# Ponto 4 Instructions for Use







## The Instructions for Use

The Ponto 4 sound processor is intended for improvement of hearing for patients with conductive or mixed hearing losses, whether unilaterally or bilaterally fitted, or for those with single sided deafness. It is designed so that it can be optimised for each individual person. This will help ensure you get the maximum benefit from your sound processor.

The Instructions for Use gives you guidance on how to use and maintain your new sound processor.

Please read through this manual carefully to learn how to get the most out of your sound processor. Pay extra attention to the **Warnings** section, **the important information** and **Care and Maintenance.** Discuss any questions or concerns with your hearing care professional.

## About:

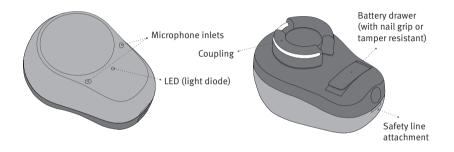
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## In the box

- Ponto 4 sound processor
- Ponto Case
- Batteries (size 312)
- Safety line
- Plug for programming socket, including left/right indication
- Ponto 4 stickers
- Test rod
- Abutment covers, black and beige
- Tamper resistant battery drawer kit
- Tool for opening the tamper resistant battery drawer

## **Processor view**



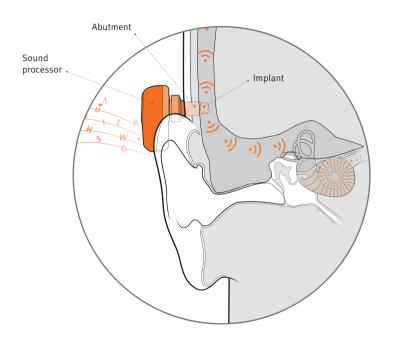
Warning: The sound processor, batteries, parts and accessories are not toys and should be kept out of reach of children and anyone who might swallow these items or otherwise cause injury to themselves. These small parts may be a choking hazard for small children.

# The Ponto bone anchored hearing system

Your Ponto 4 is designed to help you gain improved hearing through direct bone conduction. The sound processor converts sound into vibrations that are transmitted via the abutment and implant through the skull bone to the inner ear. This method works independently of the function of the ear canal and middle ear. Therefore, Ponto 4 is a possible solution for hearing losses where there is a problem in the outer or middle ear preventing sound from reaching the inner ear.

The sound processor can also pick up sound from one side and transfer it to the inner ear on the opposite side. This makes it suitable for those who are deaf on one side, but have a functioning inner ear on the other side (called unilateral profound sensorineural hearing loss or single-sided deafness).

The sound processor can also be used on a soft band for children or for individuals who are unsuitable for implantation.



# Turning the sound processor ON and OFF

The battery drawer is also used to switch the sound processor on and off. To save battery life, make sure your sound processor is switched off when you are not wearing it. During longer storage, it is recommended that you remove the battery from the sound processor.





**Note:** Do not use the mute function as an off switch, as the sound processor still draws current from the battery in this mode.

# When to replace the battery

When it is time to replace the battery, you will hear three beeps repeated in moderate intervals until the battery runs out. The battery lifetime depends on the listening environment





**Note:** To make sure the sound processor is always working, bring spare batteries with you or replace the battery before you leave home. Batteries need to be replaced more often if you are streaming to your sound processor.

#### Optional LED (can be turned on by your hearing care professional)

Orange blinks, continuously repeated, to indicate battery low.

<sup>\*</sup> Bluetooth® will be turned off and it will not be possible to use wireless accessories.

# How to replace the battery

Ponto 4 uses a size 312 zinc-air battery. Use high-quality zinc-air batteries for optimal performance.

1. Open



Fully open the battery drawer. Remove the battery.

2. Uncover



Remove the sticky label from the + side of the new battery.

Note: Wait 2 minutes so that the battery can draw air, to ensure optimal functionina.

Warning: The sound processor contains small parts that may be a choking hazard for small children. Batteries can also be harmful if swallowed. Always keep batteries out of reach of small children or people of diminished mental capacity. If a battery is accidentally swallowed, seek medical attention at the nearest emergency department.

#### 3. Insert



Insert the new battery into the battery drawer. Make sure the + side is facing down.

Note: If the battery is inserted incorrectly, the battery drawer cannot be closed. Using force risk damaging the battery compartment.

#### 4. Close



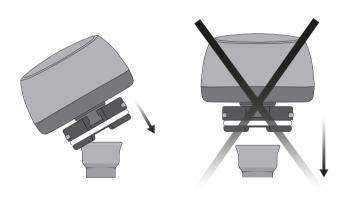
Close the battery drawer. The sound processor will play a jingle.



Note: A MultiTool can be used for battery change. Use the magnetic end to remove and insert batteries. The MultiTool can be provided by your hearing care professional.

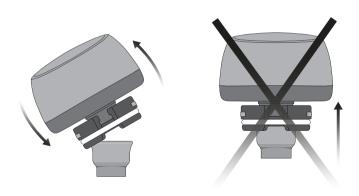
## Connection

To safely and comfortably connect the sound processor, tilt it slightly and carefully push it onto the abutment. It is important to keep hair out of the way when the sound processor is connected to the abutment.



## Disconnection

The sound processor is safely and comfortably disconnected by carefully tilting it away from the abutment.

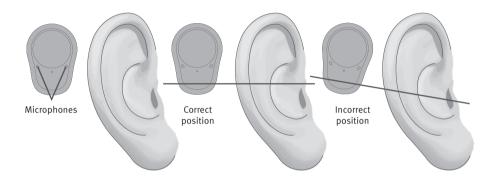


# **Correct position**

To get optimal performance from the directional microphone system, the sound processor should be positioned vertically with the microphone inlets positioned horizontally.



**Note:** Please note, it is important that the sound processor does not touch anything, e.g. the ear, skin or a hat. This can cause feedback (a whistling sound).



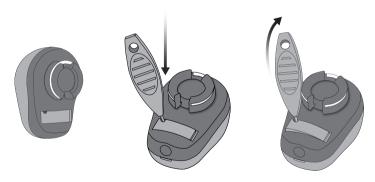
# Optional features and accessories

The features and accessories described in the following pages are optional. Please contact your hearing care professional to find out how your sound processor is programmed.

If you experience difficult listening situations, a special programme may be helpful. These are programmed by your hearing care professional.

# Tamper resistant battery drawer

Your hearing care professional can attach a tamper resistant battery drawer. To unlock the tamper resistant drawer insert the tip of the tool into the hole on the left side of the battery drawer. Lever the tool against the sound processor and press downwards to open the battery drawer.





*Important:* Children under the age of 36 months must always use the tamper resistant battery drawer due to risk of swallowing and choking.

## Volume control

The volume can be controlled from a Bluetooth-connected device, e.g. Smartphone, connectivity products etc. (see pages 24–28). When the volume is changed, it will be indicated by beeps. When the maximum or minimum volume has been reached three beeps are heard.

When passing the default start-up volume, two beeps are heard.



# **Programmes**

By default, your sound processor has one programme, your hearing care professional can define more. To change the programme use your Bluetooth-connected device e.g. Smartphone or Remote Control.

To be filled out by the hearing care professional.

| Programme | Sound you will hear<br>when activated |           | When to use |
|-----------|---------------------------------------|-----------|-------------|
| 1         | <b>,</b>                              | "1 beep"  |             |
| 2         | 77                                    | "2 beeps" |             |
| 3         | ررر                                   | "3 beeps" |             |
| 4         | תתתת                                  | "4 beeps" |             |

## Mute

Use the mute function if you need to silence the sound processor in shorter periods of time. Your sound processor can be muted by using one of the following optional devices:

Oticon ON App ConnectClip Remote Control 3.0

#### How to unmute your sound processor

The sound processor can be unmuted using one of the optional devices.



 $\it Note:$  Do not use the mute function as an off switch, as the sound processor still draws current from the battery in this mode.

# Use the sound processor with iPhone and iPad

Your sound processor is a Made for iPhone® device and allows for direct communication and control with iPhone, iPad® or iPod touch®. For assistance in using these products with your sound processor, please contact your hearing care professional or visit: www.oticonmedical.com/wireless-connectivity



For information on compatibility, please visit: www.oticonmedical.com/wireless-compatibility

Use of the Made for Apple badge means that an accessory has been designed to connect specifically to the Apple product(s) identified in the badge, and has been certified by the developer to meet Apple performance standards.

Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards. Please note that use of this Accessory with iPod, iPhone, or iPad may affect wireless performance.

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# Pairing the sound processor with iPhone

#### 1. Settings



Open your iPhone and go to "Settings". Make sure Bluetooth is on. Then choose "General".

#### 2. General



On the "General" screen, choose "Accessibility".

### 3. Accessibility



On the "Accessibility" screen, choose "Hearing Aids".

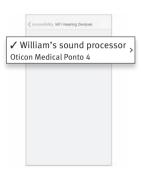
#### 4. Turn on





Open and close the battery drawer on the sound processor. The sound processor remains in pairing mode for 3 minutes.

#### 5. Hearing devices



Check if your iPhone has detected your sound processor.

#### 6. Your hearing device



Here you can see the options for your sound processor.

# Oticon ON App

Oticon ON App for iPhone, iPad, iPod touch and Android<sup>™</sup> devices offers an intuitive and discreet way to control your sound processor. The App is available on the App Store<sup>®</sup> and on Google Play<sup>™</sup>.

When installing Oticon ON App on iPad, search for iPhone apps in App Store.









Please find more details on: www.oticonmedical.com

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## Wireless accessories

Your sound processor offers wireless connection to a range of wireless accessories.

#### ConnectClip

When ConnectClip is paired with your mobile phone, you can use the sound processor as a handsfree headset.

#### Remote Control 3.0

Remote Control offers the ability to change programme, adjust volume or mute your sound processor.

#### TV Adapter 3.0

TV Adapter is a wireless transmitter of sound from TV and electronic audio devices. The TV Adapter streams sound directly to your sound processor.

For more information, please contact your hearing care professional or visit: www.oticonmedical.com/ wireless-connectivity

**Note:** If you are not using the Oticon ON App with your iPhone or SmartPhone and ConnectClip when using a telephone, please hold the receiver of the telephone close to the sound processor. To avoid feedback (a whistling sound), make sure the telephone does not touch the sound processor.

### Sound and LED indications

Different sound indications and LED light patterns help caregivers, parents, and teachers to operate the sound processor and to give instructions on relevant functions and modes of the sound processor. The different setting options are listed on the following pages.

Your hearing care professional can set sound and LED indications to match your preferences.

| Programme status                      | Sound   | LED  | LED Comments                           |
|---------------------------------------|---------|------|--|
| Programme 1                           | 1 beep  | 0    |  |
| Programme 2                           | 2 beeps | 00   |  |
| Programme 3                           | 3 beeps | 000  | Continuously repeated                  |
| Programme 4                           | 4 beeps | 0000 | repeated three times with small pauses |
| Wireless accessories incl. microphone | 2 beeps |      | min smar pauses                        |
| Wireless accessories                  | 2 beeps |      |  |

Green, short blink Green, long blink Orange, short blink Orange, long blink

Continues on next page

| On/Off   | Sound              | LED | LED comments         |  |
|--|--------------------|-----|----------------------|--|
| On   | Start-up jingle    |     | Shown one time       |  |
| Off  | 4 descending tones |     |                      |  |
| Volume   | Sound              | LED |                      |  |
| Preferred volume   | 2 beeps            |     |                      |  |
| Minimum/maximum volume   | 3 beeps            |     | Shown one time       |  |
| Volume up/down   | 1 beep             | 0   |                      |  |
| Mute activated on Oticon<br>ON App, ConnectClip or<br>Remote Control 3.0 |                    | 0   | Repeated three times |  |

Green, short blink Green, long blink Orange, short blink Orange, long blink

| Warnings                        | Sound              | LED   | LED comments                                |
|---------------------------------|--------------------|-------|---|
| Battery low indication          | 3 beeps            | ••••• | Continuously repeated                       |
| Battery shut down               | 4 descending tones |       |   |
| Microphone service check needed | 8 beeps            | 0000  | Repeated<br>four times with small<br>pauses |

Orange, short blink Orange, long blink

# Sound processor maintenance

Your sound processor is dust tight and protected against ingress of water, which means it is designed to be worn in daily life situations. However, the sound processor is **not** waterproof. If the sound processor accidentally gets wet, open the battery drawer and let the sound processor dry.

The chemicals in cosmetics, hair spray, perfume, aftershave lotion, suntan lotion and insect repellent can damage the sound processor. Always remove your sound processor before applying such products and allow time to dry before use. You may use the special abutment cover provided with your sound processor to protect your abutment.

Note: Use a soft, dry cloth to clean the sound processor. Special attention should be given to the coupling to remove any dirt or entangled hair. The sound processor must never be washed or immersed in water or other liquids.

# Skin hygiene

#### Daily cleaning

In order to reduce the risk of skin infections around the abutment, it is important to maintain a good daily cleaning routine.

Before the skin has fully healed, antibacterial soap and non-alcohol baby wipes may be used to clean the area around the abutment.

When healing has progressed, you should start using a cotton swab or a soft brush. Use the brush on a daily basis, together with soap and water, to gently clean the outside and inside of the abutment.

The brush should be replaced every 3 months. Only very soft brushes should be used. If you have two implants, you should use two soft brushes – one for each abutment.

#### Cleaning every few days

In addition to the daily cleaning routines, the skin should be cleaned more thoroughly to remove debris at least twice a week. During hair washing, debris becomes softer and is easier to remove. The cleaning brush should still be used with care.

If you have persistent problems with soreness surrounding the abutment, contact your ENT clinic. Parents or caregivers are responsible for maintaining good hygiene around a child's abutment.

Please note: it is essential to clean both the inside and outside of the abutment. This is important to prevent debris build-up.

## Accessories

#### Safety line

The safety line is designed to help you avoid dropping your sound processor during physical activity or in other situations where the device could fall off. To avoid dropping your sound processor, attach the safety line to the sound processor and the clip to your clothing. We also recommend that you use the safety line at first when you are getting used to wearing the device.

Please make sure the safety line is not pulled, as the sound processor could be disconnected from the abutment.

#### Abutment cover

The abutment cover can be connected to the abutment when the sound processor is not being used. This prevents dirt from getting into the abutment and also conceals the abutment.





#### Test rod

The test rod allows you to listen to the sound processor without connecting it to an abutment. Connect your Ponto 4 to the test rod and press it against your head to listen. When holding the rod, your hand should not touch the sound processor. This may cause a feedback/a whistling sound.



#### Stickers

The sticker allows you to change the appearance of your sound processor. The sticker is applied to the round element of the sound processor's front. Be gentle when removing the sticker.

#### Skins

A skin can change the look and colour of your sound processor. Please make sure it does not cover the microphone inlets. Skins are not intended for children below 36 months due to risk of swallowing/choking. Please ask your clinic for more information.

## Plug for programming socket

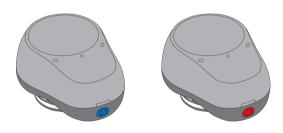
The sound processor comes with a black plug in the programming socket. The safety line can be threaded while using the plug and it does not need to be removed from the device. If removal is needed, the tool for opening the tamper resistant battery drawer can be used.





# Left and right indication (when using two sound processors)

The Ponto 4 devices are non-side specific and will be programmed to the left or right side by your hearing care professional. To help distinguish between the devices, left and right indication plugs can be inserted in the programming socket. Your hearing care professional can apply these.



# Service and repair

If your Ponto 4 sound processor does not function properly, please contact your clinic to get it checked.

| Contact person at the Audiology Clinic – name and contact information: |
|--|
|  |
|  |
| Contact person at the ENT Clinic — name and contact information:       |
|  |
|  |

| Ponto 4 is compatible with the following articles   |  |  |  |
|---|--|--|--|
| Description Article                                 |  |  |  |
| Abutments in Oticon Medical<br>Ponto implant system | All  |  |  |
|   | Genie Medical BAHS (Fitting software, version 2019.1 or later) |  |  |
| Oticon Medical accessories                          | Ponto Softband   |  |  |
|   | SoundConnector   |  |  |
|   | Test band  |  |  |
|   | Head band  |  |  |
| Oticon A/S accessories                              | ConnectClip  |  |  |
|   | TV Adapter 3.0   |  |  |
|   | Remote Control 3.0   |  |  |
|   | Oticon ON App  |  |  |
|   | EduMic   |  |  |

| Compatibility Guide  |   |  |  |
|--|---|--|--|
| Description  | Article                                     |  |  |
|  | Baha® abutments (90305, 90410)              |  |  |
| Compatible products<br>from Cochlear Bone Anchored<br>Solutions AB (BAS) | Baha® implants with abutment (90434, 90480) |  |  |
|  | Baha® audio adapter (90065)                 |  |  |
|  | Baha® telecoil unit (90185)                 |  |  |
| Incompatible products<br>from Cochlear BAS                               | Baha® BA300 Series abutments                |  |  |
|  | Baha® BA210 Series abutments                |  |  |
|  | Baha® BA400 Series abutments                |  |  |

| Common problems and their possible solutions |                                       |  |
|--|---------------------------------------|--|
| Symptom                                      | Possible causes                       |  |
| No sound                                     | Worn-out battery                      |  |
| No sound                                     | Sound processor is on stand-by (mute) |  |
|  | Dirt in the coupling or sound inlet   |  |
| Intermittent or reduced sound                | Moisture                              |  |
|  | Worn-out battery                      |  |
| Whistling noise                              | Sound processor is touching something |  |

| Solutions  |             |
|--|-------------|
| Change battery   | pages 12-13 |
| Check the Oticon ON App if mute is enabled   | page 22     |
| Clean the sound processor  | page 32     |
| Open the battery drawer and let the sound processor dry in its case                          | page 10     |
| Change battery   | pages 12–13 |
| Check if the sound processor is correctly connected and is not touching e.g. skin or glasses | pages 16–17 |
|  |             |

If none of the above solutions solve the problem, please contact your clinic for assistance.

### Manufacturer's warranty

Oticon Medical sound processors are covered by a limited warranty issued by the manufacturer for a period of 12 months from the date of delivery. This limited warranty covers manufacturing and material defects in the sound processor itself, but not batteries.

Problems arising from improper handling or care, excessive use, accidents, repairs carried out by an unauthorised party, exposure to corrosive conditions, damage due to foreign objects entering the device, or incorrect adjustments are NOT covered by the limited warranty and may void the warranty.

The above warranty does not affect any legal rights that you might have under applicable national legislation governing the sale of consumer goods. Your clinic may have issued a warranty that goes beyond the clauses of this limited warranty. Please contact your clinic for further information.

If you have any comments or suggestions related to the Oticon Medical bone anchored hearing system, please contact us using the contact form at https://www.oticonmedical.com/about-oticon-medical/contact-us.

### Important information

- It is important to follow the skin hygiene guidelines. Please contact your ENT clinic if you have questions or concerns.
- Always keep your sound processor in its case when not in use to protect it from dust and dirt. If you are using a skin, please make sure you remove the skin before placing the sound processor in its case.
- Whenever the sound processor is not in use, ensure it is switched off by opening
  the battery drawer. The battery drawer should be left open to allow any moisture in
  the sound processor to evaporate.
- The expected service life of the sound processor is 5 years.

- At the airport, inform the personnel that you are wearing implantable hearing devices. Recommendation whether or not to remove the sound processor(s) will be given at the security check point.
- When travelling by plane, turn the instruments off during take off and landing to disable Bluetooth, unless Bluetooth is permitted by the flight personnel.
- The power source in your sound processor has insufficient energy to cause fire
  under normal conditions of use. The sound processor has not been tested for compliance with international standards concerning explosive atmospheres. It is recommended not to use your sound processor in areas with danger of explosion.

### Regulatory compliance statements

#### Operation is subject to the following two conditions:

- 1. This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.



**Note:** This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules.

These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the distance between the equipment and the receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The legal manufacturer hereby declares that this Ponto 4 is in compliance with the essential requirements and other relevant provisions of the Radio Equipment Directive 2014/53/EU. Declaration of conformity is available at: Oticon Medical AB.







The sound processor contains a radio transceiver using Bluetooth Low Energy (BLE) and a proprietary short-range radio technology, both working at 2.4 GHz. The 2.4 GHz radio transmitter is weak and is always below 4 dBm EIRP in total radiated power.

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

 $\label{thm:condition} Additional information can be found in the "Product Information" on www.oticonmedical.com/downloads$ 

FCC ID: 2AHJWPONTO4 IC: 21199-PONTO4

The device complies with Part 15 of the FCC rules and RSS-210 of Industry Canada.

# **⚠** Warnings

- If you drop the sound processor, make sure the shell is not cracked or any parts
  of the sound processor have broken. If you find something is wrong with your sound
  processor please contact your hearing care professional or local Oticon Medical
  representative.
- Never dispose of your sound processor, its parts or batteries by burning them.
   There is a risk that they will explode and cause serious injury.
- Although the sound processor has achieved IP57 classification it is referred to as being water resistant, not waterproof. Always disconnect the sound processor before showering or bathing/swimming.
- Electromagnetic interference may occur in the vicinity of equipment with
  the symbol to the right. Portable and mobile RF (radio frequency) communications equipment can affect the performance of your sound processor.
   If your sound processor is affected by electromagnetic interference, move
  away from the source to reduce the interference.



- Although unlikely, nearby electronic devices may be affected by your sound processor. In that case, move the sound processor away from the affected electronic device.
- The sound processor is MR Unsafe. If you need to undergo MRI (Magnetic Resonance Imaging) the sound processor must be disconnected. The implant and the abutment can remain in place. When scheduling and visiting the location of your MRI be sure to inform the doctor or technician that you have a bone anchored system (for children and mentally impaired persons this is the responsibility of the caregiver).
- Remove your sound processor before X-ray, CT/MR/PET scanning electrotherapy, surgery etc. as your sound processor may be damaged when exposed to strong fields.

# **⚠** Warnings

- You should familiarise yourself fully with the following general warnings before using your sound processor for your personal safety and to ensure correct use.
- Please note that a hearing device will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. Furthermore, note that in most cases, infrequent use of a hearing device does not permit a user to attain full benefit from it. A hearing device is only part of hearing rehabilitation and may need to be supplemented by auditory training and lip reading.
- Consult your hearing care professional if you experience unexpected operations or events with your sound processor.

#### Battery use

- Always use batteries recommended by your hearing care professional. Batteries of low quality may leak and cause bodily harm.
- Never attempt to recharge your batteries and never dispose of batteries by burning them. There is a risk that the batteries will explode.

#### Usage of sound processors

- Sound processors should be used only as directed and adjusted by your hearing care professional.
- Never allow others to wear your sound processor. It is fitted to you.

#### Choking hazards & risk of swallowing batteries

- Sound processors, their parts, and batteries should be kept out of reach of children and anyone who might swallow these items, or otherwise cause injury to themselves.
- Most sound processors can be supplied with a tamper resistant battery drawer upon request. This is strongly recommended for infants, small children and people with learning difficulties due to the risk of swallowing and choking.
- Children below 36 months must always use a tamper resistant battery drawer.

# **⚠** Warnings

#### Dysfunction

 Be aware of the possibility that your sound processor may stop working without notice. Keep this in mind when you depend on warning sounds (e.g. when you are in traffic).

#### When wearing Ponto 4 and an active implant

- Caution must be taken with active implants. In general, follow the guidelines recommended by manufacturers of implantable defibrillators and pacemakers regarding use of mobile phones and magnets.
- The sound processor contains a wireless transmitter. Please keep the sound processor at least 15 cm away from the implant, e.g. do not carry it in a breast pocket.
- When the sound processor is mounted on the head, the distance between the sound processor and the implant is more than 15 cm.
- The MultiTool (which has a built-in magnet) should be kept more than 30 cm away from the implant, e.g. do not carry it in a breast pocket.

 If you have an active brain implant, please contact the manufacturer of your implantable device for information about the risk of disturbance.

#### Heat and chemicals

- The sound processor must never be exposed to extreme heat e.g. left inside a parked car in the sun.
- The sound processor must not be dried in microwave ovens or other ovens.

| Operating conditions                  | Temperature: +1°C to +40°C<br>Relative humidity: 5% to 93%, non-condensing<br>Atmospheric pressure: 700 hPa to 1060 hPa   |
|---------------------------------------|---|
| Storage and transportation conditions | Temperature and humidity should not exceed the following limits for extended periods during transportation and storage.  Temperature: -25°C to +55°C Relative humidity: 5% to 93%, non-condensing Atmospheric pressure: 700 hPa to 1060 hPa |

**For USA only:** Federal law restricts this device to sale by or on the order of a medical practitioner.

- A prospective user of a bone anchored sound processor should always have a
  medical evaluation by a licensed physician to ensure that all medically treatable
  conditions that may affect hearing are identified and treated before a sound processor is purchased.
- The audiologist or hearing instrument dispenser will conduct a hearing instrument evaluation to assess your ability to hear with and without a hearing instrument. The hearing instrument evaluation will enable the audiologist or dispenser to select and fit a hearing instrument to your individual needs. If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial, rental or purchase-option programme. Many hearing instrument dispensers now offer programmes that permit you to wear a hearing instrument for a period of time for a nominal fee, after which you may decide if you want to purchase the hearing instrument. Federal law limits the sale of hearing instruments to those individuals who have obtained a medical evaluation from a licensed physician.

#### Children with hearing loss

- In addition to seeing a physician for 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 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.
- 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.

| Symbol clarifications |   |             |   |  |
|-----------------------|---|-------------|---|--|
| REF                   | Reference number  |             | Waste from electronic equipment must be handled according to local regulations                    |  |
| SN                    | Serial number   | ∱           | Type B Applied part   |  |
| ***                   | Manufacturer  |             | IP Code classifies and rates the degrees of protection provided                                   |  |
| $\sim$                | Date of manufacture   | IP57        | against the intrusion of solid<br>objects (including body parts<br>like hands and fingers), dust, |  |
| [i]                   | Consult instructions for use  |             | accidental contact, and water in<br>mechanical casings and with elec-<br>trical enclosures        |  |
| <u> </u>              | Caution. Consult instructions for use for warnings and precautions that are not found in the device itself                      | YY.XXXXXXXX | The two first digits in the serial number "YY" indicate the year of manufacturing.                |  |
| Rx Only               | RX Only Caution: Federal law (USA)<br>restricts this device to sale by or<br>on the order of a licensed medical<br>practitioner |             | Regulatory compliance mark for<br>ACMA (Australian Communications<br>and Media Authority)         |  |

| <b>C €</b> 0413   | CE mark with notified body number   |   | Ť          | Keep dry  |
|---|---|---|------------|---|
|   | Keep away from small children to reduce the risk of accidental swallowing, choking and strangulation. |   | -25°C 55°C | Temperature limits to which the medical device can be exposed |
| Bluetooth Bluetooth logo Registered tradem requires a license |   | nark of Bluetooth SIG, Inc. where any use of such |            |   |
| Made 101  |   |   | •          | patible with iPhone, iPad and iPod                            |

# **C**€ 0413

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