## Oticon Acto

## **INSTRUCTIONS** FOR USE

BTE





## Thank you

Thank you for choosing our product as your means to better hearing.

To support your efforts, we have put great care and attention into making sure that your new hearing instruments are of the highest quality and that they are easy to use and maintain.

We recommend that you read this manual carefully to achieve the maximum benefit of your new hearing instruments.

Congratulations on your decision to actively improve your hearing with the most advanced hearing technology in the market.

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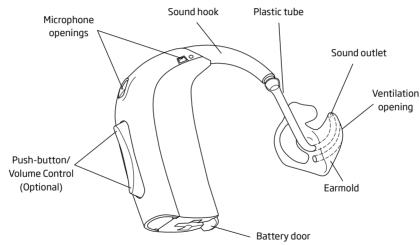
### IMPORTANT NOTICE

Please familiarize yourself with the entire contents of this booklet before using your hearing instruments. It contains instructions and important information about the use and handling of your hearing instruments and batteries.

#### CAUTION

The BTE Power is a powerful hearing instrument. In case you are fitted with BTE Power, never allow others to wear your hearing instruments as incorrect or wrongful usage could cause permanent damage to their hearing.

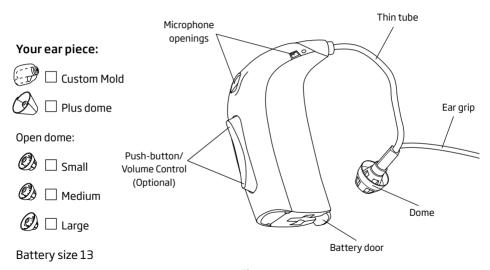
## **Instrument View BTE 13**



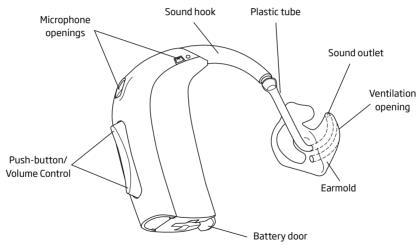
Battery size: 13

## Instrument View BTE 13 with Corda<sup>2</sup>

Not available for BTE Power



## Instrument View BTE 13 Power



Battery size: 13

## **Changing batteries**

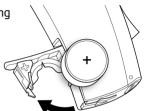
Your hearing instrument battery size is 13. Batteries perform differently. Ask your hearing care professional for help choosing a high quality battery for your hearing instrument.

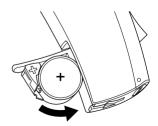
A worn out battery should be removed immediately and disposed of according to local regulations.

When the battery power is low, you will hear 2 beeps. This pre-warning starts when the battery has only a few hours of operation left. The pre-warning will be repeated in moderate intervals to indicate it is time to change the battery.

If the battery runs out, the instrument turns off. When that happens, 4 beeps are played to indicate that the instrument is no longer operating.

This is not an indication of a malfunction.





#### To replace the battery, follow these instructions:

- Open the battery door completely by pushing the raised edge in the bottom of the instrument. Remove the old battery.
- Remove the sticky label from the + side of the new battery.
- Insert the new battery so that its + marking faces the + sign printed on the battery door. Close the battery door.

Any moisture on the battery surface should be wiped off before use.

When you change battery, it will take a few seconds before the battery works to full capacity.

To assist the handling of the batteries, the magnet placed at the end of the tool can be used.



## Turning your instrument ON and OFF

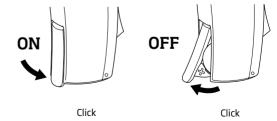
Turn **ON** your hearing instrument by closing the battery door completely with the battery in place. When the battery door is closed the instrument will start up by playing a jingle. This indicates that the battery is working and the instrument is operating.

Turn OFF your hearing instrument by opening the battery door slightly until a "click" is felt.

To preserve the battery, make sure your hearing instrument is switched off when you are not wearing it.

### IMPORTANT NOTICE

Open the battery compartment fully to allow air to circulate whenever you are not using your hearing instrument, especially at night!

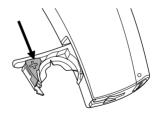


## Left/Right ear marking

Hearing instruments are fitted to the uniqueness of each ear, which means if you have two instruments then your left hearing instrument is programmed differently from your right. That is why it is important to distinguish between the left hearing instrument and the right.

In order to easily identify whether it is the left ear or right ear instrument, color markings may be applied inside the battery door.

Blue marks the LEFT instrument. Red marks the RIGHT instrument.

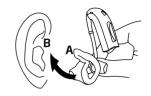


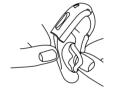
# Putting on your instrument with earmold

Place the tip of the earmold in your ear canal, twisting slightly, making sure that the top part of the earmold (A) is pushed behind and under the fold (B) of your ear.

Gently pull up your ear and press the earmold in the direction of the ear canal.

With the earmold positioned correctly in your ear, place the hearing instrument behind your ear by lifting its lower part and sliding it over the top of your ear.







# Putting on your hearing instruments with a Corda<sup>2</sup> (thin tube)

Not available for BTE Power

## Putting on your hearing instrument with a thin tube correctly every time takes practice:

- 1. Place the hearing instrument behind your ear.
- 2. Hold the bend of the tube between your thumb and index finger. The dome should point towards the ear canal opening. Gently push the dome into your ear canal until the sound tube sits close against the side of your head.
- 3. Position the ear grip in the concha using your index finger. Look in a mirror. If the sound tube is sticking out from your ear, the dome has not been placed correctly in the ear canal. If the ear grip is visibly sticking out from your ear it has not been positioned correctly. To remove the instrument pull the bend of the tube.



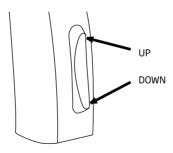




## **Push-button**

Your hearing instrument has a push-button to adjust volume and to switch between different programs.

The push-button can be activated by pressing either the upper part (UP) or the lower part (DOWN).



The push-button on your hearing instrument can be programmed to one of 3 functionalities.

Left	Right	
		Program shift: Short push to change program.
		Volume control: Short push to adjust the volume.
		Both volume control and program shift:  Short push to adjust the volume and long push (about 2 seconds) to shift the program.

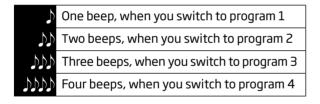
☐ Binaural Coordination enabled (see "Using 2 instruments").

To be filled out by your Hearing Care Professional!

## **Programs (Optional)**

Your hearing instrument can have up to 4 different programs.

When switching between the different programs, your hearing instrument will beep. The number of beeps will indicate which program you are using.



Press the upper part to go forwards in the program cycle e.g from P1-P2. Press the lower part to go backwards in the program cycle e.g from P3-P2.

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rg. 1:	
rg. 2:	
rg. 3:	
rg. 4:	

#### Using 2 instruments

If you have two instruments the push-button on one instrument can be programmed to change the program on both hearing instruments (Binaural Coordination). This means, when you adjust the program for one instrument, it automatically adjusts the other.

## **Volume Control (Optional)**

A volume control may be activated. The volume control allows you to adjust the volume in specific listening situations to the level you feel comfortable with.

To **increase volume**, shortly press the upper part of the push-button.

To **decrease volume**, shortly press the lower part of the push-button.

You hear a beep when you increase or decrease the volume.

When the hearing instrument is turned on, it starts up at a preferred volume level. When adjusting the volume control to the preferred level, this is indicated by a beep.

#### Using 2 instruments

If you have two instruments the push-button on one instrument can be programmed to adjust the volume on both hearing instruments (Binaural Coordination). This means, when you adjust the volume for one instrument, it automatically adjusts the other.

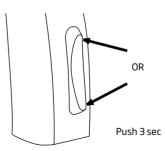
## Stand-by (Optional)

Push the button for a minimum of 3 seconds to set the instrument in stand-by mode.

To reactivate the instrument, push the button briefly again.

Use the stand-by function if you need to silence the instrument while you have the instrument on.

Note: pushing either side of the button will set the instrument on stand-by.



## **IMPORTANT NOTICE**

Do not use the stand-by function as a switch off as the hearing aid still draws power from the battery in this mode.

## Tamper-resistant battery door (Optional)

This is strongly recommended for infants, small children and people with learning difficulties.

The battery door is designed only to be opened by using a tool. Use the MultiTool to unlock the door by inserting it into the slit in the bottom of the hearing instrument and push on the door to open.

Important: Do not force the battery door beyond its fully opened position. Insert the battery correctly. Excessive force can deform the battery door, which will reduce its tamper resistant effectiveness.



## Telecoil (Optional)

The telecoil is a receiver for audio signals transmitted from an inductive loop installation. The telecoil is meant for telephone conversations and for loop systems in e.g. theaters, churches or lecture rooms.

The telecoil is activated by the push-button as switching between programs. When activated, you will hear a certain number of beeps corresponding to the telecoil program.

See "Programs" for where the telecoil program is placed.

## **Auto Phone (Optional)**

Your hearing instrument may have a built-in Auto Phone functionality. When the hearing instrument is close to a telephone receiver, the Auto Phone will activate a Phone Program. When the Phone Program is activated you will hear a number of beeps.

When you end your telephone conversation, the hearing instrument will automatically return to the previous program.

Not all telephones can activate the Auto Phone. The telephone receiver must have a special magnet fitted. Please follow the separate instructions for mounting the magnet, which is available from your Hearing Care Professional.



#### WARNING

If you use an Auto Phone magnet:

- Keep magnets out of reach of children and pets. If a magnet is swallowed, see a doctor immediately.
- Do not keep the magnet in a breast pocket and always keep it 12 inches away from active implantable devices. Preferably, use the telephone with magnet on the opposite side of the body from a pacemaker or other active implantable device.
- Keep the magnet 12 inches away from credit cards and other magnetically sensitive devices.

## **DAI (Direct Audio Input)**

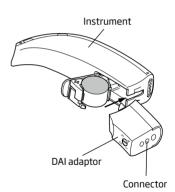
If your hearing instrument is connected by means of a DAI adaptor with an external sound source, like a media player/MP3 or hand mic, the signals of these devices will be directly transferred to your hearing instrument.

#### Mounting of the DAI adaptor

Start by opening the battery door and slide the DAI adaptor onto the instrument.

Then insert the DAI cord into the adaptor.

When the DAI adaptor is connected, the instrument will automatically switch to a combination of DAI and microphone input of the instrument.



If you would like the DAI input alone, you can switch to the next program by using the program switch button.

As long as the DAI adaptor is connected to the instrument, two programs will automatically be added after the standard programs which have been programmed into your hearing instrument by your Hearing Care Professional.

#### IMPORTANT NOTICE

When the DAI is connected to mains-operated equipment, this equipment must comply with IEC-60065, IEC-60601 or equivalent safety standards.

## **FM**

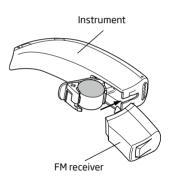
An FM receiver enables the hearing instrument to receive signals directly from an external wireless FM transmitter.

#### Mounting of the FM receiver

Start by opening the battery door. Slide the FM receiver onto the instrument.

As long as the FM receiver is connected to the instrument, two FM programs will automatically be added after any standard programs that have been programmed into your instrument by your Hearing Care Professional.

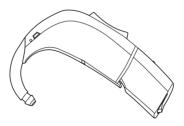
When the FM receiver is connected and turned on, the instrument will automatically switch to a program that receives signals from the microphone in combination with an external wireless FM transmitter.



If you would like to receive input from the FM transmitter alone, you can advance to the next FM program by using the program switch button.

With the FM receiver mounted, the push button of the hearing instrument can be used to switch back and forth between standard programs and FM programs.

For detailed instructions on handling and use of the FM receiver, refer directly to the dedicated receiver guide.



## Caring for your hearing instrument

Your ear canal produces ear wax (cerumen) which may clog up the sound outlet or the ventilation opening of your earmold. To prevent wax accumulation causing a change in performance, the quidelines in this section should be followed.

When handling a hearing instrument, keep it over a soft surface to avoid damage if you drop it.

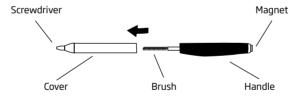
#### Before retiring at night:

- Make sure that there is no ear wax in any of the earmold openings since it may reduce the hearing instrument's efficiency.
- Open the battery door to allow air to circulate.

#### Cleaning the instrument

The multi-purpose tool contains a brush for the special purpose of cleaning your instruments. This should be used to ensure the best care and performance of your hearing instruments.

## MultiTool



#### Cleaning the earmold

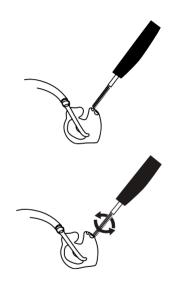
- Use the brush to clean away any traces of wax from around the sound outlet.
- Clean the ventilation opening by pressing the brush through the hole while twisting it slightly.

Use the cloth to clean the surface of the instrument.

Replace the brush when necessary. Just pull it out of the handle and insert a new fresh brush. Press the new one firmly into the handle.

Brushes can be purchased from your Hearing Care Professional.

The hearing instrument itself must **never** be washed or immersed in water or other liquids!



#### Washing the earmolds

The earmolds should be washed regularly:

- Disconnect the earmold and the tubing from the sound hook of the hearing instrument.
- Wash the earmold in lukewarm water using a mild soap.
   Do not use strong detergents.
- · Rinse with water.
- Dry the earmold.
- Any water drops inside the earmold or tubing should be blown out. A special device for this purpose (an earmold blower) is available from your Hearing Care Professional.







 Make sure the earmold and tubing are completely dry before they are reconnected to the hearing instrument. Be careful that left ear earmold and tubing are connected to the hearing instrument with left ear marking and vice versa for the right ear instrument.



#### Replacing the tubing

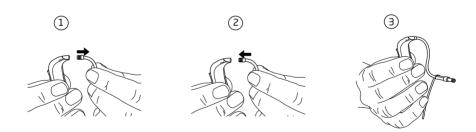
The tubing in the earmold should be replaced when it becomes yellow or stiff. Consult your Hearing Care Professional in relation to this.

### **IMPORTANT NOTICE**

The hearing instrument itself must **never** be washed or immersed in water or other liquids!

# How to change Corda<sup>2</sup> (thin tube)

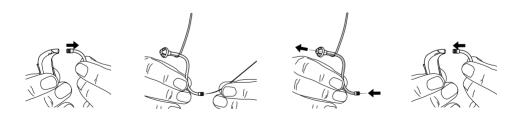
- 1. Pull tube out of the Hearing Instrument.
- 2. Push tube into the Hearing Instrument.
- 3. Correct.



# Cleaning your hearing instrument with Corda<sup>2</sup> (thin tube)

### To remove cerumen from the thin tube:

- Pull tube out of the hearing instrument.
- Insert the cleaning tool in the tube all the way through.
- Remove the tool and push the tube into the hearing instrument.



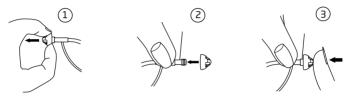
### Daily maintenance with Corda<sup>2</sup> (thin tube) Domes

The dome should not be cleaned. When you require a fresh, clean dome, remove the existing one and put on a fresh one.

We recommend the dome to be replaced at least once a month or as directed by your Hearing Care Professional.

# Changing the Corda<sup>2</sup> Dome

The dome is easy to replace. Hold the widest part of the dome and pull it off from the connections joint on the tube. Place the new dome on the speaker and ensure that it is fastened securely.



### IMPORTANT NOTICE

The dome is made of a soft, medically approved material. If the dome comes off in the ear canal, it will not cause any harm. If you can, carefully take it out. If necessary, let another person help you. Do not push the dome into the ear canal.

Do not push the tube into the ear again before the dome is removed from the ear. If you have any doubts, contact your Hearing Care Professional.

### IMPORTANT NOTICE

- Only use parts designed for your hearing instruments.
- The cleaning tools should only be used for cleaning the tubing when it is detached from the hearing instrument and not on the ear.
- The dome must be properly attached to the sound tube before inserting it in your ear. Failure to follow the instructions could result in injury.
- If the dome is not correctly attached and falls off in the ear: Please see your hearing care professional or seek medical consultation.
- The tube should never be used without a dome attached.
- Do not use hearing instruments in ears with excessive ear wax accumulation or infection.
- Proper preventive care and maintenance will go a long way toward ensuring reliability and safe performance.
- Clean your sound tube on a regular basis.
- Do not share your hearing aids or any of the parts with other people.
- Ensure your hands are clean when handling the hearing instrument and its parts.

# Avoiding heat, humidity and chemicals

Your hearing instrument must never be exposed to extreme heat e.g. left inside a parked car in the sun. They must never be exposed to a lot of moisture e.g. steam baths, showers or heavy rain. Nor must they be dried in microwave ovens or other ovens.

Wipe the batteries carefully if moisture is present as it may affect their performance. Using an anti-humidity kit can help to avoid these problems and may even extend the life of your hearing instrument. Consult your Hearing Care Professional for further advice.

The chemicals in cosmetics, hairspray, perfume, aftershave lotion, suntan lotion and insect repellant can damage your hearing instrument. You should always remove your hearing instrument before applying such products and allow time for the product to dry before refitting your hearing instrument. If you use lotion, be sure to wipe your hands dry before putting on your hearing instrument.

# Seven easy steps to better hearing

It takes time to adjust to a new hearing instrument. How long this adjustment takes differs from person to person. It will depend on a number of factors, such as whether you have had a hearing instrument before and the degree of your hearing loss.

### 1. In the quiet of your home

Try to acclimate yourself to all the new sounds. Listen to the many background sounds and try to identify each sound. Bear in mind that some sounds will seem different from what you are used to. You may have to learn to identify them again. Note that in time you will get accustomed to the sounds in your environment – if not please contact your Hearing Care Professional.

If using the hearing instruments makes you tired, take them off for a little while and have a rest. Gradually, you will begin to be able to listen for longer periods of time. Soon, you will be able to wear your hearing instruments comfortably all day long.

### 2. Conversation with another person

Sit with someone else in a quiet room. Face each other so you can read facial expressions easily. You may notice new speech sounds, which can seem a little different in the beginning. However, after the brain has adapted to the new speech sounds, you should hear speech clearer.

#### 3. Listen to radio or TV

When listening to the TV or the radio, start out by listening to news commentators since they usually speak clearly, then try other programs.

If you find it difficult to listen to TV or radio, ask your Hearing Care Professional for more information regarding the Oticon ConnectLine system and other available accessories.

### 4. In group conversations

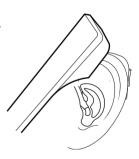
Group situations are usually accompanied by a greater degree of background noise, and are, therefore, naturally more difficult to cope with. In such situations, therefore, focus your attention on the person you want to hear. If you miss a word, ask the speaker to repeat.

### 5. Telecoil use in church, theater or cinema

An increasing number of churches, theaters and public buildings may have loop systems installed. These systems send out wireless sound to be received by the telecoil in your hearing instrument. Typically, a sign will let you know whether the place has a loop system. Ask your Hearing Care Professional for details.

### 6. Using the telephone

When using the telephone tilt the receiver edge lightly on your cheek-bone and position the phone slightly over the ear close to the hearing instrument's microphone. The sound then flows directly into the hearing instrument's microphone opening. This way, the hearing instruments will not whistle, and you ensure the best conditions to understand the conversation. When you have the receiver in this position, remember to speak directly into the mouthpiece of the telephone in order to ensure good understanding on the other "end of the line".



If you find it difficult to use the telephone, ask your earing Care Professional for more information regarding the Oticon ConnectLine system and other available accessories.

If your hearing instrument has a telecoil (and your telephone has a built in tele-loop) you can switch into telecoil program in order to improve the sound reception further.

Remember that the telecoil in your hearing instruments may pick up unwanted signals from electronic devices, such as fax machines, computers, televisions or similar. Make sure that the hearing instrument has a distance of 6-10 feet from such devices when using the telecoil program.

### 7. Wireless and cell phones

Your hearing instrument is designed to comply with the most stringent Standards of International Electromagnetic Compatibility. However not all cell phones are hearing instrument compatible. The varying degree of disturbance can be due to the nature of your particular cell phone.

If you find it difficult to obtain a good result while using your cell telephone, ask your Hearing Care Professional for more information regarding the Oticon ConnectLine system and other available accessories.

### Use your hearing instruments all day long

The best way to ensure better hearing is to practice listening until you can wear your hearing instruments comfortably all day. In most cases, you will not get the full benefit of the hearing instruments if you use them infrequently.

Your hearing instruments will not restore normal hearing. Nor will they prevent or improve a hearing impairment resulting from a physiological condition. What they will give you, however, is help towards making better use of the hearing ability that you have. If you have two hearing instruments, always wear both.

### These are the most important benefits of wearing two hearing instruments:

- Your ability to localize sounds will improve.
- It will be easier to understand speech in noisy surroundings.
- You will experience a fuller, more comfortable sound picture.

Common problems and their solutions		
Symptom	Possible causes	
No sound	Worn-out battery	
	Clogged sound outlet	
Intermittent or reduced sound	Clogged sound outlet	
	Moisture	
	Worn-out battery	
	Clogged damping filter in hook	
Squealing noise	Hearing instrument inserted improperly	
	Ear wax accumulated in ear canal	

If none of the above solutions solves the problem, ask your Hearing Care Professional for assistance.

Solutions	
Change battery	pg. 7
Clean earmold	pg. 30 & 34
Clean earmold	pg. 30 & 34
Wipe battery and instrument with dry cloth	pg. 38
Change battery	pg. 7
Contact your Hearing Care Professional for assistance	
Reinsert hearing instrument	pg. 11
Have ear canal examed by your doctor	

# **International Warranty**

Your hearing instruments 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 hearing instrument itself, but not accessories such as batteries, tubing, earwax filters etc.

Problems arising from improper handling or care, excessive use, accidents, repairs made by an unauthorized party, exposure to corrosive conditions, physical changes in your ear, damage due to foreign objects entering the device, or incorrect adjustments are NOT covered by the limited warranty and may void it.

The above warranty does not affect any legal rights that you might have under applicable national legislation governing sale of consumer goods. Your Hearing Care Professional may have issued a warranty that goes beyond the clauses of this limited warranty. Please consult him/her for further information.

### If you need service

Take your hearing instrument to your Hearing Care Professional, who may well be able to sort out minor problems and adjustments on the spot.

# **Warranty Certificate**

Name of Owner:	
Dispenser:	
Dispenser Address:	
Dispenser Phone:	
Purchase Date:	
Warranty Period:	Month:
Model Left:	Serial no.:
Model Right:	Serial no.:
Battery Size: 13	

# Product approval, precautions and markings

The hearing instrument contains a radio transmitter using short range magnetic induction technology working at 3.84 MHz. The magnetic field strength of the transmitter is < -42 dBµA/m @ 10m.

The emission power from the radio system is well below international emission limits for human exposure. For comparison, the radiation of the hearing instrument is lower than unintended electromagnetic radiation from, for example, halogen lamps, computer monitors, dishwashers etc. The hearing instrument complies with international standards concerning Electromagnetic Compatibility.

Due to the limited space available on the instruments all relevant approval markings are found in this document.

### Cell Phone

"Some hearing aid users have reported a buzzing sound in their hearing aids when they are using cell phones, indicating that the cell phone and hearing aid may not be compatible. According to the ANSI C63.19 standard (ANSI C63.19-2006 American National Standard Methods of Measurement of Compatibility Between Wireless Communications Devices and Hearing Aids), the compatibility of a particular hearing aid and cell phone can be predicted by adding the rating for the hearing aid immunity to the rating for the cell phone emissions. For example, the sum of a hearing aid rating of 2 (M2/T2) and a telephone rating of 3 (M3/T3) would result in a combined rating of 5. Any combined rating that equals at least 5 would provide "normal use"; a combined rating of 6 or greater would indicate "excellent performance."

The immunity of this hearing instrument is at least M2/T2. The equipment performance measurements, categories and system classifications are based upon the best information available but cannot guarantee that all users will be satisfied.

### IMPORTANT NOTICE

The performance of individual hearing instruments may vary with individual cell phones. Therefore, please try this hearing instrument with your cell phone or, if you are purchasing a new phone, be sure to try it with your hearing instrument prior to purchase. For additional guidance, please ask your cell phone provider for the booklet entitled "Hearing Aid Compatibility with Digital Wireless Cell Phones."

The hearing instrument contains a module with:

FCC ID: U28FUBTE03 IC: 1350B-FUBTE03

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

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.

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

# Warnings

You should familiarize yourself fully with the following general warnings and the entire contents of this booklet before using your hearing instrument.

Hearing instruments and batteries can be dangerous if swallowed or used improperly. Such actions can result in severe injury, permanent hearing loss, or can even be fatal.

- Hearing instruments, their parts, and batteries 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.
- Never change the battery or adjust the controls of the hearing instruments in front of infants, small children or people with learning difficulties.
- Discard batteries carefully in a place where infants, small children or people with learning difficulties cannot reach them.
- Batteries have occasionally been mistaken for pills. Therefore check your medicine carefully before swallowing any pills.
- Never put your hearing instrument or batteries in your mouth for any reason, as they
  are slippery and could be swallowed by accident.

- Most hearing instruments can be supplied with a tamper-resistant battery compartment upon request. This is strongly recommended for infants, small children, and people with learning difficulties.
- Hearing instruments may stop functioning, for instance if the battery goes dead.
   You should be aware of this possibility, in particular when you are in traffic or otherwise depend on warning sounds.

If a battery or hearing instrument is swallowed, see a doctor immediately and call the National Poison Center, collect (202) 625-3333.

If a battery or hearing instrument is swallowed, see a doctor immediately.

### Usage of hearing instruments

- Hearing instruments should be used only as directed and adjusted by your Hearing Care Professional. Misuse can result in sudden and permanent hearing loss.
- Never allow others to wear your hearing instrument as incorrect/wrongful usage could cause permanent damage to their hearing.

### **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. They may explode and cause serious injury.
- Never dispose of batteries by burning them. There is a risk that they will explode and cause serious injury.

### Dysfunction in hearing instruments

Hearing instruments may stop functioning, for instance if the batteries have expired or
if the tubing is blocked by moisture or earwax. You should be aware of this possibility,
in particular when you are in traffic or otherwise dependent on warning sounds.

### Warning to hearing instrument dispensers

A hearing instrument dispenser should advise a prospective hearing instrument user to consult immediately with a licensed physician (preferably an ear specialist) before dispensing a hearing instrument. If the hearing instrument dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

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

Special care should be exercised in selecting and fitting a hearing instrument whose maximum sound pressure capability exceeds 132 dB SPL as there may be risk of impairing the remaining hearing of the hearing instrument user.

### Important notice for prospective hearing instrument users

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing instrument. Licensed physicians who specialize in diseases of the ear are often referred to as Otolaryngologists, Otologists or Otorhinolaryngologists. The purpose of medical evaluation is to ensure that all medically treatable conditions that may affect hearing are identified and treated before the hearing instrument is purchased. Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing instrument.

The physician will refer you to an audiologist or a hearing instrument dispenser, as appropriate, for a hearing instrument evaluation.

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 program. Many hearing instrument dispensers now offer programs 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.

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. A hearing instrument will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions. A hearing instrument is only part of hearing rehabilitation and may need to be supplemented by auditory training and lip reading.

### Possible side effects

The hearing instrument or earmold is a custom-made product. If you are experiencing discomfort, see your audiologist or hearing instrument dispenser immediately for modification of the hearing instrument or earmold at the point of irritation. A hearing instrument or earmold may cause an accelerated accumulation of cerumen (earwax). Also in rare cases, the otherwise non-allergenic material may cause a discharge from the ear, allergic reaction, or any other unusual condition. Please seek immediate consultation with a physician if these conditions occur.

### 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. If the user is an infant, small child, or person of mental incapacity, it is recommended that the hearing instrument be modified with a tamper-resistant battery compartment.

#### Interference

Your hearing instrument has been thoroughly tested for interference, according to the
most stringent international standards. But new technical developments constantly
bring new products into society, and some may emit electromagnetic radiation, leading
to unforeseen interference in hearing instruments. Examples include induction
cooking appliances, shop alarm systems, mobile telephones, fax machines, personal
computer devices, X-rays, Computer tomography etc.

Your hearing instruments are designed to comply with the most stringent Standards
of International Electromagnetic Compatibility. However, your hearing instrument may
cause interference with other medical devices. Such interference can also be caused by
radio signals, power line disturbances, airport metal detectors, electromagnetic fields
from other medical devices and eletrostatic discharges.

### Safety requirements regarding Direct Audio Input (DAI)

The safety of hearing instruments with DAI (Direct Audio Input) is determined by the
external signal source. When the DAI is connected to mains-operated equipment, this
equipment must comply with IEC-60065, IEC-60601 or equivalent safety standards.

### Warning to hearing instrument dispenser and user

- Special care should be excercised in selecting, fitting and using a hearing instrument
  where maximum sound pressure capability exceeds 132 dB SPL (IEC 711) as there may
  be risk of impairing the remaining hearing of the hearing instrument user.
- The included case for instrument storage has a built-in magnet. If you have an implantable device, such as pacemakers or defibrillators, the instrument case should not be carried in a chest pocket or near to the chest.

Hereby, Oticon A/S declare that this hearing instrument is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. Declaration of Conformity is available at:

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# People First

People First is our promise to empower people to communicate freely, interact naturally and participate actively



