



# Beltoné Tinnitus Breaker

## **Instructions for use**

Digital sound generator instrument

TBR05M

 **Beltoné**<sup>®</sup>

## A new Beltone instrument

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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

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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.

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## **Prescription use of this device**

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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**

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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**

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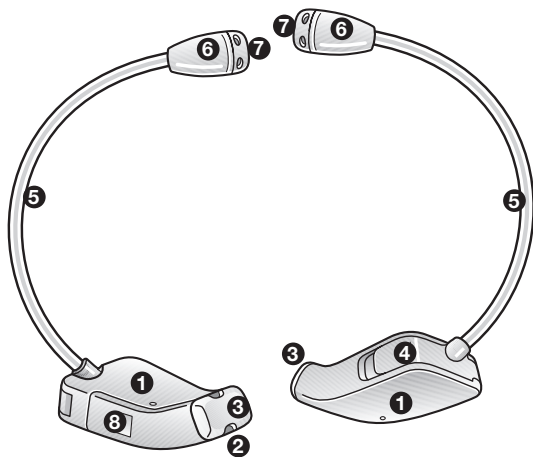
Good health practice requires that a person with a tinnitus condition have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before using a sound generator, such the Beltone Tinnitus Breaker. Licensed physicians who specialize in diseases of 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.

## The Parts of Your TBR05M Instrument

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1. Body
2. Sound Outlet/Receiver  
(under wax filter)
3. Wax Filter
4. Battery Door
5. Microphone Tubing
6. Microphone
7. Microphone Outlets
8. Model and Serial Number



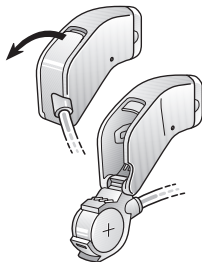
## On/Off function

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

It has two positions:

- On, when the battery door is fully closed. Note: the battery door may not appear fully closed when a battery is not in the battery compartment.
- Off, when the battery door is open.

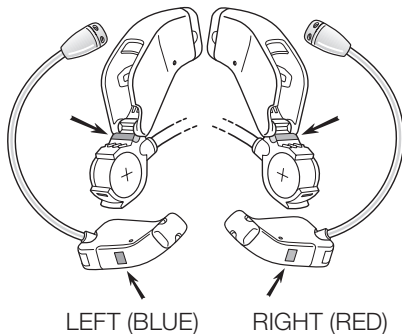


To turn your instrument off, grasp the battery compartment door with a fingernail and gently pull downward. When you are not wearing the instrument, remember to turn it off to reduce battery consumption.

## Insertion and Removal of Your Instrument

### Insertion:

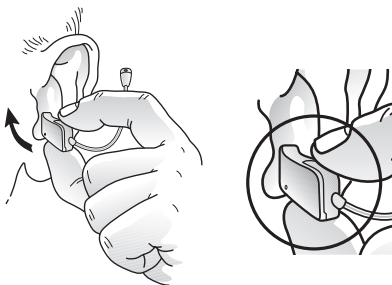
1. Determine if you have a left or right instrument in your hand. With the battery compartment open, you will see either a RED or BLUE marker:
  - The instrument with the RED marker is always for the RIGHT ear.
  - The instrument with the BLUE marker is always for the LEFT ear.



2. Check that the body of the instrument feels smooth before inserting into your ear canal. If the surface feels spiky or rough, contact your hearing care professional.
3. Grasp the instrument near the base, where the tubing connects to the battery compartment, with your index finger on top and your thumb on bottom.

## Insertion continued...

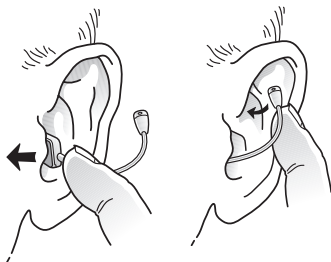
Notice that the battery door is pointing up. This is the correct way to insert the instrument.



4. When properly lined up, gently push the instrument into the ear canal until it is flush with the opening of the ear canal.
5. After the instrument has been properly seated in the ear canal, locate microphone and tubing.

6. Gently push the microphone into the creased area of the ear that is located above the ear canal entrance.

7. After the microphone is in place, push the tubing into place.



## Insertion continued...

8. This drawing shows how the instrument should look when inserted properly into the ear canal. It is important that the microphone tube fits correctly in your ear. If the microphone tube irritates your ear, please contact your hearing care professional.



### Removal:

1. Find the microphone and tubing in the crease of the ear that is located above the ear canal entrance.
2. Once you have located the tubing, GENTLY grasp and pull, and the instrument should come out of the ear.
3. Each time the instrument is removed from the ear canal, make sure that the wax filter is still attached to the instrument. If not, contact your hearing care professional immediately.

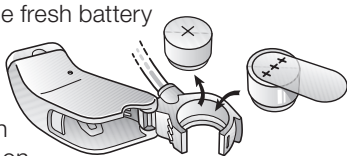


## Changing batteries

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If so set by your hearing care professional, 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.

- Remove the protective seal from the fresh battery and insert it in the battery door, with the plus side facing up. You will recognize the plus side of the battery because marked with a +. Check whether the + symbols on the battery and on the battery door are on the same side.
- Always insert a battery in the opened door, never directly into the instrument.
- A new battery should be inserted into the battery compartment with the microphone tubing pointed up.



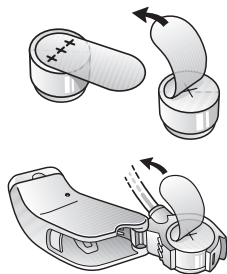
Close the battery door. This should go smoothly, so never force it as this could damage your instrument.

## Additional Battery Information

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- The correct battery size for your instrument is 10A with a yellow tab. It will be labeled on the battery packaging. This is a standard-sized zinc air battery.
- Make sure to remove the sticker before closing the battery compartment door. If the door does not close, take the battery out and try again.

- When the instrument is not in use, please remove the battery. This will help to prevent corrosion from occurring inside the battery compartment, and it will also ensure that battery life is not shortened.



## Battery warning information

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Batteries, although very small, contain dangerous substances and should be disposed of carefully. This is for the safety of you and the environment. Please note:

- 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 the batteries, as they could 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.

## Daily maintenance

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It is important to keep your instrument clean and dry. Failing to do so will likely shorten the life of the instrument and cause more repairs than is necessary.

Begin by wiping the instrument with a dry soft cloth/tissue after each use. This helps to remove any oil, moisture, or cerumen (wax) from the instrument. Inspect the end that fits into your ear canal for debris, and replace the wax filter as needed.

Also inspect the microphone for debris and the receiver for wax. Clean as necessary.

Microphone and receiver maintenance are covered in the next sections.

Each night, the instrument should be stored in a dry place, such as in the hard case you were provided, with the battery door open and the battery preferably taken out. This helps to ensure that any moisture that has gotten into the instrument has a chance to escape.

Optionally, you can purchase a container that contains a drying agent (a desiccant). Some containers are electric, and in addition to drying the instrument, they help to sanitize. Check with your hearing care professional for options.

## Additional Maintenance

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In addition to daily cleaning of your instrument, you should periodically check and clean the microphone and receiver:

## The Microphone Tube

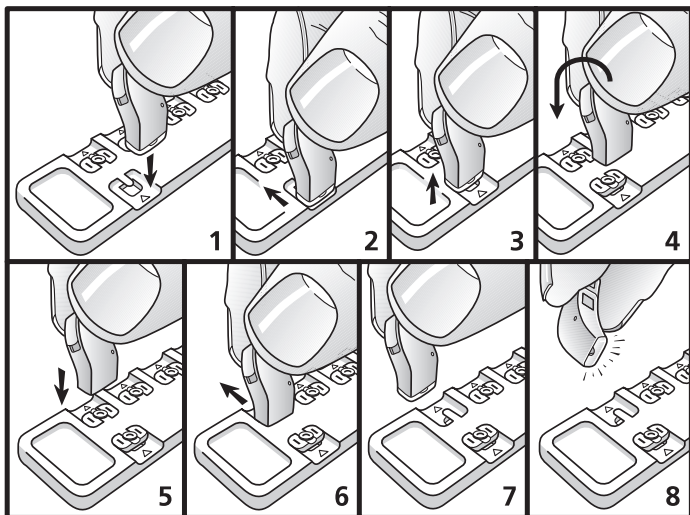
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The microphone tip and tubing can be cleaned by gently wiping them with a soft dry cloth. This will help to ensure that the ports stay open and allow sound to get into the microphone.

Note that the tube may wear out or become discolored over time with usage of the instrument. Should the tubing become discolored or should the instrument fail to produce sound, contact your hearing care professional to have the tubing replaced.

## Wax Filter

The wax filter is located at the receiver end of the instrument. This filter is designed to decrease the likelihood that wax will get into the instrument's sound outlet and cause decreased performance or damage.



## To replace the wax filter:

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1. Hold the instrument with the sound outlet pointing down.
2. Slide the prong of the wax filter tool under the wax filter.
3. Lift to remove the wax filter.  
Dispose of the old wax filter.
4. Hold the instrument's sound outlet over a new wax filter.
5. Push the instrument onto the new wax filter.
6. Slide the instrument forward.
7. The new wax filter should now be in place.
8. Check that the new wax filter is in place. It may be necessary to give the filter an extra push to ensure that it is securely attached.

Note: It is not recommended that wax filters be reused, as wax filters may not reattach securely.

## Handling Precautions with Your Instrument

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In addition to daily maintenance and in order to avoid unwanted repairs, it is recommended that you take certain precautions while handling your instrument:

- Avoid exposing your instrument directly to moisture such as heavy rain or water from a shower.
- Never immerse the instrument into water or other liquids, as this may cause permanent damage to the circuitry and/or internal components.
- Protect the instrument from rough handling.
- Avoid dropping it on hard surfaces or floors.
- Do not leave the instrument in or near direct heat or sunlight. Excessive heat can damage the instrument or deform the casing or the microphone tube.
- You should never attempt to modify the shape of the microphone tube yourself.
- Never force the battery door closed, as this may damage the instrument.

## Telephone Use

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Should you experience any feedback or whistling while trying to talk on the telephone, you can avoid this by taking the following precautions:

- Hold your telephone handset close to the lower part of the ear, and firmly push it towards the outside of the ear canal.
- Listen to the dialing tone and move the handset a little to find the position that give the best reception.
- The best position to hold a telephone may be determined by the shape of telephone you are using.

By employing these techniques while using the instrument on the telephone, you will be able to minimize feedback and keep your listening experience enjoyable.



## Repairs and Warranty

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

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

## General warnings

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Sound generators can be dangerous if improperly used.

- 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.
- 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 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.
- Sound generators should be used only as advised by your doctor, audiologist, or hearing care practitioner. 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

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The maximum output of the Tinnitus Breaker sound generator feature 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 90 db 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.

# TROUBLESHOOTING GUIDE

SYMPTOM	CAUSE
<b>Instrument is dead</b>	Not turned on
	Battery is dead
	Battery improperly inserted
	Blocked wax filter
	Broken receiver
<b>Not clear, distorted</b>	Weak battery
	Poor fitting microphone tube
	Instrument is damaged
<b>Not loud enough</b>	Instrument not properly inserted
	Microphone not properly seated
	Blocked wax filter
	Instrument settings not at optimum
	Excessive ear wax
	Change in hearing

If there are any other problems not mentioned in this guide, or should

## POSSIBLE REMEDY

Turn on

Replace battery

Reinsert battery properly

Consult your hearing care professional or, if you have been instructed to do so, change the wax filter

Consult your hearing care professional

Replace battery

Consult your hearing care professional

Consult your hearing care professional

Re-insert carefully

Re-seat carefully

Consult your hearing care professional or, if you have been instructed to do so, change the wax filter

Consult your hearing care professional

Consult your physician

Consult your hearing care professional

questions arise, please contact your hearing care professional.

# Technical specifications

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## Audio signal technology

Digital

### Available sounds – Tinnitus Breaker sound generator

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 level

Instrument type	Max overall output
TBR05M	100 dB SPL

## Your selected model

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Your hearing care professional place a check mark in the below table to identify the model you have received.

**Model received**

**Hearing care professional**

TBR05M

\_\_\_\_\_

Serial number Right:

\_\_\_\_\_

Serial number Left:

\_\_\_\_\_





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

CE  
0297

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

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