-2051:2017 where denoted with **	
Maximum output (OSPL90) curve Frequency response curve	<p>The graph plots Output/dB SPL against Frequency/Hz. The solid line represents the Maximum output (OSPL90) curve, and the dashed line represents the Frequency response curve. The OSPL90 curve starts at 115 dB SPL at 250 Hz, remains relatively flat until 1000 Hz, then gradually decreases to 110 dB SPL at 2000 Hz, 105 dB SPL at 3000 Hz, 95 dB SPL at 4000 Hz, 100 dB SPL at 5000 Hz, and finally 95 dB SPL at 8000 Hz. The Frequency response curve starts at 82 dB SPL at 250 Hz, rises to 90 dB SPL at 1000 Hz, 92 dB SPL at 2000 Hz, 90 dB SPL at 3000 Hz, 91 dB SPL at 4000 Hz, 92 dB SPL at 5000 Hz, and 92 dB SPL at 8000 Hz.</p>
Maximum output (OSPL90)	115 dB SPL
High-frequency average (HFA) OSPL90	110 dB SPL
High-frequency average full-on gain (HFA-FOG)	44 dB

Reference test gain	33 dB																												
Frequency range	< 200 – 8000 Hz																												
Harmonic distortion	≤ 3% max																												
Equivalent input noise	≤ 23 dB SPL max																												
Input-output curve	 <p>The graph plots Output/dB SPL (y-axis, 60 to 110) against Input/dB SPL (x-axis, 40 to 90). Three curves are shown: a solid line for 500 Hz, a dashed line for 1000 Hz, and a dash-dot line for 2000 Hz. All curves show a non-linear, compressing relationship where output increases at a slower rate than input. The 500 Hz curve is the highest, followed by 1000 Hz, and then 2000 Hz.</p> <table border="1"> <caption>Approximate data points from the input-output curve graph</caption> <thead> <tr> <th>Input/dB SPL</th> <th>500 Hz Output/dB SPL</th> <th>1000 Hz Output/dB SPL</th> <th>2000 Hz Output/dB SPL</th> </tr> </thead> <tbody> <tr> <td>40</td> <td>90</td> <td>85</td> <td>78</td> </tr> <tr> <td>50</td> <td>98</td> <td>92</td> <td>85</td> </tr> <tr> <td>60</td> <td>102</td> <td>98</td> <td>92</td> </tr> <tr> <td>70</td> <td>104</td> <td>100</td> <td>95</td> </tr> <tr> <td>80</td> <td>105</td> <td>101</td> <td>97</td> </tr> <tr> <td>90</td> <td>105</td> <td>102</td> <td>98</td> </tr> </tbody> </table>	Input/dB SPL	500 Hz Output/dB SPL	1000 Hz Output/dB SPL	2000 Hz Output/dB SPL	40	90	85	78	50	98	92	85	60	102	98	92	70	104	100	95	80	105	101	97	90	105	102	98
Input/dB SPL	500 Hz Output/dB SPL	1000 Hz Output/dB SPL	2000 Hz Output/dB SPL																										
40	90	85	78																										
50	98	92	85																										
60	102	98	92																										
70	104	100	95																										
80	105	101	97																										
90	105	102	98																										
Latency**	10.2ms																												
Attack time* at 250Hz/500Hz/1000Hz/2000Hz/4000Hz (ms)	10/30/30/10/90																												
Release time* at 250Hz/500Hz/1000Hz/2000Hz/4000Hz (ms)	200/330/380/280/100																												

## Power supply specification

Power adapter input voltage	100-240V 50/60Hz 0.2A
Nominal input	5V d.c. 35mA (Hearing Aid) 5V d.c. 300mA (Charging Case)
USB cable specifications	USB 2.0 Type-C
Wireless Charging	1W

## Transport and storage conditions

	Temperature range	Humidity range	Atmospheric pressure
Transport conditions	5°C – 40°C	5% – 93% RH	860hPa - 1060hPa
Storage	-20°C – 55°C	5% – 93% RH	860hPa - 1060hPa

## 3. Regulatory and legal information

### Compliance information

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.

Changes or modifications not directly approved by Orka may void the user's authority to operate this equipment.

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

Hearing aids FCC ID: 2BBZIH020S; Charging case FCC ID: 2BBZIC020S

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. Users must ensure the hearing aid is used in such a specified electromagnetic environment.



<b>Emission test</b>	<b>Iec 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment guidance</b>
RF emissions CISPR 11	Group 1	Group 1	The hearing aid uses RF energy only for its internal function. Therefore, its RF emissions are very low and is not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	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>
Electro-static discharge (ESD)	IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 kV air
Radiated RF EM Fields	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

Immunity test	Standard	Iec 60601 test level	Compliance level
Proximity fields from RF wireless communications equipment	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; 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

## **Classification**

The hearing aids are classified as a Type B Applied Part, IEC 60601-2-66

## **Expected service life of product and components**

3 Years

## **Disposals**

The Orka Two™ hearing aids and components are electronic components which should be discarded in accordance with national, regional, and local regulations.

The Orka Two™ hearing aids comply with the following regulations for medical devices:

IEC 60601-1:2005

IEC 60601-1-2:2014

IEC 60601-2-66:2019

ANSI/ASA S3.22-2014

FCC 47 Part 15.247

## **Privacy policy**

The Orka Privacy Policy is available at: [www.hiorka.com](http://www.hiorka.com)

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







## **Limited warranty**





The hearing aids are covered by a limited warranty. Visit our website at: [www.hiorka.com](http://www.hiorka.com) for details of the limited warranty.

## **Returns and exchanges**

Satisfaction is guaranteed on all Orka products purchased by consumers directly from Orka. We want you to be thrilled, so if you're not satisfied with your purchase for any reason, simply return it within the trial period for a full refund. Please see the Orka Support page at: [www.hiorka.com](http://www.hiorka.com) for details.

## Information of symbols

	General warning sign		Manufacturer
	Type B applied part		Fragile, handle with care
	Keep dry		Date of manufacture
	Serial number		IEC 60417-5172 CLASS II equipment
	Humidity range		Rechargeable battery
	Pressure range		Follow instructions for use or follow electronic instructions for use.
	Temperature range		Consult instructions for use or consult electronic instructions for use

	Do not use if package is damaged and consult instructions for use.
	"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.
	This symbol confers that the electromagnetic interference from the device is under limits approved by the US Federal Communications Commission.
	The Bluetooth word mark and logos are trademarks owned by the Bluetooth SIG, Inc. and any use of such marks by Orka Health Co., Ltd. is under license. Other trademarks and trade names are those of their respective owners.



**Manufactured by:**

**After-sales service provided by:**

ORKA HEALTH CO., LTD.

ROOM 01B101,BUILDING 2, NO. 118 RONGKE ROAD, SHANGHAI,  
201203, CHINA

**Period of use:**

3 years

Information in this brochure is  
subject to change without notice.

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