



Safety manual for hearing aids



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1 Safety information

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

1a 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.

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

1b 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.

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

Symbols on the device or packaging

-  CE 0123 CE compliance label, confirms compliance with certain European Directives, 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".
-  Read and follow the instructions in the user guide.

1c 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 your NHS Provider.

-  **WARNING**
Note that any unauthorised changes to the product may cause damage to the product or cause injury.
▶ Use only approved parts and accessories. Ask your NHS Provider for support.

-  **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. in 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**
Only use zinc-air 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.

-  **NOTICE**
▶ Protect your hearing aids from extreme heat. Do not expose them to 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. 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 hearing aids are interference-free, for example some induction cookers may cause audible interference.

Contraindications

-  **WARNING**
Consult your NHS Provider 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.

-  **WARNING**
A NHS Provider should advise a prospective hearing aid user to consult a licensed physician before using the hearing aid if the NHS Provider 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.

1c General warnings (Continued)

For hearing aids with wireless functionality

- i** 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.

1d For certain aid types

BTE models

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.

RIC models

The receiver is placed within the ear canal and connected to the 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.

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



Other models

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

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 NHS Provider.

⚠ 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.

1e 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 NHS Provider 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 ear mould.
▶ Consult your NHS Provider 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 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.

1f 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.

1g For NHS Providers

⚠ 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 aid.

⚠ 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.

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 NHS Provider.

2 Important information

2a Transport and storage conditions

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 %

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

2c Conformance information

The CE mark indicates conformity with the following European directives:

- 93/42/EEC concerning medical devices
- 99/5/EC (R&TTE) concerning radio and telecommunications equipment (only for products with wireless functionality)
- 2011/65/EU RoHS concerning the restriction of hazardous substances

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

Technical details

Operating frequency: $f_c = 3.28 \text{ MHz}$

Wireless platform, model: e2e 3.0

Changes or modifications made to this equipment, not expressly approved by the legal manufacturer may void the warranty of this equipment.

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.

2b Disposal information

- ▶ Recycle hearing aids, accessories and packaging according to local regulations.
- ▶ To avoid environmental pollution, do not throw batteries into household household waste.
- ▶ Recycle or dispose of batteries according to local regulations or return them to your NHS Provider.

This equipment has been tested and found to comply with the limits as stipulated in the relevant EU Directive. 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 an experienced radio/TV technician for help.