



Safety manual for hearing aids



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Safety information

This safety manual provides safety information and other important information about your hearing aids. It covers several hearing aid types and optional features.

- Refer to the user guide of your hearing aids, to check the hearing aid type and the activated features.



WARNING

A Hearing Care Professional should advise a prospective hearing aid user to consult a licensed physician before using the hearing aid if the Hearing Care Professional determines that the prospective user has any of the following conditions:

- ▶ Visible congenital or traumatic deformity of the ear.
- ▶ History of active drainage from the ear within the previous 90 days.
- ▶ History of sudden or rapidly progressive hearing loss within the previous 90 days.
- ▶ Acute or chronic dizziness.
- ▶ Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- ▶ Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1,000 Hz, and 2,000 Hz.
- ▶ Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- ▶ Pain or discomfort in the ear (e.g. recent or current ear infection).

Intended purpose / (use)

Hearing aids are intended to improve the hearing of hearing impaired persons. Diagnosis and prescription of a hearing aid must be performed by hearing health specialists, e.g. acousticians, audiologists or ENT doctors.

Use the hearing aids and accessories only as described in the respective user guides.

Explanation of symbols

Symbols used in this document



Points out a situation that could lead to serious, moderate, or minor injuries.



Indicates possible property damage.



Information and warnings for children with hearing aids.

Symbols on the device or packaging



CE compliance label, confirms compliance with certain European Directives, refer to section "Conformance information".



EMC and radio communications compliance label Australia, refer to section "Conformance information".



Optional symbol for custom models with wireless functionality.

Symbols on the device or packaging



Indicates the legal manufacturer of the device.



Do not dispose of the device with general domestic waste. Read more in section "Disposal information".



Packaging can be recycled.



Read and follow the instructions in the user guide.



According to IEC 60601-1, the applied parts of this device are classified as type B.



Keep dry during transportation.



Temperature during transportation. Read more in section "Operating, transport and storage conditions".



Relative humidity during transportation. Read more in section "Operating, transport and storage conditions".



Atmospheric pressure during transportation. Read more in section "Operating, transport and storage conditions".



Medical device

Symbols on the device or packaging



Compatible with Qi-certified wireless chargers.



Bluetooth® low energy technology.

General warnings



WARNING

Risk of impairing the residual hearing of the user.

- ▶ Use only hearing aids that have been fitted especially for your needs.



WARNING

Risk of injury!

- ▶ Do not use obviously damaged devices and return them to point of sale.



WARNING

Note that any unauthorized changes to the product may cause damage to the product or cause injury.

- ▶ Use only approved parts and accessories. Ask your Hearing Care Professional for support.
- ▶ Do not modify this product without authorization from the manufacturer.
- ▶ If this product is modified, appropriate inspection and testing must be conducted to ensure safe use of the product.

**WARNING**

Your hearing aids may reduce certain background sounds, potentially also traffic or warning signals.

**WARNING**

Risk of explosion!

- ▶ Do not use your hearing aids in explosive atmospheres (e. g. mining areas).

**WARNING**

Choking hazard!

Your hearing aids contain small parts which can be swallowed.

- ▶ Keep hearing aids, batteries and accessories out of reach of children and mentally disabled persons.
- ▶ If parts have been swallowed consult a physician or hospital immediately.

If you have hearing aids that are intended for the fitting of children under the age of 3 years or persons with a developmental age of under 3 years, refer also to section "For children under the age of 3 years".

**NOTICE**

- ▶ Protect your hearing aids from high humidity*. Do not wear them in the shower** or when you apply make-up, perfume, aftershave, hairspray or suntan lotion.

**NOTICE**

- ▶ Protect your hearing aids from extreme heat. Do not store them in direct sunlight.

**NOTICE**

- ▶ Do not dry your hearing aids in the microwave oven.

**NOTICE**

Different types of strong radiation, e.g. during X-ray or MRI head examinations, may damage hearing aids.

- ▶ Do not wear the hearing aids during these or similar procedures like electrosurgery (diathermy, electrocautery, HF-surgery).

Weaker radiation, e.g. from radio equipment or airport security, does not damage the hearing aids.

* Statement "high humidity" is obsolete for water resistant devices!

** Statement "Do not wear them in the shower" is obsolete for water resistant devices!

**NOTICE**

Your devices comply with international standards. However, it cannot be guaranteed that all products on the market work interference-free, for example some induction cookers, electromagnetic security systems (e.g. anti-theft systems and metal detectors) cellular telephones, RFID, room surveillance systems may cause audible interference. If you encounter unwanted noise in the vicinity of such device, you should increase the distance between the hearing aid and that device.

**NOTICE**

In case of a serious incident, report the occurrence to the manufacturer of the device.

**NOTICE**

When not in use, please store your hearing aids in the supplied jewel case or charging case (if applicable) and keep out of the reach of children.

Contraindications



WARNING

In case of a known contact allergy, consult the hearing aid manufacturer regarding the presence of the allergen before using the hearing aid. If an allergic reaction develops after wearing the hearing aid, immediately discontinue use and consult a licensed physician.



WARNING

Consult a Hearing Care Professional if you experience any unusual side effects like skin irritation, excessive accumulation of ear wax, dizziness, change in your hearing, or if you think there may be a foreign object in your ear canal.

For hearing aids with wireless functionality



In some countries restrictions for the usage of wireless equipment exist.

- ▶ Refer to local authorities for further information.



WARNING

Risk of affecting electronic equipment!

- ▶ In areas where the use of electronics or wireless devices are restricted, verify if your device has to be turned off.



NOTICE

Your hearing aids are designed to comply with international standards on electromagnetic compatibility but interference with nearby electronic devices could occur. In this case, move away from the source of interference.



WARNING

Interference with implantable devices

- ▶ The device can be used with all electronic implants that comply with the ANSI/AAMI/ISO 14117:2012 Electromagnetic compatibility standard for human implants.
- ▶ In case your implant does not comply with the ANSI/AAMI/ISO 14117:2012 standard, consult the manufacturer of your implantable device for information about the risk of disturbance.

For hearing aids with a tinnitus feature

Your hearing aid may be equipped with a tinnitus feature (e.g. with a tinnitus therapy signal, a tinnitus noiser, or another special function). The use of the tinnitus feature should be only on the advice and in consultation with your Hearing Care Professional.



WARNING

Risk of further impairment to the user's hearing health.

The volume of the tinnitus feature can be set to a level which could lead to permanent hearing damage when used for a prolonged period of time.

- The tinnitus feature should never be used at uncomfortable levels.

For hearing aids with AutoPhone magnet



WARNING

Risk of affecting life support systems!

- ▶ Use a magnet only when it is a safe distance away from life support systems, such as pacemakers or magnetic valves. For example, the safe distance between pacemaker and magnet should be at least 10 cm (4 inches).



NOTICE

Magnets can disturb electrical devices and delete stored data.

- ▶ Keep magnets away from computers, monitors, television sets, storage media and other electronic equipment/devices.



NOTICE

In close proximity, AutoPhone magnets can damage receiver units of RIC hearing aids.

- ▶ Keep a minimum distance of 2 cm (0.8 inches) between the RIC receiver and any magnet, including the AutoPhone magnet.

For example, do not store your RIC hearing aids and a smartphone with attached AutoPhone magnet together in a small pocket or box.

For hearing aids with a magnet in the battery compartment



WARNING

Risk of interference with active and non-active implants!

There is a magnet in the battery compartment, therefore if you wear an active or a non-active implant, e.g. a brain implant:

- ▶ Prior to use, have the electromagnetic compatibility verified.
Consult the physician that implanted the device before using your hearing aids.
- ▶ Keep a safe distance of about 4 cm (1.6 inches) between the implant and hearing aids.

For certain hearing aid types

BTE models

Hearing aids that are worn behind the ear and that have a tube.



CAUTION

Risk of injury!

- ▶ Always wear the tube with an ear piece.
- ▶ Make sure that the ear piece is completely attached.



CAUTION

Risk of injury!

- ▶ Insert the ear piece carefully and not too deeply into the ear.



CAUTION

Risk of injury!

- ▶ In very rare cases the ear piece could remain in your ear when removing the hearing aid. If this happens, have the ear piece removed by a medical professional.

RIC models

The receiver is placed within the ear canal and connected to the hearing aid via a receiver cable.



CAUTION

Risk of injury!

- ▶ Always wear the receiver cable with an ear piece.
- ▶ Make sure that the ear piece is completely attached.



CAUTION

Risk of injury!

- ▶ Insert the ear piece carefully and not too deeply into the ear.



CAUTION

Risk of injury!

- ▶ In very rare cases the ear piece could remain in your ear when removing the hearing aid. If this happens, have the ear piece removed by a medical professional.



NOTICE

- ▶ Do not pull the receiver connection as this could damage your hearing aids.



Instant fit models

The hearing aid is placed within the ear canal and kept in place with an ear piece.



CAUTION

Risk of injury!

- ▶ Always wear the hearing aid with an ear piece.
- ▶ Make sure that the ear piece is completely attached.



CAUTION

Risk of injury!

- ▶ Insert the hearing aid carefully and not too deeply into the ear.



CAUTION

Risk of injury!

- ▶ In very rare cases the ear piece could remain in your ear when removing the hearing aid. If this happens, have the ear piece removed by a medical professional.

Custom, IIC, CIC and ITC models

The hearing aid is placed within the ear canal.



CAUTION

Risk of injury!

- ▶ Insert the hearing aid carefully and not too deeply into the ear.

Other models

For all other models, no model-specific safety information applies.

For children under the age of 3 years

There are special hearing aids for the fitting of children under the age of 3 years or persons with a developmental age of under 3 years. Ask your Hearing Care Professional for further information.



WARNING



Choking hazard!

Your hearing aids contain small parts which can be swallowed.

- ▶ Ensure adequate supervision if infants, small children or mentally disabled persons need to wear hearing aids.
- ▶ Check the completeness of the hearing aids regularly.
- ▶ Ensure that your child or the mentally disabled person does not detach the hearing aid from the earmold.
- ▶ Consult your Hearing Care Professional if the housing is deformed.
- ▶ Keep the battery compartment locked. Verify the proper function of the locking mechanism.
- ▶ Keep batteries and accessories out of children's or mentally disabled person's reach.
- ▶ If swallowed consult a physician or a hospital immediately.

For certain battery types

For hearing aids with built-in power cells (lithium-ion rechargeable batteries)

Read the safety information on power cells in the hearing aid's user guide.

For hearing aids with replaceable batteries



NOTICE

Only use zinc-air batteries or nickel-metal hydride (NiMH) rechargeable batteries.

Do not use e.g. silver-zinc or lithium-ion rechargeable batteries.



NOTICE

Leaking batteries damage the hearing aids.

- ▶ Turn the hearing aids off when not in use to preserve the battery.
- ▶ Remove batteries when the hearing aids are not in use for a prolonged period of time.

The following table helps you to find the correct zinc-air battery. The suitable battery size for your hearing aids is listed in the user guide.

Battery size	IEC code	ANSI code	Typical color code
10	PR70	7005ZD	yellow
13	PR48	7000ZD	orange
312	PR41	7002ZD	brown
675	PR44	7003ZD	blue

When using remote control apps

When using an app for controlling hearing aids:



WARNING

Risk of hearing damage!

The device with the app for controlling hearing aids generates short control signals which may be audible. If the device running the app has a very high audio output there is the risk of hearing damage.

While using the app:

- ▶ Do not hold the loudspeaker of the device to your ears or the ears of others.
- ▶ Do not use the device with headphones, headsets or other audio playback devices.

For Hearing Care Professionals



WARNING

For hearing aids with an output sound pressure level of 132 dB SPL or more:

Risk of impairing the residual hearing of the user.

- ▶ Take special care when fitting this hearing aid.

Tinnitus feature

The target population is primarily the adult population over 21 years of age. The patient may have some control of the level or volume of the signal and the patient should discuss this adjustment as well as his or her comfort level and sound of the signal with their Hearing Care Professional.



WARNING

Risk of further impairment to the user's hearing health.

The volume of the tinnitus feature can be set to a level which could lead to permanent hearing damage when used for a prolonged period of time.

- ▶ Should the tinnitus feature be set to such a level in the hearing aid, advise the user of the maximum amount of time per day he or she should use the tinnitus feature.

For example, occupational safety guidelines restrict continuous noise exposure of 80 dBA SPL to 8 hours per day.

- ▶ The tinnitus feature should never be used at uncomfortable levels.

For hearing aids that are not specially designed for the fitting of children under the age of 3 years or persons with a developmental age of under 3 years:



WARNING

(for hearing aids NOT intended for small children and if conversion kit for child-safe battery door is available)

Choking hazard posed by small parts.

This hearing aid is not intended for the fitting of infants, children under 3 years and persons of mental incapacity.



WARNING

for hearing aids for small children:

Instructions for the fitter of hearing aids for small children (e.g. in data sheet or fitting guide):

Choking hazard posed by small parts!

- ▶ Infants, children under 3 years and persons of mental incapacity must not wear the hearing aid without appropriate supervision.
- ▶ Acoustic coupling tube and earpiece must not be detachable by the child.
- ▶ The diameter of the earpiece is recommended to be in the range of 32 mm and may enclose the outer ear.
- ▶ Demonstrate and explain the battery door locking mechanism to the child's parents or caretaker.

Important information

Operating, transport and storage conditions

For hearing aids with built-in power cells (lithium-ion rechargeable batteries)

Read the operating, transport and storage conditions in the hearing aid's user guide.

For hearing aids with replaceable batteries

The hearing aids operate in the following environmental conditions (also valid in between uses):

Temperature	0 to 50 °C (32 to 122 °F)
Relative humidity	5 to 93 %
Atmospheric pressure	700 to 1060 hPa

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

	Storage	Transport
Temperature	10 to 40 °C (50 to 104 °F)	-20 to 60 °C (-4 to 140 °F)
Relative humidity	10 to 80 %	5 to 90 %
Atmospheric pressure	700 to 1060 hPa	700 to 1060 hPa

For other parts, such as batteries, other conditions may apply.

Expected service lifetime

The hearing aids are designed for an expected service life of 5 years. They are expected to remain safe for use for this duration.

Disposal information

- ▶ Recycle hearing aids, accessories and packaging according to local regulations.

For hearing aids with replaceable batteries

- ▶ To avoid environmental pollution, do not throw batteries into household trash.
- ▶ Recycle or dispose of batteries according to local regulations or return them to your Hearing Care Professional.

Conformance information

The CE mark indicates conformity with the following European directives:

- Regulation (EU) 2017/745 for products manufactured by WSAUD A/S and 93/42/EEC for products manufactured by Signia GmbH and Sivantos GmbH*
- 2011/65/EU RoHS concerning the restriction of hazardous substances
- Only for products with wireless functionality:
2014/53/EU RED concerning radio equipment

* see declaration of conformity

The full text of the declaration of conformity can be obtained from www.wsaud.com.

The ACMA compliance mark  indicates conformity with the electromagnetic interference standards set by the Australian Communications and Media Authority (ACMA).

Devices with the FCC marking comply with the standards of the FCC regarding electromagnetic interference (only for products with wireless functionality).

Technical details

If the certification information for USA and Canada is not listed in the hearing aids' user guide, the following certification numbers apply:

- Wireless platform, model: e2e 3.0
- **USA** FCC ID: SGI-WL003BTE
- **Canada:** 267AB-WL003BTE

Notices

This Class B digital apparatus complies with Canadian ICES-003.

Changes or modifications made to this equipment not expressly approved by the legal manufacturer may void the FCC authorization to operate this equipment.

This device complies with Part 15 of the FCC Rules and withISED's licence-exempt RSSs.

Operation is subject to the following conditions:

- this device may not cause harmful interference, and
- 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 to 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.

For body worn operation, this device has been tested and meets the FCC RF exposure guidelines when used with the legal manufacturer's accessories supplied or designated for this product. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

Data is stored inside the hearing aid. This contains:

- the audiogram,
- the average daily wearing,
- the frequency distribution of acoustic environments (i.e., what percentage of the wearing time you were in a quiet environment, in a noisy environment, in an environment with speech, in a car and how often you listened to music),
- the different noise levels (including wind noise) within the last 24 hours,
- the average frequency of changes to user controls,
- the average frequency that algorithms in hearing aids are actively in operation,
- an identification number.

Part of the information inside your hearing aids is additionally stored in separate databases in anonymized form (meaning, it cannot be connected to you) in order to improve the quality of future hearing devices. This information may help your acoustician provide the optimal fitting for you. However, he/she will not read out this information without your consent. Also, when you send in your device for service, this information will not be read out without your consent.

Nearfield magnetic induction functionality

The following table shows the main information on NFMI connectivity, some parameters are different from product to product, so the worst case is indicated:

Wireless technology	Nearfield magnetic induction (NFMI)
Magnetic field strength	0.14 A/m
Output power (EIRP)	53 μ W
Range	< 20 cm between hearing aids
Center frequency	3.27 MHz
Channel	Single Channel Radio
Bandwidth	330 kHz (-15 dB)
Modulation type	PSK (Phase Shift Keying)

Bluetooth® low energy*

The following table shows the main information on BLE, some parameters are different from product to product, so the worst case is indicated:

Wireless technology	Radio frequency - Bluetooth low energy (BLE)
Output power (EIRP)	3.9 mW
Range	< 10 m between smartphone/ accessory and hearing aids
Frequency	2,400 – 2,480 MHz
Channel	40 channels
Bandwidth	2 MHz per channel , 2 MHz spacing
Modulation type	Gaussian Frequency Shift Keying

* The Bluetooth word mark and logos are owned by the Bluetooth SIG, Inc., and any use of such marks by the legal manufacturer of this product is under licenses. Other trademarks and trade names are those of their respective owners.

EMI/EMC compliance

Wireless hearing aids comply with the following EMC/EMI standards:

Standard	Test Type	Note
47 CFR Part 15, Subpart C	RF emissions	U.S. FCC requirements for intentional radiators.
EN 300 330	RF emissions including spurious emission	EMC and radio spectrum matters for short range devices in the frequency range 9 kHz - 25 MHz.
EN 301 489-1/3/17	Immunity, RF and ESD	Standard for low power transmitters in the frequency range 9 kHz - 40 GHz.
EN 300 328	Signal integrity and emissions	Wideband transmission systems; data transmission equipment operating in the 2.4 GHz ISM band and using wide band modulation techniques

Standard	Test Type	Note
IEC 60118-13	RF immunity	International product standard for hearing aids to ensure adequate immunity to radio interference from mobile telephones.
ANSI C63.19	RF immunity	American National Standard method of measurement of compatibility between wireless communication devices and hearing aids.
ANSI/AAMI PC69	RF emissions	Implantable medical device EMC immunity, American National Standard.
ISO 14117	RF emissions	Implantable medical device EMC immunity, International Standard.
EN 45502-2-1	RF emissions	Particular requirements for pacemakers.

Emissions	CISPR 11, Group 1, Class B
Immunity	ESD, Conducted up to +/-8 kV, Air discharge up to +/-15 kV Power frequency magnetic fields: 30 A/m, 50/60 Hz
Immunity to RF fields	80 MHz-2.7 GHz 10 V/m, 2.7 GHz-6 GHz 3 V/m
Proximity to wireless communication devices	Up to 28 V/m – See IEC 60601-1-2:2014/AMD1:2020, Table 9
Proximity to magnetic fields	8 A/m@30 kHz, 65 A/m@134.2 kHz, 7.5 A/m@50 kHz

Warranty and service

The terms of any warranty for this product are set out in the contract between you and the supplier from whom you purchased this product. This document is not intended to create any additional warranty rights directly against the manufacturer.

Where in accordance with such contract this product is received for warranty repair or replacement by the manufacturer, any repair or replacement may be with products or parts that are new, used or refurbished. Repairs or replacements shall not interrupt, extend or prolong the term of any warranty.

Country specific information

Important information: Australia and New Zealand



WARNING

Keep batteries out of reach of children.

- ▶ For some types of button batteries, severe or fatal injuries can occur in 2 hours or less, if it is swallowed or placed inside any part of the body.
 - ▶ If you suspect your child has swallowed or inserted a button battery, call the 24-hour Poisons Information Centre immediately on 13 11 26 for fast, expert advice.
 - ▶ Examine devices and make sure the battery compartment is correctly secured, e.g. that the screw or other mechanical fastener is tightened. Do not use if compartment is not secure.
 - ▶ Dispose of used button batteries immediately and safely. Used/discharged batteries can still be dangerous.
 - ▶ Tell others about the risk associated with button batteries and how to keep their children safe.
-



WARNING

If battery is swallowed, contact the Poisons Information Hotline on 0800 764 766 for New Zealand.

For other countries, please contact the local Poisons Information Hotline.

Support

For more detailed information or in case of unexpected operation or events please contact

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This document applies to hearing aids manufactured by Sivantos GmbH and by Signia GmbH.

This document applies to hearing aids manufactured by AS AUDIO-SERVICE GmbH.

This document applies to hearing aids manufactured by WSAUD A/S.

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