

USER GUIDE

RESOUND ALERA™ TS HEARING INSTRUMENT

ReSound



rediscover hearing

ReSound Alera™ TS

Congratulations on your new ReSound Alera™ TS hearing instrument!

Wearing ReSound Alera™ TS hearing instruments enables you to hear sounds that you may not have heard in years, in addition to assisting in your tinnitus treatment programme.

While some people adjust quickly to wearing hearing instruments and hearing the lost sounds again, others may need more time. By wearing the instruments regularly you will get accustomed to the new world of hearing more quickly and soon experience the full benefit of quality listening and interaction. ReSound Alera™ TS can also be a part of your tinnitus treatment programme. A Tinnitus Sound Generator (TSG) feature emits soothing sounds that can help reduce the unwanted effects of tinnitus. ReSound Alera™ TS instruments have been adjusted according to your individual hearing loss and tinnitus needs. Familiarising yourself with the functions of your new hearing instruments will help you get optimal benefit.

ReSound is a registered trade mark of GN ReSound A/S

Hearing instrument model: _____

Battery size: _____ Tube type: _____ Dome size: _____

Left serial number: _____ Right serial number: _____

This user guide is valid for ReSound Alera™ devices including Tinnitus Sound Generator (TSG) and describes the TSG related topics.

The user guide is only valid in connection with the ReSound BTE user guide, ref. number 17483300, or ReSound RIE user guide, ref. number 17332100.

Standard/Power BTE

ALT987-DVIW

ALT977-DVIW Open - ALT977-DVIW

ALT787-DVIW

ALT777-DVIW Open - ALT777-DVIW

ALT587-DVIW

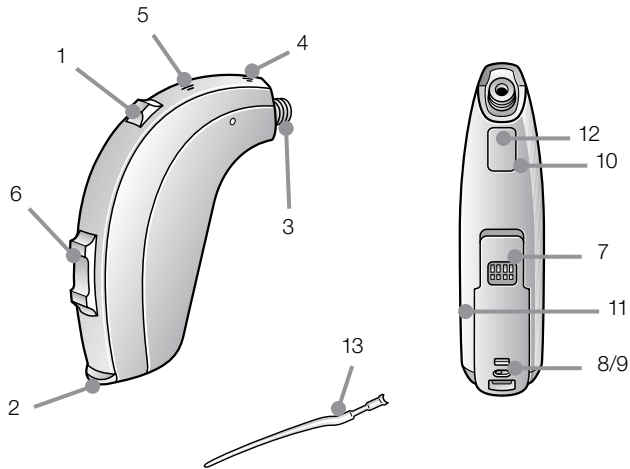
ALT577-DVIW Open - ALT577-DVIW

Mini-BTE

ALT967-DIW Open - ALT967-DIW

ALT767-DIW Open - ALT767-DIW

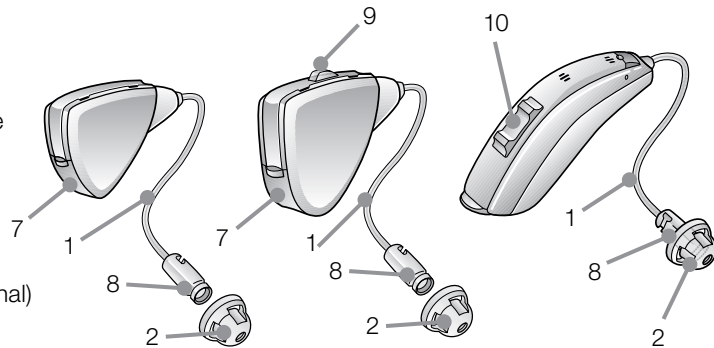
1. Programme button
2. Battery compartment & On/Off switch
3. Sound outlet
4. Front microphone inlet
5. Back microphone inlet
6. Volume control (optional)
7. Direct audio input
8. Left/Right indicator (Left=Blue/Right=Red)
9. Battery lock (optional)
10. Model
11. Manufacturer
12. Serial number
13. Sports lock



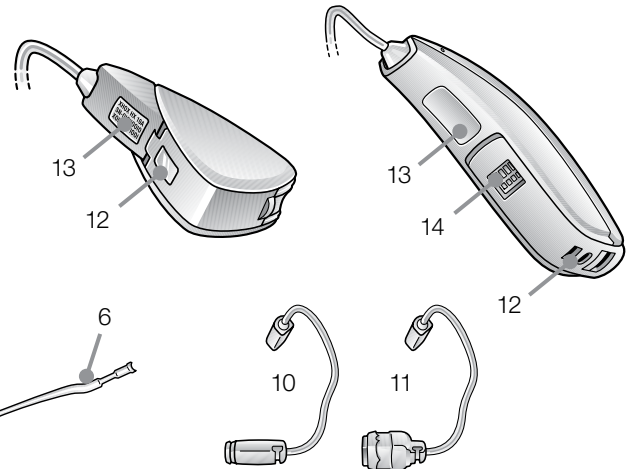
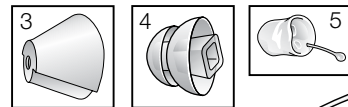
RIE Mini-BTE
RIE BTE

ALT960-DR
ALT961-DRW
ALT962-DVIRW, ALT762-DVIRW

1. Receiver tube
2. Receiver Open Dome
3. Receiver Tulip Dome
4. Receiver Power Dome
5. RIE mould
6. Sports lock
7. Battery compartment
8. Receiver
9. Push button
10. Volume Control (optional)



10. NP receiver tube
11. HP receiver tube
12. Left/right indicator
13. Model, and serial number
14. Direct audio input



DESCRIPTION OF THE DEVICE

The Tinnitus Sound Generator (TSG) Module is a software tool generating sounds to be used in tinnitus management programs to relieve suffering from tinnitus.

EXPLANATION OF HOW THE DEVICE FUNCTIONS

The TSG Module is a frequency and amplitude shaped white noise generator. 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, crashing waves on a shore. Modulation level and speed can also be configured to your likes and needs.

If your tinnitus troubles you only in quiet environments, your doctor, audiologist, or hearing

care practitioner can set the TSG Module so that it becomes audible exclusively in such surroundings. The overall sound level can be adjusted via an optional volume control. Your doctor, audiologist, or hearing care practitioner will review with you the need for having such a control.

THE SCIENTIFIC CONCEPTS THAT FORM THE BASIS FOR THE DEVICE

The TSG Module provides sound enrichment with the aim of surrounding the tinnitus sound with a neutral sound which is easily ignored. Sound enrichment is an important component of most approaches to tinnitus management, such as Tinnitus Retraining Therapy (TRT). To assist habituation to tinnitus, this needs to be audible. The ideal level of the TSG Module, therefore, should be set so that it starts to blend with the tinnitus, and so that you can hear both your tinnitus as well as the sound used. In a majority of instances, the TSG Module can also be set to mask the tinnitus sound, so to provide temporary relief by introducing a more pleasant and controllable sound source.

SIGNIFICANT PHYSICAL CHARACTERISTICS

Audio signal technology

Digital

Available sounds

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

High-pass filter: 500 Hz Low-pass filter: 2 kHz

High-pass filter: 750 Hz Low-pass filter: 3 kHz

High-pass filter: 1 kHz Low-pass filter: 4 kHz

High-pass filter: 1.5 kHz Low-pass filter: 5 kHz

High-pass filter: 2 kHz Low-pass filter: 6 kHz

The white noise signal can be modulated in amplitude with an attenuation depth of up to 14dB.

PRESCRIPTION USE OF THIS DEVICE

The TSG Module should be used as prescribed by your doctor, audiologist, or hearing care practitioner. In order to avoid permanent hearing damages, the maximum daily usage depends on the level of the generated sound.

Should you develop any side effects from using the sound generator, such as dizziness, nausea, headaches, perceived decrease in auditory function or increase in tinnitus perception, you should discontinue use of sound generator 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 containing the TSG module.



WARNING

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.

VOLUME CONTROL

The sound generator is set to a specific loudness level by the hearing care practitioner. When switching the sound generator on, the volume will have this optimal setting. Therefore, it might not be necessary to control the volume (loudness) manually. However, the volume

control provides the ability to adjust the volume, or amount of stimulus, to the liking of the user. The volume control is an optional feature in the TSG module used for adjusting the sound generator output level. 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.



CAUTION

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

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



WARNING TO HEARING CARE PRACTITIONER

A hearing care practitioner should advise a prospective sound generator user to consult promptly with a licensed physician (preferably an ear specialist) before setting a sound generator if the hearing care practitioner determines through inquiry, actual observation, or review or 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.



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 (2) hours per day. In no case should the sound generator be worn at uncomfortable levels.

IMPORTANT NOTICE FOR PROSPECTIVE SOUND GENERATOR 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. 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.

Technical Data

Hearing Instrument <i>Model</i>	Tinnitus Sound Generator <i>Maximum Output</i> <i>(IEC 60118-7)</i>
ALT960-DR & ALT961-DRW RIE HP Closed/Open	89 dB SPL (Typical)
ALT960-DR & ALT961-DRW RIE NP Closed/Open	88 dB SPL (Typical)
ALT962-DVIRW & ALT762-DVIRW RIE HP Closed/Open	88 dB SPL (Typical)
ALT962-DVIRW & ALT762-DVIRW RIE NP Closed/Open	88 dB SPL (Typical)
ALT967-DIW & ALT767-DIW Closed	91,9 dB SPL (Typical)
ALT967-DIW & ALT767-DIW Open	86 dB SPL (Typical)

Technical Data

Hearing Instrument <i>Model</i>	Tinnitus Sound Generator <i>Maximum Output</i> <i>(IEC 60118-7)</i>
ALT977-DVIW, ALT777-DVIW & ALT577-DVIW Closed	92,3 dB SPL (Typical)
ALT977-DVIW, ALT777-DVIW & ALT577-DVIW Open	89,5 dB SPL (Typical)
ALT987-DVIW, ALT787-DVIW & ALT587-DVIW	91,7 dB SPL (Typical)

Be aware of information marked with the warning symbol



WARNING points out a situation that could lead to serious injuries,
CAUTION indicates a situation that could lead to minor and moderate injuries”



Advice and tips on how to handle your hearing instrument better.



Equipment includes RF transmitter



Product is a Type B applied part



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

Worldwide Headquarters

ReSound A/S
Lautrupbjerg 7
DK-2750 Ballerup, Denmark
Tel.: +45 45 75 11 11
Fax: +45 45 75 11 19
www.resound.com

United Kingdom

GN ReSound Ltd.
Kirtlington Business Centre
Portway
Kirtlington
Oxon OX5 3JA
Tel.: +44 1869 352 800
Fax: +44 1869 343 466
www.gnresound.co.uk

Australia

GN ReSound Pty. Ltd.
Unit R1 Regents Park Estate
391 Park Road
Regents Park NSW 2143
Tel.: (free) 1800 658 955
Fax: +61 2 9743 7472
www.gnresound.com.au

New Zealand

GN ReSound (NZ) Ltd.
12 Parkway Drive
Mairangi Bay
Auckland
Tel.: (free) 0800 900 126
Fax: (free) 0800 007 695
www.gnresound.co.nz

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Any issues relating to the EU Medical Device Directive 93/42/EEC, or Council Directive 1999/5/EC on Radio Equipment and Telecommunications terminal equipment should be directed to ReSound A/S

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