



Safety and maintenance information

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Safety information

It is important to read this safety and maintenance information thoroughly and completely. Follow the safety information to avoid damage or injury.

Intended 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.

Contraindications



WARNING

Do not use the product if you have any of these conditions:

- ▶ a visible deformity of the ear
- ▶ a history of active discharge from the ear within the previous 90 days
- ▶ a history of sudden or rapidly progressive hearing loss within the previous 90 days
- ▶ acute or chronic dizziness
- ▶ sudden onset of hearing loss in one ear within the previous 90 days
- ▶ visible evidence of significant ear wax accumulation or a foreign body in the ear canal

**WARNING**

Do not use the product if you have any of these conditions:

- ▶ pain or discomfort in the ear
- ▶ Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1,000 Hz, and 2,000 Hz

**WARNING**

In case you have any doubt whether this device is appropriate for you, consult a licensed physician before using this device.



WARNING

In case of a known contact allergy, consult the customer service 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

Contact your physician if you experience any unusual skin irritation, excessive accumulation of ear wax, dizziness, change in your hearing, or if you think there might be an object in your ear canal

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.

Symbols on the device or packaging



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

Symbols on the device or packaging



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



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.

Symbols on the device or packaging



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".

Symbols on the device or packaging



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



Medical device

Risk of damaging your hearing



WARNING

Risk of impairing the residual hearing of the user.
This hearing aid is intended for you only and should not be worn by others.

**WARNING**

Do not use this device as hearing protection in loud environments.

**WARNING**

Frequent exposure to loud sounds may harm your hearing. Keep the loudness at comfortable listening levels. Wear hearing protection when exposed to loud environmental noise.

**WARNING**

Risk of hearing damage!

- ▶ The smartphone generates short tone sequences to control the hearing aids. Do not hold the smartphone close to the ear while using the app.

Ear pieces



WARNING

Risk of injury!

Always wear the hearing aid with a click sleeve.

- ▶ Make sure that the ear piece is completely attached.
- ▶ Push the device into the intended position, making sure there is no discomfort/resistance.
- ▶ In the very rare case that the click sleeve gets stuck in the ear canal and you cannot remove it yourself, please contact a physician.



NOTICE

Select the click sleeve size that gives you the best wearing comfort in each ear. Left and right ear sizes may differ. Choose a larger size in case of whistling problems.

Sound awareness



WARNING

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



WARNING

Do not adjust the hearing aid when your attention is required on other activities, for example when crossing a street or driving a car.



WARNING

Where appropriate, adjust the hearing aid to ensure you can hear surrounding sounds, including alarms and warning signals. Be aware that it may be more difficult to identify where a sound is coming from during the first few weeks of use.

Cleaning and maintenance

Ear wax may accumulate in the click sleeves which may affect sound quality.



NOTICE

- ▶ Clean your hearing aids daily with a soft and dry tissue. Never use water. Only use cleaning products declared for use with hearing aids.



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.

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 aids are not in use for a prolonged period of time.

The following table helps you to identify the correct zinc air battery for your hearing aid:

Battery size	IEC code	ANSI code	Typical color code
10	PR70	7005ZD	yellow



NOTICE

- ▶ To avoid environmental pollution, do not throw batteries or hearing aids into household trash.
- ▶ Recycle or dispose of batteries or hearing aids according to local regulation.

General warnings



WARNING

Risk of injury!

- ▶ Do not use damaged devices.
Please consult the customer service.



WARNING

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

- ▶ Use only approved parts and accessories. Contact the customer service for suitable accessories.

**WARNING**

Risk of explosion!

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

**WARNING**

This product can expose you to nickel, which is known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov.



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 pets.
- ▶ If parts have been swallowed consult a physician or hospital immediately.



WARNING

Switch off the hearing aid in areas where the use of wireless devices is restricted.



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.

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



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 may cause audible interference.

Important information

Operating, transport and storage conditions

The hearing instruments 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.


Disposal information

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

Conformance information

The CE mark indicates conformity with the following European directives:

- Regulation (EU) 2017/745 concerning medical devices*
- 2011/65/EU RoHS concerning the restriction of hazardous substances
- 2014/53/EU RED concerning radio equipment

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

* see declaration of conformity

Devices with the FCC marking comply with the standards of the FCC regarding electromagnetic interference.

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 with ISED'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.

For US and Canadian markets only

For hearing aid users

Hearing aids will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. In most cases infrequent use of hearing aids prohibits the wearer from attaining the full benefit from it. The use of hearing aids is only part of hearing rehabilitation and may need to be supplemented by auditory training and instruction in lip reading.

Health considerations

If soreness or skin irritation develops, discontinue wearing your hearing aids.

Battery tips

If a battery is accidentally swallowed, seek medical attention immediately, or call the National Battery Hotline collect at **(202) 625-3333**.

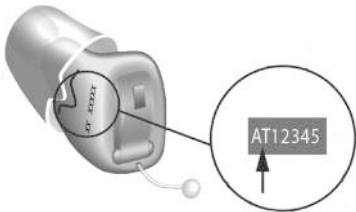
Identification information

Your hearing aids have a serial number imprinted on them. The location of the serial number will vary according to the style of hearing aid you have chosen. Record the serial number in your user guide for future reference.

The year of manufacture is incorporated into the serial number.

For in-the-ear devices, the year of manufacture is derived from the first two digits.

The month of manufacture is derived from the first digit, the year of manufacture from the second digit:



Code (first digit)	Month	Code (first digit)	Month
A, N	Jan	G, U	Jul
B, P	Feb	H, V	Aug
C, Q	Mar	J, W	Sep
D, R	Apr	K, X	Oct
E, S	May	L, Y	Nov
F, T	Jun	M, Z	Dec

Code (second digit)	Year	Code (second digit)	Year
W, X	2020	B, C	2022
Y, A	2021	D, E	2023

Wireless functionality

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

Wireless technology	Nearfield magnetic induction
Antenna type	Inductive antenna
Antenna dimensions	Ø: 3.3 mm, L: 4.2 mm, respectively, Ø: 2.0 mm, L: 6.7 mm
Modulation	PSK (Phase Shift Key)
Magnetic field strength	0.07 A/m, (1 cm ² coil; average)
Output power (EIRP)	53 µW

EIRP = Equivalent isotropically radiated power

Range	< 20 cm between hearing aids
Center frequency	3.28 MHz
Channel	Single channel radio
Bandwidth	138 kHz
Data rate	324 kbit/sec (raw channel capacity)
Data flow	Simplex or semi-duplex capability
Protocol	Random access, no collision avoidance
S.A.R.	6.63 nW/kg

S.A.R. = Specific Absorption Rate (S.A.R.) based on 10 g ICNIRP testing.

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.

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

Standard	Test Type	Note
ISO 14117	RF emissions	Implantable medical device EMC immunity, International Standard.
EN 45502-2-1	RF emissions	Particular requirements for pacemakers.

Wireless security measures

Wireless signal security is assured through the device system design that includes:

- A built-in pairing table which specifies valid and legitimate pairing among units.
- A proprietary communication protocol which checks the package numbers during each transmission.
- A Cyclic Redundancy Check (CRC) to check data validity.
- A convolutional encoder/decoder (Viterbi) to correct errors.

For 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.

Warranty and service

Your hearing aid, with the exception of the battery, is covered by a comprehensive warranty. All covered instrument parts received for warranty service at an authorized service center will be repaired or replaced with new or reconditioned components, without charge, to meet the performance specifications for that model.

This warranty does not cover malfunctions due to unusual wear and tear or mistreatment of the instrument such as physical shock, excessive wax build-up, or tampering with the instrument, any of which voids all warranties. Your Hearing Care Professional may charge a service fee for processing warranty service.

Warranty service must only be performed by an authorized service center. Service performed by unauthorized service depots voids this warranty, and repairs so necessitated will be done on a parts and labor cost basis.

Please refer to the warranty card included with your hearing aids for warranty period effective dates.

Your hearing aids may have additional loss and damage coverage. Please consult your Hearing Care Professional to determine if this is applicable to your hearing aids.

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

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