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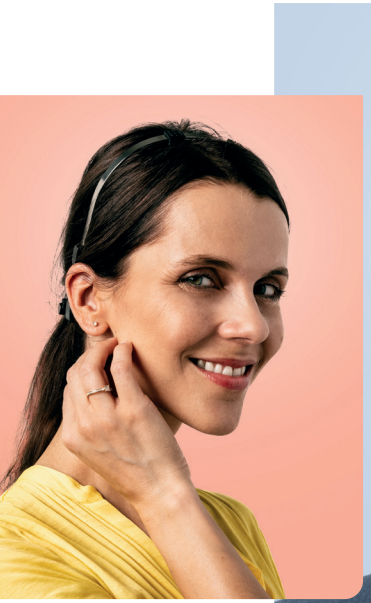
INSTRUCTIONS FOR USE

BONE CONDUCTION HEARING SYSTEMS



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INSTRUCTIONS FOR USE

These instructions for use apply to the following bone conduction hearing aids:
- Spectacle hearing system – la belle BC D50 and la belle BC D70
- Headband hearing system (children's hearing system) – la belle junior BC Delta 50
- Headset hearing system - la belle BC D50
- For these bone conduction hearing aids, we only offer service: la belle junior BC D70, la belle headset BC D70

1 PURPOSE

1.1 INTENDED USE AND INDICATION

Bone conduction hearing aids are used to compensate conductive and/or combined hearing losses, as well as single-sided deafness (SSD).

Bone conduction hearing aids are suitable for people with ear deformities, especially for those with no outer ear and/or auditory canals due to conditions such as Treacher Collins syndrome or Goldenhar syndrome. Bone conduction hearing aids are also suitable for patients with chronic middle ear disorders that involve ear discharge or other conditions affecting the middle ear (such as otosclerosis or acute otitis media), as well as for those with allergic reactions in the auditory canal or very narrow auditory canals.

Headband hearing systems are indicated for babies over the age of six months, infants and children. The spectacle hearing system and the headset hearing system are suitable for adults.

For hygiene reasons, bone conduction hearing aids must only be used by one patient.
Bone conduction hearing aids are designed for repeated use, up to a maximum of 16 hours per day, and have an expected lifetime of six years. Bone conduction hearing aids should only be programmed by professionals with expertise in hearing aids, such as a hearing aid specialist or a qualified audiologist.

Bone conduction hearing aids should only be used by people who understand the contents of the instructions for use and are able to operate the devices safely. For their safety, individuals belonging to the following groups must be supervised by a responsible person:

- Babies over the age of six months, infants and children
- People with disabilities (e.g. physical, mental or sensory)

If the patient is unable to operate the bone conduction hearing aid her/himself, the device must be operated by the responsible person.

1.2 CONTRAINDICATIONS AND SIDE-EFFECTS

Patients must not use the bone conduction hearing aid:

- if the hearing loss is not covered by the adjustment range of the device;
- if the hearing-impaired person suffers from skin irritation that is attributable to the materials used in the device; or
- if the patient suffers from bilateral deafness.

2 INFORMATION AND SAFETY INFORMATION

2.1 GENERAL INFORMATION

Read these instructions for use in their entirety. Keep the instructions for use for later reference. If the instructions for use are not followed, it is not possible to rule out injury or damage to the device.

2.2 HOW SAFETY INFORMATION IS ORGANISED

Safety-relevant information in these instructions for use is divided into risk levels:

WARNING:

The signal word WARNING denotes risks that, if ignored, may result in severe injury or severe limitations on use.

CAUTION:

The signal word CAUTION denotes risks that, if ignored, may result in mild to moderate injury or limitations on use.

2.3 GENERAL SAFETY INFORMATION

WARNING:

- Your bone conduction hearing aid must not be worn by anyone else. There is a danger it this could damage their hearing.
- Do not adjust the settings or other components of the bone conduction hearing aid. Unauthorised modifications to the bone conduction hearing aid can damage your hearing.
- Never wear your bone conduction hearing aid in areas with an explosion risk or in oxygen-rich environments.
- For their safety, individuals belonging to the following groups must be supervised by a responsible person:
  - Babies over the age of six months, infants and children
  - People with disabilities (e.g. physical, mental or sensory)

If the patient is unable to operate the bone conduction hearing aid her/himself, the device must be operated by the responsible person. Never leave the persons listed above with the hearing aid without supervision.

- When using children's hearing systems, it must be ensured that children do not pull the headband over their neck. There is a risk of suffocation resulting from strangulation with the headband.
- Never use a cable to attach your bone conduction hearing aid to an external audio device, such as a radio. This may result in physical injury (electric shock).

CAUTION:

- The bone conduction hearing aid will not restore normal hearing, nor will it prevent or correct loss of hearing from organic causes.
- Keep the bone conduction hearing aid out of reach of small children, people with cognitive impairment (other than the patient) and pets. Swallowing hearing aid components, especially batteries, can endanger life. There is a risk of asphyxiation and/or poisoning. In serious cases, seek the assistance of a doctor or hospital straight away.
- If you experience pain on or behind the ear, for example due to pressure points, talk to your hearing aid specialist or doctor immediately.
- If the sound impression you receive from the bone conduction hearing aid changes, please contact your hearing aid specialist immediately.
- Be aware that hearing programs that use the directional microphone mode reduce background noises. Warning sounds or noises from behind will be only very weak.
- Please never submerge the bone conduction hearing aid in water or use it in the shower, in the bath or when swimming. This could damage the electronics of the hearing aid.
- Never use liquids to clean the microphone inputs. They will lose their special acoustic properties if you do.
- Protect your bone conduction hearing aid from heat.
- Do not dry the bone conduction hearing aid in the microwave.

NOTES:

- Follow the instructions for use for the RogerX from Phonak when using the accessories.
- Use of the bone conduction hearing aid by people with an active implanted medical device (for example, a cardiac pacemaker, defibrillator etc.) requires prior discussion with and evaluation by a medical specialist.
- Always handle the bone conduction hearing aid with care and do not drop the bone conduction hearing aid.
- Certain medical and dental examinations that use X-rays, such as CT scans and MRI/NMRI scans, may adversely affect the functionality of your bone conduction hearing aid. Take your bone conduction hearing aid off before tests of this type.
- You do not need to remove the bone conduction hearing aid before passing through a security checkpoint (at the airport, for example). The low level of X-ray radiation used at checkpoints will not affect the bone conduction hearing aid.
- Do not use your bone conduction hearing aid in places where electronic aids are prohibited.
- If you are not using your hearing aid, leave the battery compartment open to allow any moisture that has entered the battery compartment to escape.
- Ensure that you always dry your hearing aid thoroughly after use.
- Keep the hearing aid in a safe, dry and clean place.
- Remove the battery if you will not be using your hearing aid for a prolonged period.

2.4 KEY TO SYMBOLS

The following symbols are displayed on the device and packaging:

SYMBOL	MEANING	SYMBOL	MEANING
	Manufacturer		Temperature limit
	Article number		Humidity limit
	Follow instructions for use		Air pressure limit
	Serial number		Protection class II device
	Medical device as per MDR		Type B applied part
	Date of manufacture		Keep dry
	Fragile, handle with care	RoHs	The product meets the requirements of 2011/65/EU (RoHS).
CE 0123	The product meets the requirements specified in 93/42/EEC (medical devices) and 2011/65/EU (RoHS).		
	The medical device was placed on the market after 13 August 2005. This product must not be disposed of in the normal domestic waste. The crossed-out refuse bin indicates that this device must be disposed of separately.		

3 PRODUCT DESCRIPTION

3.1 VARIANTS AND CONFIGURATIONS

la belle BC Delta bone conduction hearing aids are available in three versions with the following configurations:

Table 1: 1. Spectacle hearing system version
la belle BC D50, la belle BC D70

CE
0123

CONFIGURATION	BATTERY TYPE	ARTICLE NUMBER (REF)
la belle BC D50 listeners downstairs, left*	312	48016
la belle BC D50 listeners downstairs, right*	312	48017
la belle BC D50 listeners downstairs, left	13	48305
la belle BC D50 listeners downstairs, right	13	48307
la belle BC D50 listeners above, left*	312	48018
la belle BC D50 listeners above, right*	312	48019
la belle BC D50 listeners above, left	13	48304
la belle BC D50 listeners above, right	13	48306
la belle BC D70 listeners downstairs, left*	312	48020
la belle BC D70 listeners downstairs, right*	312	48021
la belle BC D70 listeners downstairs, left	13	48313
la belle BC D70 listeners downstairs, right	13	48315
la belle BC D70 listeners above, left*	312	48022
la belle BC D70 listeners above, right*	312	48023
la belle BC D70 listeners above, left	13	48312
la belle BC D70 listeners above, right	13	48314

* only service

Table 2: 2. Children's hearing system version (headband hearing system) la belle Junior BC Delta 50, la belle BC Delta 70

CE 0123

CONFIGURATION	BATTERY TYPE	ARTICLE NO. (REF)
la belle junior BC Delta 50, left*	312	48028
la belle junior BC Delta 50, right*	312	48029
la belle junior BC Delta 50, left	13	48302
la belle junior BC Delta 50, right	13	48303
la belle junior BC Delta 50, left stereo*	312	48392
la belle junior BC Delta 50, right stereo*	312	48473
la belle junior BC Delta 50, left stereo*	13	48474
la belle junior BC Delta 50, right stereo*	13	48393
la belle junior BC Delta 70, left*	312	48030
la belle junior BC Delta 70, right*	312	48031
la belle junior BC Delta 70, left*	13	48310
la belle junior BC Delta 70, right*	13	48311
la belle junior BC Delta 70, left stereo*	312	48394
la belle junior BC Delta 70, right stereo*	312	48475
la belle junior BC Delta 70, left stereo*	13	48476
la belle junior BC Delta 70, right stereo*	13	48395

* service only

Table 3: 3. Headset hearing system version
la belle headset BC D50, la belle headset BC D70

CE
0123

CONFIGURATION	BATTERY TYPE	ARTICLE NUMBER (REF)
la belle headset BC D50, left*	312	48034
la belle headset BC D50, right*	312	48035
la belle headset BC D50, left	13	48300
la belle headset BC D50, right	13	48301
la belle headset BC D50, left stereo*	312	48388
la belle headset BC D50, right stereo*	312	48477
la belle headset BC D50, left stereo	13	48478
la belle headset BC D50, right stereo	13	48389
la belle headset BC D70, left*	312	48038
la belle headset BC D70, right*	312	48039
la belle headset BC D70, left*	13	48308
la belle headset BC D70, right*	13	48309
la belle headset BC D70, left stereo*	312	48390
la belle headset BC D70, right stereo*	312	48479
la belle headset BC D70, left stereo*	13	48480
la belle headset BC D70, right stereo*	13	48391

3.2 PRINCIPLE OF OPERATION

Bone conduction hearing aids are an alternative to a normal air conduction hearing aid for people with outer and middle ear problems. They use bone vibration to conduct sound directly to the working cochlea, bypassing the outer and middle ear. This type of hearing aid is beneficial for patients with conductive hearing loss and mixed forms of hearing loss, as well as for patients suffering from single-sided deafness.

3.3 TECHNICAL DATA

TECHNICAL DATA	SPECTACLE HEARING SYSTEM LA BELLE BC		HEADSET HEARING SYSTEM LA BELLE BC	
	LA BELLE BC D50	LA BELLE BC D70	LA BELLE BC D50	LA BELLE BC D70
WDRC[3]	16 channels	16 channels	16 channels	16 channels
Feedback canceller	4th generation	4th generation	4th generation	4th generation
Noise reduction	yes	yes	yes	yes
Wind noise reduction	yes	yes	yes	yes
MPO[4]	yes	yes	yes	yes
Volume control	yes	yes	yes	yes
Channels	16	16	16	16
Programmable frequency bands	16	16	16	16
Programs	4	4	4	4
Integrated sound generator	yes	yes	yes	yes
Buttons	Programs	Programs	Programs	Programs
Program selection tone	yes	yes	yes	yes
Manual program selection	n/a	n/a	n/a	n/a
Battery warning tone	yes	yes	yes	yes
Telecoil	yes	yes	yes	yes
Number of microphones	1 omnidirectional	2 omnidirectional or directional	1 omnidirectional	2 omnidirectional or directional
Adaptive directional	no	yes	no	yes
Phonak Roger X compatible	no	no	no	no
BC-dedicated fitting software	BC-Fit	BC-Fit	BC-Fit	BC-Fit
NOAH from version 4.3	yes	yes	yes	yes
NOAH Link	yes	yes	yes	yes
Audio input	Two-level	Two-level	Two-level	Two-level
Max. output force level (OFL @90 dB)[5]	116 dB	116 dB	116 dB	116 dB
Max. acousto-mechanical force level @60 dB[5]	48 dB	48 dB	48 dB	48 dB
Frequency range[5]	200 – 5000 Hz	200 – 5000 Hz	200 – 5000 Hz	200 – 5000 Hz
Input-related inherent noise[5]	29 dB	29 dB	29 dB	29 dB
Operating current[5] **(mA)**	1.2 mA	1.2 mA	1.2 mA	1.2 mA
Distortion[5]	< 3%	< 3%	< 3%	< 3%

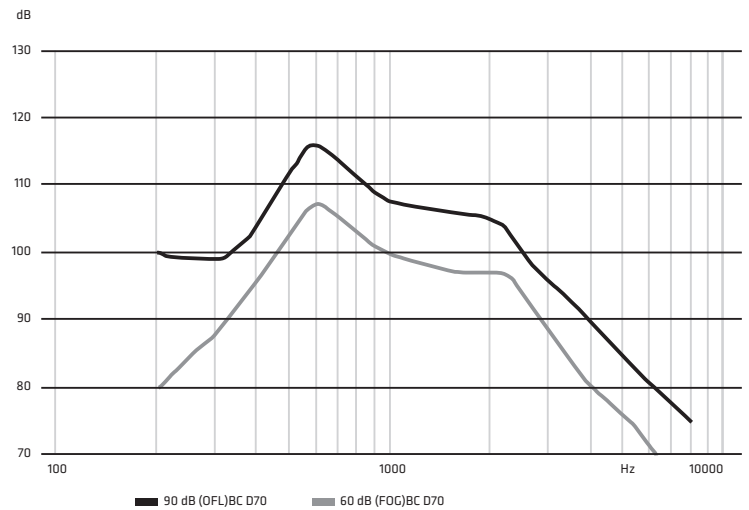
[3] WDRC = wide dynamic range compression [4] MPO = maximum power output
[5] according to IEC 60118-9 Measurement of bone conduction hearing aid characteristics

TECHNICAL DATA	CHILDREN'S HEARING SYSTEM (HEADBAND HEARING SYSTEM) LA BELLE	
	LA BELLE BC D50	LA BELLE BC D70
WDRC[3]	16 channels	16 channels
Feedback canceller	4th generation	4th generation
Noise reduction	yes	yes
Wind noise reduction	yes	yes
MPO[4]	yes	yes
Volume control	yes	yes
Channels	16	16
Programmable frequency bands	16	16
Programs	4	4
Integrated sound generator	yes	yes
Buttons	Programs	Programs
Program selection tone	yes	yes
Manual program selection	n/a	n/a
Battery warning tone	yes	yes
Telecoil	yes	yes
Number of microphones	1 omnidirectional	2 omnidirectional or directional
Adaptive directional	no	yes
Phonak Roger X compatible	yes	yes
BC-dedicated fitting software	BC-Fit	BC-Fit
NOAH from version 4.3	yes	yes
NOAH Link	yes	yes
Audio input	Two-level	Two-level
Max. output force level (OFL @90 dB)[5]	116 dB	116 dB
Max. acousto-mechanical force level @60 dB[5]	48 dB	48 dB
Frequency range[5]	200 – 5000 Hz	200 – 5000 Hz
Input-related inherent noise[5]	29 dB	29 dB
Operating current[5] **(mA)**	1.2 mA	1.2 mA
Distortion[5]	< 3%	< 3%

[3] WDRC = wide dynamic range compression [4] MPO = maximum power output
[5] according to IEC 60118-9 Measurement of bone conduction hearing aid characteristics

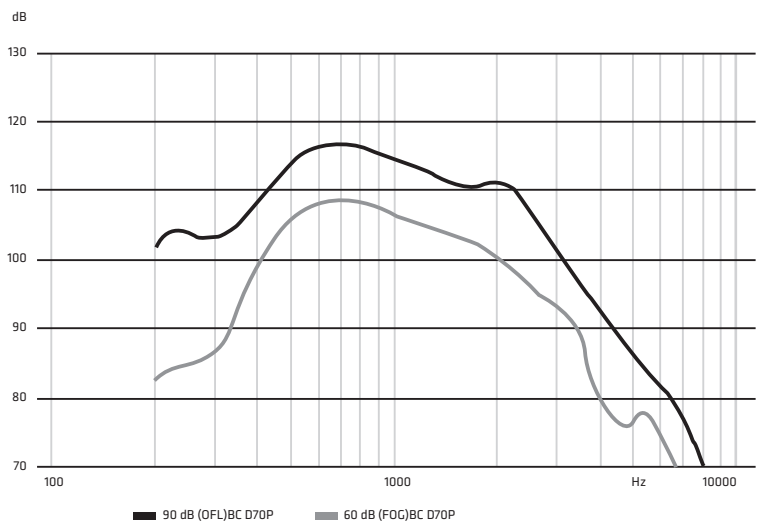
TECHNICAL DATA IN ACCORDANCE WITH EN 60601-2	SPECTACLE HEARING SYSTEM LA BELLE BC		HEADSET HEARING SYSTEM LA BELLE BC	
	LA BELLE BC D50	LA BELLE BC D70	LA BELLE BC D50	LA BELLE BC D70
Operating current (mA)	1.2	1.2	1.2	1.2
Electric shock protection type	Protection class II	Protection class II	Protection class II	Protection class II
Electric shock protection for the applied part	Type B	Type B	Type B	Type B
Mode of operation	maximum 16 hours per day	maximum 16 hours per day	maximum 16 hours per day	maximum 16 hours per day

OFL90 OUTPUT FORCE LEVEL, FOG(60) ACOUSTOMECHANICAL FORCE LEVEL



TECHNICAL DATA IN ACCORDANCE WITH EN 60601-2	CHILDREN'S HEARING SYSTEM (HEADBAND HEARING SYSTEM) LA BELLE	
	LA BELLE BC D50	LA BELLE BC D70
Operating current (mA)	1.2	1.2
Electric shock protection type	Protection class II	Protection class II
Electric shock protection for the applied part	Type B	Type B
Mode of operation	maximum 16 hours per day	maximum 16 hours per day

OFL90 OUTPUT FORCE LEVEL, FOG(60) ACOUSTOMECHANICAL FORCE LEVEL



3.4 INFORMATION ABOUT MATERIALS USED

MATERIAL	LA BELLE BC D50-70	HEADSET BC D50-70	JUNIOR BC D50	JUNIOR BC D70
Stainless steel 1.4404 (316L) X2CrNiMo17-12-2	X	X		X
Zirconium oxide ZrO2	X	X	X	X
Cellidor CAB-13A Black	X	X	X	X

Headbands
Lycra = 77% polyester and 23% elastane
Jersey = 95% cotton and 5% elastane

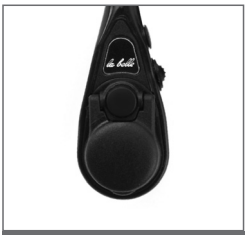
3.5 ELECTROMAGNETIC COMPATIBILITY INFORMATION

Electrical medical devices are subject to special precautions in terms of electromagnetic compatibility (EMC). They must only be installed and operated in accordance with EMC information.

4 OPERATION/USE – LA BELLE BC DELTA

4.1 TURNING ON/OFF

Closing the battery compartment cover turns on the bone conduction hearing aid.
To turn off the bone conduction hearing aid, simply open the battery compartment cover.



Device view

Battery compartment cover closed
Device turned on

Battery compartment cover open
Device turned off

4.2 SETTING OPTIONS

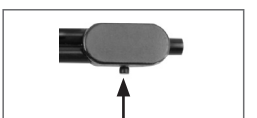
Setting options on control element 1

Bone conduction

• la belle BC • la belle junior BC • la belle headset BC

You can change the settings for the following functions yourself:

- Volume setting
- Hearing program selection
- Turning the device on/off



Volume control

left

Programming button

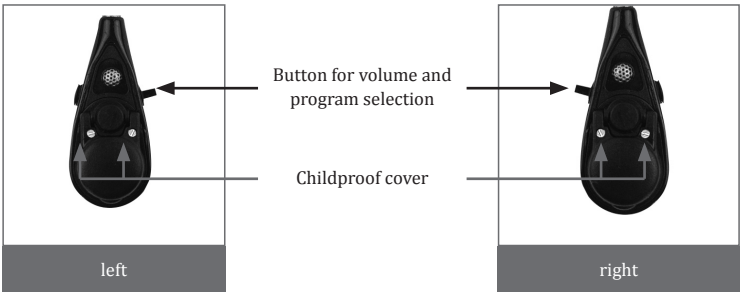
right

The programming button is located on the programming cell.

Setting options on control element 2

Bone conduction
• la belle junior BC

You can change the settings for the following functions yourself:
• Hearing program setting
• Volume setting
• Turning the device on/off



Button function

Volume
1x short forwards: one level louder
1x short backwards: one level quieter

Program selection
1 x long forwards: go to next program
1 x long backwards: go to previous program

4.3 CHANGING THE BATTERY

Depending on the version, the following battery types can be used for the la belle BC Delta bone conduction hearing aids:

• Type 312
• Type 13

For details, please consult the Versions and configurations section to find out which battery types to use.

Same for all control elements:

1. Open the battery compartment cover.
2. Remove the battery with the included magnetic stylus.
3. Using the magnetic stylus, insert the new battery with the “+” symbol facing up.
4. Close the cover.
5. This automatically turns the hearing aid back on.

Magnetic stylus

Type 312

Type 13

For the headband hearing system version

For the la belle junior BC Delta 50 and la belle BC Delta 70 headband hearing system, the childproof cover must be released before the battery can be changed.

1. Using the screwdriver supplied, remove the two screws.
2. Remove the dead battery and insert a new battery.
3. Then re-insert and tighten the two screws.

Childproof cover

Insert screws

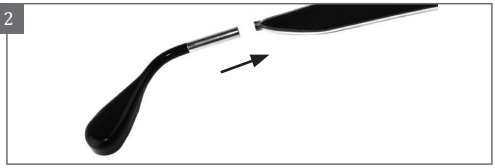
Tighten screws

NOTE:

- Always replace weak or defective batteries (for example, leaking batteries) immediately.
- Never use silver-zinc or lithium-ion batteries.
- Do not change the battery while you are using the bone conduction hearing aid.

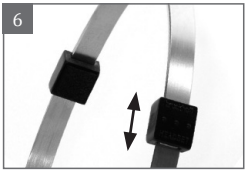
4.4 FITTING AND WEARING INSTRUCTIONS

Spectacle hearing system
la belle BC D50, la belle BC D70
Insert the la belle hearing module (1) onto the temple arm of your glasses. You can use your glasses without the hearing aid by inserting the attachable glasses temple arm end piece (2).



Headband hearing system
la belle junior BC Delta 50, la belle BC Delta 70
Use the two poppers (4) to attach the junior headband hearing system (3) to the headband.

Headset hearing system
la belle BC D50, la belle BC D70
You can adjust your headset hearing system (5) to fit the head easily using the size adjustment (6) on the headset.



5 OTHER INFORMATION

5.1 STORAGE

We recommended that you keep the bone conduction hearing aid in its original packaging until it is used for the first time. Once opened, always keep your bone conduction hearing aid in a safe, dry and clean place.

CAUTION:
Dead batteries may cause damage to the device. Therefore, remove the battery when the device will not be used for a prolonged period of time (for example, overnight).

5.2 AMBIENT CONDITIONS

Operation:	
Ambient temperature	0°C to 40°C
Relative humidity	20% to 80%
Air pressure	500 hPa to 1200 hPa
Shipping:	
Ambient temperature	-20°C to 60°C
Relative humidity	20% to 80%
Air pressure	500 hPa to 1200 hPa
Storage:	
Ambient temperature	0°C to 45°C
Relative humidity	20% to 60%
Air pressure	500 hPa to 1200 hPa

5.3 CARE AND MAINTENANCE

The bone conduction hearing aids are maintenance-free. Regularly inspect the bone conduction hearing aid. If you notice any damage on the device, contact your audiologist immediately.

Clean the hearing system at least once daily with a suitable soft, dry and lint-free cloth. Do not use cleaning agents and/or disinfectants. The device must not be sterilised.

We recommend that you wash the headband before wearing the headband system for the first time. The headband should be hand washed only, and you should always remove the device before washing.

5.4 DISPOSAL

This device falls within the scope of the WEEE directive (Directive 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment). Accordingly, this device must not be disposed of in household waste. Local regulations for disposal should be followed (such as disposal via local authorities or retailers).

Old batteries must also not be disposed of in household waste. Your audiologist will dispose of them for you correctly.

5.5 CONTACT

If you need support with the set-up, use or care of the hearing aid or hearing aid system, or if you experience unexpected operational states or events, please contact AUDIA AKUSTIK GMBH or your audiologist immediately.

AUDIA AKUSTIK GMBH
Franz-Mehring-Str. 13
99610 Sömmerda
Germany

Tel: +49 (3634) 693 - 0
Email: service@bruckhoff.com
www.bruckhoff.com

5.6 MANUFACTURER'S OBLIGATIONS

In accordance with the European Regulation on Medical Devices (2017/745), AUDIA AKUSTIK GMBH is obligated to inform you of the following:

All serious incidents related to the product must be reported to AUDIA AKUSTIK GMBH and the competent authorities of the Member State in which the user and/or patient resides.

NOTE:
Serious incidents are defined as incidents involving the death of a patient, user or other person, or the temporary or permanent serious deterioration in the health of a patient, user or other person. It is immaterial whether such incidents have occurred or might have occurred. You can find an exact definition in Regulation (EU) 2017/745 Article 2 (65).

You can find the contact information for the competent authorities in your Member State online by searching for "Competent Authorities for Medical Devices EU".

YOUR NOTES

YOUR NOTES

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2023-12-20 Version 1: Art. 48167

MANUFACTURING AND DISTRIBUTION: AUDIA AKUSTIK GMBH
Franz-Mehring-Str. 13 | 99610 Sömmerda | Germany

WWW.BRUCKHOFF.COM