

BiCore C R-Li BiCore C R-Li T

RECHARGEABLE
HEARING AIDS



USER GUIDE 1
(SAFETY MANUAL FOR US AND CANADIAN MARKETS)

Content

Safety information	4
Intended use	10
Explanation of symbols	11
General warnings	12
For certain hearing aid types	18
For hearing aids with built-in power cells (lithium-ion rechargeable batteries)	19
When using remote control apps	19
Important information	20
Operating, transport and storage conditions	20
Disposal information	20
Conformance information	20
For US and Canadian markets only	23
For prospective hearing aid users	23
For hearing aid users	24
For children with hearing loss	31
Warranty and service	31

This User Guide 1 (Safety Manual for US and Canadian markets) is valid for:

Hearing aids

BiCore C R-Li

BiCore C R-Li T

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 User Guide 2 (Instructions for Use) for your hearing aids to check the hearing aid type and the activated features.



WARNING

People younger than 18 should go to a doctor before using this.

People younger than 18 years old need specialized care, and using this without a medical evaluation may worsen impairment or disability. A hearing aid user who is younger than 18 should have a recent medical evaluation from a doctor, preferably an ear-nose-throat doctor (an ENT). Before using this, a doctor should determine that the use of a hearing aid is appropriate.



WARNING to Hearing Aid Dispensers:

You should advise a prospective hearing aid user to consult promptly with a doctor, preferably an ear specialist such as an ENT, before dispensing a hearing aid if you determine through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

- ▶ Visible deformity of the ear, either congenital or traumatic
- ▶ Fluid, pus, or blood coming out of the ear within the previous 6 months
- ▶ Pain or discomfort in the ear
- ▶ History of excessive ear wax or suspicion that something is in the ear canal
- ▶ Dizziness, either recent or long-standing
- ▶ Sudden, quickly worsening, or fluctuating hearing loss within the previous 6 months
- ▶ Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears
- ▶ Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz, and 2000 Hz



WARNING to Hearing Aid Dispenser, Outputs over 132 dB SPL:

You should exercise special care in selecting and fitting a hearing aid with a maximum output that exceeds 132 dB SPL because it may impair the remaining hearing of the hearing aid user.



CAUTION

This is not hearing protection.

You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.



CAUTION about excessive sound output

Caution. The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your device.



CAUTION

You might need medical help if a piece gets stuck in your ear. If any part of your hearing aid, like the eartip, gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as you can. You should not try to use tweezers or cotton swabs because they can push the part farther into your ear, injuring your eardrum or ear canal, possibly seriously.



NOTICE

What you might expect when you start using a hearing aid.

A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss.

People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counseling can help them get more out of their devices.

If you have hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening - for example, noisy environments.



NOTICE

Tell FDA about injuries, malfunction, or other adverse events.

To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. FDA calls them “adverse events,” and they might include: skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated batter), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc.

Instructions for reporting are available at <https://www.fda.gov/Safety/MedWatch>, or call 1-800-FDA-1088. You can also download a form to mail to FDA.



NOTICE

Hearing loss in people younger than 18.

- ▶ People younger than 18 should see a doctor first, preferably an ear-nose- throat doctor (an ENT), because they may have different needs than adults.
- ▶ The doctor will identify and treat medical conditions as appropriate.
- ▶ The doctor may refer the person to an audiologist for a separate test, a hearing aid evaluation.
- ▶ The hearing aid evaluation will help the audiologist select and fit the appropriate hearing aid.

A person who is younger than 18 years old with hearing loss should have a medical evaluation by a doctor, preferably an ENT, before buying a hearing aid.

The purpose of a medical evaluation is to identify and treat medical conditions that may affect hearing but that a hearing aid won't treat on its own.

Following the medical evaluation and if appropriate, the doctor will provide a written statement that the hearing loss has been medically evaluated and the person is a candidate for a hearing aid.

The doctor may refer the person to an audiologist for a hearing aid evaluation, which is different from the medical evaluation and is intended to identify the appropriate hearing aid.

The audiologist will conduct a hearing aid evaluation to assess the person's ability to hear with and without a hearing aid. This will enable the audiologist to select and fit a hearing aid for the person's individual needs. An audiologist can also provide evaluation and rehabilitation since, for people younger than 18, hearing loss may cause problems in language development and educational and social growth. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of hearing loss in people younger than 18.


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.


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".


 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".

 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".



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



Medical device



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.



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

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 mentally disabled persons.
- ▶ If parts have been swallowed consult a physician or hospital immediately.



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.

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.



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.

**WARNING**

If battery is swallowed, contact the Poisons Information Hotline on 13 11 26 for Australia and 0800 764 766 for New Zealand. For other countries, please contact the local Poison Information hotline.

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 certain hearing aid types

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

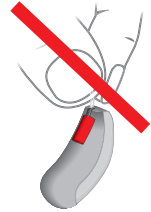
Risk of injury!

- ▶ 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.



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.

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.

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.

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 for products manufactured by WSAUD A/S
 - *
- 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.

* see declaration of conformity

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).

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 prospective hearing aid 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 aid. 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 aid 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 aids. The physician will refer you to a Hearing Care Professional for a hearing aid evaluation.

The Hearing Care Professional will conduct a hearing aid evaluation to assess your ability to hear with and without hearing aids. The hearing aid evaluation will enable the Hearing Care Professional to select and fit hearing aids 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 aids 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 aids 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 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

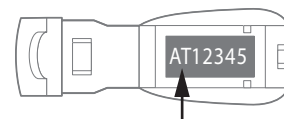
If soreness or skin irritation develops, discontinue wearing your hearing aids, and bring the hearing aids and earmolds to your Hearing Care Professional. Minor fit adjustments or earmold modification can often correct this condition. If soreness persists, discontinue wearing the hearing aid and see your physician. If excessive earwax accumulates when wearing your hearing aids, consult your Hearing Care Professional.

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 RIC hearing aids, the year of manufacture is derived from the second digit:



Code (second digit)	Year	Code (second digit)	Year
K, L	2026	U, V	2019
H, J	2025	S, T	2018
F, G	2024	Q, R	2017
D, E	2023	N, P	2016
B, C	2022	L, M	2015
Y, A	2021	G, H	2014
W, X	2020	D, E, F	2013

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 aid.

Wireless functionality

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

Wireless technology	Nearfield magnetic induction
Antenna type	Inductive antenna
Antenna dimensions	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
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	140 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

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	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 aids
Center frequency	2.45 GHz

* 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.

Channel	40 channel radio
Bandwidth	2 MHz per channel
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 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.
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 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.

Standard	Test Type	Note
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.

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.

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 hearing aid 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 hearing aid such as physical shock, excessive wax build-up, or tampering with the hearing aid, 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.

REXTON

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

For Canada: Manufactured by WS Audiology Canada Inc.

Document No. D00285591 EN
Order/Item No. 21026571
Master Rev01, 02.2023
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