Safety manual for hearing instruments

for US and Canadian markets | Master

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Safety information

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

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

Intended use

Hearing instruments 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 instruments 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 instruments.

Symbols on the device or packaging	
CE 0123	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.
	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.

General warnings

WARNING

Risk of impairing the residual hearing of the user.

- Use only hearing instruments 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.

WARNING

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

WARNING

Risk of explosion!

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

WARNING

Choking hazard!

Your hearing instruments contain small parts which can be swallowed.

- Keep hearing instruments, 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 instruments 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 instruments 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 instruments from extreme heat. Do not expose them to direct sunlight.

NOTICE

- Do not dry your hearing instruments in the microwave oven.

NOTICE

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

- Do not wear the hearing instruments during these or similar procedures.

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

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.

Contraindications

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.

WARNING

A Hearing Care Professional should advise a prospective hearing instrument user to consult a licensed physician before using the hearing instrument 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.

For hearing instruments 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 instruments 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.

For hearing instruments with a tinnitus feature

Your hearing instrument 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 instruments 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 instruments.

- Keep a minimum distance of 2 cm between the RIC receiver and any magnet, including the AutoPhone magnet.

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

For hearing instruments with a magnet in the battery compartment

WARNING

Risk of interference with active and non-active implants!

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 instruments.
- Keep a safe distance of about 1.6 inches (4 cm) between the implant and hearing instruments.

For certain instrument types

BTE models

Instruments 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 instrument via a receiver cable.

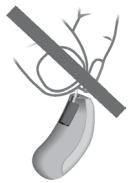
CAUTION

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 instruments.



Other models

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

For children under the age of 3 years

There are special hearing instruments 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 instruments contain small parts which can be swallowed.

- Ensure adequate supervision if infants, small children or mentally disabled persons need to wear hearing instruments.
- Check the completeness of the hearing instruments regularly.
- Ensure that your child or the mentally disabled person does not detach the hearing instrument 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 instruments with built-in power cells (lithium-ion rechargeable batteries)

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

For hearing instruments 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 instruments.

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

When using remote control apps

When using an app for controlling hearing instruments:

WARNING

Risk of hearing damage!

The device with the app for controlling hearing instruments 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 instruments 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 instrument.

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 instrument, 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.

Important information

Transport and storage conditions

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

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

Read the transport and storage conditions in the hearing instrument's user guide.

For hearing instruments with replaceable batteries

	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.

Disposal information

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

For hearing instruments 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:

- 93/42/EEC concerning medical devices
- Only for products with wireless functionality: 99/5/EC R&TTE concerning radio and telecommunications equipment (valid until June 12th, 2016) or 2014/53/EU RED concerning radio equipment (valid from June 13th, 2016)
- 2011/65/EU RoHS concerning the restriction of hazardous substances

The full text of the declaration of conformity can be obtained from www.signia-hearing.com/doc (for hearing instruments manufactured by Signia GmbH) or from www.sivantos.com/doc (for hearing instruments manufactured by Sivantos GmbH).

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 instruments' 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 with ~~Canada's RSS-210~~ 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 prospective hearing instrument users

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing instrument. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing instrument is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for hearing instruments. The physician will refer you to a Hearing Care Professional for a hearing instrument evaluation.

The Hearing Care Professional will conduct a hearing instrument evaluation to assess your ability to hear with and without hearing instruments. The hearing instrument evaluation will enable the Hearing Care Professional to select and fit hearing instruments to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of

a trial-rental or purchase-option program. Many Hearing Care Professionals now offer programs that permit you to wear hearing instruments for a period of time for a nominal fee after which you may decide if you want to purchase them.

U.S. federal law restricts the sale of hearing instruments to those individuals who have obtained a medical evaluation from a licensed physician. U.S. federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

For hearing instrument users

Hearing instruments 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 instruments prohibits the wearer from attaining the full benefit from it. The use of hearing instruments 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 instruments, and bring the instruments and earmolds to your Hearing Care

Professional. Minor fit adjustments or earmold modification can often correct this condition. If soreness persists, discontinue wearing the hearing instrument and see your physician. If excessive earwax accumulates when wearing your hearing instruments, consult your Hearing Care Professional.

Battery tips

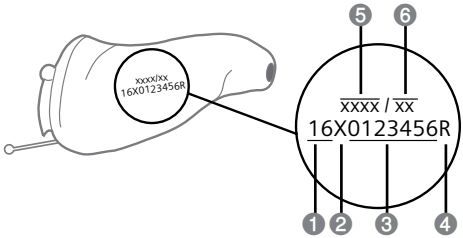
If a battery is accidentially swallowed, seek medical attention immediately, or call the National Battery Hotline collect at **(202) 625-3333**.

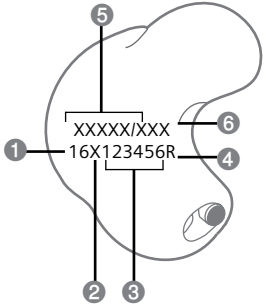
Identification information

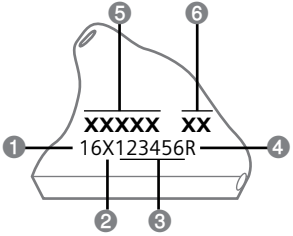
Your hearing instruments have a serial number imprinted on them. The location of the serial number will vary according to the style of hearing instrument you have chosen. Record the serial number in your user guide for future reference.

The year of manufacture is incorporated into the serial number.

For custom instruments, the year of manufacture is derived from the first two digits. In the following examples, the year of manufacture is 2016.







❶ 16:
year manufactured

❷ X:
facility code where instrument was manufactured

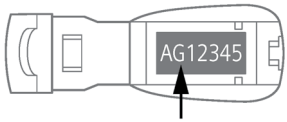
❸ Serial number

❹ L or R:
left or right ear instrument

❺ Manufacturer/Distributor

❻ Model

For BTE and RIC instruments, the year of manufacture is derived from the second digit:



Code (second digit)	Year
D, E, F	2013
G, H	2014
L, M	2015
N, P	2016
Q, R	2017
S, T	2018

Please note the warranty is based upon the date of purchase, not the date of manufacture.

Your Audiologist or Hearing Care Professional can answer any questions you may have about the identifying code on your hearing instrument.

Wireless functionality

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

Wireless technology	Nearfield magnetic induction
Antenna type	Inductive antenna
Antenna dimensions	BTE or RIC models: Ø: 1.9 mm, L: 6.5 mm, respectively, Ø: 2.3 mm, L: 5.7 mm, respectively, Ø: 2.8 mm, L: 4.4 mm Custom models: 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 instruments
Center frequency	3.28 MHz
Channel	Single channel radio
Bandwidth	BTE or RIC models: 140 kHz Custom models: 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.	2.36 nW/kg (BTE) 6.63 nW/kg (custom models)
S.A.R. = Specific Absorption Rate (S.A.R.) based on 10 g ICNIRP testing.	

Bluetooth® low energy*

Wireless technology	Radio frequency - Bluetooth low energy
Antenna type	Electromagnetic dipole antenna
Antenna dimensions	BTE or RIC models: H: approx. 4 mm, L: approx. 15 mm
Magnetic field strength	not applicable
Output power (EIRP)	150 µW
EIRP = Equivalent isotropically radiated power	
Range	< 10 m between smartphone/ accessory and hearing instruments
Center frequency	2.45 GHz
Channel	40 channel radio
Bandwidth	2 MHz per channel

* 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.

Data rate	1 Mbit/sec, respectively, 2 Mbit/sec
Data flow	Simplex or semi-duplex capability
Protocol	Bluetooth network FHSS (Frequency Hopping Spread Spectrum)
S.A.R.	1.31 nW/kg
S.A.R. = Specific Absorption Rate (S.A.R.) based on 10 g ICNIRP testing.	

EMI/EMC compliance

Wireless hearing instruments 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 300 330-1/2	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	Immunity, RF and ESD	Standard for low power transmitters in the frequency range 9 kHz - 40 GHz.

Standard	Test Type	Note
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
IEC 60118-13	RF immunity	International product standard for hearing instruments 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 instruments.
ANSI/AAMI PC69	RF emissions	Implantable medical device EMC immunity.
ISO 14117	RF emissions	Implantable medical device EMC immunity.
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.

The Bluetooth low energy connection uses the security measures that are defined in the Bluetooth low energy standard.

Tinnitus feature

Your hearing instrument may be equipped with a tinnitus feature. Many tinnitus patients also suffer from some degree of hearing loss. Many hearing instruments can be used alone or in combination with the tinnitus feature. The tinnitus feature is fixed to a broadband noise that can be adjusted by your Hearing Care Professional for your tinnitus therapy.

The feature may provide temporary relief of your tinnitus.

Prescription Use Only

U.S. federal law restricts this device to sale by or on the order of a doctor or Hearing Care Professional licensed to dispense hearing instruments in your state. The use of any sound generating tinnitus therapy device should be only on the advice and in consultation with your Hearing Care Professional. Your Hearing Care Professional will properly diagnose and fit the device to your personal needs and requirements. This should include its use in a prescribed tinnitus treatment program. Your Hearing Care Professional will also be able to offer the appropriate follow-up care. It is important that you follow your Hearing Care Professional's advice and direction regarding such care.

There are some potential concerns associated with the use of any sound generating tinnitus therapy device. Discontinue use and seek medical evaluation if any of the following conditions occur:

- Chronic skin irritation on, near, or around the site of device placement.
- Unusual side effects (e.g., dizziness, nausea, headaches, heart palpitations).
- Perceived decrease in auditory function (e.g., decreased loudness, speech not as clear).

For Hearing Care Professionals

Indications for use

The tinnitus feature is a tool to generate sounds to be used in a tinnitus management program to relieve patients suffering from tinnitus. The target population is primarily the adult population over 21 years of age. The tinnitus feature is targeted for healthcare professionals treating patients suffering from tinnitus, as well as conventional hearing disorders. The fitting of the tinnitus feature should be done by a Hearing Care Professional participating in a tinnitus management program.

Device description

The tinnitus feature is a software function that generates sound which is programmed into a hearing instrument. Depending on the type of hearing instrument, the hearing instrument may be used in up to three modes of operation: as a hearing instrument, as a tinnitus treatment device, or as a hearing instrument and tinnitus treatment device.

When enabled, the tinnitus feature generates the sound and allows a patient's Hearing Care Professional to design and program appropriate settings for an individually prescribed sound treatment plan. The treatment plan should be used in a tinnitus management program for relief of tinnitus.

The tinnitus feature generates a broadband noise signal that varies in frequency and amplitude. These characteristics are adjustable by the Hearing Care

Professional and are specific to the prescribed therapy designed by the professional for the patient's needs and comfort. 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.

A Hearing Care Professional should advise a prospective tinnitus feature user to consult promptly with a licensed physician (preferably an ear specialist) before using the tinnitus feature if the Hearing Care Professional determines through inquiry, actual observation, or review or any other available information concerning the prospective user 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.

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 instrument, 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 instruments for warranty period effective dates.

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

Risk mitigations (for internal use only)

IFU101 | interference induction cooker | device 6
M11 | explosion | HI 5
M15 | choking | non-ped HI 5
M18_2/2 | Battery type 14
M20_1/4 | heat | HI 6
M20_2/4 | humidity | HI not Aquaris 6
M20_3/4 | microwave | HI 6
M20_4/4 | X-Ray | HI 6
M23 | wireless interference 8
M28, M213 | environmental pollution 18
M29 | recycle HI 18
M31_1/3 | tube with ear piece 12
M35 | choking | pediatric 13
M38_1/2 | autophone | interference 10
M38_2/2 | autophone | life support 10
M48_1/3 | cable with ear piece 12
M78a | more than 132 dB 16
M90 | only fitted | HI 4
M91 | interference 8
M102 | magnet in HI 11
M105_2/2 | tinnitus D8 und D9 9
M106_1/2 | tinnitus dispenser 16
M107 | directionality 5
M108 | app acoustic control signal 15
M109 | damaged device | HI 4
M110 | unauthorized modifications 5
M111 | contraindications dispenser (replaces M106_2/2) ab RA V29 .. 7
M112 | contraindications user (replaces M105_1/2) ab D9 7

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

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Order/Item No. ### ### ##
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