

Beltoné Tinnitus Breaker

Instructions for use

Digital Sound generator instrument

TBR25, TBR62 and TBR 76

A new Beltone instrument!

Congratulations on your choice of a Beltone instrument. Your Tinnitus Breaker device is a tool for generating sounds to be used in tinnitus management programs to relieve suffering from tinnitus.

The Tinnitus Breaker can generate frequency and amplitude shaped white noise. Noise signal level and frequency characteristics can be adjusted to the specific therapeutic needs as determined by your doctor, audiologist, or hearing care practitioner.

Your doctor, audiologist, or hearing care practitioner can modulate the generated noise with the purpose of making it more pleasant. The noise can then resemble, for example, crushing waves on a shore. Modulation level and speed can also be configured to your like and needs.

This booklet is a short guide to assist you in getting acquainted with your instrument. Read it carefully and use it as a guideline.

We wish you happiness and success with your new instrument.

Beltone

Caution

Should you develop any side effects from using the Tinnitus Breaker device, such as dizziness, nausea, headaches, perceived decrease in auditory function or increase in tinnitus perception, you should discontinue use of the device and seek medical evaluation.

Contents

Prescription use of this device	4
Warning to hearing care professionals	4
Notice to prospective Tinnitus Breaker users	5
Your Tinnitus Breaker instrument	6-7
On/Off function	8-9
Changing the battery	10-11
Inserting and removing the device	12-16
Setting the volume	17
Program button	18-19
Daily maintenance	20
Maintenance – TBR62	20-25
Maintenance – TBR76	26-27
Maintenance – TBR25	27-30
General warnings	32-33
General precautions	33
Repairs	34
Technical data	35
Troubleshooting guide	36-37
International warranty and service	38
Your selected Tinnitus Breaker model	38

Prescription use of this device

A Tinnitus Breaker device should be used as prescribed by your doctor, audiologist, or hearing care practitioner. In order to avoid the possibility of damaging your hearing, the maximum daily usage depends on the level of the generated sound.

Should you develop any side effects from using the Tinnitus Breaker instrument, such as dizziness, nausea, headaches, perceived decrease in auditory function or increase in tinnitus perception, you should discontinue use of the device and seek medical evaluation.

The target population is primarily the adult population over 18 years of age. This product may also be used with children 5 years of age or older. However, children and physically or mentally challenged users will require training by a doctor, audiologist, hearing care practitioner or the guardian for the insertion and removal of the device.

Warning to hearing care professional

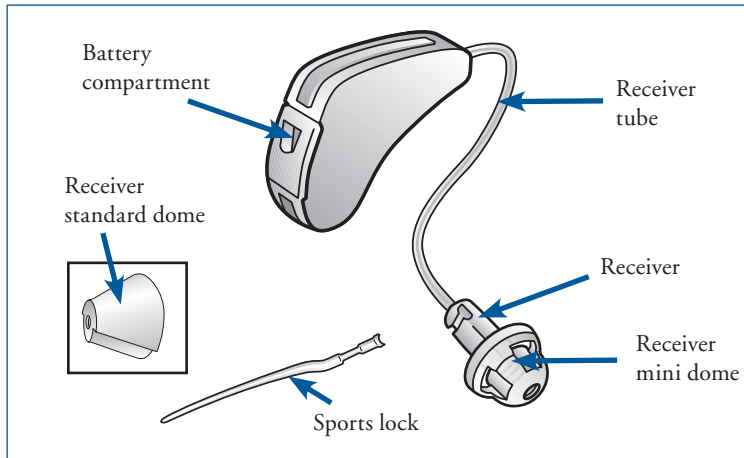
A hearing care professional should advise a prospective user of Tinnitus Breaker to consult promptly with a licensed physician (preferably an ear specialist) before setting the Tinnitus Breaker if the hearing care professional determines through inquiry, actual observation, or review of any other available 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 15dB at 500 Hz (hertz), 1000 Hz, and 2000 Hz;
- (vii) visible evidence of significant cerumen accumulation or a foreign body in the ear canal;
- (viii) pain or discomfort in the ear.

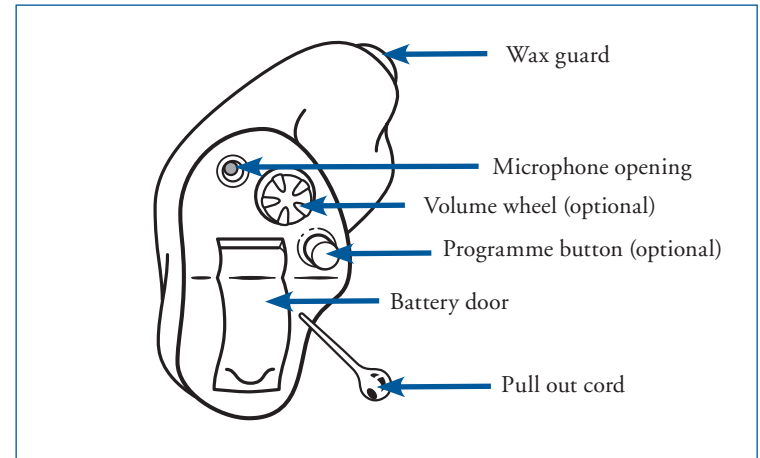
Important notice to for prospective Tinnitus Breaker users

Good health practice requires that a person with a tinnitus condition have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before using a sound generator, such the Beltone Tinnitus Breaker. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists, or otorhinolaryngologists. The purpose of a medical evaluation is to assure that all medically treatable conditions that may affect tinnitus are identified and treated before the sound generator instrument is used.

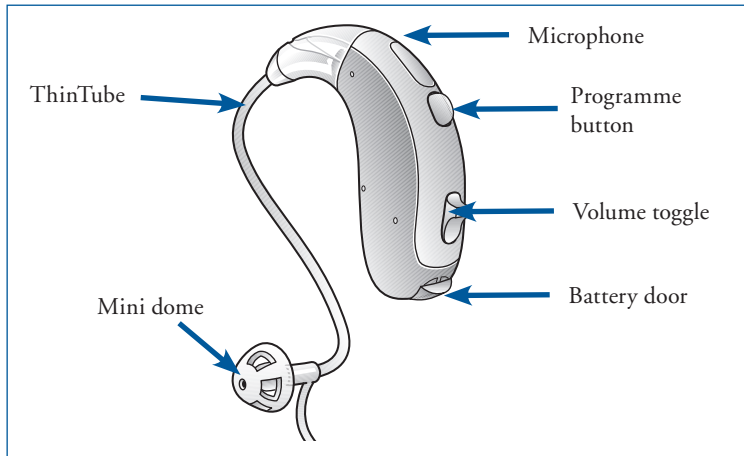
The sound generator instrument is a tool to generate sounds to be used with appropriate counselling and/or in a tinnitus management program to relieve patients suffering from tinnitus.



TBR62 Instrument



TBR25 Instrument



TBR76 Instrument

On/Off Function

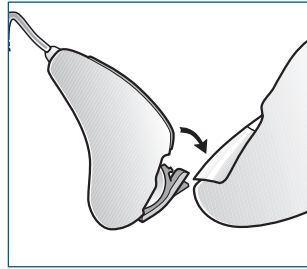
Your instrument is equipped with an on/off switch integrated into the battery compartment.

When the battery compartment is fully closed, the instrument is turned on.

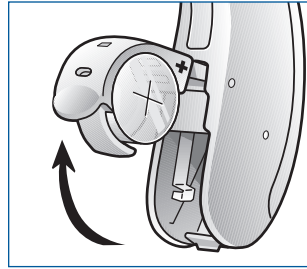
In the TBR62 and TBR76, to turn the instrument off grasp the battery compartment door with your fingernail and gently pull downwards (TBR62) or upwards (TBR76). The power will switch off at the point where you can feel a small click.

In the TBR25, fully open the battery compartment to ensure the device is correctly switched off.

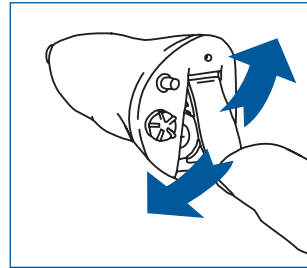
In the TBR76 and TBR25 there could be an optional volume control. After switching on the device, the volume will be as set by your hearing care practitioner. Read more on this subject on page 17.



TBR 62



TBR 76



TBR 25

In the TBR76 (standard) and TBR25 (optional) your instrument can have a push button to switch programs. If you close the battery door your instrument will always start in program number 1. Read more on this subject on page 18.

- Switch your instrument off if you are not using it. This will increase the battery life.
- At night, switch off your instrument and open the battery door completely. It allows moisture in your instrument to evaporate and will increase the instrument's life span.

Changing the Battery

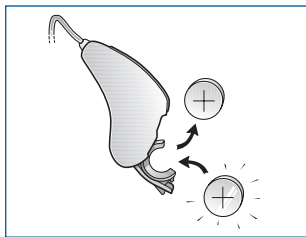
When the battery voltage/power decreases to a certain level, the instrument will emit a soft beeping signal. This signal will continue for about one minute, and the sequence will continue every five minutes until the instrument will be automatically switched off. It is therefore advisable to keep an extra battery at hand.

Open the battery compartment completely by using your fingernail. The end of the cleaning brush is magnetic. Use this for easy battery removal and insertion.

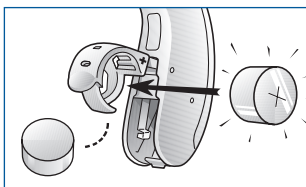
The replacement battery has to be a zinc-air battery or an appropriate Nickel Metal Hydride rechargeable battery. Size depends on your instrument:

Instrument type	Battery size
TBR25	10A
TBR62	10A
TBR76	13

Remove the protective seal from the fresh battery and insert it in the battery door. Check that the + symbols on the battery and on the battery door are on the same side.



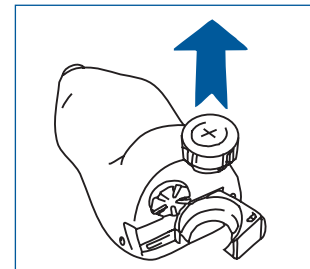
TBR62



TBR 76

Always insert a battery in the opened door, never directly into the instrument.

Close the battery door. This should go smoothly, so never force it as this could damage your instrument.



TBR 25

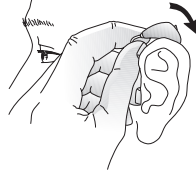
Warnings

- Keep batteries away from children and mentally challenged persons.
- Batteries can be harmful if swallowed. If you do, seek medical attention immediately.
- Do not attempt to recharge batteries (Zinc Air) which are not specifically designated rechargeable as they may leak or explode.
- Do not burn the batteries, as they could explode.
- Replace spent batteries and do not leave them in the instrument for a prolonged period.
- Used batteries are harmful to the environment. Please dispose of them according to local regulations or return them to your hearing care practitioner.

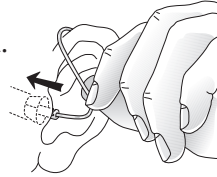
Inserting and removing the device - TBR62:

Inserting:

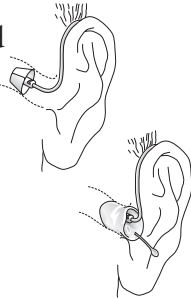
1. Hang the instrument over the top of the ear.



2. Grasp the receiver tube where it bends and push the receiver dome into your ear canal. The receiver dome should be placed far enough into the ear so that the receiver tube lies flush with your head. When the receiver dome is placed appropriately, you should not see the receiver tube sticking out when you look directly into a mirror.

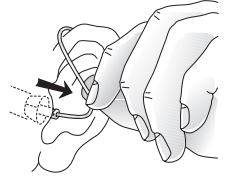


3. If the hearing care professional has provided you with a sport lock on the receiver tube, make sure to position it into the indentation above the earlobe.

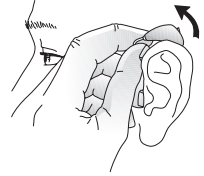


Removing:

1. Grasp the receiver tube where it bends and pull the receiver dome out of your ear canal.



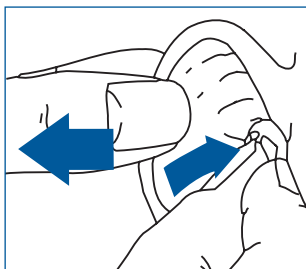
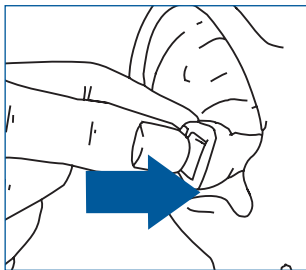
2. Lift the instrument from your ear.



Inserting and removing the instrument - TBR25

Inserting

- The insertion process varies with the shape of your ear canal. A fairly straight ear canal allows easy insertion. However, some ear canals have sharper curves and may require more care.
- Take the instrument between thumb and index finger and position its 'point' in your ear canal. If available, the colour dot must point upwards.
- Now slide the instrument all the way into your ear canal with a gentle, twisting motion. Insertion can be easier if you gently pull your auricle backward with your other hand.
- Move the instrument up and down with your index finger and press gently to ensure it is positioned correctly. Opening and closing your mouth can aid insertion. You will feel when the instrument is inserted correctly.



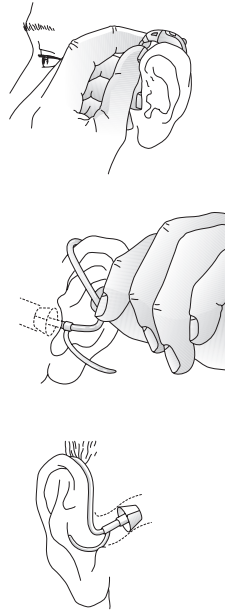
Removing your instrument

- Using your thumb and index finger gently pull the instrument (not the battery door) from your ear. TBR25 instruments often have a thin plastic pullout cord. Use this. Never pull the battery door.
- Removal may be easier if you open and close your mouth while simultaneously pulling your auricle backward with your other hand.

Take some time at home to practice how to insert and remove your instrument. Work conveniently positioning your elbows on a table and maybe using a mirror.

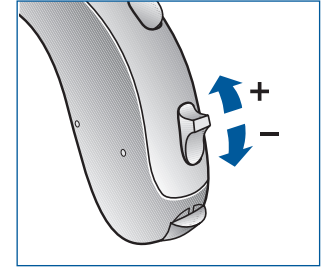
Inserting and removing the instrument - TBR76

- Hang the instrument over the top of the ear.
- Grasp the sound tube where it bends. The dome should be placed far enough into the ear that the sound tube lies flush with your head. When the dome is placed appropriately, you should not see the sound tube sticking out when you look directly into a mirror.

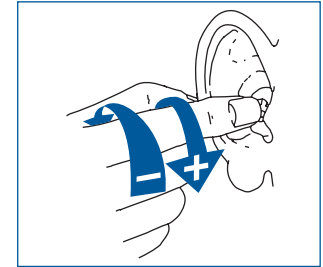


Setting the volume - TBR25 and TBR76

Your Tinnitus Breaker device is set to a specific loudness level by the hearing care professional. When switching it on, the volume will have this optimal setting. Therefore, it might not be necessary to control the volume (loudness) manually. However, the optional volume control of the TBR25 and TBR76 provides the ability to adjust the volume, or amount of stimulus, to your liking.



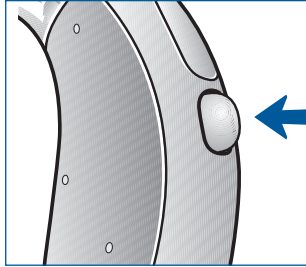
Use your index finger to adjust the volume. In the TBR25, turn the wheel forwards to increase and turn it backwards to decrease the volume. In the TBR76, push the toggle horizontally or upwards to increase and downwards to decrease the volume.



- To prevent unintended usage by paediatric or physically or mentally challenged users, the volume control must, if enabled, be configured to only provide a decrease of the sound generator output level.
- If you prefer not to use the volume control your hearing care professional can switch it off.

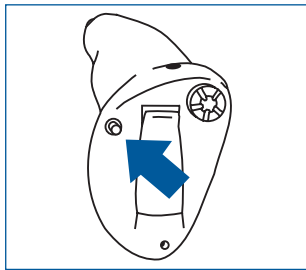
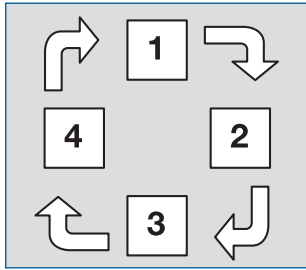
Program Button - TBR25 and TBR76

Your instrument might have a push-button, optional in the TBR25, allowing you to use up to four different listening programs, each of them suitable for certain situations.



After pressing the program button, the instrument will switch program. If it was in program 1 it will switch to program 2, if it was in program 2 it will switch to program 3 etc. If program 2, 3 or 4 are not activated, nothing will happen. Your instrument will give an audible signal after pressing the program button. A little later, the instrument will give:

- one single beep if set in program 1
- two beeps if set in program 2
- three beeps if set in program 3
- four beeps if set in program 4



When you close the battery door and switch the instrument on it will start in program 1, confirmed by one single beep.

Press the program button if you want to move to a different listening program.

Let your hearing care professional fill out the following table:

Program number	Type of program	Intended for
1		
2		
3		
4		

Daily Maintenance

Keep your instrument clean and dry. Wipe the shell with a soft cloth or tissue after use to remove grease or moisture. You should avoid exposing your instrument directly to moisture such as rain or water from the shower. If your instrument does get wet or if it has been exposed to high humidity or perspiration, it should be left to dry out overnight with the battery out and the battery compartment open. It is also a good idea to put them in a sealed container together with a drying agent (desiccator) overnight. Consult your hearing care professional as to which drying agent to use.

To avoid the need for unwarranted repairs:

- Never immerse the instrument in water or other liquids since this may cause permanent damage to the circuitry.
- Protect your instrument from rough handling, and avoid dropping it on hard surfaces or floors.
- Do not leave the instrument in or near direct heat or sunlight since excessive heat can damage the instrument or deform the casing or the receiver tube.

Maintenance - TBR62

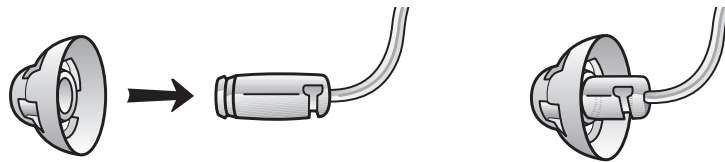
The receiver tube and the receiver dome should be cleaned regularly. Use a damp cloth to clean the receiver tube and receiver dome on the outside. Do not use water when you are cleaning the receiver tubes or the receiver domes. Please see instruction on page 25 for how to change the HF3 wax guard filter.

The Receiver Domes

The Receiver Mini Dome / Receiver Standard Dome should be changed every third month or sooner if needed. We recommend that you have your hearing care professional change the Receiver Mini Dome / Receiver Standard Dome for you. If your hearing care professional instructs you to change the Receiver domes yourself, make sure that they are securely fastened to the receiver tube before inserting them in your ear. A failure to change the domes in accordance with the instructions could result in injury.

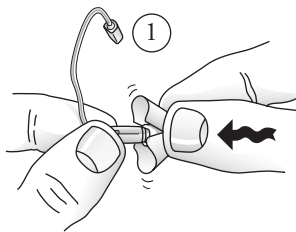
How to mount the Receiver Mini Dome

The Receiver Mini Dome is mounted by pushing it gently over the receiver at the end of the receiver tube.

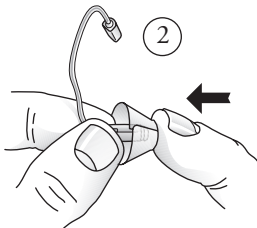


How to mount the Receiver Standard Dome

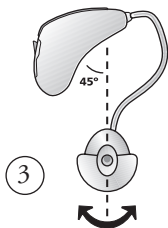
(1) + (2) The Receiver Standard Dome is mounted by gently pushing it over the receiver at the end of the receiver tube.



The Receiver Standard Dome should be directed with the sound outlet hole facing either down towards your shoulders or up towards your hair. (3)



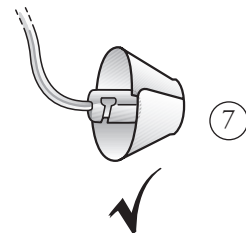
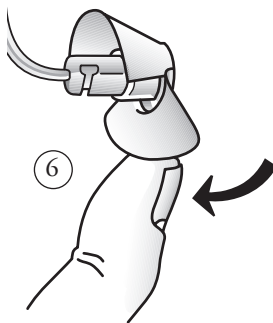
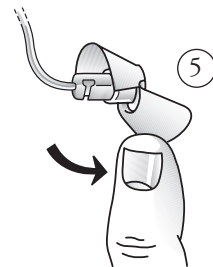
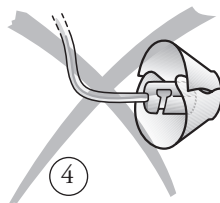
The sound outlet hole can turn both ways; the direction of the sound outlet hole affects the length of the sound tube according to the entrance of your ear canal.



Please ask your hearing care professional which way the sound outlet hole should turn in your ear.

The Receiver Standard Dome consists of two “leaves” and it is important that the largest “leaf” is the outermost “leaf” (4).

This can easily be done by pushing the “leaves” away from the receiver tube with your forefinger and middle finger (5). This will make the large “leaf” bend forward. Then you push it back and it will be placed on top of the smaller “leaf” (6). Now the Receiver Standard Dome is ready for insertion (7).



Double Wax Guard Filter

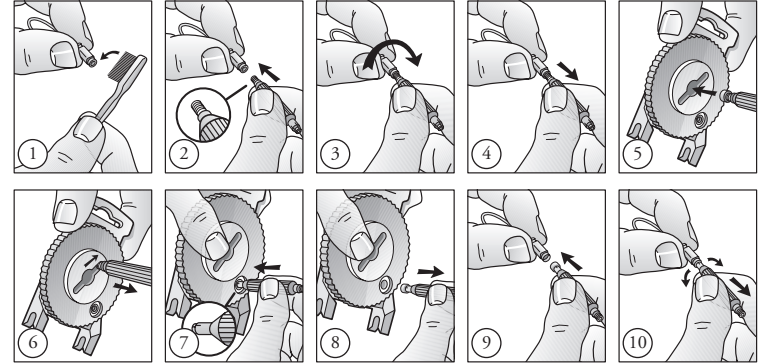
Your instrument has two types of wax guard filters to increase the protection against wax and moisture to damage the instrument.

The first wax guard filter is in-moulded in the Receiver domes. This will act as the front protection.

The second wax guard filter is placed at the front of the receiver. The type is called HF3. They come in both red and blue. This will indicate on what ear the instrument is sitting. Red for right and blue for left.

We recommend that your hearing care professional change them for you. If your hearing care professional has instructed you to change them yourself, please follow the following instructions.

Changing wax guard



Storing your instrument

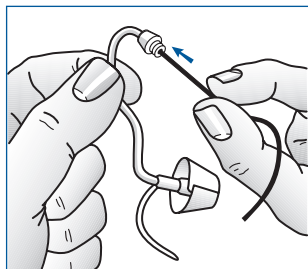
When you are not using your instrument, keep or transport it in the box supplied. Leave the battery door open. Keep your instrument in a dry place, not in a bathroom or other humid place. Alternatively, you could store the instrument in a desiccator from your hearing care practitioner.

Maintenance - TBR76

The ThinTube

The ThinTube feeds the sound from the instrument into the ear. It is important that the ThinTube and the dome fit correctly into your ear. If the ThinTube or the dome irritate your ear in any way and prevent you from wearing your instrument, please contact your hearing care professional. You should never attempt to modify the shape of the ThinTube yourself.

The ThinTube and the dome should be cleaned regularly. Remove the ThinTube from the instrument before cleaning by unscrewing it. Use a damp cloth to clean the ThinTube and dome on the outside and use the black cleaning rod to “push” any debris out of the sound tube. The cleaning rod should be inserted where the ThinTube attaches to the instrument and pushed all the way through the ThinTube and out through the dome. It is not recommended to submerge or rinse the ThinTube and dome with water, as there is a risk that a water drop may become lodged in the ThinTube. If this should occur, it will prevent sound coming through the ThinTube, and may be harmful for the instrument’s electronics.

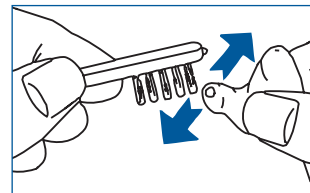


The ThinTube and dome should be changed every third month or sooner if the ThinTube becomes stiff or brittle. We recommend that you have your hearing care professional change the dome for you. If your hearing care professional instructs you to change the domes yourself, make sure that they are securely fastened to the ThinTube before inserting them in your ear. A failure to change the domes in accordance with the instructions could result in injury.

Maintenance - TBR25

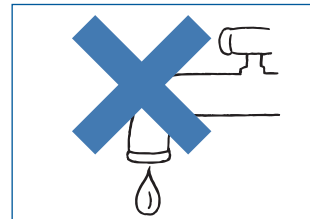
Earwax (cerumen) will accumulate on your instrument during use. If earwax enters the instrument it can damage it. The instrument has a protection system, the wax guard. Clean the instrument and replace the wax guard filter regularly. Failure to do so can lead to an accumulation of earwax impairing sound quality.

Cleaning is easier when accumulated earwax is dry; e.g., in the morning, before you insert the instrument into your ear.



Cleaning the instrument

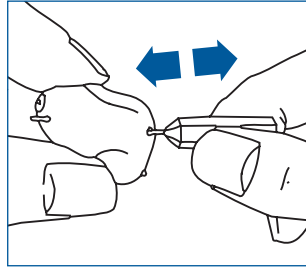
- Clean your instrument with a soft, dry cloth and the small brush. Do this above a soft surface or table to avoid damage if the instrument falls.
- Do not use water or fluids.



Cleaning the vent

Your instrument may have a vent, a small canal through the entire device. If so, clean it regularly.

- Insert the vent-cleaning tool – plastic line with handle – into the vent. Push the cleaning line completely through the vent.
- Wipe off any collected earwax.
- Pull the line out and wipe off again.
- Repeat this until all the earwax has been removed.



Wax guard

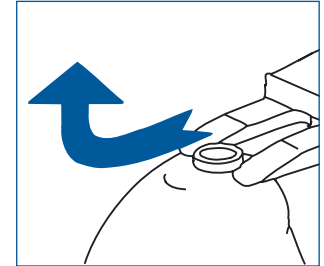
Your instrument is usually equipped with a wax guard system. This prevents earwax entering the instrument. Replace the wax guard every two weeks or sooner, depending on earwax accumulation.

- Work at a table. It is easier and avoids your instrument falling onto the floor or items getting lost.

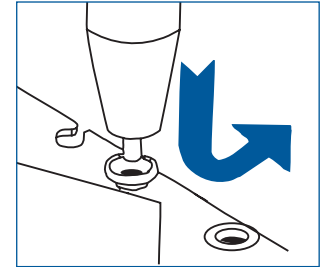
Replace wax guard 'Sentry II'

Sentry II wax guards are available in a set, containing red guards, blue guards, and a dedicated tool for changing them. Use red wax guards for right instruments and blue guards for left instruments.

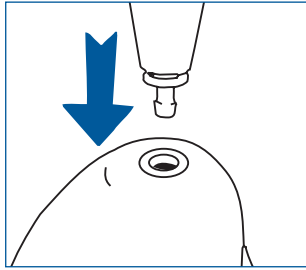
- To remove the wax guard from your instrument, slide the forked side of the tool under the wax guard and pull it upwards.



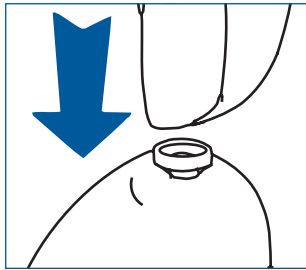
- Pick up a new wax guard from the front side of the card by using the other 'nub' end of the tool. The large red and blue arrows on the card indicate the front side. Slide the wax guard to the side, through the card.



- Insert the wax guard into the sound outlet of the instrument.



- Remove the tool and press the wax guard down with your thumb to secure it.



General warnings

Sound generators can be dangerous if improperly used.

- Sound generators should be used only as advised by your doctor, audiologist, or hearing care practitioner.
- Sound generators are not toys and should be kept out of reach of anyone (especially children and pets) who might cause themselves injury.
- Do not leave your instrument in the sun, near an open fire or in a hot, parked car.
- Do not wear your instrument while showering, swimming, in heavy rain or in a moist atmosphere such as steam bath or sauna.
- Should your instrument become moist, put it in a dessicator. Your hearing care professional will be happy to counsel on this.
- Remove your instrument when applying cosmetics, e.g. perfume, aftershave, hair spray, suntan lotion.
- Instruments should be used only as prescribed by your hearing care professional. Incorrect use may result in sudden and permanent hearing loss.
- Do not allow others to use your instrument. It may cause permanent damage.
- Instrument usage by children or mentally challenged persons should be supervised at any time.

- Do not take your instrument into rooms where you receive treatment with X-rays or MRI.
- Wearing an instrument might cause an increased production of earwax. In rare cases, the anti-allergenic materials may cause skin irritation. If so, or if in doubt, consult your physician or ENT.

General Precautions

- Consult a physician if you find a foreign object in your ear canal, if you experience skin irritation or if excessive ear wax accumulates with the use of the instrument.
- Different types of radiation, e.g. from NMR or CT scanners, may damage the instrument. Therefore, do not wear the instrument during these or other corresponding scanning procedures. Other types of radiation (burglary alarms, room surveillance systems, radio equipment, mobile telephones, etc) will not damage the instrument. They could, however, momentarily affect the sound quality or create strange sounds from the instruments.
- **Warning:** Do not wear the instrument in mines or other explosive areas, unless those areas are certified for hearing instrument use.
- Keep the instrument away from children under the age of 3 as it contains small parts which may present a choking hazard.

CAUTION

The maximum output of the sound generator falls into the range that can cause hearing loss according to OSHA regulations. The user should not use the sound generator for more than eight (8) hours a day when this is set below 90db SPL. Above that level, the device should not be used for more than two hours per day. In no case should the sound generator be worn at uncomfortable levels.

Children and physically or mentally challenged users will require guardian supervision while wearing the device.

Repairs

If your instrument malfunctions, it must be repaired by your hearing care professional or by a qualified technician. Do not attempt to open the case of the instrument since this would invalidate the warranty. If your instrument requires service, please contact your hearing care professional for assistance.

Technical data

Audio signal technology

Digital

Available sounds

White noise signal which can be shaped with the following configurations:

- Low-pass filter: 500 Hz
- Low-pass filter: 1 KHz
- Low-pass filter: 2 KHz
- High-pass filter: 2 KHz
- High-pass filter: 3 KHz
- High-pass filter: 4 KHz
- High-pass filter: 5 KHz
- High-pass filter: 6 KHz

The white noise signal can be modulated in amplitude with an attenuation depth of up to 12dB.

Maximum overall output (OES)

Instrument type	Max overall output
TBR25	100 dB SPL
TBR62	99 dB SPL
TBR76	100 dB SPL

TROUBLESHOOTING GUIDE

SYMPTOM	CAUSE	POSSIBLE REMEDY
<i>Device is dead</i>	Not turned on	Turn on
	Dead battery	Replace battery
	Battery improperly inserted	Insert battery properly
	Broken receiver or tube	Consult your hearing care professional
	Blocked Wax Guard Filter	Consult your hearing professional or if you have been instructed change dome or/and wax guard filter
<i>Not loud enough</i>	Dome not inserted properly	Reinsert carefully
	Blocked Wax Guard Filter	Consult your hearing professional or if you have been instructed change dome or/and wax guard filter
	Change in hearing	Consult your hearing care professional
	Excessive ear wax	Consult your physician
	Instrument settings not optimum	Consult your hearing care professional
<i>Not clear, distorted</i>	Weak battery	Replace battery
	Poorly fitting tube	Consult your hearing care professional
	Instrument damaged	Consult your hearing care professional
	Instrument settings not optimum	Consult your hearing care professional

International warranty and service

Any instrument from Beltone has an international warranty. Read more on this subject on the warranty card you received with your instrument.

Your selected Tinnitus Breaker model

Your hearing care professional will tick off in below table to identify which model you have received.

Model/variant Model received	Signature of hearing care professional
<input type="checkbox"/> TBR25	_____
<input type="checkbox"/> TBR62	_____
<input type="checkbox"/> TBR76	_____



Please ask your local hearing care professional concerning disposal of your hearing instrument



Faceplate/Electronics by: Beltone A/S

Any issues relating to the EU Medical Device Directive 93/42/EEC should be directed to Beltone A/S.

CE
0297

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Device Directive 93/42/EEC should be
directed to Beltone A/S, Denmark*



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Beltone A/S
Lautrupbjerg 9
DK-2750 Ballerup
Denmark
Tel.: +45 45 75 11 11
Fax: +45 45 75 11 19