

# contact forte

Digital bone conduction hearing system

# **Instruction for Use**



Congratulations on acquiring your digital bone conduction hearing system **contact forte** – a quality product from BHM. Your state-of-theart hearing system 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 technological innovations. It bears the CE mark, signalling its adherence to the latest quality and safety requirements.

The bone conductiond hearing system is suitable for the home healthcare environment and due to their portability it may happen that it is used in professional healthcare facility environment like physician offices, dental offices etc. Your bone conduction hearing system, which is characterised by its high-quality signal processing, can be worn on a number of different wearing options. **Please be aware of the different sizes of these when choosing your wearing option, to make sure that you will be comfort-** **able wearing your device.** This Instruction for Use contains many hints and tips on how to get the best from your new **contact forte** 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 forte 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 conductive hearing loss, mixed hearing loss and single sided deafness. 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.

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

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

Your **contact forte** has been specially chosen for you by your hearing care professional based on your personal hearing impairment, and has been adapted to meet your hearing needs. Your hearing care professional will provide you with comprehensive instruction on first-time use, proper handling, how to wear it, and regular maintenance. 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 the sounding of warning tones or their volume is the responsibility of your hearing care professional. Please fit these settings together. Your **contact forte** uses radio technology with Bluetooth Low Energy and operates in a frequency range of 2.4 GHz to 2.48 GHz. Always pay attention to the environment in which you use it. Any restrictions must be observed. When flying please check if flight operator requires devices to be switched into flight mode, see chapter "Wireless".

The couplings to the **contact forte** contain a magnet. Magnets generate a farreaching, strong magnetic field. Among other things, they can damage televisions, laptops, computer hard disks, credit and debit cards, data carriers, mechanical watches, loudspeakers, etc. Keep magnets away from any equipment or objects that may be damaged by strong magnetic fields.

Magnets can also affect medical devices (pacemakers, defibrillators,...) or electronic systems and cause malfunctions.

Use the **contact forte** 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 of coupling and magnetically sensitive devices (e.g. pacemaker) must be at least 30 cm.

### Please read this Instruction for Use fully and carefully before using the device. If you are not the person using the hearing system, please bear in mind the following information on behalf of the person concerned.

Before using the device, please make sure that it is functioning correctly and in good working condition. Never use the device if you suspect that it is not working flawlessly or is in any way damaged, especially the battery compartment or the battery compartment safety lock! Do not put your device under any excessive mechanical strain. If it has fallen onto the ground or is damaged in any other way, please send it to your hearing care professional to be checked and repaired. Never pass your bone conduction hearing system to other people i.e. please prevent any unauthorised use.

Each hearing system is intended for use on the left-hand side when shipped. Your hearing care professional will adjust the device for the right-hand side if necessary.

For a binaural system, your hearing care professional will mark one device with a blue sticker and one device with a red sticker (Symbolic image 1). The blue marked device must then be worn on the left-hand side and the red marked device on the right-hand side.



In order to ensure that your hearing system is safe and functional, please only use BHM accessories!

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# Key

| Symbols            |   |
|--------------------|---|
| 3                  | Follow instructions for use!  |
| ***                | Manufacturer  |
| <b>C E</b><br>0297 | CE marking and Notified Body number   |
| X                  | Do not dispose of in household waste  |
| í                  | Important information for usage and product safety                          |
| $\triangle$        | Warning! Pay attention to the warnings notices in these instruction for use |
| -20°C              | Temperature during transport and storage                                    |
| 10%                | Humidity during transport and storage                                       |
| Ť                  | Protect from moisture   |

#### **Symbols**



The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by BHM-Tech Produktionsgesellschaft m.b.H. is under license. Other trademarks and trade names are those of their respective owners.



Japanese Radio Law and Japanese Telecommunications Business Law Compliance



Equipment includes radio transmitter



RCM - Regulatory compliance mark for ACMA (Australian Communications and Media Authority)



SN

Type B Applied part

Serial number

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

# **Technical data**

| According | to | IFC  | 6011 | 8-9-2 | 2018 |
|-----------|----|------|------|-------|------|
| ACCOLUTIN | u  | ILU. | 001  | 0-3.4 |      |

| Weight, incl. battery       | < 15 g   |
|-----------------------------|--|
| Dimensions                  | Height: < 15 mm; Length: < 35 mm; Width: < 22 mm |
| Battery size                | 13 (PR 48, Zinc-Air)                             |
| Battery current             | 1.6 mA (@ 65 dB SPL Input, 1 kHz)                |
| Battery rating              | up to 13 mA                                      |
| Operating temperature range | +5° C to +40° C                                  |

| According to IEC 60118-9:2018                                   | Measured on Artificial Mastoid<br>with Headband adapter | Measured on Skull Simulator |
|---|---|-----------------------------|
| Frequency Range   | 300 Hz – >8000 Hz                                       | 350 Hz – >8000 Hz           |
| Max. Output Vibratory Force Level<br>(@ 90 dB SPL, FOG)         | 119 dB rel. 1 µN  | 127 dB rel. 1 µN            |
| Max. Acousto-Mechanical Sensitivity Level<br>(@ 50 dB SPL, FOG) | 43 dB rel. 1 μN / 20 μPa                                | 49 dB rel. 1 μN / 20 μPa    |

# The hearing system contact forte





Symbolic image 2





3

Control buttons (programme and volume)

Coupling for wearing options



Battery compartment Battery compartment safety lock Programming socket (under the cover)

# Inserting/replacing battery

- 1. To open the battery compartment and to insert or replace the battery, turn the battery compartment safety lock anti-clockwise with the BHM screwdriver supplied (Symbolic image 3a & 3b).
- 2. Carefully open the battery compartment until it is fully open (Symbolic image 3c).
- 3. When replacing the battery, please remove the old battery and dispose of this in accordance with local regulations.
- 4. Take a new battery, size 13, from the package and remove the adhesive strip from the positive terminal. Then wait the amount of time stipulated 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 (Symbolic image 3d)!

 Close the battery compartment carefully with your fingers and then seal the battery compartment safety lock in a clockwise direction using the BHM screwdriver supplied until it clicks into place (Symbolic image 3c, 3b, 3a).

### Battery warning sound

The **contact forte** is equipped with a battery warning as standard. When the battery is weak, the device will emit a warning tone and the signal gain will automatically be reduced. Please replace the battery immediately!

Swallowing a battery is harmful to health and may cause severe damage or even death! Therefore: 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 and an intact battery compartment safety lock!

The use of the BHM screwdriver by children and persons with cognitive impairment is prohibited. In this case, the battery must be changed by the supervisor or the person in charge. Improper handling may result in injuries.

Images: Opening and closing the battery compartment with the BHM screwdriver supplied.





Symbolic image 3d

# Switching on/off

The hearing system contact forte does not have an ON/OFF switch. The device switches on when the battery compartment is closed and switches off when it is opened. After your day's use and/or when the device is not being used, the battery must be removed. The hearing system must be stored with the battery compartment open, in a safe place, out of reach of anyone. Opening the battery compartment also enables you to dry any moisture that has accumulated. Use only non rechargable size 13 zinc-air hearing aid batteries.

A **stand-by function** can be programmed by your hearing care professional for you.

# **Key functions**



Symbolic image 4

#### Adjusting the volume

Press the control buttons (Symbolic image 4) briefly to increase (+) or reduce (-) the volume of the device. A signal confirms whether

the volume has been increased or decreased. The device will beep three times to signal that the maximum or minimum volume has been reached.

### Selecting a programme

In your hearing system, up to four programmes for various hearing situations can be stored. Use the control buttons to switch between the programmes that your hearing care professional has set for you with your approval.

Pressing one of the two control buttons (approx. 1 second) will – depending on the button selected – switch to the next programme or switch it back. When the battery compartment is closed and the hearing system switches on, it will automatically start with programme 1. If you switch to a different programme by pressing one of the control buttons, you will hear a confirmation signal. For a better overview, please complete the following table:

| Programme | Confirmation signal | Description of hearing situation |
|-----------|---------------------|----------------------------------|
| 1         | 1 beep              |                                  |
| 2         | 2 beeps             |                                  |
| 3         | 3 beeps             |                                  |
| 4         | 4 beeps             |                                  |

### Key lock

Key lock prevents you from accidentally adjusting the sound processor settings (such as programme selection or volume). Your hearing care professional can activate or deactivate this function. We recommend activating the key lock if the hearing system is used by a child or a person with a mental impairment.

# Programme "Automatic" 🕰

In the programme setting "Automatic", the signal received via the microphone is analysed and classified as one of several different hearing situations. These are:

- Quiet environment
- Speech in quiet environment
- Loud environment
- Speech in loud environment
- Musical environment
- Windy environment

Depending on the classification, the parameters of the hearing system are configured in such a way as to achieve optimum hearing comfort and optimum speech intelligibility.

# Wearing options

When selecting a suitable option for wearing the device, please consider the various sizes! Incorrect use and selection of the sizes of the wearing options can lead to skin irritation, pressure points and pain.



The device or its parts must not be touched or covered by headgear or other things!

## Attaching to wearing options

The **contact forte** can only be used with a variety of wearing options. BHM offers a range of options to get the most out of your hearing system. After the selected wearing option has been positioned correctly on the wearer's head (options listed on the following pages), simply attach the magnetic snap coupling of the hearing system to the mechanism (conductor plate) integrated into the wearing option (Symbolic image 5).

The hearing system must be positioned behind the ear on the head (mastoid) or – if recommended by your hearing care professional – elsewhere on the head. The microphones must be pointing downward and positioned level with one another when in a standing position (Symbolic image 6). The device must not touch the pinna! To adjust the tilt, the hearing device can be individually aligned in 6-degree increments.

To remove the hearing system from the wearing options, do not simply pull the hearing system from the conductor plate. The coupling will detach more easily by tilting it to the side (Symbolic image 7).



For babies and children, care must be taken to ensure that, due to the soft cranial bones, the wearing option is repositioned at regular intervals to avoid deformation. Your hearing care professional will show you how to proceed.

# Adapter for individual headbands or softbands

The BHM **contact forte** adapters can be used to make custom-made headbands or softbands. The adapters are already fitted with the necessary conductor plate. The **contact forte** is simply attached to the coupling on the back of the conductor plate (Symbolic image 8).



### Plastic headband

BHM plastic headbands also come already fitted with the conductor plate. The **contact forte** is simply placed onto the back of the conductor plate using the coupling (Symbolic image 9). Plastic headbands are available in both monaural and binaural models, and in the sizes **small, medium, standard and large**. Your hearing care professional will

advise you on the correct size.

Image shows plastic headband in unilateral (monaural) use (Symbolic image 9).

### Adhesive adapter

The **contact forte** can be worn virtually invisibly by using an adhesive adapter. We kindly point out that using the adhesive adapter results in a lower signal gain!

Adhesive adapters (consisting of adhesive pad and sticker) are available for both the right-hand and left-hand side.

You can obtain the sticker from your hearing care professional.

The sticker is intended for single use. If the sticker is used several times, it will no longer stick to the skin. There is a risk of inadequate supply of the hearing system and loss of the device. Only stickers from BHM may be used.







right-hand side The following images depicts use on the left-hand side.

 Find a suitable point behind the ear on the mastoid bone and clean this thoroughly (Symbolic image 10). This area must be clean and hair-free; if necessary, please shave this area.



Symbolic image 10

2. Peel the large protective liner from the sticker and make sure that the exposed adhesive surface remains clean (Symbolic image 11).



Symbolic image 11

3. Place the adhesive surface onto the adhesive pad and firmly stroke down (Symbolic image 12).



Symbolic image 12

4. Now remove the small protective liner from the sticker itself and ensure that the exposed adhesive surface remains clean (Symbolic image 13).



Symbolic image 13

5. Now apply the adhesive adapter to the selected area and press the system firmly for approx. 5 seconds (Symbolic image 14).



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6. The hearing system simply snaps onto the adhesive adapter via the coupling (Symbolic image 15).



Symbolic image 15

The adhesive adapter can be worn on the skin for several days. The adhesive pad is intended for multiple use; the sticker is intended for single use. After use, simply remove the adhesive adapter from the skin. Remove the sticker from the adhesive pad and dispose of this properly. Then, clean the adhesive pad with a clean cloth and store it in a safe, preferably dustfree place, out of reach of children.

In case of skin irritation, consult a doctor or your hearing care professional.

The use of accessories made by other manufacturers i.e. 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.

# Making phone calls

Making phone calls becomes quite easy with your **contact forte**. Simply hold the telephone loudspeaker close to the two microphones in your device. If you hear feedback (whistling), simply move the two devices further apart. Depending on your individual requirements, your hearing care professional can also set up a special phone programme. It is important that you find the position between your hearing system and your phone that is right for you.

## Wireless

The illustration (Symbolic image 16) below shows the connectivity options available for your **contact forte**.



\* The TV Streamer can be connected to any audio source such as a TV, PC or hi-fi system.

### Wireless-Streaming

Your **contact forte** hearing system can receive wireless audio signals from a TV streamer. In order for these audio signals to be received by your hearing system, your hearing care professional must set an appropriate hearing programme. Your hearing care professional will instruct you how to use the TV Streamer and programme your hearing system accordingly.

To obtain a TV Streamer, please contact your hearing care professional. For more information, please refer to the TV Streamer instruction for use.

# Initial pairing to a Bluetooth® enabled mobile device

It is only necessary to perform the pairing procedure once with each mobile device featuring Bluetooth Low Energy. After the initial pairing, your hearing system **contact forte** will connect automatically to the mobile device. This can take up to 2 minutes. On your mobile device (e.g. a phone), ensure that Bluetooth function is enabled and search for Bluetooth enabled devices in the connectivity setting menu. Switch on the hearing system. Your hearing system can now be paired. Your device shows a list of Bluetooth enabled devices. Select your hearing instrument from the list to pair it.

### Connecting to the device

After your hearing system **contact forte** has been paired to your mobile device, they will automatically connect again when switched on.

The connection will be maintained as long as the mobile device remains ON and within range.

For more information and options on connecting to Bluetooth enabled mobile devices, please consult your hearing care professional.

## Flight mode

Your hearing system **contact forte** operates between 2.4 GHz – 2.48 GHz frequency range. When boarding a flight, wireless functionality must be deactivated because radio signals may not be transmitted during flights. Entering flight mode will not disable normal hearing system functionality, only the Bluetooth connectivity functions.

### Activate flight mode

To disable the wireless function and activate flight mode in the hearing system: Press the (+) control button (Symbolic image 4) for approx. 5 seconds until a 3-fold acoustic signal sounds. In flight mode, your hearing system cannot connect directly to your mobile device.

### Deactivate flight mode

To enable the wireless function and deactivate flight mode in the hearing system: Turn the hearing system off and back on again (by opening and closing the battery compartment).

# Fitting & programming

#### (For hearing care professional only)

To fit the **contact forte** 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 accidentally 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 forte hearing system is available as a monaural hearing system. Each hearing system is intended for use on the left-hand side when shipped. For binaural support, two monaural devices are used. The decision regarding which device should be worn on the left-hand or right-hand side is made by the hearing care professional during the fitting. In order to identify each device clearly, a marking sticker must be attached onto the hearing system, as depicted in symbolic image 1.

### Mechanical fitting

The hearing system is used together with the corresponding wearing option. Make sure that the wearing options are the correct size and fit the patient correctly!

Improper use and incorrect selection of the sizes of the wearing options 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.

#### **Plastic headband**

When selecting the correct size of plastic headband, make sure that it fits comfortably on the patient. The conductor plate of the plastic headband 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 plastic headband should be perceived as comfortable as possible. The plastic headband is available in 4 different sizes (small, medium, standard, large) from BHM. Only plastic headbands from BHM may be used.

### Headbands and softbands

The adapters for wearing the hearing system, which are included with the hearing system, can be sewn into individual headbands and softbands. Appropriate instructions for this are available from BHM. Ensure that the headband or softband fits comfortably on the patient. The conductor plate of the integrated adapter 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 headband or softband should be perceived as comfortable as possible.

#### Adhesive adapter

Adhesive adapters (adhesive pad plus sticker) for the left and right wearing side are included

with the hearing system. Instructions for using the adhesive adapters can be found in this instructions for use. Pay attention to the correct positioning of the adhesive adapter behind the ear on the patient's mastoid. The skin area where the adhesive adapter is to be attached must be clean, dry and free of hair. If necessary, the position can be varied accordingly. The patient must be instructed accordingly.



The stickers are available from BHM. Only stickers from BHM may be used.

### Before programming



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

Before programming, please remove the socket cover and socket seal (Symbolic image 17). To do this, please use the BHM screwdriver supplied and push downward through the loop onto the cover. This is then easy to fold away. Then simply remove



the socket seal. The programming socket is now visible at the bottom, where you can connect the programming cable (Symbolic image 18).

Please make sure that the red marking on the programming cable connector 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 respective wearing option 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 **conatct forte** hearing system. The programming interface must be installed on your computer. For installation, please use the programming interface manufacturer's documents and software.

#### contact forte fitting software

In order to ensure that your device works smoothly, please use only the software approved by BHM for this hearing system. In case of any doubts or uncertainties, please contact your suppliers or BHM directly.

### After programming

After programming, remove the programming cable and assemble the socket seal and then the cover by inserting it into the mechanism at the bottom (1) and carefully pressing at the top (2) (Symbolic image 19).



era ia available directly from

The current software is available directly from BHM.

# Troubleshooting

### Feedback problems (whistling)

For feedback issues:

 Make sure that nothing is touching the hearing system: a head covering, pair of glasses or your ear.

- Please check that your hearing system is free and that nothing is touching it. The hearing system may only be connected to the conductor plate via the coupling.
- Please check that the battery compartment is properly closed.
- Please check to see if your hearing system is showing signs of any external damage.
- Check that the device has been correctly attached to the wearing option.

Please contact your hearing care professional if problems persist.

# **i** Tips

• Please note that your hearing system will switch off automatically if the batteries are too weak.

- Check that the battery compartment has a battery inside and is closed properly.
- Does the battery still have enough power, is it the right size and has it been inserted properly? Please ensure that you always carry replacement batteries with you.
- Check that the hearing system has been correctly attached to the wearing option and that it fits correctly on your head.
- Background noise and 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 immediate 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 mentioned points, please take it to your hearing care professional with a concise description of the error or fault.

## Notes for troubleshooting

| Symptom                                 | Possible cause   | Possible solution  |
|---|--|--|
| Hearing system<br>doesn't work          | <ul> <li>Hearing system is not switched on / no battery has been inserted</li> <li>Empty battery</li> <li>Battery compartment won't close</li> <li>Hearing system not coupled correctly</li> </ul> | <ul> <li>Switch on hearing system /<br/>insert battery and close battery compartment</li> <li>Replace battery</li> <li>Insert battery correctly / insert correct size 13<br/>battery</li> <li>Couple hearing system correctly</li> </ul> |
| Hearing system<br>is not loud<br>enough | <ul><li>Hearing ability has changed</li><li>Volume set too low</li></ul>   | <ul> <li>Go to your hearing care professional</li> <li>Increase volume or ask your hearing care professional to do so for you</li> </ul>   |
| Sound is<br>distorted /<br>unclear      | <ul> <li>Weak battery</li> <li>Hearing system is damaged</li> <li>Hearing system setting are not optimal</li> <li>Hearing system is soiled</li> </ul>  | <ul> <li>Replace battery</li> <li>Contact your hearing care professional</li> <li>Contact your hearing care professional</li> <li>Clean hearing system</li> </ul>  |

# Cleaning

In order to ensure the **guarantee** and **warranty** of your hearing system, we kindly advise you that your hearing system must be cleaned thoroughly and in accordance with instructions at least once a day. Wipe your hearing system 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 every evening after its daily clean. When not in use, please store it with the battery compartment open in order for any moisture present in the device to evaporate.

Please ensure that you have removed your hearing system from the wearing option before cleaning the latter.



Please remove your hearing device before showering, bathing or visiting a

sauna and before using any body care products, hairspray or cosmetic powder, as these kinds of deposits can contaminate your hearing system 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 batteries may endanger your health. Please read the following points with great care.

• Swallowing batteries puts your health at risk and can cause serious injury and even death! Therefore: Never store batteries alongside medicines! Never replace your hearing system's battery when you are with children and the mentally impaired. Please seek immediate medical attention in the event of swallowing a battery.

- Incorrect handling and use of incorrect batteries may cause the battery to leak and endanger your health! Always use size 13 hearing aid batteries and replace them regularly.
- Improper handling of the hearing system may loosen its smallest components. Please do not swallow small detachable components, this may harm your health and can have serious consequences!
- Improper use and wrong sizes of the wearing options can lead to skin irritation, pressure points and pain. In this case, consult your hearing care professional or doctor.
- For safety reasons (risk of swallowing and suffocation), children or people with a mental impairment may only wear the hearing system under supervision.
- Keep other people away from your contact forte hearing system and its components,

when it is not in use! There is the risk of swallowing small parts!

- Remove your hearing system when you sleep, there is a risk of injury.
- Switch your hearing system off in mines, oxygen enriched atmosphere and other places exposed to explosion hazards.
- The wearing options may only be applied to skin that is intact.
- 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

Please read the information on the following pages before using your hearing system.



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 operating elements intended, as per instructions.

- Adjust the volume according to individual requirements and as per your hearing care professional's instructions.
- In order to enable optimal hearing, the hearing system must be adapted by a qualified hearing care professional.
- Never expose your hearing system to extreme solar irradiation (for example, on your car windshield), extreme heat (do not place on heaters or radiators) 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 must be removed daily from your hearing system.
- 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.
- Changes or modifications of the hearing system will invalidate the operating license and are not permitted!

- 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.
- Before switching on the wireless connection, check whether the use in your environment is permissible.
- When boarding a flight or entering an area where radio transmitters are prohibited, wireless functionality must be deactivated, as it is not allowed to radiate radio signals during flights or in otherwise restricted areas.
- When the wireless function is activated, the hearing system uses low-powered digitally coded transmissions in order to communicate with other wireless devices. Although unlikely, nearby electronic devices may be affected. In that case, move the hearing system away from the affected electronic device.

- When using wireless functionality and the hearing system is affected by electromagnetic interference, move away from the source of this interference.
- Hearing programmes in the directivity mode reduce background noises. Please be aware that warning signals or noises coming from behind, e. g. cars, are partially or entirely suppressed.

# 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. Your hearing system requires regular maintenance. Contact your hearing care professional for this.

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 system resulting from the use of accessories that do not come from BHM.

# Disposal

Your hearing system plus wearing options 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.

# **Required information**

The following additional information is provided in compliance with U.S. Food and Drug Administration (FDA) regulations:

### Warning to Hearing Aid Dispensers

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines 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:

- i Visible congenital or traumatic deformity of the ear.
- ii History of active drainage from the ear within the previous 90 days.
- iii History of sudden or rapidly progressive

hearing loss within the previous 90 days.

- iv Acute or chronic dizziness.
- v Unilateral hearing loss of sudden or recent onset within the previous 90 days.
- vi Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.
- vii Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.
- viii Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).

### Important Notice 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 a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation. The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid 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 purchaseoption programme. Many hearing aid dispensers now offer programmes that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. 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.

#### 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.

# **Declaration of Conformity for** the hearing system

Hereby, BHM-Tech Produktionsgesellschaft mbH declares that the contact forte meets the requirements of the Medical Devices Directive 93/42/FEC and restriction of the use of certain hazardous substances in electrical and electronic equipment 2011/65/EU.

Hereby, BHM-Tech Produktionsgesellschaft mbH declares that the radio equipment type contact forte is in compliance with Directive 2014/53/EU.

The full text of the FU Declaration of Conformity can be obtained from BHM-Tech. www. bhm-tech.at.

### Radio Information of your contact forte hearing system

Wireless connection Operation frequency Radiated power

Bluetooth Low Energy 2.4 GHz – 2.48 GHz < 1 mW

### Japanese Radio Law:

This device is granted pursuant to the Japanese Radio Law (電波法). This device should not be modified (otherwise the granted designation number will become invalid).



## Australia:



Indicates a device's compliance with applicable Radio Spectrum Management's (RSM) and Australian Communications and Media Authority (ACMA) regulatory arrangements for the legal sale in New Zealand and Australia.



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BHM-Tech Produktionsgesellschaft mbH Grafenschachen 242 7423 Grafenschachen, Austria www.bhm-tech.at

CC According to European Medical Device Directive 93/42/EEC 0297 RoHS 2011/65/EU | RED 2014/53/EU Quality management system according to DIN EN ISO 13485:2016



Content may be changed without notice in order to improve product performance.