





Digitales Knochenleitungshörsystem
Digital bone conduction hearing system

Gebrauchsanweisung / Instruction for Use

Congratulations on acquiring your digital bone conduction hearing system **contact star evo1** – a quality product from BHM. The digital bone conduction hearing system contact star evol is manufactured in Austria in accordance with provisions set by the European Medical Device Directive 93/42/EEC, and is in line with the latest audiological findings and technical innovations. It bears the CE mark, signalling its adherence to the latest quality and safety requirements. You can use your bone conduction hearing system, which is characterized by high-quality signal processing, with the help of spectacles (wearing option). When selecting the appropriate spectacles, please pay attention to the various sizes in order to quarantee comfortable wearing. This Instruction for Use contains many hints and tips on how to get the best from your new contact star evo1 and how to care for it properly. Please read these carefully, and always keep this Instruction for Use handy in order to get the best out of your hearing system.

Intended Use: The bone conduction hearing system contact star evo1 has been designed to compensate hearing loss by processing sound and transmitting it to the inner ear.

User group(s): The hearing system is suitable for people of any age with hearing loss.

Indications: For mild to moderate hearing loss.

Contraindications: Do not use in case of irritated and injured skin or pressure marks.

Warning! Potential side effects: Possible pressure points, irritation of the skin or pain in case of wrong size selection of the wearing option.

The **contact star evo1** is designed for a lifetime of 5 years.

For additional, current information, please visit **www.bhm-tech.at**

Your **contact star evo1** has been selected for you by your hearing care professional according to your hearing impairment and has been adapted to your needs. Your hearing care professional will provide you with comprehensive instruction on first-time use, proper handling and regular maintenance measures.

You may of course contact your hearing care professional to discuss any questions or issues concerning your hearing or use of the hearing system.

Various individual settings, such as activating/deactivating of signal tones or their volume is the responsibility of your hearing care professional. Please fit these settings together.



The **contact star evo1** contains a magnet. Magnets can affect medical devices

(pacemakers, defibrillators, ...) or electronic systems and cause malfunctions.

Use the **contact star evo1** only if there are no doubts about the safety.

Manufacturers of equipment that may be susceptible or sensitive to magnets (such as pacemakers) must provide reasonable safety advice.

The safety margin from the hearing system and magnetically sensitive devices (e.g. pacemaker) must be at least 30 cm.

Please read this Instruction for Use carefully before using your device. If you will not be wearing the hearing system yourself, please take note of the following information as relates to the person who will.

Please check that the device functions safely and is in proper condition before use. The device must under no circumstances be used if there is any suspicion that it does not work flawlessly or is damaged, especially the battery compartment.

Do not place any excessive mechanical strain on your device. Should it be dropped on the ground or otherwise damaged, please send it to your hearing care professional for checking and repair.

Never give your bone conduction hearing system to others in order to prevent unauthorised use.

Description

The **contact star evo1** bone conduction hearing system consists of a whole part. (Symbolic image 1).

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Key

Follow instructions for use!
Manufacturer
CE marking and Notified Body number
Do not dispose of in household waste
Important information for usage and product safety
Warning! Pay attention to the warnings notices in these instruction for use

Symbols	
-20°C - +60°C	Temperature during transport and storage
10%	Humidity during transport and storage
Ť	Protect from moisture
∱	Type B Applied part
SN	Serial number

Due to the limited size available on the device, relevant approval markings are found in this document.

Technical data

Dimensions	
Dimensions	Length: 108 mm; Hight: 38 mm Width temple: 6.4 mm Width bone conduction receiver: 11.2 mm
Weight	13.6 g (incl. battery); 11.8 g (excl. battery)

Technical Data according to DIN IEC 118-9	
Frequency Range	200 Hz – >8000 Hz
Max. Acousto-Mechanical Sensitivity Level	52 dB
Max. Output Force Level	111 dB0FL
Current consumption	0.95 mA
Battery size	675 (PR 44, Zinc-Air)
Battery life (@ 610 mAh battery capacity)	approx. 640 h
Operating temperature range	+5 °C bis +40 °C

The hearing system contact star evo1



- 3 Battery size 675
- 4 Battery compartment
- (5) Bone conduction receiver
- 6 Microphone (under protective cover)
- 7) Programming socket (under protective cover)
- 8 Battery compartment safety lock screw

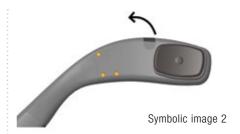
Operation

Your hearing care professional will decide which spectacles are the most suitable for your **contact star evo1**. Your hearing care professional will provide you with full instructions on how to use your **contact star evo1** and spectacles.

The use of accessories made by other manufacturers respectively products not approved by BHM may put your health at risk and cause irreparable damage to your health. Only accessories from BHM may be used. Your hearing care professional will advise you on this matter.

Opening the battery compartment and inserting the battery

To open the battery compartment, to insert, or replace the battery, open the battery compartment with your fingernail (Symbolic image 2).



Your **contact star evo1** is equipped with a battery compartment safety lock. Before opening the battery compartment, the battery compartment safety lock screw must be removed. To do this, unscrew the battery compartment safety lock screw counterclockwise from the intended position in the battery compartment using a screwdriver (symbolic image 3).

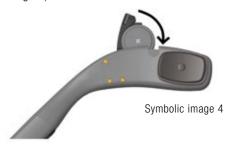
The battery compartment safety lock screw is available from BHM. Only this battery compartment safety lock screw from BHM may be used.



Symbolic image 3

Carefully open the battery compartment until it is fully open. When replacing the battery, please remove the old battery and dispose of this in accordance with local regulations. Take a new battery, size 675, from the package and remove the adhesive strip from the positive terminal. Then wait the amount of time recommended by the manufacturer before inserting the battery into the hearing system. Please ensure that the battery has been inserted correctly, in alignment with the correct terminal (please check the + marking on the battery). Always insert the battery into the battery compartment, never directly into the hearing system!

Close the battery compartment carefully with your fingers until it locks into place (Symbolic image 4).



The battery compartment safety lock screw must be inserted after closing the battery compartment.

To do this, screw the battery compartment safety lock screw clockwise at the intended position in the battery compartment using a screwdriver (symbolic image 3).

We recommend storing your device in a safe place after daily use, with the battery compartment open. Opening the battery compartment also enables you to dry residual moisture.

Battery

Use only non-rechargable size 675 zinc-air hearing aid batteries. Your hearing care professional will be pleased to advise you in this regard.

If the hearing system is not in use, please open the battery compartment. Store it without battery and out of reach of anyone.

Battery warning tone

contact star evo1 is equipped with a battery warning tone. When the battery is weak, amplification will automatically be reduced. When the warning tone sounds, the battery must be changed immediately.

Swallowing a battery is harmful to health and may cause severe damage or even death! Never change the batteries of the hearing system in the presence of infants, toddlers, children or mentally impaired persons. The insertion or replacement of the battery may only be carried out after instruction by the hearing care professional. Never store batteries alongside, for example, medicines! If you have swallowed a battery, please seek medical attention immediately. Always store batteries out of reach of children! Pay attention to an intact battery compartment!

Switching on and off Switching on:

To switch on the device put the O-T-M switch ② in position "M" (= microphone).

Sound Dynamix (BHM Automatic (A))

In Automatic mode, the signal received by the microphone is analysed and categorised into

different hearing situations. These are:

- Quiet environments
- Speech in quiet environments
- Speech in background noise
- · Music and movie
- · Background noises
- Wind noises

The parameters of the hearing system are always configured according to this categorisation such that an optimal level of hearing comfort and optimal speech comprehension are attained.

Switching to telecoil:

In order to switch the setting, set the O-T-M switch to the "T" position. The program change is confirmed by an acoustic signal. The telecoil enables you to receive inductive signals (e.g. from the telephone or induction loop). This enables you, for example, to hear the person on the other end of the line more clearly, as

the microphone is switched off and disruptive background noises are therefore prevented. The telecoil can also be used in public buildings that have an induction loop, for example in schools, theatres, concert halls or cinemas.

It is also possible to select a combined microphone/telecoil mode using the fitting software. This mode enables you to receive inductive signals whilst also hearing your environment better as the microphone is switched on.

Switching off:

To switch off the device, put the O-T-M switch ② in position "0".

Setting the volume

Please consult your hearing care professional about the ideal volume for you. Please ensure that you are properly informed by your hearing care professional as regards setting the volume.

Select the most comfortable volume for you by rotating the volume control ①. The volume becomes "louder" when you turn the volume control forward. The volume becomes "lower" when you turn the volume control backward.

Important notes on operating the hearing spectacles:

Switch off the device by using the O-T-M switch ②, put on your hearing spectacles, select volume level low and switch the device back on. Select the most pleasant volume level only after switching on and checking volume of device!

Special care must be taken to ensure that the conductor plate of the bone conduction receiver (5) is firmly seated against the mastoid bone. Partial or weak contact will cause feedback (whistling).

Wearing option spectacles

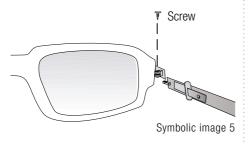
When selecting a suitable wearing option (spectacles front and extension tips), please consider the various sizes! Incorrect use and selection of the sizes of the wearing option can lead to skin irritation, pressure points and pain.

Please make absolutely sure that the spectacles of the **contact star evo1** is positioned correctly on the head and that the conductor plate of the bone conduction receiver rests against the head. Please make sure that the conductor plate is touching the skin.

- Hair between the conductor plate and the skin may reduce transmission considerably.
- Poor contact with the skin and a high volume may cause feedback.

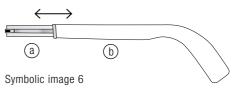
Assembly of the extension tips with the spectacles front (Only for your hearing care professional)

Mount the extension tips on the spectacles front using the hinge screws supplied with the spectacles front. First remove the hinge screws from the hinges of the spectacles front using a suitable screwdriver. The extension tips are attached to the spectacles front through the hinges and screwed in place with the hinge screws (Symbolic image 5).



Mounting the hearing system to the extension tip

The hearing system **(b)** is mounted to the extension tip **(a)** via a build-in click system. The parts are fixed together by sliding the front side of the hearing system onto the click system of the extension tip. Disassembling is done by pulling the hearing system off the extension tip (Symbolic image 6).



The **contact star evo1** can be used for monaural or binaural fitting. In case of monaural, one hearing system is used on one side (left or right) and one dummy device (without any electronics) is used on the opposite side. In case of binaural, two hearing systems are used (left and right).

Cleaning your spectacles

Please make sure that the hearing system is removed before cleaning the spectacles. Sweat and moisture should be wiped away on a daily basis with a damp cloth, and then wiped down with a dry cloth.

Adjustment and programming

(Only for your hearing care professional)

To fit the **contact star evo1** hearing system and use the BHM fitting software, the hearing care professional must have appropriate experience in fitting hearing systems and performing standardized audiological tests and measurements. A basic technical understanding of hearing systems, especially bone conduction hearing systems, is required.

Special instructions in case of the care of children and persons with cognitive impairment: This hearing system is suitable for patients of all ages. However, for safety reasons, children and persons with cognitive impairment may only use this device **under supervision**. The hearing system is a small device and contains small parts.

Children and persons with cognitive impairment should never be left unattended with this hearing system. If the hearing system or parts of it are swallowed, there is a risk of danger of suffocation. In this case a doctor or hospital must be consulted immediately! The supervisors or persons in charge of children and persons with cognitive impairments must be instructed in this regard by the hearing care professional!

The **contact star evo1** hearing system is available as a monaural hearing system in a version for the left or right side.

Mechanical fitting

The hearing system is used together with the corresponding wearing option (spectacles front and extension tips). Make sure that the wearing option is the correct size and fits the patient correctly!

Improper use and incorrect selection of the sizes of the wearing option (spectacles front and extension tips) can lead to skin irritation, pressure points and pain for the patient. If any of these symptoms occur during use, the application must be stopped immediately and a new fitting must be performed.

Spectacles

When selecting the correct size of the spectacles, make sure that it fits comfortably on the patient. The conductor plate of the bone conduction receiver must be placed behind the ear on the mastoid. If necessary, the position can be varied accordingly. The patient must be

instructed accordingly. Wearing the spectacles should be perceived as comfortable as possible.

The spectacles fronts and extension tips are available in different variations and sizes at BHM. Only spectacles fronts and extension tips from BHM may be used.

Before programming – opening the protective cover

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There must not be a battery in the device during programming!

Open the protective cover on the underside of the **contact star evo1** using a screwdriver (Symbolic image 7).

The programming socket will now be visible. Insert the programming cable plug into the socket.



Please ensure that the red marking on the programming cable plug is on the same side as the yellow marking on the programming socket. Otherwise, you will have no connection i.e. may destroy the programming socket!

The acoustic fitting via programming is carried out directly on the patient. To do this, mount the hearing system on the spectacles and ensure that it is correctly fitted on the patient.

Programming interface

Only the programming interfaces NOAHlink and HI-PRO may be used for the **contact star evo1** hearing system. The programming interface must be installed on your computer. For installation, please use the programming interface manufacturer's documents and software.

Fitting software

In order to guarantee flawless function, please only use the BHM software released for this product. If you have any doubts or queries, please contact your supplier or BHM.

After programming

Remove the programming cable and close the protective cover again until it locks into place.

Recommendation: If you wish to switch off the volume control function, you can do so by deactivating it using the fitting software.

Troubleshooting

- Please note that your hearing system will automatically switch off when the battery is low.
- Please check that your hearing system is connected by cable and that the battery compartment has a battery inside and is closed properly.
- Does the battery have enough power and has it been inserted correctly? Please make sure that you always carry replacement batteries with you.
- Has the volume control been adjusted correctly? Make sure that the bone conduction receiver is correctly positioned on your head.
- Background noise und noise signals may not necessarily indicate a fault or error in the hearing system – this may be interference from mobile phones or other electronic devices in your vicinity. In that case, move the hearing system away from the affected electronic device.

 If your hearing system still does not work after checking all the above points, please take your device to your hearing care professional with a concise description of the error.

Notes for troubleshooting

Symptom	Possible cause	Possible solution
Hearing system doesn't work	 Hearing system is not switched on / no battery has been inserted Empty battery Battery compartment won't close 	 Switch on hearing system / insert battery and close battery compartment Replace battery Insert battery correctly / insert correct size 675 battery
Hearing system is not loud enough	Hearing ability has changed Volume set too low	Go to your hearing care professional Increase volume or ask your hearing care professional to do so for you
Sound is distorted / unclear	 Weak battery Hearing system is damaged Hearing system setting are not optimal Hearing system is soiled 	 Replace battery Contact your hearing care professional Contact your hearing care professional Clean hearing system

Cleaning

In order to ensure the quarantee and warranty of your hearing system, we kindly advise you to clean your hearing system thoroughly and properly at least once a day. Wipe your hearing device with a clean, dry cloth and make sure that your fingers are clean and dry too. Remove any sweat and moisture from your hearing device. If not using, it is also necessary to remove the battery from your hearing device after daily cleaning, and to store it with the battery compartment open in order for any moisture to evaporate. Please ensure that you have removed your hearing system from the spectacles before cleaning the latter.

Please remove your hearing device before showering, bathing or visiting a sauna and before using body care products, hairspray or cosmetic powder, as these kinds of deposits contaminate your hearing device and may impair or damage its function. We kindly request that you follow these instructions at all times, as otherwise there can be no guarantee claim and no warranty repairs can be carried out!

Warnings

Improper use of your hearing system and battery may endanger your health. Please read the following points with great care.

- Keep other people (predominantly children) away from your contact star evo1 hearing system and its parts, when it is not in use. There is the risk of swallowing small parts!
- Swallowing batteries puts your health at risk and can cause serious injury and even death!
 Never change the batteries of the hearing system in the presence of infants, toddlers, children or mentally impaired persons. The insertion or replacement of the battery may

only be carried out after instruction by the hearing care professional. Never store batteries alongside medicines! Please seek immediate medical attention in the event of swallowing a battery.

- Incorrect handling may cause the battery to leak and endanger your health!
- The use of incorrect batteries or non-hearing aid batteries may cause the hearing system to malfunction. Always use size 675 batteries and replace them regularly.
- Improper handling of the hearing system may loosen its components.
- Please do not swallow small detachable components, this may harm your health and can have serious consequences!
- Switch off your hearing system in mines or in places areas exposed to explosion hazards.
- For safety reasons, children or people with a mental impairment may only wear the hearing system under supervision (risk of swallowing and suffocation).

- The hearing system may only be applied to skin that is intact.
- Improper use and wrong size of the wearing option can lead to skin irritation, pressure points and pain. In this case, consult your hearing care professional or doctor.
- Remove your hearing system when you sleep, there is a risk of injury.
- Do not make a wire connection from your hearing system to any external audio sources like radio etc. That could cause injuries on your body (electric shock).

Important information

The basic settings of your hearing system are put in place by authorised experts according to the particular hearing loss at hand. The user must therefore only use the easily accessible operator elements intended for him or her, as per instructions.

- Adjust the volume according to individual requirements and upon instruction by your hearing care professional.
- Never expose your hearing system to extreme solar irradiation (for example on your car windshield), extreme heat (do not place on heating devices) or extreme cold (overnight in a cold car) and avoid contact with chemicals or harsh detergents.
- Please always be aware that hearing systems will no longer function properly if, for example, battery power is running out. This poses a particular danger in traffic or when you are in any other way dependent on warning signals.
- Sweat and moisture should be removed from your hearing system on a daily basis (wipe with a dry cloth). Please remove your hearing system before showering, washing your hair, stepping into a sauna or steam bath.
- For a particularly deep clean or a mild clean that is gentle on the skin, we recommend special products available from specialist stores.

- Under no circumstances use petrol or similar chemical cleaning products.
- A faulty hearing system must be repaired by a specialist. Do not try to open the device yourself. Improper handling will result in the guarantee becoming void.
- If your hearing system is defective, please consult your hearing care professional. Regular maintenance and checking can prevent repairs from becoming necessary.
- In the case of interference fields with electromagnetic interference such as transmitters, the hearing quality of your hearing system may be impaired.
- The hearing system must be removed before undergoing any special diagnostic tests such as MR scans, x-rays, radiotherapy, etc.
- Do not use your hearing system in places where electronic aids are prohibited.
- Only connect devices that comply with the relevant international safety standards.

- In order to enable optimal hearing, the hearing system must be adapted by a qualified hearing care professional.
- Changes or modifications of the hearing system will invalidate the operating license and are not permitted!
- The telecoil program can improve speech understanding with hearing aid compatible (HAC) telephones and in theaters, cinemas, churches, etc. where a hearing loop system is installed. However, if you move out of the hearing loop system's reception area, the connection may be lost.

Warranty, maintenance & repairs

BHM guarantees for material and manufacturing defects in the hearing system as stated in the guarantee conditions. In its service concept, BHM guarantees safe function through the use of BHM original components or hearing systems.

There is a one-year guarantee period for the hearing system; the warranty is two years. Please go to your hearing care professional if you wish you have your hearing system maintained.

If your BHM hearing system does not work, it must be repaired by a qualified service technician. Do not try to open the hearing system casing, as this will void the guarantee and warranty for the hearing system. The guarantee does not cover any defect or damage to your hearing device resulting from the use of wearing options that do not come from BHM.

Disposal

Your hearing system including the spectacles and battery is a modern technology product that must be disposed of responsibly within the scope of environmental protection. As such, please take these items to a special disposal site. Your specialist adviser will be happy to help you in this.





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nach Medizinprodukterichtlinie 93/42/EWG RoHS 2011/65/EU | RED 2014/53/EU

Qualitätsmanagementsystem nach DIN EN ISO 13485:2016

According to European Medical Device Directive 93/42/EEC RoHS 2011/65/EU | RED 2014/53/EU Quality management system according to DIN EN ISO 13485:2016

