



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.

Intended purpose/Intended use

The user guide for your hearing aids usually contains a statement about the intended purpose and intended use of that specific device. If such a statement is not included in the user guide for your hearing aids, the following statement applies:

Hearing aids are intended to improve the hearing of hearing impaired persons. Diagnosis and prescription of a hearing instrument 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



Information about potentially dangerous and harmful situations that the user should be aware of.



Information about potential situations that might damage the device and other property.



Information that improves or eases the experience of using and handling the device.



Information relevant to children using or handling the device.

Symbols on the device or packaging



Indicates that the device complies with the requirements in the European CE marking directives.

Symbols on the device or packaging



Indicates that the device complies with the requirements for electrical safety, EMC, and radio frequencies for products sold in Australia or New Zealand.



Indicates that the device has wireless functionality.



Indicates the legal manufacturer of the device.



Indicates the manufacturer's part number to identify the device.



Indicates the manufacturing date of the device.



Indicates the serial number of the device.

Symbols on the device or packaging



Indicates that the product should not be disposed of with general domestic waste, and that it must be sent to a designated collection point for recycling and recovering to prevent the risk of harm to the environment and human health as a result of the presence of hazardous substances.



Indicates that the product's packaging can be recycled.



Indicates that the instructions for use contain important information, warnings, and notices that the user should familiarize themselves with before using the product.



Indicates that components contained in the product are classified as type B under the EN 60601-1 standard.

Symbols on the device or packaging



Indicates that the product should be kept dry during transport and storage.



Indicates the range of acceptable temperatures for transporting and storing the device.



Indicates the range of acceptable humidity levels for transporting and storing the device.



Indicates the range of acceptable pressure levels for transporting and storing the device.



Indicates that the product is classified as a medical device.



Indicates that the product is compatible with Qi-certified chargers. The Qi logo is a trademark of the Wireless Power Consortium.

Symbols on the device or packaging



Indicates that the product uses Bluetooth® Low Energy technology¹.

- 1 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

Cybersecurity

Proper set-up and operation of your hearing aids requires a safe, private and secure operating environment.

NOTICE

Privacy and data security notice for hearing aid users

Your hearing aids may contain Bluetooth technology to enable features like audio streaming, remote control, and connectivity with smartphones or other devices. While these features enhance usability, they may also pose data privacy and security risks.

Be aware of the following:

- ▶ Bluetooth connections can potentially be intercepted if not properly secured. Always ensure your hearing aid is paired only with trusted devices.
- ▶ Your hearing aids are open for pairing 3 minutes after power-on. If you hear an unexpected pairing signal, this could indicate a malicious intrusion.
- ▶ Be attentive when pairing your hearing aids in public or unsecured environments, such as airports or cafés.
- ▶ Do not restart your hearing aid if requested by someone you do not trust.
- ▶ For further guidance, consult your hearing aid provider or audiologist.

General warnings



WARNING

Risk of impairing the residual hearing of the user.

- Only use hearing aids that have been specifically fitted to your needs.



WARNING

Risk of injury!

- Do not use or repair obviously damaged devices. Return them to the point of sale.



WARNING

Take your hearing aids out when you are not using them. This will help to ventilate the ear canal and prevent ear infections.

 WARNING

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

Streaming sound to your hearing aids at a high volume can prevent you from hearing other important sounds such as alarms and traffic noise. In such situations make sure to keep the volume of the streamed sound at a suitable level.



WARNING

Risk of explosion!

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



WARNING

Choking and poisoning hazard!

Hearing aids and batteries are small enough to be swallowed. Swallowing a battery or any part of a hearing aid can be hazardous to health and may result in severe or fatal injury. To minimize the risk of anyone swallowing a battery or any part of a hearing aid, take the following precautions:

- ▶ Keep hearing aids, and batteries and accessories out of reach of children, pets, and cognitively impaired people.
- ▶ Store hearing aids and batteries in a secure place when they are not in use.

- ▶ Do not store hearing aids and batteries in places where they might be mistaken for edible objects like pills and candy.

If a battery or any part of a hearing aid is swallowed, seek immediate medical attention.

WARNING

Keep batteries out of reach of children.

Swallowing or inserting a coin battery into any part of the body can result in severe or fatal injury within two hours.

If you suspect your child has swallowed or inserted a battery, call your local poison control hotline immediately.

- ▶ For Australia, call the Poisons Information Centre at 13 11 26.
- ▶ For New Zealand, call the National Poisons Centre at 0800 764 766.
- ▶ For Canada, contact the poison center for your province. The phone number can be found at <https://infopoison.ca>.

Examine devices to make sure battery compartments are correctly secured, and that screws and other mechanical fasteners are tightened. Do not use a device if its battery compartment is not secure.

Dispose of used batteries immediately and safely. Used and discharged batteries can still be dangerous.

Tell others about the risk associated with button batteries and how to keep their children safe.

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**

- ▶ Do not wear your hearing aids when you apply make-up, perfume, aftershave, hairspray, or suntain lotion.
- ▶ If your hearing aids are not water resistant, protect them from high humidity, and do not wear them in the shower.

! **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, MRI procedures, proximity of idle MRI or CT scan, 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.

NOTICE

Your hearing aids are designed to comply with international standards on electromagnetic compatibility, but interference from nearby electronic devices like induction cookers, electromagnetic security systems, anti-theft systems, metal detectors, mobile phones, RFID, and surveillance systems could occur. In this case, move away from the source of interference.



WARNING

- To avoid potential degradation of radio performance, your device should be separated by at least 25 cm (10 inches) to other radio communications equipment.



NOTICE

In case of a serious incident, report the occurrence to the device manufacturer and the competent authority under whose jurisdiction the user and/or patient resides or is established.



NOTICE

In the unlikely event corrosion becomes visible on the surface of the charging contacts and cannot be wiped off, discontinue wearing the device and contact your hearing care professional.

NOTICE

When not in use, please store your hearing aids in the jewel case/charging case (if applicable) or any other appropriate storage solution and keep out of the reach of children.

Contraindications

WARNING

If you know you have any contact allergies, ask the manufacturer of the hearing aids about potential allergens before you start using the hearing aids. If you get an allergic reaction from wearing the hearing aids, stop using them, and talk to a licensed physician.

WARNING

Consult a hearing care professional if you experience any unusual side effects such as skin irritation, excessive ear wax buildup, dizziness, a change in your hearing, or if you suspect something is stuck in your ear canal.

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.

- ▶ Sudden or recent unilateral hearing loss 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, for example due to a recent or current ear infection.

For hearing aids with wireless functionality

NOTE

In some countries, there are restrictions on the usage of wireless equipment.

- ▶ Refer to your local authorities for further information.



WARNING

Risk of affecting electronic equipment!

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



WARNING

Interference with implantable devices.

- ▶ The device can be used with all electronic implants that comply with the ANSI/AAMI/ISO 14117:2019 Electromagnetic compatibility standard for human implants.
- ▶ In case your implant does not comply with the ANSI/AAMI/ISO 14117:2019 standard, consult the manufacturer of your implantable device for information about the risk of disturbance.

For hearing aids with tinnitus feature

Your hearing aid may be equipped with a tinnitus feature. 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 over a prolonged period.

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

When using Zen programs



WARNING

Using a Zen program may interfere with hearing everyday sounds, including speech. Do not use the program when hearing these sounds is important. In such cases, use a non-Zen program.

For hearing aids with AutoPhone magnet



WARNING

Risk of affecting life support systems!

Only use a magnet if it is at a safe distance 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.

NOTE

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!

The battery compartment contains a magnet. Therefore, if you wear an active or non-active implant, such as a brain implant:

- ▶ Before use, have the electromagnetic compatibility checked.
- ▶ Consult the doctor who implanted the device before using your hearing aids.
- ▶ Keep a safety distance of approximately 4 cm (1.6 inches) between the implant and the hearing aids.

For certain hearing aid types

BTE models

The hearing aid is worn behind the ear and has 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 cognitively impaired persons need to wear hearing aids.
- ▶ Check hearing aids regularly for completeness.
- ▶ Ensure that your child or the cognitively impaired 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 reach of children and cognitively impaired people.

- ▶ 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)

WARNING

Risk of injury, fire or explosion!

A lithium-ion rechargeable battery is permanently built into your device. Incorrect use of the device can cause the lithium-ion rechargeable battery to burst.

- ▶ Follow the safety instructions for lithium-ion rechargeable battery in this section.

WARNING

- ▶ Observe the operating conditions.

- ▶ Pay special attention to protect your device from extreme heat (e.g. fire, microwave oven, induction oven or other high induction fields) and sunlight.
- ▶ Charge your hearing aids only with the approved charger. Ask your hearing care professional for support.
- ▶ Do not disassemble the device.
- ▶ Do not use the device in explosive atmospheres.
- ▶ Do not use devices that are deformed or obviously damaged.
- ▶ Do not use the device when its performance after charging reduces considerably. Return the device to your hearing care professional.
- ▶ Do not dispose of the device in fire or water.

WARNING

Replacement and repair have to be performed by a professional. Therefore:

- ▶ Do not repair or replace the lithium-ion rechargeable battery yourself.
- ▶ In the unlikely event of a lithium-ion rechargeable battery bursting or exploding, keep all combustible materials away.

In any of the above cases, return your device to the hearing care professional.

For hearing aids with replaceable batteries

WARNING

- ▶ In the event of battery ingestion, seek medical attention immediately.
- ▶ In case of battery leakage, avoid contact with skin and clothing. If skin contact occurs, rinse the

affected area thoroughly with water and seek medical advice if necessary.

 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 18 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 over a prolonged period.

- ▶ If the tinnitus feature is set to such a level in the hearing aid, inform the user of the maximum duration per day that 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 cognitively impaired people.



WARNING

Warning for hearing aids for small children:

Instructions for the fitter of hearing aids for small children:

Choking hazard posed by small parts!

- ▶ Infants, children under 3 years and cognitively impaired persons must not wear the hearing aid without appropriate supervision.
- ▶ Acoustic coupling tube and earpiece must not be detachable by the child.

- ▶ It is recommended that the diameter of the earpiece be around 32 mm and that it can enclose the outer ear.
- ▶ Demonstrate and explain the battery door locking mechanism to the parents or caregiver.

Power cells

This section contains important safety information regarding the lithium power cell.

NOTICE

- ▶ Do not exchange power cells. This may only be performed by Service Center.

Defective power cells

In case you think the power cell is defective, comply with the following steps:

- Place the hearing aid into the charger. If you get a red LED, then the power cell is defective.

- Perform visual inspection of the hearing aid. The test is considered failed if it has any of below criteria:
 - There is physical sign of deformation caused by bloated power cell inside.
 - There is visible leakage from the power cell.
 - Product is generating heat on its own or hot to the touch.

If any of the test steps failed, consider the power cell defective. Due to safety concerns the hearing aid cannot be shipped anymore. Please record the serial number of the hearing aid, take a photo of the damages, and consult with the Customer Service team before disposal of the product according to local regulations.

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 90 %
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.



WARNING

Risk of injury, fire, or explosion during shipment.

- Ship lithium-ion batteries and hearing aids according to local regulations.

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:

- Regulation (EU) 2017/745 for products manufactured by WSAUD A/S and 93/42/EEC for products manufactured by Signia GmbH and Sivantos GmbH¹
- 2011/65/EU RoHS concerning the restriction of hazardous substances
- Only for products with wireless functionality: 2014/53/EU RED concerning radio equipment

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).

¹ see declaration of conformity

Notices

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.

Operation is subject to the following conditions:

- 1 This device may not cause harmful interference, and
- 2 this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to

radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment 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® Classic/Bluetooth® Low Energy

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

Bluetooth Classic

Wireless technology	Radio frequency Bluetooth
Output power (EIRP)	4 mW
Range	< 10 m between smartphone/ accessory and hearing aids
Frequency	2,400 – 2,480 MHz
Channel	79 channels
Bandwidth	1 MHz per channel , 1 MHz spacing
Modulation type	Gaussian Frequency Shift Keying, Pi/4 DQPSK, 8 DPSK

Bluetooth Low Energy

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

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.
ETSI 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.
ETSI EN 301 489-1/3/17	Immunity, RF and ESD	Standard for low power transmitters in the frequency range 9 kHz - 40 GHz.

Standard	Test Type	Note
ETSI 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
EN IEC 60118-13	RF immunity	International product standard for hearing aids to ensure adequate immunity to radio interference from mobile telephones.

Standard	Test Type	Note
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 EN 60601-1-2+A1, Table 9
Proximity to magnetic fields	8 A/m@30 kHz, 65 A/m@134.2 kHz, 7.5 A/m@50 kHz

Additional information

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.

Support

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

Legal manufacturer

WSAUD A/S

Nymoellevej 6

3540 Lyngø

Denmark

www.wsa.com

Phone: +45 44 35 56 00

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

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.

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