

# Sentio 1 Mini

## Instructions for Use



Sound processor



## The Instructions for Use

The Sentio System is intended for improvement of hearing for patients with conductive and mixed hearing losses by unilateral or bilateral fitting, and single sided deafness. The system comprises of an implant and an externally worn sound processor. The implant is placed fully under the skin and the sound processor is retained to the implant site with a magnet.

The Sentio 1 Mini sound processor is designed to be optimised for each individual person. This will help ensuring you get the maximum benefit from your sound processor.

The Sentio 1 Mini sound processor is intended for use in homes, hospitals, health care institutions as well as in public environments. However, make sure that cautions related to specific situations mentioned in the “Important Information” and the “Warnings” sections are considered.

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 **Warnings** section, **Important information**, **Skin care and retention comfort** and **Sound Processor maintenance**. Discuss any questions or concerns with your hearing care professional.

Summary of Safety and Clinical Performance (SSCP) report for the Sentio System is publicly available in the EUDAMED database.<sup>1</sup>

<sup>1</sup><https://ec.europa.eu/tools/eudamed>.  
Entering key Sentio 1 Mini sound processor:  
Basic UDI-DI: 57121491001185

Entering key Sentio Ti Implant:  
Basic UDI-DI: 57121491001083

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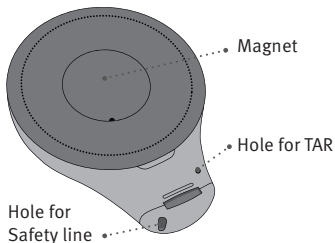
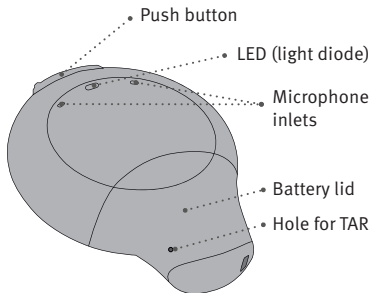


## In the box

- Sentio 1 Mini sound processor
- Sentio 1 Mini case
- Batteries (size 675)
- Safety line
- Left/right indication (blue/red)
- Tamper resistant battery lid tool



## Processor view

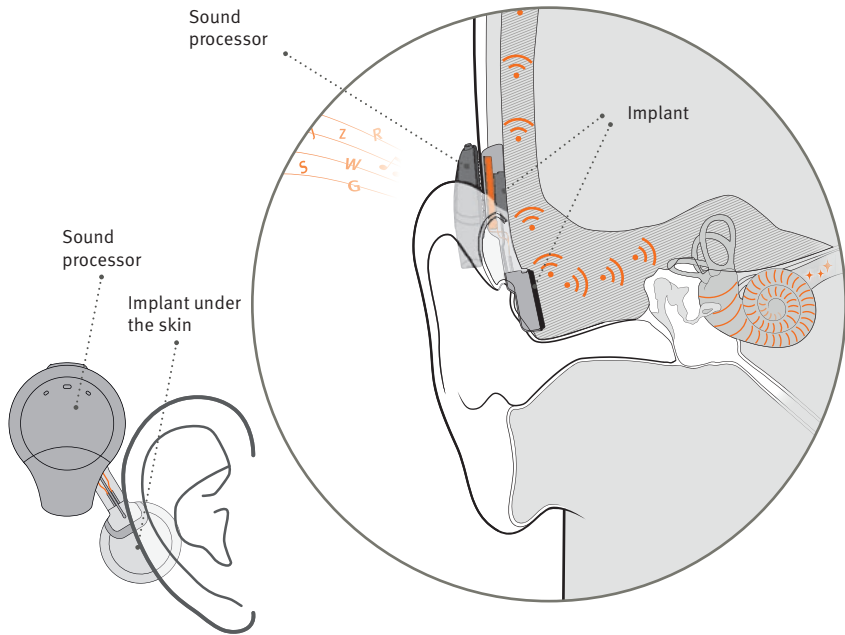


**⚠ Warning:** The sound processor contains small parts that may be a choking hazard for small children. Batteries can also be harmful if swallowed. Always keep batteries out of reach of small children or people of diminished mental capacity. If a sound processor is accidentally swallowed, seek medical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

## The Sentio bone conduction hearing system

Your Sentio 1 Mini sound processor is designed to help you gain improved hearing through direct bone conduction. The sound processor converts sound into signals which are transmitted to the Sentio Ti Implant where they are converted into vibrations. The vibrations pass through the skull bone to the inner ear where they are perceived as sound. This works independently of the function of the ear canal and middle ear.

Therefore, the Sentio system 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 Sentio hearing system 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).

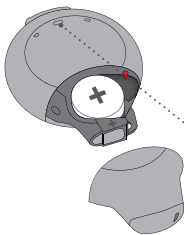


## Switching the sound processor ON and OFF

Insert or remove the battery to switch the sound processor ON or OFF. To save battery life, make sure your sound processor is switched off when you are not wearing it.

### Switch ON

Insert the battery and put on the battery lid to start up the sound processor

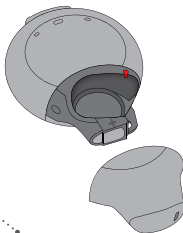


### Optional LED

Two long green flashes indicate that the sound processor is turned on.

### Switch OFF

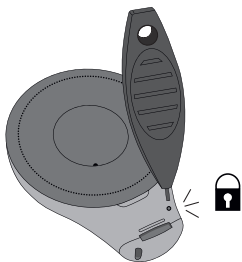
Remove the battery lid and battery to switch the sound processor off



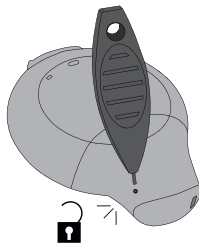
## Tamper-resistant battery lid

Sentio 1 Mini comes with a built-in tamper-resistant battery lid. To lock the tamper-resistant battery lid, insert the tip of the TAR tool into the hole on the back of the battery lid and push lightly. Check that the lid cannot be opened to confirm that the TAR mechanism is locked.

Insert the tip of the TAR tool from the front to unlock the tamper-resistant battery lid.



Lock the tamper-resistant battery lid



Unlock the tamper-resistant battery lid

**Important:** The tamper-resistant battery drawer function must always be used for children under the age of 36 months due to risk of swallowing and choking.

## When to replace the battery

The battery lifetime varies with usage time and sound environment. When it is time to replace the battery, you will hear three consecutive beeps repeated in moderate intervals. Four beeps in a descending tone indicate that the battery is running completely out. When the battery runs low, Bluetooth® will be turned off and it will not be possible to use wireless accessories.



Three alternate beeps\*  
= The battery is running low



Four descending tones  
= The battery has run out

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

Orange blinks, continuously repeated, to indicate battery low.

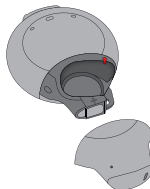


**Note:** To make sure the sound processor is always working, bring spare batteries with you or replace the battery before you leave home. Batteries need to be replaced more often if you are streaming to your sound processor.

## How to replace the battery

Sentio 1 Mini uses a size 675 zinc-air battery. Use high-quality zinc-air batteries for optimal performance.

### 1. Open



Remove the battery lid from the sound processor.

 **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.

## 2. Uncover

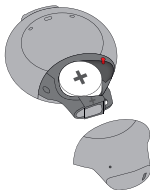


Remove the sticky label from the + side of the new battery.



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

## 3. Insert



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



**Note:** If the battery is inserted incorrectly it may damage the battery compartment.

## 4. Close

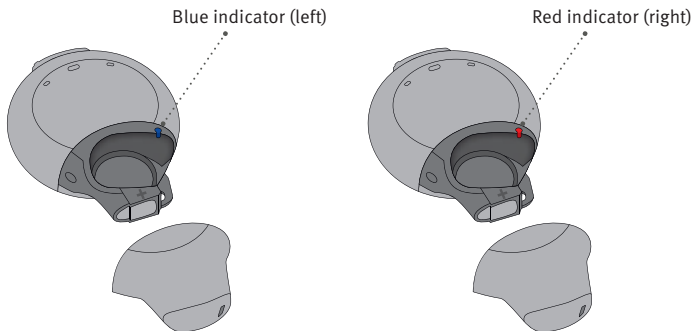


Close the battery lid. The sound processor will play a jingle. The jingle is played when the battery is inserted, unrelated to the lid.



## Left or right marking

The Sentio 1 Mini devices are non-side specific and will be programmed to the left or right side by your hearing care professional. When using two sound processors, left and right indication plugs can be inserted under the battery lid. Your hearing care professional can apply these.



## Connection

The Sentio 1 Mini sound processor is retained to the implant under the skin by magnetic force. To attach the sound processor to the head, place it close to the implant site to allow the magnet in the sound processor to attract to the magnet in the implant.



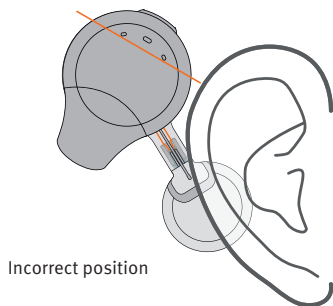
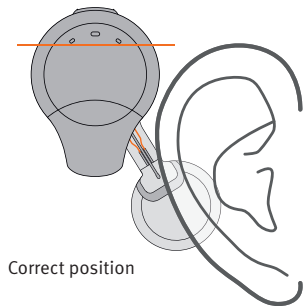
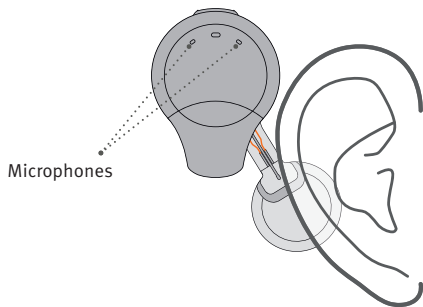
**Note:** No other magnet than your Sentio sound processor shall be placed over the implant site. This may damage the implant and/or your skin.

## Disconnection

The sound processor is disconnected by carefully sliding it away from the implant.

## Correct position

To get optimal performance from the directional microphone system, the sound processor should be positioned with the microphone inlets positioned horizontally. The correct position is best ensured before the magnets in the processor and the implant connect completely.



## Skin care and retention comfort

The sound processor should sit comfortably and securely in place with the right balance between comfort and retention. If the magnetic force is too weak there is a risk of the sound processor falling off too easily. If the magnetic force is too strong there is a risk of discomfort and skin irritation.

If the sound processor causes redness or discomfort, or if the sound processor seems to fall off frequently, contact your hearing care professional to have the magnet exchanged.

In case of significant skin irritation, blistering, or signs of skin breakdown, you should stop wearing the device and seek assistance from a medical professional to assess your implant site.

Parents or caregivers are responsible for skin care and retention comfort of a child's implant.

## Sound processor maintenance

Always keep your sound processor in its case when not in use to protect it from dust and dirt.

Your sound processor is dust tight and protected against ingress of water, designed to be worn in daily life situations. However, the sound processor is not waterproof and must never be washed or immersed in water or other liquids. If the sound processor accidentally gets wet, take off the battery lid, remove the battery 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.

## 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.

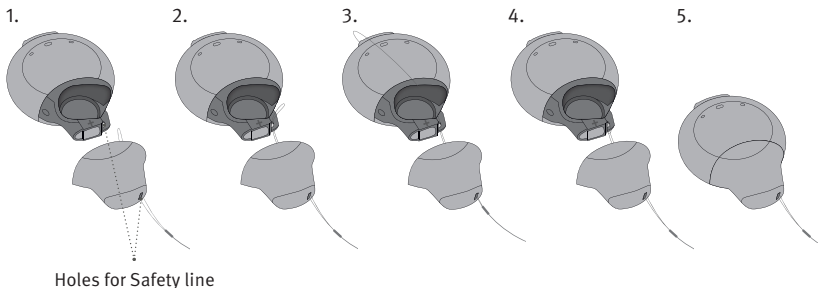
### Safety line

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. We also recommend that you use the safety line at first when you are getting used to wearing the device.



### How to attach safety line to the sound processor:

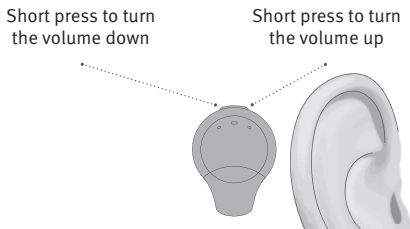
1. Pass the loop of the safety line through the attachment hole in the battery lid
2. Then pass the loop through the attachment hole in the sound processor
3. Insert the sound processor through the loop of the safety line and tighten
4. Attach the safety line clip to your clothing. Make sure the safety line is not pulled, as the sound processor could be disconnected.



## Volume control

The volume can be adjusted on the double push button. Use a short press to adjust the volume. When worn on the head, the front-facing button turns the volume up, and the back-facing button turns the volume down. You will hear a tone when you increase or decrease the volume. The volume can also be controlled from a Bluetooth-connected device, e.g. smartphone or connectivity products.

If you experience persistent problems with the volume control please contact your hearing care professional



**Note:** The volume control and optional LED can be enabled or disabled by your hearing care professional. For information regarding tones and light patterns, see the Sound and LED light indicators section.

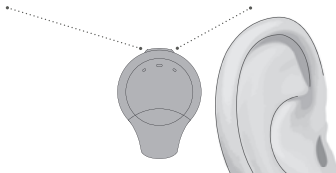


## Programmes

Your sound processor can have up to four different programmes. These are programmed by your hearing care professional. Press the double push button to switch between programmes. Use a long press (two sec.). If the front-facing push button is pressed, the programme cycle switches one programme forward, for example from programme 1 to 2. If the back-facing push button is pressed, the programme cycle goes backwards, for example from programme 2 to 1. Depending on the programme you choose (1, 2, 3 or 4), you hear one to four tones.

Two sec. long press to  
change programme going  
down in programme order

Long press to change  
programme going up in  
programme order



**Note:** For information regarding tones and light patterns, see the Sound and LED light indicators section.

## Mute

Use the mute function if you need to silence the sound for shorter periods of time while wearing the sound processor. Your sound processor can be muted by pressing either end of the push button for at least three seconds until a jingle is heard.

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

Continuous green and orange flashes indicate mute.

### **How to unmute your sound processor**

The sound processor can be unmuted by pressing either side of the button briefly or by using one of the optional devices.



**Note:** Do not use the mute function as an off switch, as the sound processor still draws current from the battery in this mode. For information regarding tones and light patterns see the Sound and LED light indicators section.

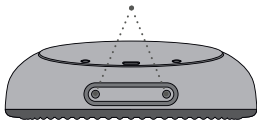
## Flight mode

When flight mode is activated, Bluetooth® is turned off. The sound processor will still be working.

Activate or deactivate Flight mode by pressing either the front- or back-facing part of the double push button for seven seconds. After a few seconds you will hear a jingle that indicates Mute mode. Keep pressing the button until a final jingle is heard which confirms your action.

Removing and reinserting the battery will also deactivate Flight mode. A short jingle confirms your action.

To activate and deactivate flight mode press either end of the push button for at least 7 seconds.



**Note:** Note: For information regarding tones and light patterns, see the Sound and LED light indicators section.

## 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](http://www.oticonmedical.com/wireless-connectivity)



For information on compatibility, please visit:  
[www.oticonmedical.com/wireless-compatibility](http://www.oticonmedical.com/wireless-compatibility)

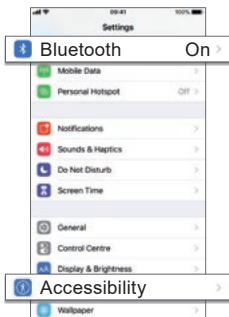
Use of the Made for Apple badge means that an accessory has been designed to connect specifically to the Apple product(s) identified in the badge, and has been certified by the developer to meet Apple performance standards.

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.

Apple, the Apple logo, iPhone, iPod touch are trademarks of Apple Inc., registered in the U.S. and other countries.

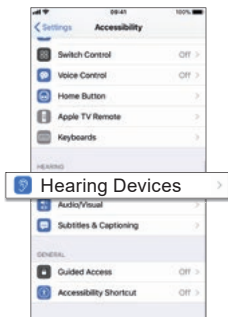
# Pairing the sound processor with iPhone

## 1. Settings



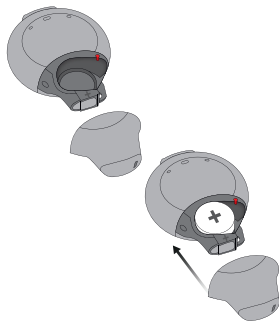
Open your iPhone and go to "Settings". Make sure Bluetooth is on. Then choose "Accessibility".

## 2. Accessibility



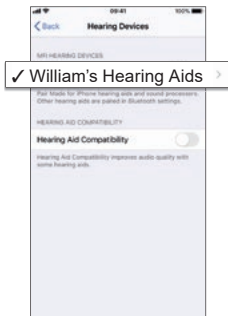
On the "Accessibility" screen, choose "Hearing Devices".

## 3. Turn on



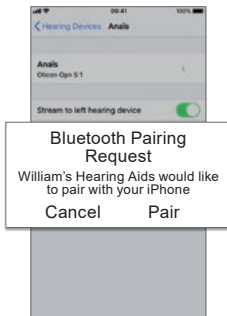
Open the battery lid and remove the battery. Re-insert the battery and close the battery lid on the sound processor. The sound processor remains in pairing mode for 3 minutes.

#### 4. Hearing devices



Check if your iPhone has detected your sound processor.

#### 5. Your hearing device



Here you can see the options for your sound processor.

## 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.

### EduMic

Wireless remote microphone system that supports users with a hearing loss in a classroom setting.

### 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](http://www.oticonmedical.com/wireless-connectivity)



**Note:** *If you are not using Bluetooth® enabled devices, when using a telephone, please hold the receiver of the telephone close to the sound processor for optimal volume.*

## Sentio 1 compatible with the following articles

| Description                                                                            | Article                          |
|----------------------------------------------------------------------------------------|----------------------------------|
| Oticon Medical Sentio Implants<br>Oticon Medical accessories<br>Oticon A/S accessories | Sentio Ti Implants               |
|                                                                                        | Genie Medical BAHS 23.1 or later |
|                                                                                        | ConnectClip                      |
|                                                                                        | TV Adapter 3.0                   |
|                                                                                        | Remote Control 3.0               |
|                                                                                        | Oticon app                       |
|                                                                                        | EduMic                           |



## Service and repair

If your Sentio 1 Mini sound processor does not function properly, please contact your clinic to get it checked.

Contact person at the Audiology Clinic – name and contact information:

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Contact person at the ENT Clinic – name and contact information:

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## 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 conduction hearing system, please contact us using the contact form at

<https://www.oticonmedical.com>

| Common problems and their possible solutions |                                       |                                                                                                        |
|----------------------------------------------|---------------------------------------|--------------------------------------------------------------------------------------------------------|
| Symptom                                      | Possible causes                       | Solutions                                                                                              |
| No sound                                     | Worn-out battery                      | Change battery                                                                                         |
|                                              | Sound processor is muted              | Unmute or reset the sound processor by removing and reinserting the battery                            |
| Intermittent or reduced sound                | Dirt in the sound inlet               | Refer to Sound processor maintenance                                                                   |
|                                              | Moisture                              | Take off the battery lid, remove the battery, let the sound processor dry                              |
|                                              | Worn-out battery                      | Change battery                                                                                         |
| Whistling noise                              | Sound processor is touching something | Check if the sound processor is correctly connected and is not touching e.g. glasses or hat            |
| Sound processor falls off frequently         | Magnet is too weak                    | Contact your hearing care professional to have the magnet strength evaluated and exchanged if relevant |
|                                              |                                       | Use a safety line to reduce risk of dropping the sound processor                                       |

| Common problems and their possible solutions              |                            |                                                                                                                                                                                                 |
|-----------------------------------------------------------|----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Symptom                                                   | Possible causes            | Solutions                                                                                                                                                                                       |
| Discomfort or skin being affected at sound processor site | Magnet strength too strong | Contact your hearing care professional to have the magnet strength evaluated and exchanged if relevant                                                                                          |
|                                                           |                            | In case of significant skin irritation, blistering, or signs of skin breakdown, you should stop wearing the device and seek assistance from a medical professional to assess your implant site. |

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

## Important information

- It is important to follow the skin care 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.
- Whenever the sound processor is not in use, ensure it is switched off by removing the battery lid and battery. The battery lid should be kept off 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 to remove the sound processor(s) will be given at the security check point.
- When travelling by plane, enable Flight Mode 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

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s) and complies with part 15 of the FCC Rules.

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

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

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNRd'Innovation, Sciences et Développement économique Canada applicables aux appareils radioexempts de licence.

L'exploitation est autorisée aux deux conditions suivantes:

1. L'appareil ne doit pas produire de brouillage;
2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement

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 Sentio 1 Mini 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.



Equipment  
includes  
RF transmitter



In the case of a serious incident in relation to the Sentio 1 Mini sound processor, the incident should be reported to the manufacturer as well as the local competent authority on safety and health.

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. This device use a weak magnetic field transmitter communicating with the implant at 120 kHz with a field strength of approx.12.5 dBuA/m (64.0 dBuV/m) measured in 3 meter distance.

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

Additional information can be found in the “Product Information” on [www.oticonmedical.com/downloads](http://www.oticonmedical.com/downloads)

HVIN: Sentio 1 Mini

FCC ID: 2AHJWSENTIO1

IC: 21199-SENTIO1

*This equipment has been tested and found to comply with the emission limits for a Class B GROUP 1 equipment, pursuant to CISPR11/EN55011 and with the immunity limits for a Home Healthcare Environment, pursuant to IEC 61000-4-2, IEC 61000-4-3, and IEC 61000-4-8.*



## 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.
- 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. Dispose the sound processor according to local regulation for electronic equipment.
- 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.



- Retention properties of sound processor's magnet can be degraded after exposure to strong magnetic fields. Please contact your hearing care professional to exchange the magnet.
- Although unlikely, nearby electronic devices may be affected by your sound processor. Similarly, the sound processor may be affected by nearby electronic devices which may cause odd sounds in the sound processor. In that case, move the sound processor away from the affected electronic device.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 Inches) to any part of Sentio 1 sound processor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could be the result.
- The sound processor is MR Unsafe. If you need to undergo MRI (Magnetic Resonance Imaging), the sound processor must be disconnected. The implant 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.
- 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.
- Do not tamper with the device.

### **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.

## 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). Contact your Hearing care professional as soon as possible.

### When wearing Sentio 1 Mini and any type of active implants

- 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.
- 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.

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

| Description of symbols and abbreviations used in this booklet                     |                                                                                                                                                                                                                  |
|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <b>Caution</b><br>Consult instructions for use for warnings and precautions that are not found on the device itself.                                                                                             |
|  | <b>Manufacturer</b><br>The device is produced by the manufacturer whose name and address are stated next to the symbol.                                                                                          |
|  | <b>CE mark</b><br>The device complies with all required EU regulations and directives.<br>The four digit number indicates the identification of the notified body.                                               |
|  | <b>Regulatory Compliance Mark (RCM)</b><br>The device complies with electrical safety, EMC and radio spectrum requirements for devices supplied to the Australian or New Zealand markets.                        |
|  | <b>IP code</b><br>Indicates the class of protections against harmful ingress of water and particulate matter. IP57 indicates dust protection and protection against the effects of temporary immersion in water. |
|  | <b>Radio Frequency (RF) transmitter</b><br>Your sound processor contains an RF transmitter.                                                                                                                      |

| Description of symbols and abbreviations used in this booklet                     |                                                                                                                                                      |
|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <b>Bluetooth logo</b><br>Registered trademark of Bluetooth SIG, Inc. where any use of such requires a license.                                       |
|  | <b>Made for Apple badges</b><br>Indicates that the device is compatible with iPhone, iPad and iPod touch.                                            |
| Description of symbols and abbreviations used on device or packaging              |                                                                                                                                                      |
|  | <b>Electronic waste (WEEE)</b><br>Waste from electronic equipment must be handled according to local regulations.                                    |
|  | <b>Unique Device Identifier</b>                                                                                                                      |
| Rx Only                                                                           | <b>RX Only Caution</b><br>Federal law (USA) restricts this device to sale by or on the order of a licensed medical practitioner.                     |
|  | <b>Type BF Applied Part</b><br>Classification of protection against electrical shock.                                                                |
|  | <b>Warning: Contains coin battery</b><br>Indicates that the device contains coin batteries.                                                          |
|  | The device complies with the medical device regulation in Great Britain.<br>The four digit number indicates the identification of the approved body. |
|  | <b>Single patient multiple use</b>                                                                                                                   |

## Description of additional symbols used on device or packaging



### Keep dry

Indicates a medical device that needs to be protected from moisture.



### Consult instructions for use

Consult instructions for use for warnings and cautions.



### Product Catalogue number

Indicates the manufacturer's catalogue number so that the medical device can be identified.



### Serial number

Indicates the manufacturer's serial number so that a specific medical device can be identified.

YY.XXXXXXXX

The two first digits in the serial number "YY" indicate the year of manufacturing.



### Medical Device

The device is a medical device.



### Temperature limit

Indicates the temperature limits to which the medical device can be safely exposed.



### MR Unsafe

The device is MR Unsafe. If you need to undergo MRI (Magnetic Resonance Imaging) the device must be disconnected.

## Sound and LED light indicators

Different sounds and light patterns indicate the sound processor status. The different indicators are listed on the following pages.

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

| Programme | <input type="checkbox"/> Sound | <input type="checkbox"/> LED light*                                               | When to use |
|-----------|--------------------------------|-----------------------------------------------------------------------------------|-------------|
| 1         | 1 tone                         |  |             |
| 2         | 2 tones                        |  |             |
| 3         | 3 tones                        |  |             |
| 4         | 4 tones                        |  |             |

 Short GREEN blink

\*LED light blinks continuously or is repeated three times with short pauses

Continues on next page

| ON/OFF                                                   | Sound                                       | LED light                                                                                                                                                                                    | LED light comments                 |
|----------------------------------------------------------|---------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| ON                                                       | <input type="checkbox"/> Start-up jingle    | <input type="checkbox"/>   | Shown once                         |
| OFF                                                      | <input type="checkbox"/> 4 descending tones | <input type="checkbox"/>   |                                    |
| Volume                                                   | Sound                                       | LED light                                                                                                                                                                                    |                                    |
| Start-up volume                                          | <input type="checkbox"/> 2 beeps            | <input type="checkbox"/>                                                                                    |                                    |
| Minimum/maximum volume                                   | <input type="checkbox"/> 3 beeps            | <input type="checkbox"/>                                                                                    |                                    |
| Volume up/down                                           | <input type="checkbox"/> 1 beep             | <input type="checkbox"/>                                                                                    |                                    |
| Mute activated on App, ConnectClip or Remote Control 3.0 |                                             | <input type="checkbox"/>   | Continuous or repeated three times |

 Long GREEN blink  
  Short GREEN blink  
  Long ORANGE blink  
  Short ORANGE blink

| Accessories              | <input type="checkbox"/> Sound | <input type="checkbox"/> LED light                                                                                                                                  | LED light comments                 |
|--------------------------|--------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| TV Adapter 3.0 or EduMic | 2 different tones              |   | Continuous or repeated three times |
| ConnectClip              | 2 different tones              |   |                                    |

| Warnings                        | Sound                                      | LED light                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | LED light comments    |
|---------------------------------|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Low battery                     | <input type="checkbox"/> 3 alternate tones | <input type="checkbox"/>       | Continuously blinking |
| Battery shut down               | 4 descending tones                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                       |
| Microphone service check needed | 8 beeps repeated 4 times                   | <input type="checkbox"/>                                                                                                                                                                        | Repeated four times   |

 Long GREEN blink
  Short GREEN blink
  Long ORANGE blink
  Short ORANGE blink





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